Project Completion Report

The Project for Establishment of Laboratory Surveillance System for Viral Diseases of Public Health Concern (SYMAV)

February 2022

Japan International Cooperation Agency
(JICA)

Nagasaki University

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I. Basic Information of the Project

1. Country: Gabon

2. Title of the Project:

The Project for Establishment of Laboratory Surveillance System for Viral Diseases of Public Health Concern (SYMAV)

3. Duration of the Project:

2016/4/29-2021/4/28 (Planned)
2016/4/29-2022/2/28 (Actual)

4. Background (from Record of Discussions(R/D))

The infectious diseases account for a large part of the cause of death in Gabon (56% 2011, WHO), in particular, Malaria is the largest cause of under-5-year-old mortality and the infection rate of HIV and the prevalence rate of tuberculosis are higher than the average rates of Sub-Saharan Africa. In addition to these three major infectious diseases, a variety of infectious diseases such as dengue fever, chikungunya fever and Ebola virus disease have occurred in Gabon. Moreover, Gabon is geographically close to Nigeria, where Lassa fever is endemic, and the Democratic Republic of Congo, which has experienced the repeated Ebola virus disease outbreaks, hence Gabon is also exposed to the risk of these infectious diseases. However, the ability of Gabon to take measures to cope with the emerging and reemerging infectious diseases is not sufficient.

In this situation, Gabon has set the establishment of a monitoring system for infectious disease control in the national development strategy, “National Strategic Plan Gabon Emergent 2011-2016” and positioned infectious diseases as a particular problem to be solved preferentially.

The project aims to enhance the research and development capacity of the Gabonese research center through collaborative research by the Institute of Tropical Medicine, Nagasaki University (hereinafter referred to as “NEKKEN”) and the Center of Medical Research Lambaréné (hereinafter referred to as “CERMEL”) about identification and characterization analysis of known and unidentified pathogenic viruses based on the survey. The results of the project are expected to be beneficial to the countermeasures against viral diseases in Gabon and also in the Central Africa region in the future.

5. Project Purpose (from Record of Discussions(R/D)):

The research and development capacity of the Gabonese research center is enhanced through the collaborative research with the Japanese research institute regarding identification of pathogens of known and unidentified infectious diseases as well as development of rapid diagnostic methods for viral diseases of public health concern.

6. Implementing Agency:

Ministry of Higher Education, Scientific Research (MoHESR), Technology transfer and National Education in charge of Civic Education of Gabon (MoHESRTTNE), CERMEL, Research Institute in Tropical Ecology (IRET), Japan International Cooperation Agency (JICA), and NEKKEN.

II. Results of the Project

1. Results of the Project

The details are shown in Annex 1.

1-1 Input by the Japanese side

(1) Amount of input by the Japanese side

As planned, the Japanese side provided JPY 47.2 million yen as overseas activity costs for the project excluding Japanese experts' overhead costs. However, due to the COVID-19 pandemic, between April in 2020 and February in 2021, the frequency and length of travel for the Japanese experts were extremely reduced and training for Gabonese in Japan was cancelled. The budget balance of approximately JPY 10 million yen resulting from these changes was switched to cover the transportation of materials and equipment for facilitating the Project research by counterparts.

(2) Expert dispatch

The Japanese team dispatched one Chief Advisors, five Experts, two Project Coordinator, two long-term experts based in Gabon, including one Project Assistant/Translator and one Project Nurse.

(3) Receipt of business travelers in Japan

There were two business travelers in Japan.

No.	Purpose	Period	Travelers
1	Inspection of the BSL-2/3 laboratory in Nara prefecture and discussion of research at Nagasaki University	13 March – 25 March 2017	Prof. Bertrand Lell
2			Dr. Marguerite Massinga Loembe

Table 1. The business traveler in Japan

(4) Receipt of training participants in Japan and the third-country

There were no participants for the long-term training course in Japan, eight participants trained in Japan, and one participant trained in Senegal as shown in Table 2.

No.	Name of training course	Period	Participants
1	Analysis of DNA sequencers and next-generation sequencers at Nagasaki University	29 October – 20 November 2017	Dr. Marguerite Massinga Loembe
2			Mr. Rodrigue Bikangui
3	Genetic identification by DNA sequencer and phylogenetic analysis, and acquisition of rapid diagnostic method (LAMP method) at Nagasaki University	9 November – 29 November 2018	Mr. Rodrigue Bikangui
4			Mr. Georgelin Nguema Ondo
5			Ms. Malinga Emma Gladis
6	Sequencing of viral genomes and acquisition of rapid diagnostic methods (LAMP method) at Nagasaki University	14 July – 3 August 2019	Dr. Paulin Essono Ndong
7			Mr. Georgelin Nguema Ondo
8			Mr. Marien Juliet Magossou Mbadinga
9	Maintenance of biomedical equipment in Senegal	15 November – 15 December 2021	Mr. Arnold Mexan Kouamba Mouckala

Table 2. The participants for training course in Japan and the third-county

(5) Receipt of training participants in Gabon

In addition to the daily on-site training such as basic techniques of molecular

biological and serological experiments, there were 29 participants trained for advanced techniques in Gabon as shown in Table 3.

No.	Name of on-site training course	Period	Participants Number
1	Molecular biology techniques - Dengue virus gene detection -	May 2018	13
2	Practical training for the analysis using the 3500 Genetic Analyzer	December 2019	5
3	Pathogen handling in a BSL-2/3 laboratory and pathogen detection	March 2020	3
4	Sequence analysis to detect novel variants of SARS-CoV-2	March 2021	6
5	DNA sequencing techniques and its analysis	May 2021	2

Table 3. The on-site training course in Gabon

(6) Overseas activities cost

As planned, the Japanese side provided about JPY 48 million yen as overseas activities costs.

(7) Equipment Provision:

The Japanese side purchased equipment of about JPY 98 million yen in total, which include a biosafety level-2/3 (BSL-2/3) laboratory system, a pathogen identification and analysis system, a DNA sequencer, a next generation sequencer, a printer, a projector, etc. The details of the equipment are listed on ANNEX 1: List of Products: Equipment (Japan).

Issue to be concerned:

Next-generation sequencer (MiniSeq) showed an operation error in May 2021. Although the project researchers attempted to repair via remote communication with the responsible person in the supplier, it was concluded that an on-site maintenance is necessary in order to replace 2 parts, a single computer board and a new HDD with Win10. In December 2021, Illumina support company, ISN Product Nigeria has completed the documentation on

the territory expansion with Illumina and the project's order is being processed with the Illumina customer service team. For assuring the completion of repairment after the project, ISN Product, CERMEL and the project team signed three-party agreement in February 2022. It was agreed that ISN Product should send the engineers to project site and complete repairment, and CERMEL should support any logistic assistance to the company.

1-2 Input by the Gabonese side

(1) Counterpart assignment

The following officials have been assigned:

- The Project Director: Director General, MoHESRTTNE
- The Project Manager: Co-Director, CERMEL

Additionally, the following officials worked for the project (approximately 200 persons in total).

- Head of Research Laboratory, CERMEL
- Young Biologist, CERMEL
- Senior Consultant, CERMEL
- Equipment Officer, CERMEL
- Responsible Officer for Biomedical Waste, CERMEL
- Human Resources Manager, CERMEL
- Administrative Assistant, CERMEL
- Human Resources and Logistics, CERMEL
- Logistics Assistant, CERMEL
- Inventory Manager and Logistics, CERMEL
- Director, IRET
- Deputy Director, IRET
- Researcher, IRET
- Research assistant, IRET

(2) Provision of offices, etc.

As planned, the Gabonese side provided the following:

- Office space
- Medical services such as PCR tests for COVID-19
- Free access to related departments for the implementation of the project with the key of each building
- Available data and information related to the project

- Running expenses necessary for the implementation of the project such as utilities and internet cost
- Expense necessary for operation and maintenance of the equipment such as fuel for generator and replacement of HEPA filters in the BSL-2/3 laboratory
- Supply of machinery, equipment, and any other materials necessary for the implementation of the project: high-performance incinerator, plate washer, centrifuge, autoclave, generator, uninterruptible power supply (UPS), voltage stabilizer, etc.

(3) Other items borne by the counterpart government
N/A

1-3 Activities
For the original plan of operation and actual result of the Project activities, see PO, and major changed in the schedule are summarized as follows.

- Delay in determining construction site of the BSL-2/3 laboratory as authorization of the Ministry of Health required 1 year (from May 2016 to April 2017), and as acquisition of land ownership/land-use rights of the proposed site registered to Albert Schweitzer Hospital in January 2017 was completed in March 2017.
- Delay in installation of the BSL-2/3 laboratory and the pathogen identification and analysis system for 3 months (from April to July 2017) due to long-term custom clearance of shipment.
- Delay in commencement of the short-term training in Japan due to post-election violence continued during August-October 2016 and absence of a Project Coordinator during April-October 2016.
- Delay in investigation of unidentified viruses using a next-generation sequencer (Activities 1-4) due to difficulties in optimizing the condition.
- Earlier commencement of PCR screening and serological investigation against public health-concerned viruses (Activities 1-3 and 1-5) than planned due to provision of stored human blood samples by CERMEL.
- Delay in isolation of viruses (Activities 2-1) due to difficulties in finding a suitable sample for its isolation.
- Delay in the risk assessment of newly-identified virus(es) (Activities 2-3) due to the delay in virus isolation described previously.
- While earlier commencement of rapid diagnostic method development than planned using the LAMP method (Activities 3-2-2), delay in evaluation of the

clinical utility of the developed rapid diagnostic method (Activities 3-2-3) due to difficulties in obtaining suitable clinical samples.

- Delay in development of a rapid diagnostic test kit that can detect multiple pathogens (Activities 3-3) due to the delay described previously.
- Earlier commencement of development of serological methods (Activities 3-4) due to earlier completion of optimization using blood samples provided from CERMEL.

2. Achievements of the Project

2-1 Outputs and indicators

All the indicators were achieved as described below.

2-1-1 Output 1

The prevalence of known and unidentified viral diseases was clarified in the areas around Lambaréné.

(1) In Output 1-1, that would be completed within one year after the commencement of the Project, the establishment of the specimen library at CERMEL for the research of viral diseases was accomplished as scheduled. Finally, a total of more than 3000 samples from human, 375 samples from wild animals, and more than 4000 samples from mosquitoes were collected during the Project. Data were assembled with patient information (if applicable) and deposited in REDCap database software (open source).

(2) In Output 1-2, that would be done by six months before the termination of the Project, research outcomes regarding the prevalence of infectious diseases caused by known and/or newly-identified viruses in the areas around Lambaréné gained from the viral and serological investigations had been summarized in reports and/or scientific articles, and was accomplished as scheduled. Specifically, viral investigations using samples from febrile patients revealed that the target viruses of the Project accounted for the cause of approximately 8% of the febrile illness. The most prevalent virus was enterovirus. Dengue virus serotype has changed over time since the outbreak in 2010 (serotype 2 → serotype 3 → serotype 1). From serological investigation, almost all Gabonese residents were infected with hepatitis A virus, and Gabonese residents had high risks of mosquito-borne viral diseases such as dengue virus and chikungunya

virus. Subclinical infections with ebolaviruses were also indicated. These results were summarized and some of them can be publicly accessed through scientific journal websites (see 2-2 Project Purpose and indicators).

2-1-2 Output 2
Characteristics such as genetic information and pathogenicity of viruses that were regarded as public health concern and newly identified in Gabon is defined.

(1) In Output 2-1, that would be completed by two years and six months after the commencement of the Project, public health-concerned and newly-identified (if detected) virus identification and isolation was accomplished two years behind the schedule. Specifically, dengue virus serotype 1 and 3 were isolated as public health-concerned viruses.

(2) In Output 2-2, that would be achieved by six months before the termination of the Project, research outcomes regarding genetic information, pathogenicity, etc. of the target viruses were published in reports and/or scientific articles as scheduled. Specifically, hepatitis virus (A, B, and C), dengue virus (serotype 1 and 3), chikungunya virus, zika virus, cytomegalovirus, adenovirus, enterovirus, human pegivirus 1 were detected in human samples. In addition, a new orthonairovirus was detected in wild animal samples. The viral genome sequences were identified and phylogenetic analyses revealed the genotype and inferred transmission route and year. The results can be publicly accessed through 3 scientific articles (see 2-2 Project Purpose and indicators).

(3) Output 2-3, that would be done by six months before the termination of the Project, was accomplished 3 months behind as scheduled. The results of the risk assessment for newly-identified virus(es) were published in reports and/or scientific articles. Specifically, growth curve was investigated using isolated dengue virus serotype 1 and 3, and the serotype 1 replicated faster than the serotype 3. Since this tendency was also observed in the previous reports of other research groups, it would be necessary that dengue virus serotype 1 requires more careful follow-up after infection in Gabon. In 2021, only dengue virus serotype 1 was detected in the country and the number of severe cases should be carefully monitored in the future.

2-1-3 Output 3
Rapid diagnostic methods for viral diseases of public health concern and/or newly identified viruses were developed.

(1) Output 3-1, that would be completed by two years and six months after the commencement of the Project, was accomplished as scheduled. Rapid diagnostic methods for the selected viruses were developed, Specifically, in addition to PCR methods targeted for 30 viruses, rapid diagnostic methods using a LAMP method were developed for dengue virus serotype 1-4, chikungunya virus, yellow fever virus, zika virus, and SARS-CoV-2, which were found to be public health concern based on the comprehensive results produced by the Project, with high sensitivity and specificity.

(2) Output 3-2, that would be completed within three years and six months after the commencement of the Project, was accomplished as scheduled. Serological testing methods for the selected viruses were developed at CERMEL. Specifically, ELISAs were developed for 16 viruses of the targets: dengue virus (serotype 1-4), chikungunya virus, zika virus, yellow fever virus, West Nile virus, ebolavirus species (Zaire, Sudan, Bundibugyo, and Tai Forest), Marburg virus, Crimean-Congo hemorrhagic virus, Lassa virus, and lymphocytic choriomeningitis virus. Western blot analysis and neutralization assay were also developed.

(3) Output 3-3, that would be achieved by six months before the termination of the Project. The clinical utilities of the rapid diagnostic methods were evaluated. Specifically, the clinical utilities were evaluated for dengue virus serotype 1 and 3, which were isolated in Gabon, and the developed LAMP method detected the viruses rapidly within 30 minutes and showed equivalent sensitivity to the gold-standard PCR methods.

In addition to the above-mentioned points, under the COVID-19 pandemic, the Project researchers also worked on the analysis of SARS-CoV-2 with CERMEL researchers for the sufficient transfer of techniques on molecular analysis of SARS-CoV-2 and for clarification of the COVID-19 situation in Gabon.

2-2 Project Purpose and Indicators
As described below, in consideration of the achievements of Indicators, the Project Purpose was certainly achieved within the Project period based on Project

Design Matrix (PDM) version 2.

(1) Indicator 1, that would be achieved by six months before the termination of the Project, is that at least six research papers are published in peer-reviewed international journals with the themes of the prevalence of viral diseases in the areas around of Lambaréné. A total of 9 research papers were published in the international academic journals within the period of the Project on the genetic and epidemiological characteristics of the target viruses and/or rapid diagnostic methods. Several results of collaboration studies were accepted by academic journals with a high impact for researchers and clinicians in the world (Science, The Lancet Microbe).

Publication list:

*Corresponding author

① Abe H, Ushijima Y, Loembe MM, Bikangui R, Nguema-Ondo G, Mpingabo PI, Zadeh VR, Pemba CM, Kurosaki Y, Igasaki Y, de Vries SG, Grobusch MP, Agnandji ST, Lell B, and ***Yasuda J**. Re-emergence of dengue virus serotype 3 infections in Gabon in 2016-2017, and evidence for the risk of repeated dengue virus infections. *Int J Infect Dis*. 2020;91:129-136.

② Abe H, Ushijima Y, Bikangui R, Loembe MM, Agnandji ST, de Vries SG, Grobusch MP, Lell B, and ***Yasuda J**. Ongoing evolution of hepatitis B virus during viremia in patients with febrile in Central Africa. *J Med Virol*. 2020;92(2):251-256.

③ Yoshikawa R#, Abe H#, Igasaki Y, Negishi S, Goto H, and ***Yasuda J**. Development and evaluation of a rapid and simple diagnostic assay for COVID-19 based on loop-mediated isothermal amplification. *PLoS Negl Trop Dis*. 2020;14(11):e0008855.　#These authors contributed equally to this work.

④ Abe H, Ushijima Y, Bikangui R, Ondo GN, Zadeh VR, Pemba CM, Mpingabo PI, Igasaki Y, de Vries SG, Grobusch MP, Loembe MM, Agnandji ST, Lell B, and ***Yasuda J**. First evidence for continuous circulation of hepatitis A virus subgenotype IIA in Central Africa. *J Viral Hepat*. 2020;27(11):1234-1242.

⑤ Ushijima Y, Abe H, Ozeki T, Ondo GN, Mbadinga MJVM, Bikangui R, Nze-Nkogue C, Akomo-Okoue EF, Ella GWE, Koumba LBM, Nso BCBB, Mintsa-Nguema R, Makouloutou-Nzassi P, Makanga BK, Nguelet FLM, Zadeh VR, Urata S, Mbouna AVN, Massinga-Loembe M, Agnandji ST, Lell B, and ***Yasuda J**. Identification of potential novel hosts and the risk of infection with

lymphocytic choriomeningitis virus in humans in Gabon, Central Africa. *Int J Infect Dis*. 2021; 105:452-459.

⑥ Ushijima Y, Abe H, Nguema Ondo G, Bikangui R, Massinga Loembé M, Zadeh VR, Essimengane JGE, Mbouna AVN, Bache EB, Agnandji ST, Lell B, and ***Yasuda J**. Surveillance of the major pathogenic arboviruses of public health concern in Gabon, Central Africa: increased risk of West Nile virus and dengue virus infections. *BMC Infect Dis*. 2021;21(1):265.

⑦ Zoa-Assoumou S, Ndeboko B, Manouana GP, Houechenou RMA, Bikangui R, Mveang-Nzoghe A, Ondo GN, Mbongo-Kama E, Lell B, Abe H, Ushijima Y, Antchouey AM, **Yasuda J**, Adegnika AA, Siawaya JFD. SARS-CoV-2 emerging variants in Africa: view from Gabon. *Lancet Microbe*. 2021 Aug;2(8):e349.

⑧ Abe H#, Ushijima Y#, Bikangui R, Zoa-Assoumou S, Ondo GN, Manouana GP, More A, Skarwan E, Yali-Assy-Oyamli Y, Ndeboko B, Myrabelle Avome Houechenou R, Djoba Siawaya JF, Lell B, Adegnika AA, and ***Yasuda J**. Unrecognized introduction of SARS-CoV-2 variants of concern to Central Africa: Import and local transmission of B.1.1.7 in Gabon in the very early stage of the variant spread to the African continent. *J Med Virol*. 2021;93(10):6054-6058.　#These authors contributed equally to this work.

⑨ Wilkinson E, …, Abe H, ..., **Yasuda J**, et al. A year of genomic surveillance reveals how the SARS-CoV-2 pandemic unfolded in Africa. *Science*. 2021; 374(6566):423-431.

(2) For Indicator 2, that would be done by six months before the termination of the Project, discussions were commenced with relevant organizations such as the Ministry of Health (MoH) concerning the possibility for future clinical application of the rapid diagnostic methods developed by the Project (registration of the methods as standard diagnostic methods in Gabon, commercialization of the kit, etc.). After recognition of efficiency and usefulness of the developed rapid diagnostic methods by MoH in the last JCC, the discussion has been continued on future clinical application of the method.

(3) For Indicator 3, that would be performed by six months before the termination of the Project, a comprehensive report of research outcomes including policy recommendations (such as viral diseases to be monitored in the study area) was submitted to MoH and other relevant organizations. Final research report was submitted to MoH and MoHESR. With the support of a research grant “JICA

private sector collaboration project for clinical application", Canon Medical Systems Co., that is a professional company on a rapid diagnostic method and has been conducting joint research for more than 10 years with the chief advisor of the project, has started a local fact-finding survey in Gabon to develop a market of the method.

3. History of PDM Modification

(1) The Project expected that the inclusion of animal sample collection would enhance the achievement of Output "the prevalence of known and unidentified viral diseases is clarified in the areas around Lambaréné". In view of this situation, in September 2019, at the 3rd Joint Coordination Committee (JCC) held in the meeting room in MoHESR, Resident Representative of JICA, Prof. YASUDA, Director General of MoHESR and Co-director of CERMEL signed Minutes of Meetings (MM) for the amendment of activities and Inputs on Gabonese side of PDM and for the addition of the Project implementers of R/D.

(2) Because of the global spread of coronavirus disease 2019 (COVID-19), some of the Project activities have been suspended. In order to achieve the Project Purpose after the project team resume the activities, project duration needed to be extended. This extension results in the Project period from April 29, 2016 to February 28, 2022.

4. Others

4-1 Results of Environmental and Social Considerations (if applicable)
For details, see Environmental Monitoring (version 1-5)

4-2 Results of Considerations on Gender/Peace Building/Poverty Reduction (if applicable): N/A

III. Results of Joint Review

1. Results of Review based on DAC Evaluation Criteria

1.1 Relevance

The relevance of the Project is evaluated as High.

Before commencing the Project, limited information had been available regarding viral infections, negatively affecting the development of diagnostic methods for public health-concerned viral diseases in Gabon. In particular, there was a need

for the development of rapid diagnostic kits to enable the Point-of-Care (POC) testing in local health care settings among physicians and patients.

Under these situations, the Project could be evaluated as “highly relevant” due to the contribution to the "development of cooperation that contributes to the improvement of access to education and health care, and human resource development, in order to reduce social disparities" included in Japan's Country Assistance Policy to Gabon.

Since commencement of the Project, both molecular biological and serological methods were developed in CERMEL against more than 30 viruses, that resulted in strengthening a diagnostic capacity for viral diseases and monitoring systems for estimation of potential infection risks. In fact, CERMEL physicians became able to utilize the developed diagnostic methods when they faced to a febrile patient that was not caused by major pathogens such as malaria or bacteria.

Of note, CERMEL was one of the first institutes to establish a diagnostic system for COVID-19 and was approved as one of the main COVID-19 diagnostic laboratories in Gabon, contributing greatly to controlling the spread of the infection from the early phase of the COVID-19 pandemic. This is also one of good examples that clearly proved relevance of the Project. In addition, CERMEL researchers who received trainings on sequencing analyses contributed significantly to identify novel SARS-CoV-2 variants which have been an urgent issue of public health concern in Gabon since 2021.

1.2 Coherence

See the attached Annex 7 (in Japanese).

1.3 Effectiveness

The effectiveness of the Project is evaluated as High.

The outputs and the Project purpose were almost 100% achieved as described in the section of “2. Achievements of the Project”. Through the collaborative research with CERMEL and IRET, a total of 9 research papers were published regarding identification of pathogens of known and unidentified infectious diseases as well as development of rapid diagnostic methods for viral diseases of public health concern. Especially, the Project revealed the risks of hepatitis A virus, West Nile virus, and LCMV infections in Gabon for the first time by molecular biological and serological assays. One of the reasons why the Project was able to produce effectiveness is highly cooperative responses of both

CERMEL and IRET. For example, CERMEL kindly provided stored human samples when the Project had a difficulty in collecting new human samples due to the delay in getting an ethics approval from the committee. IRET, which had already had experiences to work with Japanese researchers, gave many ideas and strong supports to capture wild animals.

The human resource development of counterparts has actively and strongly pushed forward, and the higher level of counterparts' research activities was achieved in terms of both technology and knowledge. Several young collaborators have already started to plan and conduct their own research projects. Of importance, one main collaborator in CERMEL obtained a scholarship from OCEAC (Organization of Coordination for the Fight against Endemic Diseases in Central Africa) for the PhD program in 2019, and another main collaborator in CERMEL was also selected as a recipient of the PhD program supported by JSPS, "RONPAKU", in 2021 through the Project's support for preparation of their applications. Moreover, two IRET researchers acquired the national grant for their own studies with the Project's support. These young researchers have been trained enough to become a trainer in experimental techniques for researchers and research assistants in their organizations, as well as for researchers and physicians in external medical facilities. It would be fully expected that the techniques transferred to the counterparts in this Project will spread throughout Gabon in the near future and the research activities of the national institutes will be further strengthened.

1.4 Efficiency

The efficiency of the Project is evaluated as Moderate to High.

Although the Outputs and the Project Purpose were achieved within the Project period, several issues described in II. 1. 1-3 Activities affected the Project efficiency. In particular, a decline in public safety during the post-election violence and the COVID-19 pandemic significantly suppressed the Project activities for a total of 14 months out of the 6-year project period. However, the installation of the BSL-2/3 laboratory in September 2017, robustly facilitated the Project activities. Although the timing of the installation was delayed due to long-term custom clearance of shipment, both quantity and quality of the BSL-2/3 laboratory and the equipment installed with the laboratory were considered to be the highest in Gabon, improving the efficiency, quantity, and quality of the experiments to a similar condition in Japan. In particular, the DNA sequencer has enabled counterparts to conduct genetic analysis locally, which had previously been relied

on their collaborators in Europe to do, and has greatly advanced the quality of research activities of counterparts.

On the other hand, the main concern is maintenance of the BSL-2/3 laboratory and equipment. Compared to the period of the Project commencement, the frequency of electricity and water outages has decreased recently partially due to CERMEL's procurement of equipment (e.g., generator). However, the outage still remains and it resulted in occasional malfunctions in the laboratory systems and equipment. In the case that repair parts were not available in Gabon, it took a long time to get things back to a normal condition. Since the Project has prepared a stock of possible spare parts throughout the Project period, it is expected to be able to respond flexibly to such problems in the future.

1.5 Impact

The impact of the Project is evaluated as High.

The Project was conducted to clarify the actual situation of viral infections in the areas around Lambaréné in Gabon, and to characterize of the viruses identified in this study. The Project also aimed to develop rapid diagnostic methods for the viral diseases of public health concern to support local researchers/physicians for improving their capacity to accurately analyze and monitor pathogens, providing useful technology and information for infectious disease control in the country. As a result, the counterpart, CERMEL, reached to the international standard level as a diagnostic facility for viral diseases, and the environment for conducting molecular biological and serological analyses was established. CERMEL is now able to diagnose more than 30 viral infections using real-time PCR or ELISA assays. When the COVID-19 began to spread in Africa in March 2020, the Project urgently held a training to CERMEL researchers for appropriate handlings of samples and real-time PCR diagnosis. Consequently, CERMEL received government authorization for COVID-19 diagnosis and plays a central role in performing diagnostic tests in the country, to date.

Rapid diagnostic methods for major viral diseases including dengue virus and SARS-CoV-2 were developed with sufficient sensitivity and specificity in the Project, and the significant utility of the diagnostic methods were presented in the last JCC in December 2021. The Ministry of Health recognized the diagnostic methods as effective and the discussions have started with the Ministry of Health for future clinical application. Furthermore, Canon Medical Systems Co., which is a professional of rapid diagnostic methods, acquired a research grant "JICA private sector collaboration project" and started a local fact-finding survey. It is

expected that the Canon's project, with strong support from the Ministry of Health, will greatly accelerate the introduction of rapid diagnostic methods developed in the Project into clinical facilities in Gabon.

1.6 Sustainability

The sustainability of the Project is evaluated as Moderate to High.

As the Project has especially focused on the capacity development, the sustainability of the transferred technology/knowledge and counterparts' own research activities will be fully expected. This is because, as mentioned above in this report, a virtuous circle has been created in young main collaborators; they have been intensively trained by the Project and became trainers to provide trainings on molecular biological and serological techniques not only in CERMEL but also in other institutes such as the national research institutes and medical facilities. In addition to experimental skills, young collaborators also acquired knowledge and logical thinking enough to plan their own projects with remarkable motivation to get a PhD degree. These positive effects of the Project will certainly promote the counterparts' independent or collaborative research in the near future.

Regarding maintenance of the BSL-2/3 laboratory, one Equipment Officer in CERMEL, worked together throughout the Project, and the other young technicians are expected to maintain the laboratory appropriately. Sufficient external research funding was also assured by CERMEL at the end of the Project. Additionally, NEKKEN and Nagasaki University will continue to support CERMEL and IRET in procuring supplies for maintenance as much as possible on the basis of the tight and close cooperative relationships with CERMEL and IRET that were established through the Project.

2. Key Factors Affecting Implementation and Outcomes

Absence of a Project Coordinator during two periods (from April to October 2016 and from January to March 2018) caused delay of administrative/logistics works of the Project. In particular, during this period, the Project faced several difficulties not only in purchasing necessities for the Project such as lab equipment and the Project vehicle, but also in hiring local staff, because overseas activity cost was reduced due to the JICA's budgetary constraint in Japanese Fiscal Year 2017. After the respective Project Coordinator was assigned to the Project, the Project activities became smoother and easier. Local staffs supported the Project activities very well in collaboration with the Project Coordinator and counterparts'

administrative/logistics personals, although employment of local staffs started in 2018. Installation of the BSL-2/3 laboratory powerfully accelerated research activities and trainings of the Project as described above in spite of a delay in its installation. Delay in getting an ethics approval from the National Committee had an effect on new sample collection and therefore whole Project plans, whilst kind provision of human samples from CERMEL greatly contributed to promoting the Project activities. In addition, the COVID-19 pandemic regulated movement in the country, resulting in cancellation of sample collection in Bongolo Hospital. Unstable local water and electricity supply, poor internet access, and inconvenient procurement of research reagents affected the overall activities of the Project; unstable electricity was particularly problematic as running machines stopped suddenly and were damaged.

3. Evaluation on the results of the Project Risk Management

(1) Post-election violence

Post-election violence broke out in several parts of the country including Lambaréné on 31 August 2016, and JICA helped two CERMEL-based Japanese researchers evacuate on 4 September. This evacuation resulted in a minor delay in the implementation of the Project activities. The two researchers returned to Gabon in November after the travel ban was lifted by JICA.

(2) Authorization and confirmation of the ownership/land-use right of the construction site for the BSL-2/3 laboratory

In July 2017, the International Foundation of Albert Schweitzer Hospital sent a letter to JICA Cameroon Office claiming that the construction site for the BSL-2/3 laboratory is registered to the foundation and JICA should seek official permission from the foundation. JICA responded that the Project had followed recommendations of counterpart ministries (MoHESR and Scientific Research and Ministry of Public Health) and acquired necessary authorization to construct the laboratory. JICA therefore requested them to discuss directly with the related ministries.

(3) Building of the BSL-2/3 laboratory

In order to set up the BSL-2/3 laboratory, the Japanese experts proceeded to gather information on a local professional of construction through CERMEL. As a result, CERMEL introduced a reliable local technician to Japanese experts, and the Project was able to complete the foundation work which was required to

construct the laboratory, without any problems.

(4) Approval from Institutional and National Ethics Committee
An approval for stage-2 study protocol was needed from the National Ethics Committee (NEC) in order to collect new human samples. There has been months-long delay in the discussion of the protocol in NEC since 15 October 2018, when the project received an approval from the Institutional Ethics Committee (IEC) of CERMEL. After receiving the approval from IEC in CERMEL, the study protocol was then submitted to NEC on 14 February 2019. However, it was postponed due to the committee's own matter for a long time without any notification of next review schedule. Finally, NEC review was held on 1 June 2019. After discussion with CERMEL, the Project responded to the committee and submitted the modified protocol on 5 August 2019. To cope with such delay, Resident Representative of JICA requested MoHESR to take the necessary measures for the approval from NEC. CERMEL also attempted to push the committee for approval many times.

(5) COVID-19
Due to the COVID-19 pandemic since 2020, the Project Coordinator and one researcher who had stayed in Lambaréné moved to Libreville at the end of March to wait for the flight for Japan and then left Libreville on April 5, since the evacuation order was issued from JICA Headquarter (HQ). The Project Coordinator came back to Lambaréné at the beginning of December 2020 and two researchers returned in February 2021. Although the daily on-site training on basic techniques of molecular biological and serological experiments stopped due to COVID-19, the remote trainings on study design, data analysis, troubleshooting for CERMEL and IRET researchers have been continued in Japan.

4. Lessons Learnt
(1) The Project researchers faced to a lot of difficulties in administrative/logistics aspects of the Project at the beginning phase, because the dispatch of Project Coordinator was delayed. And lack of overseas activity cost, the Project could not hire a local staff for two years. This experience indicated the importance of the preparation period before the commencement of the Project.

(2) Although consumables and plastic materials were available in Gabon, it was difficult to purchase research reagents and other research materials for molecular and serological experiments. As for procurement of reagents, counterparts were also relying on third-country procurement for most of them. Although international shipment from Japan was also considered, it was not available because there was neither option of frozen/cooled shipping nor branch office in Gabon. Therefore, the Project researchers brought reagents from Japan every travel to Gabon. To obtain necessary reagents and materials smoothly, domestic suppliers in Gabon need to work efficiently (if applicable) and international shipping processes including custom clearance should be simplified in the future.

IV. For the Achievement of Overall Goals after the Project Completion

1. Prospects to achieve Overall Goal

In this Project, Overall Goal is the same as the Project Purpose, and 3 indicators were set as described above and PO.

The actual situation of viral infections revealed by the Project will be useful not only as new academic knowledge but also as a reference data for MoH and public health institutes in Gabon in order to develop a list of pathogens for continuous surveillance, and will provide important indication in the diagnosis for patients of febrile illness in medical facilities. The results of the Project study, which estimated the transmission route and year of the virus introduction into Gabon, are expected to be effectively used to prevent the spread of viral infections in the near future by strengthening quarantine measures for travelers and returnees from certain countries, and by taking early infection control measures. The rapid diagnostic methods for viral infections developed in this Project is expected to become one of solutions to provide accurate diagnosis to residents all over Gabon, where there is a difficulty in accessing medical facilities in rural areas.

2. Plan of Operation and Implementation Structure of the Gabonese side to achieve Overall Goal

Because the counterparts acquired enough knowledge how to conduct virus surveillance through the Project, continuous surveillance would be implemented by the counterparts of the Project after the Project completion to know the prevalence of the viral infections in not only humans but also animals. In fact, two

main collaborators who have been enrolling in the PhD programs by the Project support have continued their own research in terms of surveillance of viral diseases in Gabon. As mentioned in the section “2. 2-2”, the comprehensive report on public health concerned-viral diseases was shared with MoH, and a national surveillance program is expected to be commenced against several targeted viruses by the Ministry. The developed diagnostic method by the Project will be further provided as a clinical application through a new Project “JICA private sector collaboration with Canon Medical Systems Co.”.

3. Recommendations for the Gabonese side

It is highly expected that the counterparts of Gabon appropriately maintain the facilities as BLS-2/3 and equipment which procured by this project. Also, any required technical skills for maintenances are trained by the project.

In expectation of further introduction of the (rapid) diagnostic methods to whole Gabon, it will be important to continuously train researchers and physicians on techniques of molecular diagnosis to obtain accurate results in spite of differences in experience and education. For this purpose, continuous human resource development is essential from the viewpoint of the Ministries, medical facilities, and research institutions.

Countermeasures against viral infections developed from the results of this Project will be effective to a certain extent in Gabon, and similar countermeasures will also be effective in neighboring countries that are threatened by infectious diseases similar to Gabon. These countermeasures will have a broader social impact beyond national borders. It is expected that Gabon will become a country which actively push forward the infectious disease control on the African continent.

4. Monitoring Plan from the end of the Project to Ex-post Evaluation

There is no concrete monitoring plan after the end of the project. However, stable and reliable relationship with Gabonese researchers are established by the project so that continuous scientific discussions are expected.

Also, JICA will continue commitment to the counterparts of Gabon by sending Japan Overseas Cooperation Volunteers and accepting some researchers to Japanese universities for acquiring degrees.

Attached Files:

ANNEX 1: Results of the Project

(List of Dispatched Experts, List of Counterparts, List of Trainings, etc.)

ANNEX 2: List of Products (Report, Manuals, Handbooks, etc.) Produced by the Project

ANNEX 3: PDM (All versions of PDM)

ANNEX 4: R/D, M/M, Minutes of JCC (copy)

ANNEX 5: Monitoring Sheet (copy)

(Remarks: ANNEX 4 and 5 are internal reference only.)

ANNEX 6: Environmental Monitoring (copy)

ANNEX 7: Additional Review for DAC Evaluation Criteria (in Japanese).

Name	Catalog#	Manufacturer	Quantity	Year	Function/Use
BSL-2/3 Lab System		Seiko/Nihon-ika	1	2017	Biosafty-level 2 and 3 laboratory system
Microplate Reader	FilterMax F5	Molecular Dervices	1	2017	Fluorescence, luminescence and visible light detection device
CO2 Incubator	CPI-165	Astec	3	2017	Cell culture system with automatic CO2 control
CO2 Tank Mount	IM-300	Astec	1	2017	Mounting rack for CO2 tank
CO2 Regulator	IM-055	Astec	1	2017	Regulator of CO2 supply for CO2 incubator
CO2 Incubator Connection Kit		Astec	1	2017	Parts for connecting two CO2 incubators
Inverted Microscope	Leica DMIL DMi1	Leica Microsystems	1	2017	Microscope for cell culture
Fluorescence Microscope with CCD-camera	Leica DMIL LED	Leica Microsystems	1	2017	Microscope for fluorescence
Electrophoresis Power Supply	MP-3AG	Gellex International	1	2017	Power supply for protein/DNA electrophoresis
Electrophoresis Power Supply	MINI-3AG	Gellex International	1	2017	Power supply for protein/DNA electrophoresis
Storage Rack for Deep Freezer	CSU-300	Thermo Fisher Scientific	5	2017	Storage rack for deep freezer
Freezing Sample Box	ASA-1003 (20pieces)	Asahi Life Sience	8	2017	Sample storage box for deep freezer
Biomedical Showcase	BMS-351F3	Nihon Freezer	2	2017	Refrigerating showcase
Direct-Q Water Purification System	TANKS7JUV	Merck	1	2017	Water purification system for molecular biology grade purified water
Pressure Pomp for Water Purification System	ZD10SPPIN	Merck	1	2017	Pressure pomp of water purification system
Polypropylene Cartridge Filter (5um, 10um, 25um)	Barrier Pre-filter	Advantec Toyo Kaisha	5 each	2017	Pre-filter for water purification system
Plastic Housing for Barrier Pre-filter	1PP-1-FS	Advantec Toyo Kaisha	3	2017	Plastic case for barrier pre-filter
Stainless Stand for Plastic Housing		Advantec Toyo Kaisha	3	2017	Mounting rack for plastic housing of barrier pre-filter
Liquid Nitrogen Generator	ELAN2 Degital Auto	YOS	1	2017	Liquid nitrogen generator
Desk	3V16AL-MK	OKAMURA	3	2017	Office desks
Bookshelf	LK01AZ-ZA75	OKAMURA	1	2017	Bookshelf for office desk
Bookshelf	LK01BZ-ZA75	OKAMURA	2	2017	Bookshelf for office desk
Chair	CG-Rchair CN45ZR-FM	OKAMURA	4	2017	Office chair
Stool	L7C1ZA-PC	OKAMURA	4	2017	Laboratory chair
PCR Thermal Cycler	SimpliAmp Thermal Cycler	Thermo Fisher Scientific	1	2017	PCR device for amplification of DNA
Electric Down Transformer		Nihon Freezer	6	2017	Electrical voltage transformer from 220V to 100V
High Speed Refrigerated Micro Centrifuge	MX-307	Tomy Digital Biology	2	2017	High speed chilled centrifuge
Rack in Rotor	TMA-300	Tomy Digital Biology	2	2017	Rack of high speed centrifuge
Rotor	AR510-04	Tomy Digital Biology	2	2017	Rotor of high speed centrifuge
Rotor	AR015-SC24	Tomy Digital Biology	2	2017	Rotor of high speed centrifuge
Speedy Autoclave	SX-500	Tomy Digital Biology	2	2017	Infectious material sterilization device
Basket	ACA-325TP	Tomy Digital Biology	2	2017	Use in autoclave
Lid for basket	300TL	Tomy Digital Biology	2	2017	Use in autoclave
Multi Spin Centrifuge	Cryo Spin	Tomy Digital Biology	1	2017	Table-top centrifuge for spin-down
Gel Imaging System	Fusion-SOLO6	M&S Instruments	1	2017	Imaging system
Workbench	KK-48NI	SAKAE	2	2017	Workbench for laboratory
Workbench	KK-49PD	SAKAE	1	2017	Workbench for laboratory
Workbench	KK-69PD	SAKAE	1	2017	Workbench for laboratory
Wagon	PMR-152MNI	SAKAE	1	2017	Storage space for laboratory
Analytical Balance	XS105V	Mettler-Toledo Internation	1	2017	Measurement of chemicals
Precision Balance	XS1202SV	Mettler-Toledo Internation	1	2017	Measurement of chemicals
Dry Heat Sterilizer	SI400	Yamato Scientific	1	2017	Sterilizer for glassware
Suction Pomp	SP30S	Funakoshi	3	2017	Aspiration pomp for cell culture
Foot switch of suction pomp	SPFS	Funakoshi	3	2017	On/Off switch of suction pomp
UV Locker	UVL-1 OW	AS ONE	3	2017	UV sterilizer for labware
Cabinet Wagon	LC-0	SAKAE	2	2017	Storage space for laboratory
Cabinet Wagon	LA-3	SAKAE	2	2017	Storage space for laboratory
Small Amount Spectrophotometer	NanoPhotometer N50	Wako Pure Chemical Ind	1	2017	Measurement of DNA/RNA concentration
Real Time PCR System	StepOnePlus	Thermo Fisher Scientific	1	2017	Highly sensitive DNA detection system
Next-Generation Sequencer	MiniSeq	Illumina	1	2017	Table-top next-generation sequencer system
Bioanalyzer quantification system	Agilent 2100	Agilent	1	2017	DNA/RNA quarity check
Sanger Sequencer	3500 Genetic Analyzer	Thermo Fisher Scientific	1	2017	DNA Sanger Sequencer
Workstation	CLC Genomics Workbenc	Filgen	1	2017	Analysis of large-scale sequence data
Table-top Centrifuge	Centrifuge 5424	Eppendorf	1	2017	Table-top centrifuge for spin column
Clean Bench	S801CV	Showa	1	2018	Working space for molecular biology
Smart-UPS 3000	SMC3000J	APC Japan	1	2018	Electricity backup for sequencer
Hot Plate Stirrer	1-9458-01	Azone	1	2018	Buffer preparation
Miniwave Shaker	1-4103-05	Azone	1	2018	Agarose gel staining
Minidisk Rotater	BC-710I	Biocraft	1	2018	Sample mixture preparation
Block Incubator	BSR-MiniTC	Biomedical Science	1	2018	Sample incubation at fixed temperature
HEPA Filter	1T-320M	Resus techno	2	2018, 2019	Air filter to remove infectious agents
HEPA Filter	1LA-100	Resus techno	4	2018, 2019	Air filter to remove infectious agents
HEPA Filter	1A-200	Resus techno	2	2018, 2019	Air filter to remove infectious agents
HEPA Filter	1LA-130	Resus techno	6	2018, 2019	Air filter to remove infectious agents
Microplate Washer	AMW-8R	Biotech	1	2019	Automatic microplate washing device
Printgraph Classic	2305403	Atto	1	2019	Agarose gel imager
Mid-efficiency Filter		Resus techno	4	2019, 2021	Air filter to remove dust
Mupid-exU	EXU-1	Takara Bio	1	2020	Agarose gel electrophoresis
UV Transilluminator	UVP-95-0180-02	Funakoshi	1	2020	Agarose gel imager

ANNEX 1 List of Products Equipment (Gabon)

Name	Manufacturer	Quantity	Year	Function/Use
Generator		1	2017	Preparation for electricity outage
Highly efficient incinerator		1	2017	Incinerator without emitting toxic materials into the air
Microplate Washer	Molecular Dervices	1	2017	Automatic microplate washing device
Swing-rotor Centrifuge	Beckman Courter	1	2017	Centrifuge for blood samples
Autoclave	Thermoscintific	1	2017	Infectious material sterilization device
UPS	APC	8	2017, 2018, 2019, 2020	Preparation for electricity outage
Electricity Stabilizer		8	2017, 2018, 2019, 2020	Protect equipment from unstable electricity

#	Name	Type	Contents
Protocol-01	Conventional-RT-PCR	Protocol	Detection of dengue virus by RT-PCR
Protocol-02	RNA-Extraction	Protocol	Extraction of dengue virus RNA using the Qiagen kit
Protocol-03	TAE-buffer-preparation	Protocol	Preparation of TAE buffer for agarose gel electrophoresis
Protocol-04	Sequencing-DENV	Protocol	Sanger sequencing analysis of dengue virus genome
Protocol-05	3500-Genetic-Analyzer	Protocol	Instruction how to use the 3500 Genetic Analyzer instrument
Protocol-06	SARS2-Sequencing	Protocol	Sanger sequencing analysis of the S gene of SARS-CoV-2
Protocol-07	qPCR-StepOnePlus	Protocol	Highly sensitive detection of virus genome by quantitative PCR
Protocol-08	qPCR-Malaria	Protocol	Highly sensitive detection of malaria parasites by quantitative PCR
Protocol-09	qPCR-HIV1	Protocol	Highly sensitive detection of HIV genome by quantitative PCR
Protocol-10	ELISA	Protocol	Detection of antibody (IgG) against viruses by ELISA
Protocol-11	Acrylamide gel electrophoresis	Protocol	Protein separation by molecular size and detection
Protocol-12	Cell culture	Protocol	Set up and maintenance of cell culture
Protocol-13	Handling of pathogens	Protocol	Handling of pathogens in a BSL-2/3 laboratory with a personal protective equipment
Leaflet-version 1	N/A	Leaflet	Distribution to university, medical institute, etc. for advertisement of the Project in Gabon
Leaflet-version 2	N/A	Leaflet	Advertisement of progress of the Project after version 1

MINUTES OF MEETINGS

BETWEEN

JAPAN INTERNATIONAL COOPERATION AGENCY

THE MINISTRY OF HIGHER EDUCATION AND SCIENTIFIC RESEARCH AND

MEDICAL RESEARCH CENTER OF LAMBARENE

FOR AMENDMENT OF THE RECORD OF DISCUSSIONS

ON

THE PROJECT FOR ESTABLISHMENT OF LABORATORY SURVEILLANCE SYSTEM

FOR VIRAL DISEASES OF PUBLIC HEALTH CONCERN

The Japan International Cooperation Agency (hereinafter referred to as "JICA"), the Ministry of Higher Education and Scientific Research, and Medical Research Center of Lambaréné hereby agree that the Record of Discussions on the Project for Establishment of Laboratory Surveillance System for Viral Diseases of Public Health Concern signed on 12th February 2016 will be amended as follows;

1. Amendment of activities and INPUTS, the Gabonese side

Before	Amended Version
N.A.	1-2 :To collect samples from livestock, wild animals, arthropods around Lambaréné
1-2. To conduct PCR screening for known viruses such as Chikungunya virus, Dengue virus, Rift Valley Fever virus and West Nile virus in the specimens.	1-3. To conduct PCR screening for known viruses such as Chikungunya virus, Dengue virus, Rift Valley Fever virus and West Nile virus in the specimens collected through 1-1 and 1-2.
Allocation of Counterpart Personnel (1) Project Director (2) Project Manager (3) Researchers in CERMEL (4) Medical doctors in CERMEL (5) Other designated personnel when necessary	Allocation of Counterpart Personnel (1) Project Director (2) Project Manager (3) Researchers in CERMEL (4) Medical doctors in CERMEL (5) Researchers in IRET (6) Other designated personnel when necessary
Reason: The inclusion of animals to sample collections will enhance the achievement of Output 1 "The prevalence of known and unidentified viral diseases is clarified in the areas around Lambaréné." According to this addition, activity numbers from 1-3 to 1-5 will be modified.	

2. Addition of Project Implementers (R/D Appendix 1 section 6.(2))

Before	Amended Version
Project Implementers: MoHESR and CERMEL	Project Implementers: MoHESR, CERMEL, Research Institute in Tropical Ecology (IRET)

Reason: According to the amendments above, IRET who is in charge of animal research will be part of the Project.

This amendment will become effective upon the signing date.

Done in duplicate in the French and English languages, both equally authentic.
In case of any divergence of interpretation, the English text shall prevail.

Annex 1 : Amended PDM, PO
Annex 2 : Record of Discussions (signed on 12th February 2016)

Lambaréné, September 24th, 2019

Mr. Eiro YONEZAKI

Resident Representative
Gabon Office
Japan International Cooperation Agency
Japan

Prof. Dr. Joseph LANSOUD-SOUKATE

Director General of Scientific Research and Innovation
Ministry of Higher Education and Scientific Research
Gabonese Republic

Prof. Jiro YASUDA

Department of Emerging Infectious Diseases, Institute of Tropical Medicine,
Nagasaki University
Japan

Prof. Bertrand LELL

Co-Director
Centre de Recherches Médicales de Lambaréné
Gabonese Republic

Annex I

Project Design Matrix

Title of Project : The Project for Identification of Pathogens and Development of On-site Diagnostic Methods for Viral Diseases of Public Health Concern Including Viral Hemorrhagic Fever

Version 2

Implementing Agency: administrative officers, doctors and researchers engaged in the control, treatment and diagnosis of infectious diseases of public health concern including viral hemorrhagic fever

Date: 24/09/2019

【Minister of Higher Education and Scientific Research of Gabon】

【Center of Medical Research Lambaréné (CERMEL)】 【Institut de Recherche en Ecologie Tropicale (IRET)】

Target Group: Residents at risk of viral diseases in Gabon: Approx. 1.6 million

Period of Project: 2016/4/29-2021/4/28

Project Site: The area around Lambaréné in the Moyen-Ogooué province in the Gabonese Republic

【Abbreviations】 LAMP: Loop-mediated Isothermal Amplification, ELISA: Enzyme-Linked ImmunoSorbent Assay, NEKKEN: Institute of Tropical Medicine, Nagasaki University

Narrative Summary	Objectively Verifiable Indicators	Means of Verification	Important Assumption	Achievement	Remarks
Project Purpose					
The research and development capacity of the Gabonese research center is enhanced through the collaborative research with Japanese research institute regarding identification of pathogens of known and unidentified infectious diseases as well as development of rapid diagnostic methods for viral diseases of public health concern.	1.By six (6) months before the termination of the Project, at least six (6) research papers are published in peer-reviewed international journals with the themes of the prevalence of viral diseases in the areas around of Lambaréné, the characteristics analyses of the target viruses and/or rapid diagnostic methods (or kit).	(1) Project reports (2) The report submitted to governmental organizations concerned (3) Research articles published in international scientific journals			
	2. By six (6) months before the termination of the Project, the discussions are commenced with governmental organizations concerned for future clinical application of the rapid diagnostic methods developed by the Project (registration of the methods as standard methods in Gabon, commercialization of the kit, etc.).				
	3. By six (6) months before the termination of the Project, a comprehensive report of research outcomes including policy recommendations such as viral diseased to be monitored in the target area is submitted to governmental organizations concerned.				

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Annex I

Outputs					
1. The prevalence of known and unidentified viral diseases is clarified in the areas around Lambaréné.	1-1. Within one (1) year after the commencement of the Project, the operation of the library of specimens is commenced at CERMEL for the research of viral diseases. 1-2. By six (6) months before the termination of the Project, research outcomes regarding the prevalence of infectious diseases caused by known and/or newly-identified viruses in the areas around Lambaréné gained from the viral and serological investigations is compiled in a report and/or scientific articles.	(1) Project reports	1. Cooperation from governmental organizations concerned is gained for the practical application of research outcomes to the society (implementation of discussion for it, etc.)		
2. Characteristics such as genetic information and pathogenicity of viruses that are regarded as public health concern and newly identified in Gabon is defined.	2-1. By two and a half (2.5) years after the commencement of the Project, public health-concerned and newly-identified viruses (if detected) are isolated and identified. 2-2.By six (6) months before the termination of the Project, research outcomes regarding genetic information, pathogenicity, etc. of the target viruses are compiled in a report and/or scientific articles. 2-3. By six (6) months before the termination of the Project, the results of risk assessment for newly-identified virus(es) are compiled in a report and/or scientific articles insofar as it is identified.	(1) Project reports			
3. Rapid diagnostic methods for viral diseases of public health concern and/or newly identified ones are developed.	3-1. By two and a half (2.5) years after the commencement of the Project, rapid diagnostic methods for the selected viruses are developed. 3-2. Within three and a half (3.5) years after the commencement of the Project, serological testing methods for the selected viruses are developed at CERMEL. 3-3. By six (6) months before the termination of the Project, the clinical utilities of the rapid diagnostic methods are evaluated. 3-4. By six (6) months before the termination of the Project, clinical performance evaluation as well as cost analysis of the rapid diagnostic test kit that can detect multiple pathogens simultaneously are performed.	(1) Project reports			

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Annex I

Activities	Inputs		Important Assumption
		The Gabonese Side	
1. The prevalence of known and unidentified viral diseases is clarified in the areas around Lambaréné. 1-1. To develop a library of specimens (blood, urine, throat swab, etc.) in CERMEL, collected from malaria-negative febrile patients who visited medical facilities such as the Albert Schweitzer Hospital. 1-2 To collect samples from livestock, wild animals, arthropods around Lambarene 1-3. To conduct PCR screening for known viruses such as Chikungunya virus, Dengue virus, Rift Valley Fever virus and West Nile virus in the specimens collected through 1-1 and 1-2. 1-4. To investigate the possibility of unidentified virus(es) by detecting viral genes exhaustively using next-generation sequencer from the specimens that demonstrated negative for the tested viruses, followed by matching them with the known gene sequences registered in the database. 1-5. To clarify the antibody prevalence rate of residents in the area around Lambaréné by conducting serological investigation of public health-concerned viruses for the patients visited to the Albert Schweitzer Hospital using the testing methods developed in the Activity 3-4.	Dispatch of JICA Experts (1) A chief advisor (short-term expert) (2) Project coordinator(s)/Environmental and Social Considerations (long-term expert) (3) An expert with the expertise of rapid diagnostics (short-term expert) (4) Experts with the expertise of viral experiments (short-term experts) (5) A local research manager (long-term expert) (6) A researcher (long-term expert) (7) Other researcher(s) with designated expertise (short-term expert) Training in Japan and/or third country/-ies (1) Virology (2) Laboratory diagnosis (3) Other necessary training Provision of Equipment and materials (1) Necessary research instruments, equipments and/or devices for project research activities Local costs Running expenses necessary for implementation of the project activities other than those that borne by the Gabonese side.	Allocation of Counterpart Personnel (1) Project Director (2) Project Manager (3) Researchers in CERMEL (4) Medical doctors in CERMEL (5) Researchers in IRET (6) Other designated personnel when necessary Land, Facilities, Equipment and Materials (1) Office space in CERMEL (2) Laboratory space in CERMEL (3) BSL-2 laboratory in CERMEL (4) BSL-4 laboratory in other research and/or testing institute(s) (when necessary) (5) Clinical specimens form patients Local costs Running expenses necessary for implementation of the	1. Gabonese counterparts do not leave their position so as to affect the output of the project. 2. Necessary cooperation is gained by health facilities and relevant agencies for the project activities.

Annex I

2. Characteristics such as genetic information and pathogenicity of viruses that are regarded as public health concern and newly identified in Gabon is defined. 2-1. To perform the isolation of public health-concerned and/or newly-identified viruses with cultured cells, in parallel with the gene analyses under the Activities 1. Note: In case that a virus is suspected to be handled in BSL-4 laboratory, isolation of the virus is supposed to be done in the said laboratory in other research and/or testing institute(s)) 2-2. To accumulate virological findings through detailed gene analyses such as evolution (molecular) phylogenetic analyses for public health-concerned and/or newly-identified viruses. 2-3. To perform risk assessment of newly-identified virus(es) as pathogen(s) on the basis of characteristics analyses such as proliferativity, cytotoxicity (pathogenicity) and host/tissue specificity by inoculating them various types of host-derived cultured cells.	project activities such as personnel costs of researchers, research activity costs including travel expenses, consumables, and supplies, maintainance costs for researech instruments, epuipment and devices and laboratory facilities, utility costs such as water, electricity and communication,.	

Annex I

3. Rapid diagnostic methods for viral diseases of public health concern and/or newly identified ones are developed. 3-1. To select at least five (5) viral diseases that are supposed to have the needs for the development of rapid diagnostic methods on the basis of the information regarding the endemic infectious diseases in Gabon and its neighboring countries together with the results from the Activities 1. 3-2. To develop rapid diagnostic methods for the detection of the selected viruses using gene amplification technologies with a focus on the LAMP method. 3-2-1. To determine the genetic sequences with high specificity for the target pathogens base on the genome information of the pathogens of the target infectious diseases as well as that for differential diagnosis. 3-2-2. To design the primers for the LAMP or other nucleic acid amplification methods and develop the diagnostic test that specifically detect target viruses. 3-2-3. To evaluate the clinical utility of the newly-developed rapid diagnostic methods by conducting comparative studies with existing diagnostic methods in its performance such as sensitivity, specificity and reagent stability as well as the cost for testing. 3-3. To develop a rapid diagnostic test kit that can detect multiple pathogens simultaneously.			

3-3-1To select infectious diseases that have the needs for the Point-of Care (POC) testing with the focus on viral diseases (add other diseases such as malaria if needed). 3-3-2. To develop rapid diagnostic method(s) using LAMP method for the pathogens other than that developed under the Activity 3-2 through the same procedure. 3-3-3. To prepare a rapid diagnostic test kit that detect at least five (5) pathogens simultaneously by panelizing the rapid diagnosing methods developed under the Activities 3-2 and 3-4-2. 3-3-4. To evaluate the clinical utility and the testing cost of the kit. 3-4. To develop serological testing methods for the viruses selected under the Activity 3-1. 3-4-1. To determine the viral antigen for ELISA followed by the development of its mass-expressing system in eukaryotic cells or E. coli as well as purification methods at NEKKEN. 3-4-2. To develop IgG-ELISA for the target viruses using sera from infected persons at CERMEL.			**Pre-Conditions** 1. Approval is obtained by the Ethical Committee(s) for the research subjects conducted in the Project. 2. The agreement for the provision of clinical specimens to the Project for research purpose is gained from relevant hospitals and the Ministry of Health and Public Hygiene. **<Issues and countermesures>**

Project Monitoring Sheet II (Plan of Operation)

Version 7
Date: 24/09/2019

Project Title: The project for establishment of laboratory surveillance system for viral diseases of public health concern (SYMAV)

Inputs	Year	2016				2017				2018				2019				2020				Remarks	Monitoring: Issue	Monitoring: Solution
		I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV			
Expert																								
Chief Advisor (Jiro YASUDA)	Plan																							
	Actual																							
Project Coordinator (Jun AOKI MCCALL -> Izumi SUZUMORI)	Plan																							
	Actual																							
Project Assistant/Translator (Yannick Mbourou Ogoula)	Plan																							
	Actual																							
Expert 1 (Haruka ABE)	Plan																							
	Actual																							
Expert 2 (Yuri USHIJIMA)	Plan																							
	Actual																							
Expert 3 (Shuzo URATA)	Plan																							
	Actual																							
Expert 4	Plan																							
	Actual																							
Expert 5	Plan																							
	Actual																							
Equipment																								
Laboratory equipment	Plan																							
	Actual																							
Training in Japan																								
Training for handling viruses	Plan																							
	Actual																							
In-country/Third country Training																								
Training for working in biosafety level-2/3 facilities	Plan																							
	Actual																							

Activities / Sub-Activities	Year	2016				2017				2018				2019				2020				Responsible Organization: Japan	Responsible Organization: GOGR	Achievements	Issue & Countermeasures
		I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV				
Output 1:																									
1-1. To develop a library of specimens (blood, urine, throat swab, etc.) in CERMEL, collected from malaria-negative febrile patients who visited medical facilities such as the Albert Schweitzer Hospital.	Plan																								
	Actual																								
1-2. To collect samples from livestock, wild animals, arthropods around Lambarene	Plan																								
	Actual																								
1-3. To conduct PCR screening for known viruses such as Chikungunya virus, Dengue virus, Rift Valley Fever virus and West Nile virus in the specimens collected through 1-1 and 1-2.	Plan																								
	Actual																								
1-4. To investigate the possibility of unidentified virus(es) by detecting viral genes exhaustively using next-generation sequencer from the specimens that demonstrated negative for the tested viruses, followed by matching them with the known gene sequences registered in the database.	Plan																								
	Actual																								
1-5. To clarify the antibody prevalence rate of residents in the area around Lambaréné by conducting serological investigation of public health-concerned viruses for the patients visited to the Albert Schweitzer Hospital using the testing methods developed in the Activity 3-4.	Plan																								
	Actual																								
Output 2:																									
2-1. To perform the isolation of public health-concerned and/or newly-identified viruses with cultured cells, in parallel with the gene analyses under the Activities 1. Note: In case that a virus is suspected to be handled in BSL-4 laboratory, isolation of the virus is supposed to be done in the laboratory of other BSL-4 research and/or testing institute(s))	Plan																								
	Actual																								
2-2. To accumulate virological findings through detailed gene analyses such as evolution (molecular) phylogenetic analyses for public health-concerned and/or newly-identified viruses.	Plan																								
	Actual																								
2-3. To perform risk assessment of newly-identified virus(es) as pathogen(s) on the basis of characteristics analyses such as proliferativity, cytotoxicity (pathogenicity) and host/tissue specificity by inoculating them various types of host-derived cultured cells.	Plan																								
	Actual																								
Output 3:																									
3-1. To select at least five (5) viral diseases that are supposed to have the needs for the development of rapid diagnostic methods on the basis of the information regarding the endemic infectious diseases in Gabon and its neighboring countries together with the results from the Activities 1.	Plan																								
	Actual																								
3-2. To develop rapid diagnostic methods for the detection of the selected viruses using gene amplification technologies with a focus on the LAMP method.	Plan																								
	Actual																								

Activity	
3-2-1. To determine the genetic sequences with high specificity for the target pathogens based on the genome information of the pathogens of the target infectious	Plan
	Actual
3-2-2. To design the primers for the LAMP or other nucleic acid amplification methods and develop the diagnostic test that specifically detect target viruses.	Plan
	Actual
3-2-3. To evaluate the clinical utility of the newly-developed rapid diagnostic methods by conducting comparative studies with existing diagnostic methods in its performance such as sensitivity, specificity and reagent stability as well as the cost for testing.	Plan
	Actual
3-3. To develop a rapid diagnostic test kit that can detect multiple pathogens simultaneously.	Plan
	Actual
3-3-1. To select infectious diseases that have the needs for the Point-of Care (POC) testing with the focus on viral diseases (add other diseases such as malaria if needed).	Plan
	Actual
3-3-2. To develop rapid diagnostic method(s) using LAMP method for the pathogens other than that developed under the Activity 3-2 through the same procedure.	Plan
	Actual
3-3-3. To prepare a rapid diagnostic test kit that detect at least five (5) pathogens simultaneously by panelizing the rapid diagnosing methods developed under the Activities 3-2 and 3-4-2.	Plan
	Actual
3-3-4. To evaluate the clinical utility and the testing cost of the kit.	Plan
	Actual
3-4. To develop serological testing methods for the viruses selected under the Activity 3-2.	Plan
	Actual
3-4-1. To determine the viral antigen for ELISA followed by the development of its mass-expressing system in eukaryotic cells or E. coli as well as purification methods at the Institute of Tropical Medicine, the Nagasaki University (NEKKEN).	Plan
	Actual
3-4-2. To develop IgG-ELISA for the target viruses using sera from infected persons and/or animals at CERMEL.	Plan
	Actual

Duration / Phasing																						Remarks	Issue	Solution
	Plan																							
	Actual																							

Monitoring Plan	Year	1st Year				2nd Year				3rd Year				4th Year				5th Year				Remarks	Issue	Solution
		I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV			
Monitoring																								
Joint Coordinating Committee	Plan																							
	Actual																							
Set-up the Detailed Plan of Operation	Plan																							
	Actual																							
Submission of Monitoring Sheet	Plan																							
	Actual																							
Monitoring Mission from Japan	Plan																							
	Actual																							
Joint Monitoring	Plan																							
	Actual																							
Post Monitoring	Plan																							
	Actual																							
Reports/Documents																								
Project Completion Report	Plan																							
	Actual																							
Public Relations																								
To hold symposium of project results for ministries	Plan																							
	Actual																							

F

BC

JLS

PROCES VERBAL DE LA REUNION

ENTRE

L'AGENCE JAPONAISE DE COOPERATION INTERNATIONALE

LE MINISTERE DE L'ENSEIGNEMENT SUPERIEUR, DE LA RECHERCHE SCIENTIFIQUE, DU TRANSFERT DES TECHNOLOGIES ET DE L'EDUCATION NATIONALE CHARGE DE LA FORMATION CIVIQUE

ET

LE CENTRE DE RECHERCHES MEDICALES DE LAMBARENE

POUR AMENDEMENT DU PROCES VERBAL

SUR

LE PROJET D'ETABLISSEMENT D'UN SYSTEME DE SURVEILLANCE EN LABORATOIRE DES MALADIES VIRALES REPRESENTANT UN PROBLEME DE SANTE PUBLIQUE

L'Agence Japonaise de Coopération Internationale (ci-après dénommée « JICA »), le Ministère de l'Enseignement Supérieur, de la Recherche Scientifique, du Transfert des Technologies et de l'Education Nationale chargé de la Formation Civique et le Centre de Recherches Médicales de Lambaréné conviennent par la présente que le procès-verbal sur le projet d'établissement d'un système de surveillance en laboratoire des maladies virales représentant un problème de santé publique signé le 12 février 2016 sera modifié comme suit :

1. Annexe1 Description du Projet

Avant	Version amendée
7. Durée La durée de la coopération technique pour le Projet sera de cinq (5) ans à partir d' Avril 2016	7. Durée La durée de la coopération technique pour le Projet sera de cinq (5) ans et dix (10) mois à partir d' Avril 2016
Raison : À cause de l'épidémie de la COVID-19, certaines activités ont été suspendues. Pour atteindre le but du Projet après que l'équipe du projet ait repris les activités, la durée du Projet doit être prolongée. La prolongation a pour résultat que la durée du Projet est du 29 Avril 2016 au 28 Février 2022.	

2. Annexe1 Description du Projet

Avant	Version amendée
6. Site (s) du projet, les exécutants et les bénéficiaires Mise en œuvre du projet: Ministère de l'Enseignement Supérieur et de la Recherche Scientifique, CERMEL et Institut de Recherche en Ecologie Tropicale (IRET)	6. Site (s) du projet, les exécutants et les bénéficiaires Mise en œuvre du projet: Ministère de l'Enseignement Supérieur, de la Recherche Scientifique, du Transfert des Technologies et de l'Education Nationale chargé de la Formation Civique,

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	CERMEL et Institut de Recherche en Ecologie Tropicale (IRET)
Raison : En raison du remaniement ministériel, le nom du Ministère de l'Enseignement Supérieur et de la Recherche Scientifique est modifié comme suit Ministère de l'Enseignement Supérieur, de la Recherche Scientifique, du Transfert des Technologies et de l'Education Nationale chargé de la Formation Civique.	

Les parties reconnaissent et conviennent que ce procès-verbal de la réunion sera exécuté par signature électronique, qui est considérée comme une signature originale à toute fin utile et à la même force et le même effet qu'une signature originale. La «signature électronique» comprend les versions faxées d'une signature originale ou les versions scannées et transmises électroniquement (e.g. via pdf) d'une signature originale.

Cet amendement entrera en vigueur à la date de signature.

Annexe 1 : Procès-Verbal (signé le 12 février 2016)
Annexe 2 : PDM amendé, PO

Lambaréné, le 28 Janvier 2021

M. Eiro YONEZAKI

Représentant Résident
Bureau du Gabon
Agence Japonaise de Coopération Internationale
Japon

Prof. Joseph LANSOUD-SOUKATE

Directeur Général de la Recherche Scientifique et de l'Innovation
Ministère de l'Enseignement Supérieur, de la Recherche Scientifique, du Transfert des Technologies et de l'Education Nationale chargé de la Formation Civique
République Gabonaise

Prof. Jiro YASUDA

Professeur
Département des maladies infectieuses émergentes,
Institut de médecine tropicale,
Université de Nagasaki
Japon

Prof. Bertrand LELL

Co-Directeur
Centre de Recherches Médicales de Lambaréné
République Gabonaise

MINUTES OF MEETINGS

BETWEEN

JAPAN INTERNATIONAL COOPERATION AGENCY

THE MINISTRY OF HIGHER EDUCATION, SCIENTIFIC RESEARCH, TECHNOLOGY TRANSER AND NATIONAL EDUCATION IN CHARGE OF CIVIC EDUCATION, MEDICAL RESEARCH CENTER OF LAMBARENE AND RESEARCH INSTITUTE FOR TROPICAL ECOLOGY

FOR AMENDMENT OF THE RECORD OF DISCUSSIONS

ON

THE PROJECT FOR ESTABLISHMENT OF LABORATORY SURVEILLANCE SYSTEM FOR VIRAL DISEASES OF PUBLIC HEALTH CONCERN

The Japan International Cooperation Agency (hereinafter referred to as "JICA"), the Ministry of Higher Education, Scientific Research, Technology Transfer and National Education in charge of Civic Education, Medical Research Center of Lambaréné, and Research Institute for Tropical Ecology hereby agree that the Record of Discussions on the Project for Establishment of Laboratory Surveillance System for Viral Diseases of Public Health Concern signed on 12th February 2016 will be amended as follows;

1. Apprendix 1 Project Description

Before	Amended Version
7.Duration The duration of the technical cooperation for the Project will be five (5) years starting in April 2016.	7. Duration The duration of the technical cooperation for the Project will be five (5) years and ten months (10) starting in April 2016.
Reason: Because of the global spread of the coronavirus disease 2019 (COVID-19), some of the project activities have been suspended. In order to achieve the project purpose after the project team resume the activities, project duration needs to be extended. This extension results in the Project period from April 29, 2016 to February 28, 2022.	

2. Apprendix 1 Project Description

Before	Amended Version
6. Project Site(s), Implementers and Beneficiaries Project Implementers: MoHESR, CERMEL, Institut de Recherche en Ecologie Tropicale (IRET)	6. Project Site(s), Implementers and Beneficiaries Project Implementers: MoHESRTTNE, CERMEL, Research Institute in Tropical Ecology (IRET)
Reason: According to the reorganization of central government offices, the name of Minister of Higher Education and Scientific Research (MoHESR) has been amended as Ministry of Higher Education, Scientific Research, Technology Transfer and National Education in charge of Civic	

Education (MoHESRTTNE).

The parties acknowledge and agree that this Minutes of Meetings may be executed by electronic signature, which is considered as an original signature for all purposes and has the same force and effect as an original signature. "Electronic signature" includes faxed versions of an original signature or electronically scanned and transmitted versions (e.g., via pdf) of an original signature.

This amendment will become effective as of January 28, 2021.

Annex 1 : Amended Project Design Matrix
Annex 2 : Record of Discussions (signed on 12th February, 2016)

Lambaréné, January 28, 2021

Mr. Eiro YONEZAKI

Representative
Gabon Office
Japan International Cooperation Agency
Japan

Prof. Joseph MANSOUNGOUKATE

Director General of Scientific Research and Innovation
Ministry of Higher Education, Scientific Research, Technology Transfer and National Education in charge of Civic Education
Gabonese Republic

Prof. Jiro YASUDA

Professor
Department of Emerging Infectious Diseases, Institute of Tropical Medicine, Nagasaki University
Japan

Prof. Bertrand LELL

Co-Director
Medical Research Center of Lambaréné
Gabonese Republic

RECORD OF DISCUSSIONS

ON

THE PROJECT FOR IDENTIFICATION OF UNKNOWN PATHOGENS AND ESTABLISHMENT OF ON-SITE RAPID DIAGNOSTIC SYSTEM FOR VIRAL DISEASES IN THE GABONESE REPUBLIC

AGREED UPON AMONG

THE MINISTRY OF HIGHER EDUCATION AND SCIENTIFIC RESEARCH,

MEDICAL RESEARCH CENTER OF LAMBARENE AND

JAPAN INTERNATIONAL COOPERATION AGENCY

Libreville, February 12th, 2016

山形律子

Ms. Ritsuko YAMAGATA

Director
Human Development Department
Japan International Cooperation Agency
Japan

安田二朗

Dr. Jiro YASUDA

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Co-Director
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Gabonese Republic

Based on the minutes of meetings on the Detailed Planning Survey on the "Project for Identification of Unknown Pathogens and Establishment of On-site Rapid Diagnostic System for Viral Diseases" (hereinafter referred to as "the Project") signed on October 2, 2015 among the Ministry of Higher Education and Scientific Research (hereinafter referred to as "MoHESR"), Medical Research Center of Lambaréné (hereinafter referred to as "CERMEL") and the Japan International Cooperation Agency (hereinafter referred to as "JICA"), JICA held a series of discussions with MoHESR, CERMEL and other relevant organizations to develop a detailed plan of this Project.

Both parties agreed the details of the Project and the main points discussed as described in the Appendix 1 and the Appendix 2, respectively.

Both parties also agreed that CERMEL will be responsible for the implementation of the Project in cooperation with JICA, coordinate with other relevant organizations and ensure that the self-reliant operation of the Project is sustained during and after the implementation period in order to contribute toward both social and economic development of the Gabonese Republic (hereinafter referred to as "Gabon").

The Project will be implemented within the framework of the Agreement on Technical Cooperation signed on March 21, 2008 (hereinafter referred to as "the Agreement") and the Note Verbales to be exchanged before the end of March, 2016 between the Government of Japan (hereinafter referred to as "GOJ") and the Government of Gabon (hereinafter referred to as "GOGR").

Done in duplicate in the French and English languages, both equally authentic. In case of any divergence of interpretation, the English text shall prevail.

Appendix 1: Project Description
Appendix 2: Main points discussed
Appendix 3: Minutes of Meetings on the Detailed Planning Survey for the "Identification of Unknown Pathogens and Establishment of On-site Rapid Diagnostic System for Viral Diseases in Gabon"

Appendix 1

PROJECT DESCRIPTION

Both parties confirmed that there is no change in the Project Description in the Minutes of Meetings for the Detailed Planning Survey on the Project signed on October 2, 2015 (Appendix 3).

I. BACKGROUND

The infectious diseases account for a large part of the cause of death in Gabon (56% 2011, WHO), in particular, Malaria is the largest cause of under-5 mortality and the infection rate of HIV and the prevalence rate of tuberculosis are higher than the average rates of Sub-Saharan Africa. In addition to these three major infectious diseases, a variety of infectious diseases such as Dengue fever, Chikungunya fever and Ebola virus disease have occurred in Gabon. Moreover, Gabon is geographically close to Nigeria, where Lassa fever is endemic, and the Democratic Republic of Congo, which has experienced the repeated Ebola virus disease outbreaks, hence Gabon is also exposed to the risk of these infectious diseases. However, the ability of Gabon to take measures to cope with the emerging and reemerging infectious diseases is not sufficient.

In this situation, Gabon has set the establishment of a monitoring system for infectious disease control in the national development strategy, "National Strategic Plan Gabon Emergent 2011-2016" and positioned infectious diseases as a particular problem to be solved preferentially.

The project aims to enhance the research and development capacity of the Gabonese research center through collaborative research by the Institute of Tropical Medicine, Nagasaki University (hereinafter referred to as "NEKKEN") and CERMEL about identification and characterization analysis of known and unidentified pathogenic viruses based on the survey. The result of the project is expected to be beneficial to the countermeasures against viral diseases in Gabon and also in the Central Africa region in the future.

II. OUTLINE OF THE PROJECT

The Details of the Project are described in the Project Design Matrix (hereinafter referred to as "PDM") (Annex I) and the tentative Plan of Operation (hereinafter referred to as "PO") (Annex II).

1. Title of the Project

The title of the Project was modified from the original "The Project for Identification of Unknown Pathogens and Establishment of On-site Rapid Diagnostic System for Viral Diseases" to "The Project for Identification of Pathogens and Development of On-site Diagnostic Methods for Viral Diseases of Public Health Concern Including Viral Hemorrhagic Fever" at the time of the Detailed Planning Survey, so that the agreed contents of the Project were accurately reflected. After the Detailed Planning Survey, further discussion on the project title was held. As a result, it is agreed that the project title will be changed to "The Project for Establishment of Laboratory Surveillance System for Viral Disease of Public Concern" immediately after the Note Verbales is exchanged between GOJ and GOGR.

2. Project Purpose

The research and development capacity of the Gabonese research center is enhanced through the collaborative research with Japanese research institute regarding identification of pathogens of known and unidentified infectious diseases as well as development of rapid diagnostic methods for viral diseases of public health concern.

3. Outputs

(1) The prevalence of known and unidentified viral diseases is clarified in the areas around Lambaréné.
(2) Characteristics such as genetic information and pathogenicity of viruses that are regarded as of public health concern and newly identified in Gabon is defined.
(3) Rapid diagnostic methods for viral diseases of public health concern and/or newly identified ones are developed.

4. Inputs

(1) Inputs by the Japanese Side
(a) Dispatch of Experts
- Chief Advisor
- Project Coordinator
- Other Experts with the expertise of rapid diagnostics, viral experiments, research management and other designated areas

(b) Training
(c) Machinery and Equipment

- Necessary research instruments, equipment and devices for research and development activities, as shown in Annex Ⅲ

In case of importation, the machinery, equipment and other materials under II-4 (1) (c) above will become the property of the Gabonese side upon being delivered C.I.F. (cost, insurance and freight) to the Gabonese authorities concerned at the ports and/or airports of disembarkation.

Input other than indicated above will be determined through mutual consultations between JICA and CERMEL during the implementation of the Project, as necessary.

(2) Inputs by the Gabonese Side

The MoHESR and CERMEL will take necessary measures to provide at their own expense:

(a) Services of the Gabonese side counterpart personnel and administrative personnel as referred to in II-5;
(b) Suitable office space with necessary equipment;
(c) Supply or replacement of machinery, equipment, instruments, vehicles, tools, spare parts and any other materials necessary for the implementation of the Project other than those provided by JICA;
(d) Information as well as support in obtaining medical service;
(e) Credentials or identification cards;
(f) Available data (including maps and photographs) and information related to the Project;
(g) Running expenses necessary for the implementation of the Project;
(h)Expenses necessary for operation and maintenance of the equipment referred to in II-5 (1).

5. Implementation Structure

The Project Implementation Structure is shown in Annex IV. The roles and assignments of both sides are as follows:

(1) The Gabonese side will assign:

(a) Project Director (who will bear overall responsibility for the administration and implementation of the Project);
(b) Project Manager (who will be responsible for the managerial and technical matters of the Project); and
(c) Research staff and laboratory technicians.

(2) The Japanese side will dispatch:

(a) Chief Advisor (who will provide necessary recommendations and advice to

the Project Director and the Project Manager on any matters pertaining to the implementation of the Project);(b) Project Coordinator (who will coordinate the Project, supporting the Chief Advisor and other experts); and

(c) Other JICA Experts (who will give necessary guidance and advice to Gabonese counterpart researchers and personnel on technical matters pertaining to the implementation of the Project).

(3) Joint Coordinating Committee

Joint Coordinating Committee (hereinafter referred to as "JCC") will be established in order to facilitate inter-organizational coordination. JCC will be held at least once a year and whenever deems it necessary. JCC will review the progress, revise the overall plan when necessary, approve an annual work plan, conduct evaluation of the Project, and exchange opinions on major issues that arise during the implementation of the Project. A list of proposed members of JCC is shown in the Annex V.

6. Project Site(s), Implementers and Beneficiaries

(1) Project Target Area: The area in and around Lambaréné in the Moyen-Ogooué province in the Gabon

(2) Project Implementers: MoHESR and CERMEL

(3) Beneficiaries: Residents at risk of viral diseases in Gabon

7. Duration

The duration of the technical cooperation for the Project will be five (5) years starting in April 2016.

8. Reports

The Gabonese and Japanese sides will jointly prepare the following reports in French with English translation:

(1) Progress Report on bi-annual basis until the project completion; and

(2) Project Completion Report at the time of project completion.

9. Environmental and Social Considerations

(1) MoHESR, CERMEL, and NEKKEN agreed to abide by 'JICA Guidelines for Environmental and Social Considerations' in order to ensure that appropriate considerations will be made for the environmental and social impacts of the Project.

(2) Environmental Checklist

The environmental and social considerations including major impacts and mitigation measures for the Project are summarized in the Environmental Checklist attached as Annex VI. CERMEL and NEKKEN will reduce the risk of outflow of medical wastes from laboratory and laboratory acquired infections by taking adequate mitigation measures through establishing and complying with the waste management guidelines.

(3) Monitoring for Environmental and Social Considerations

Monitoring for Environmental and Social Considerations will be conducted by CERMEL in accordance with the Environmental Monitoring Plan described in Annex VII. This will be reviewed and updated after the project implementation.

(4) Disclosure of Monitoring Result on the Website

JICA will disclose the results of monitoring on JICA's website once a quarter during project period and 3 years after the end of the project as shown in Annex VII.

10. Management of Safety for Construction Works

For construction works, which will be carried out in the Project, CERMEL and JICA will assure the management of safety in accordance with the "Safety Plan" and "Method Statements of Safety"submitted by contractors based on the Guidance for the Management of Safety for Construction Works in Japanese ODA Projects.

III. UNDERTAKINGS OF GOGR and CERMEL

The GOGR and CERMEL will take necessary measures to:

(1) ensure that the technologies and knowledge acquired by the Gabonese nationals as a result of Japanese technical cooperation contributes to the economic and social development of Gabon, and that the knowledge and experience acquired by the personnel of Gabon from technical training as well as the equipment provided by JICA will be utilized effectively in the implementation of the Project; and

(2)grant privileges, exemptions and benefits to JICA Experts referred to in II-5 above and their families, which are no less favorable than those granted to experts and members of the missions and their families of third countries or international organizations performing similar missions in Gabon.

IV. MONITORING AND EVALUATION

JICA and CERMEL will jointly and regularly monitor the progress of the Project through the Monitoring Sheets based on the Project Design Matrix (PDM) and Plan of Operation (PO). The Monitoring Sheets will be reviewed every six (6) months.
Also, the Project Completion Report will be drawn up one (1) month before the termination of the Project.

JICA will conduct the following evaluations and surveys to verify sustainability and impact of the Project and draw lessons. CERMEL is required to provide necessary support for them.
(1) Ex-post evaluation three (3) years after the project completion, in principle
(2) Follow-up surveys on necessity basis

V. PROMOTION OF PUBLIC SUPPORT

For the purpose of promoting support for the Project, the Gabonese side will take appropriate measures to make the Project widely known to the people of Gabon.

VI. MISCONDUCT

If JICA receives information related to suspected corrupt or fraudulent practices in the implementation of the Project, CERMEL and relevant organizations will provide JICA with such information as JICA may reasonably request, including information related to any concerned official of the government and/or public organizations of Gabon.
CERMEL and relevant organizations will not unfairly or unfavorably treat the person and/or company, which provided the information related to suspected corrupt or fraudulent practices in the implementation of the Project.

VII. MUTUAL CONSULTATION

JICA, MoHESR and CERMEL will consult each other whenever any major issues arise in the course of project implementation.

VIII. AMENDMENTS

The Record of Discussions may be amended by the minutes of meetings among JICA, CERMEL and MoHESR. However, PO may be amended in the Monitoring Sheets. The minutes of meetings will be signed by authorized persons who may be different from the signers of the Record of Discussions.

Annex I	PDM version 0 (M/M Annex III)
Annex II	PO version 0 (M/M Annex IV)
Annex III	Tentative List of Equipment (M/M Annex V)
Annex IV	Project Implementation Structure (M/M Annex I)
Annex V	List of Proposed Members of Joint Coordinating Committee
Annex VI	Environmental Checklist
Annex VII	Environmental Monitoring Plan

Annex I

Project Design Matrix

Title of Project : The Project for Identification of Pathogens and Development of On-site Diagnostic Methods for Viral Diseases of Public Health Concern Including Viral Hemorrhagic Fever

Version 0

Implementing Agency: administrative officers, doctors and researchers engaged in the control, treatment and diagnosis of infectious diseases of public health concern including viral hemorrhagic fever

Date: February 12, 2016

【Minister of Higher Education and Scientific Research of Gabon】

【Center of Medical Research Lambaréné (CERMEL)】

Target Group: Residents at risk of viral diseases in Gabon: Approx. 1.6 million

Period of Project: 2016/4/1-2021/3/31

Project Site: The area around Lambaréné in the Moyen-Ogooué province in the Gabonese Republic

【Abbreviations】 LAMP: Loop-mediated Isothermal Amplification, ELISA: Enzyme-Linked ImmunoSorbent Assay, NEKKEN: Institute of Tropical Medicine, Nagasaki University

Narrative Summary	Objectively Verifiable Indicators	Means of Verification	Important Assumption	Achievement	Remarks
Project Purpose					
The research and development capacity of the Gabonese research center is enhanced through the collaborative research with Japanese research institute regarding identification of pathogens of known and unidentified infectious diseases as well as development of rapid diagnostic methods for viral diseases of public health concern.	1.By six (6) months before the termination of the Project, at least six (6) research papers are published in peer-reviewed international journals with the themes of the prevalence of viral diseases in the areas around of Lambaréné, the characteristics analyses of the target viruses and/or rapid diagnostic methods (or kit).	(1) Project reports (2) The report submitted to governmental organizations concerned (3) Research articles published in international scientific journals			
	2. By six (6) months before the termination of the Project, the discussions are commenced with governmental organizations concerned for future clinical application of the rapid diagnostic methods developed by the Project (registration of the methods as standard methods in Gabon, commercialization of the kit, etc.).				
	3. By six (6) months before the termination of the Project, a comprehensive report of research outcomes including policy recommendations such as viral diseased to be monitored in the target area is submitted to governmental organizations concerned.				

Outputs					
1. The prevalence of known and unidentified viral diseases is clarified in the areas around Lambaréné.	1-1. Within one (1) year after the commencement of the Project, the operation of the library of specimens is commenced at CERMEL for the research of viral diseases. 1-2. By six (6) months before the termination of the Project, research outcomes regarding the prevalence of infectious diseases caused by known and/or newly-identified viruses in the areas around Lambaréné gained from the viral and serological investigations is compiled in a report and/or scientific articles.	(1) Project reports	1. Cooperation from governmental organizations concerned is gained for the practical application of research outcomes to the society (implementation of discussion for it, etc.)		
2. Characteristics such as genetic information and pathogenicity of viruses that are regarded as public health concern and newly identified in Gabon is defined.	2-1. By two and a half (2.5) years after the commencement of the Project, public health-concerned and newly-identified viruses (if detected) are isolated and identified. 2-2.By six (6) months before the termination of the Project, research outcomes regarding genetic information, pathogenicity, etc. of the target viruses are compiled in a report and/or scientific articles. 2-3. By six (6) months before the termination of the Project, the results of risk assessment for newly-identified virus(es) are compiled in a report and/or scientific articles insofar as it is identified.	(1) Project reports			
3. Rapid diagnostic methods for viral diseases of public health concern and/or newly identified ones are developed.	3-1. By two and a half (2.5) years after the commencement of the Project, rapid diagnostic methods for the selected viruses are developed. 3-2. Within three and a half (3.5) years after the commencement of the Project, serological testing methods for the selected viruses are developed at CERMEL. 3-3. By six (6) months before the termination of the Project, the clinical utilities of the rapid diagnostic methods are evaluated. 3-4. By six (6) months before the termination of the Project, clinical performance evaluation as well as cost analysis of the rapid diagnostic test kit that can detect multiple pathogens simultaneously are performed.	(1) Project reports			

Annex I

Activities	Inputs		Important Assumption
	The Japanese Side	The Gabonese Side	
1. The prevalence of known and unidentified viral diseases is clarified in the areas around Lambaréné. 1-1. To develop a library of specimens (blood, urine, throat swab, etc.) in CERMEL, collected from malaria-negative febrile patients who visited medical facilities such as the Albert Schweitzer Hospital. 1-2. To conduct PCR screening for known viruses such as Chikungunya virus, Dengue virus, Rift Valley Fever virus and West Nile virus in the specimens. 1-3. To investigate the possibility of unidentified virus(es) by detecting viral genes exhaustively using next-generation sequencer from the specimens that demonstrated negative for the tested viruses, followed by matching them with the known gene sequences registered in the database. 1-4. To clarify the antibody prevalence rate of residents in the area around Lambaréné by conducting serological investigation of public health-concerned viruses for the patients visited to the Albert Schweitzer Hospital using the testing methods developed in the Activity 3-4.	Dispatch of JICA Experts (1) A chief advisor (short-term expert) (2) Project coordinator(s)/Environmental and Social Considerations (long-term expert) (3) An expert with the expertise of rapid diagnostics (short-term expert) (4) Experts with the expertise of viral experiments (short-term experts) (5) A local research manager (long-term expert) (6) A researcher (long-term expert) (7) Other researcher(s) with designated expertise (short-term expert) Training in Japan and/or third country/-ies (1) Virology (2) Laboratory diagnosis (3) Other necessary training Provision of Equipment and materials (1) Necessary research instruments, equipments and/or devices for project research activities Local costs Running expenses necessary for implementation of the project activities other than those that borne by the Gabonese side.	Allocation of Counterpart Personnel (1) Project Director (2) Project Manager (3) Researchers in CERMEL (4) Medical doctors in CERMEL (5) Other designated personnel when necessary Land, Facilities, Equipment and Materials (1) Office space in CERMEL (2) Laboratory space in CERMEL (3) BSL-2 laboratory in CERMEL (4) BSL-4 laboratory in other research and/or testing institute(s) (when necessary) (5) Clinical specimens form patients Local costs Running expenses necessary for implementation of the project activities such as personnel costs of researchers, research activity costs including travel expenses, consumables, and supplies, maintainance costs for researech instruments, epuipment and devices and laboratory facilities, utility costs such as water, electricity and communication,.	1. Gabonese counterparts do not leave their position so as to affect the output of the project. 2. Necessary cooperation is gained by health facilities and relevant agencies for the project activities.
2. Characteristics such as genetic information and pathogenicity of viruses that are regarded as public health concern and newly identified in Gabon is defined. 2-1. To perform the isolation of public health-concerned and/or newly-identified viruses with cultured cells, in parallel with the gene analyses under the Activities 1. Note: In case that a virus is suspected to be handled in BSL-4 laboratory, isolation of the virus is supposed to be done in the said laboratory in other research and/or testing institute(s)) 2-2. To accumulate virological findings through detailed gene analyses such as evolution (molecular) phylogenetic analyses for public health-concerned and/or newly-identified viruses. 2-3. To perform risk assessment of newly-identified virus(es) as pathogen(s) on the basis of characteristics analyses such as proliferativity, cytotoxicity (pathogenicity) and host/tissue specificity by inoculating them various types of host-derived cultured cells.			

3. Rapid diagnostic methods for viral diseases of public health concern and/or newly identified ones are developed. 3-1. To select at least five (5) viral diseases that are supposed to have the needs for the development of rapid diagnostic methods on the basis of the information regarding the endemic infectious diseases in Gabon and its neighboring countries together with the results from the Activities 1. 3-2. To develop rapid diagnostic methods for the detection of the selected viruses using gene amplification technologies with a focus on the LAMP method. 3-2-1. To determine the genetic sequences with high specificity for the target pathogens base on the genome information of the pathogens of the target infectious diseases as well as that for differential diagnosis. 3-2-2. To design the primers for the LAMP or other nucleic acid amplification methods and develop the diagnostic test that specifically detect target viruses. 3-2-3. To evaluate the clinical utility of the newly-developed rapid diagnostic methods by conducting comparative studies with existing diagnostic methods in its performance such as sensitivity, specificity and reagent stability as well as the cost for testing. 3-3. To develop a rapid diagnostic test kit that can detect multiple pathogens simultaneously. 3-3-1To select infectious diseases that have the needs for the Point-of Care (POC) testing with the focus on viral diseases (add other diseases such as malaria if needed).		Pre-Conditions

3-3-2. To develop rapid diagnostic method(s) using LAMP method for the pathogens other than that developed under the Activity 3-2 through the same procedure. 3-3-3. To prepare a rapid diagnostic test kit that detect at least five (5) pathogens simultaneously by panelizing the rapid diagnosing methods developed under the Activities 3-2 and 3-4-2. 3-3-4. To evaluate the clinical utility and the testing cost of the kit. 3-4. To develop serological testing methods for the viruses selected under the Activity 3-1. 3-4-1. To determine the viral antigen for ELISA followed by the development of its mass-expressing system in eukaryotic cells or E. coli as well as purification methods at NEKKEN. 3-4-2. To develop IgG-ELISA for the target viruses using sera from infected persons at CERMEL.			1. Approval is obtained by the Ethical Committee(s) for the research subjects conducted in the Project. 2. The agreement for the provision of clinical specimens to the Project for research purpose is gained from relevant hospitals and the Ministry of Health and Public Hygiene.  **<Issues and countermesures>**

ANNEX II

Tentative Plan of Operation

Version 0
Date 2016/2/12

Project Title (New Title): The Project for Identification of Pathogens and Development of On-site Diagnostic Methods for Viral Diseases of Public Health Concern Including Viral Hemorrhagic Fever

Inputs	Year	2016				2017				2018				2019				2020				Remarks	Monitoring: Issue	Monitoring: Solution
		I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV			
Expert																								
Chief Advisor	Plan																							
	Actual																							
Expert 1	Plan																							
	Actual																							
Expert 2	Plan																							
	Actual																							
Expert 3	Plan																							
	Actual																							
Expert 4	Plan																							
	Actual																							
Expert 5	Plan																							
	Actual																							
Equipment																								
Laboratory equipment	Plan																							
	Actual																							
Training in Japan																								
Training for handling viruses	Plan																							
	Actual																							
In-country/Third country Training																								
Training for working in biosafety level-2/3 facilities	Plan																							
	Actual																							

Activities / Sub-Activities	Year	2016				2017				2018				2019				2020				Responsible Organization: Japan	Responsible Organization: GOGR	Achievements	Issue & Countermeasures
		I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV				
Output 1:																									
1-1. To develop a library of specimens (blood, urine, throat swab, etc.) in CERMEL, collected from malaria-negative febrile patients who visited medical facilities such as the Albert Schweitzer Hospital.	Plan																								
	Actual																								
1-2. To conduct PCR screening for known viruses such as Chikungunya virus, Dengue virus, Rift Valley Fever virus and West Nile virus in the specimens.	Plan																								
	Actual																								
1-3. To investigate the possibility of unidentified virus(es) by detecting viral genes exhaustively using next-generation sequencer from the specimens that demonstrated negative for the tested viruses, followed by matching them with the known gene sequences registered in the database.	Plan																								
	Actual																								
1-4. To clarify the antibody prevalence rate of residents in the area around Lambaréné by conducting serological investigation of public health-concerned viruses for the patients visited to the Albert Schweitzer Hospital using the testing methods developed in the Activity 3-4.	Plan																								
	Actual																								
Output 2:																									
2-1. To perform the isolation of public health-concerned and/or newly-identified viruses with cultured cells, in parallel with the gene analyses under the Activities 1. Note: In case that a virus is suspected to be handled in BSL-4 laboratory, isolation of the virus is supposed to be done in the said laboratory in other research and/or testing institute(s))	Plan																								
	Actual																								
2-2. To accumulate virological findings through detailed gene analyses such as evolution (molecular) phylogenetic analyses for public health-concerned and/or newly-identified viruses.	Plan																								
	Actual																								
2-3. To perform risk assessment of newly-identified virus(es) as pathogen(s) on the basis of characteristics analyses such as proliferativity, cytotoxicity (pathogenicity) and host/tissue specificity by inoculating them various types of host-derived cultured cells.	Plan																								
	Actual																								
Output 3:																									
3-1. To select at least five (5) viral diseases that are supposed to have the needs for the development of rapid diagnostic methods on the basis of the information regarding the endemic infectious diseases in Gabon and its neighboring countries together with the results from the Activities 1.	Plan																								
	Actual																								
3-2. To develop rapid diagnostic methods for the detection of the selected viruses using gene amplification technologies with a focus on the LAMP method.	Plan																								
	Actual																								
3-2-1. To determine the genetic sequences with high specificity for the target pathogens base on the genome information of the pathogens of the target infectious	Plan																								
	Actual																								
3-2-2. To design the primers for the LAMP or other nucleic acid amplification methods and develop the diagnostic test that specifically detect target viruses.	Plan																								
	Actual																								
3-2-3. To evaluate the clinical utility of the newly-developed rapid diagnostic methods by conducting comparative studies with existing diagnostic methods in its performance such as sensitivity, specificity and reagent stability as well as the cost for testing.	Plan																								
	Actual																								
3-3. To develop a rapid diagnostic test kit that can detect multiple pathogens simultaneously.	Plan																								
	Actual																								
3-3-1. To select infectious diseases that have the needs for the Point-of Care (POC) testing with the focus on viral diseases (add other diseases such as malaria if needed).	Plan																								
	Actual																								
3-3-2. To develop rapid diagnostic method(s) using LAMP method for the pathogens other than that developed under the Activity 3-2 through the same procedure.	Plan																								
	Actual																								
3-3-3. To prepare a rapid diagnostic test kit that detect at least five (5) pathogens simultaneously by panelizing the rapid diagnosing methods	Plan																								

Item		Y1 I	Y1 II	Y1 III	Y1 IV	Y2 I	Y2 II	Y2 III	Y2 IV	Y3 I	Y3 II	Y3 III	Y3 IV	Y4 I	Y4 II	Y4 III	Y4 IV	Y5 I	Y5 II	Y5 III	Y5 IV	Remarks	Issue	Solution
developed under the Activities 3-2 and 3-4-2.	Actual																							
3-3-4. To evaluate the clinical utility and the testing cost of the kit.	Plan											■	■	■	■	■	■	■	■	■	■			
	Actual																							
3-4. To develop serological testing methods for the viruses selected under the Activity 3-2.	Plan							■	■	■	■	■	■	■										
	Actual																							
3-4-1. To determine the viral antigen for ELISA followed by the development of its mass-expressing system in eukaryotic cells or E. coli as well as purification methods at the Institute of Tropical Medicine, the Nagasaki University (NEKKEN).	Plan							■	■	■	■	■	■											
	Actual																							
3-4-2. To develop IgG-ELISA for the target viruses using sera from infected persons and/or animals at CERMEL.	Plan								■	■	■	■	■	■										
	Actual																							
Duration / Phasing	Plan																							
	Actual																							

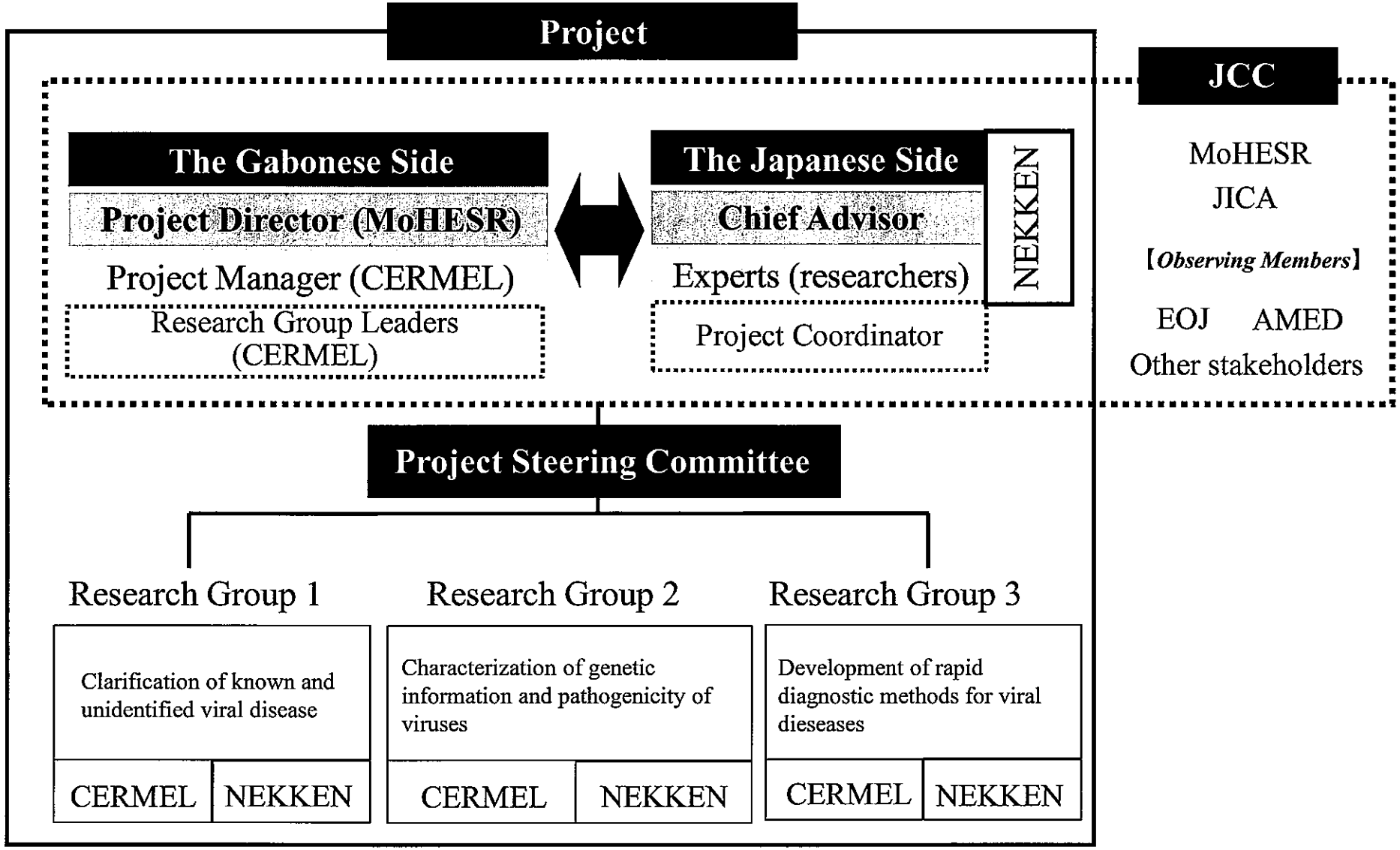
Monitoring Plan	Year	1st Year				2nd Year				3rd Year				4th Year				5th Year				Remarks	Issue	Solution
		I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV			
Monitoring																								
Joint Coordinating Committee	Plan	■				■				■				■				■						
	Actual																							
Set-up the Detailed Plan of Operation	Plan	■				■				■				■				■						
	Actual																							
Submission of Monitoring Sheet	Plan		■		■		■		■		■		■		■		■		■					
	Actual																							
Monitoring Mission from Japan	Plan										■								■					
	Actual																							
Joint Monitoring	Plan		■		■		■		■		■		■		■		■		■		■			
	Actual																							
Post Monitoring	Plan																							
	Actual																							
Reports/Documents																								
Project Completion Report	Plan																				■			
	Actual																							
Public Relations																								
To hold symposium of project results for ministries	Plan													■										
	Actual																							

Annex III

Tentative list of equipment

Category	Articles
Biosafety	BSL-2/3 laboratory, container/prefabricated lab (not determined, JICA will make a final decision)
	Biosafety cabinet, biohazard class II
	Autoclave
Identification of the viral gene sequences	Next generation sequencer
	DNA sequencer
Molecular biology for viral identification	LAMP detection device
	High speed refrigerated microcentrifuge
	Nanodrop
	Chemiluminescent detection and image capture system
	Protein & DNA electrophoresis system
Cell culture for virus isolation	CO_2 incubator
	Inverted routine microscopy
	Fluorescence microscopy
Sample storage	-80 ℃ deep freezer
	-30 ℃ biomedical freezer
	Refrigerator
Sample data management	Laptop Computer
Production of the ultrapure water	Milli-Q integral system
Others	Vehicle for Transportation

Annex IV. Project Implementation Structure



Abbreviations: **EOJ**: Embassy of Japan, **JCC**: Joint Coordinating Committee, **JICA**: Japan International Cooperation Agency, **AMED**: Japan Agency for Medical Research and Development, **MoHESR**: Ministry of Higher Education and Scientific Research, **NEKKEN**: the Institute of Tropical Medicine, the Nagasaki University

ANNEX V

LIST OF PROPOSED MEMBERS OF JOINT COORDINATING COMMITTEE

1. Functions

The JCC will be held at least once a year and whenever deems it necessary. The functions of JCC are as follows:

(1) To formulate and authorize the annual activity plan of the Project;
(2) To endorse major achievements and products of the Project;
(3) To monitor and review overall progress and supervise the Project; and
(4) To review and discuss on major issues arising from or concerning the Project.

2. Chairperson:

Director General of Scientific Research and Innovation, MoHESR, Gabon (Project Director)

3. Members:

a. The Gabonese side
- Project Manager
- Research Group Leaders
- Representative(s) from MoHESR

b. The Japanese side
- Chief Advisor, JICA Project Coordinator, and other JICA Experts
- Representative(s) from JICA Gabonese Office

4. Observing Members

a. The Japanese side
- Representative(s) from Embassy of Japan in Gabon
- Representative(s) from AMED

b. Other stakeholders appointed by the Chairperson

Annex VI

Category	Environmental Item	Main Check Items	Yes: Y No: N	Confirmation of Environmental Considerations (Reasons, Mitigation Measures)
1 Permits and Explanation	(1) EIA and Environmental Permits	(a) Have EIA reports been already prepared in official process? (b) Have EIA reports been approved by authorities of the host country's government? (c) Have EIA reports been unconditionally approved? If conditions are imposed on the approval of EIA reports, are the conditions satisfied? (d) In addition to the above approvals, have other required environmental permits been obtained from the appropriate regulatory authorities of the host country's government?	(a)N/A (b)N/A (c)N/A (d)N/A	(a)EIA reports are not prepared. They are not required. (b)EIA reports are not approved. They are not required. (c)EIA reports are not unconditionally approved. They are not required. (d)There are no other required environmental permits.
	(2) Explanation to the Local Stakeholders	(a) Have contents of the project and the potential impacts been adequately explained to the Local stakeholders based on appropriate procedures, including information disclosure? Is understanding obtained from the Local stakeholders? (b) Have the comment from the stakeholders (such as local residents) been reflected to the project design?	(a)N (b)N	(a)Contents of the project and the potential impact have not been explained to the local stakeholders yet. (b)Comment from the stakeholders has not been reflected to the project design.
	(3) Examination of Alternatives	(a) Have alternative plans of the project been examined with social and environmental considerations?	(a)Y	(a)To accomplish the project purpose, expansion of BSL-2 laboratory and establishment of BSL-3 laboratory are indispensable. Instead of taking the plan of not expanding and establishing laboratories, making guidelines and complying with that guideline will be monitored by CERMEL. The reports will be submitted to JICA to ensure that expansion and establishment of laboratories will not cause negative impacts to the environment.
2 Pollution Control	(1) Air Quality	(a) Do air pollutants, (such as sulfur oxides (SOx), nitrogen oxides (NOx), and soot and dust) emitted from the proposed infrastructure facilities and ancillary facilities comply with the country's emission standards and ambient air quality standards? Are any mitigating measures taken? (b) Are electric and heat source at accommodation used fuel which emission factor is low?	(a)Y (b)Y	(a)Polluted air from BSL-2/3 laboratory may have the potential to cause negative impacts including outflow of the polluted air and laboratory acquired infections. The establishment of exhaust/ventilation system and laboratory maintenance will be done according to the guideline which will be established in the project. (b) Fuel which emission factor is low is used for electric and heat source at accommodation.

	(2) Water Quality	(a) Do effluents or leachates from various facilities, such as infrastructure facilities and the ancillary facilities comply with the country's effluent standards and ambient water quality standards?	(a)Y	(a)Polluted water from laboratory may have the potential to cause negative impacts including outflow of the polluted water and laboratory acquired infections. The establishment of drainage facility and laboratory maintenance will be done according to the guideline which will be established in the project.
	(3) Wastes	(a) Are wastes from the infrastructure facilities and ancillary facilities properly treated and disposed of in accordance with the country's regulations?	(a)Y	(a)Wastes from laboratory may have the potential to cause negative impacts including outflow of the wastes and laboratory acquired infections. The establishment of sterilizing facility and adequate process of wastes from laboratory will be done according to the guideline which will be established in the project.
	(4) Soil Contamination	(a) Are adequate measures taken to prevent contamination of soil and groundwater by the effluents or leachates from the infrastructure facilities and the ancillary facilities?	(a)N/A	(a)Soil contamination is not expected in this project.
	(5) Noise and Vibration	(a) Do noise and vibrations comply with the country's standards?	(a)N/A	(a)Noise and vibrations is not expected in this project.
	(6) Subsidence	(a) In the case of extraction of a large volume of groundwater, is there a possibility that the extraction of groundwater will cause subsidence?	(a)N/A	(a)The extraction of groundwater is not expected in this project.
	(7) Odor	(a) Are there any odor sources? Are adequate odor control measures taken?	(a)N/A	(a)Odor sources are not expected in this project.
3 Natural Environment	(1) Protected Areas	(a) Is the project site or discharge area located in protected areas designated by the country's laws or international treaties and conventions? Is there a possibility that the project will affect the protected areas?	(a)N	(a)The project sites will not be located in protected areas.
	(2) Ecosystem	(a) Does the project site encompass primeval forests, tropical rain forests, ecologically valuable habitats (e.g., coral reefs, mangroves, or tidal flats)? (b) Does the project site encompass the protected habitats of endangered species designated by the country's laws or international treaties and conventions? (c) Is there a possibility that changes in localized micro-meteorological conditions, such as solar radiation, temperature, and humidity due to a large-scale timber harvesting will affect the surrounding vegetation?	(a)N (b)N (c)N (d)N	(a)The project site does not encompass coral reefs, mangroves or tidal flats. (b)The project site does not encompass the protected habitats of endangered species designated by the country's laws or international treaties and conventions. (c)Large-scale timber harvesting is expected in this project. (d)Large amount of water is not expected in this project.

		(d) Is there a possibility that the amount of water (e.g., surface water, groundwater) used by the project will adversely affect aquatic environments, such as rivers? Are adequate measures taken to reduce the impacts on aquatic environments, such as aquatic organisms?		
	(3) Hydrology	(a) Is there a possibility that hydrologic changes due to the project will adversely affect surface water and groundwater flows?	(a)N	(a)Hydrologic changes are not expected in this project.
	(4) Topography and Geology	(a) Is there a possibility the project will cause large-scale alteration of the topographic features and geologic structures in the project site and surrounding areas?	(a)N	(a)Large-scale alteration of the topographic features and geologic structures are not expected in this project.
4 Social Environment	(1) Resettlement	(a) Is involuntary resettlement caused by project implementation? If involuntary resettlement is caused, are efforts made to minimize the impacts caused by the resettlement? (b) Is adequate explanation on compensation and resettlement assistance given to affected people prior to resettlement? (c) Is the resettlement plan, including compensation with full replacement costs, restoration of livelihoods and living standards developed based on socioeconomic studies on resettlement? (d) Is the compensations going to be paid prior to the resettlement? (e) Is the compensation policies prepared in document? (f) Does the resettlement plan pay particular attention to vulnerable groups or people, including women, children, the elderly, people below the poverty line, ethnic minorities, and indigenous peoples? (g) Are agreements with the affected people obtained prior to resettlement? (h) Is the organizational framework established to properly implement	(a)N/A (b)N/A (c)N/A (d)N/A (e)N/A (f)N/A (g)N/A (h)N/A (i)N/A (j)N/A	(a)-(j)Involuntary resettlement is not caused by this project.

		resettlement? Are the capacity and budget secured to implement the plan? (i) Are any plans developed to monitor the impacts of resettlement? (j) Is the grievance redress mechanism established?		
4 Social Environment	(2) Living and Livelihood	(a) Is there a possibility that the project will adversely affect the living conditions of inhabitants? Are adequate measures considered to reduce the impacts, if necessary?	(a)N/A	(a)The project will not adversely affect the living condition of inhabitants.
	(3) Heritage	(a) Is there a possibility that the project will damage the local archeological, historical, cultural, and religious heritage? Are adequate measures considered to protect these sites in accordance with the country's laws?	(a)N/A	(a)The project will not damage the local archeological, historical, cultural and religious heritage.
	(4) Landscape	(a) Is there a possibility that the project will adversely affect the local landscape? Are necessary measures taken? (b) Is there a possibility that landscape is spoiled by construction of high-rise buildings such as huge hotels?	(a)N/A (b)N/A	(a)The project will not adversely affect the local landscape. (b)The project will not spoil the landscape.
	(5) Ethnic Minorities and Indigenous Peoples	(a) Are considerations given to reduce impacts on the culture and lifestyle of ethnic minorities and indigenous peoples? (b) Are all of the rights of ethnic minorities and indigenous peoples in relation to land and resources respected?	(a)N/A (b)N/A	(a)-(b)The project will not give negative impacts on ethnic minorities and indigenous peoples.

	(6) Working Conditions	(a) Is the project proponent not violating any laws and ordinances associated with the working conditions of the country which the project proponent should observe in the project? (b) Are tangible safety considerations in place for individuals involved in the project, such as the installation of safety equipment which prevents industrial accidents, and management of hazardous materials? (c) Are intangible measures being planned and implemented for individuals involved in the project, such as the establishment of a safety and health program, and safety training (including traffic safety and public health) for workers etc.? (d) Are appropriate measures taken to ensure that security guards involved in the project not to violate safety of other individuals involved, or local residents?	(a)N (b)N (c)N (d)N	(a)The project proponent is not violating any laws and ordinances associated with the working condition of the country which the project proponent should observe in the project. (b)Tangible safety considerations will be in place for individuals involved in the project. (c)Intangible measures will be planned and implemented for individuals involved in the project. (d)Appropriate measures will be taken to ensure that security guards involved in the project not to violate safety of other individuals involved, or local residents.
5 Others	(1) Impacts during Construction	(a) Are adequate measures considered to reduce impacts during construction (e.g., noise, vibrations, turbid water, dust, exhaust gases, and wastes)?(b) If construction activities adversely affect the natural environment (ecosystem), are adequate measures considered to reduce impacts?(c) If construction activities adversely affect the social environment, are adequate measures considered to reduce impacts?	(a)N(b) N/A(c) N/A	(a)Measures to reduce impacts during construction have not been considered. They will be discussed with the construction company after the company is confirmed.(b)Construction activities in this project will not affect the natural environment.(c)Construction activities in this project will not affect the social environment.
	(2) Monitoring	(a) Does the proponent develop and implement monitoring program for the environmental items that are considered to have potential impacts? (b) What are the items, methods and frequencies of the monitoring program? (c) Does the proponent establish an adequate monitoring framework (organization, personnel, equipment, and adequate budget to sustain the monitoring framework)? (d) Are any regulatory requirements pertaining to the monitoring report system identified, such as the format and frequency of reports from the	(a)Y (b)Y (c)Y (d)N	(a)CERMEL develops and implements monitoring program for the environmental items that are considered to have potential impacts. (b)To keep the air and water quality and to manage the wastes, CERMEL will do the maintenance of the laboratory regularly and submit the report to JICA once a quarter. The final report of the Environmental and Social Considerations will be submitted at Ex-post evaluation (3 years after the end of the project). (c)CERMEL will assign the person in charge of the Environmental and Social Considerations and implement the establishment of the guidelines and monitoring. (d)There are no regulatory requirements pertaining to the monitoring report system.

		proponent to the regulatory authorities?		
6 Note	Reference to Checklist of Other Sectors	(a) Where necessary, pertinent items described in the Roads, Railways and Bridges checklist should also be checked (e.g., projects including access roads to the infrastructure facilities). (b) For projects, such as installation of telecommunication cables, power line towers, and submarine cables, where necessary, pertinent items described in the Power Transmission and Distribution Lines checklists should also be checked.	(a)N/A (b)N/A	(a)This project does not include other sectors. (b)This project does not include other sectors.
	Note on Using Environmental Checklist	(a) If necessary, the impacts to trans boundary or global issues should be confirmed (e.g., the project includes factors that may cause problems, such as trans boundary waste treatment, acid rain, destruction of the ozone layer, or global warming).	(a)N/A	(a)The impacts to trans boundary or global issues are not expected in this project.

1) Regarding the term "Country's Standards" mentioned in the above table, in the event that environmental standards in the country where the project is located diverge significantly from international standards, appropriate environmental considerations are required to be made.
In cases where local environmental regulations are yet to be established in some areas, considerations should be made based on comparisons with appropriate standards of other countries (including Japan's experience).

2) Environmental checklist provides general environmental items to be checked. It may be necessary to add or delete an item taking into account the characteristics of the project and the particular circumstances of the country and locality in which the project is located.

Annex VII

ENVIRONMENTAL MONITORING PLAN

1. Outline of Monitoring

-Environmental and social impacts of the establishment BSL-3 laboratory should be considered in the project. The implementers of the project (Medical Research Center of Lambaréné (hereinafter referred to as "CERMEL") and the Institute of Tropical Medicine, Nagasaki University (hereinafter referred to as "NEKKEN")) will reduce the risk of outflow of polluted air, polluted water and medical wastes from laboratory and laboratory acquired infections by taking adequate mitigation measures.

-CERMEL sets up the medical wastes guideline for BSL-3 and monitors the listed items below according to JICA Guidelines for Environmental and Social Considerations (April 2010 version) every half-year during the project period and 3 years after the end of the project.

-CERMEL and NEKKEN appoint someone in CERMEL and NEKKEN who are in charge of the monitoring.
-The monitoring results in both English and French are submitted to JICA Gabon Office or JICA Headquarters and disclosed at the HP of Environmental and Social Considerations of JICA.
(http://www.jica.go.jp/english/our_work/social_environmental/id/africa/index.html)

-CERMEL also discloses the monitoring results to the public in Gabon.

-When negative impacts due to the project are found, CERMEL, NEKKEN and related organization response appropriately.

2. Mitigation Measures

- Monitoring items regarding air quality, water quality and waste control will be determined through the establishment of the guideline.

- Air quality

Monitoring Item	Monitoring Results during Report Period

- Water quality

Monitoring Item	Monitoring Results during Report Period

- Waste Control

Monitoring Item	Monitoring Results during Report Period

Notes

Date of Monitoring: ____/____/____

Person in Charge: _____

Appendix 2

Main points discussed

1. Involvement of Ministry of Health (MoH) and National Laboratory of Public Health (NLPH) to JCC
   MoH agreed to assign their staff of MoH and NLPH as observing members of JCC upon an official request from JICA for the future application of the Project's results.

2. Construction site of BSL-3 laboratory
   CERMEL offered two candidate places for the construction of BSL-3 laboratory. After the project starts, the construction site will be determined considering the conditions of the land, electricity and water supply, security and the relation with the other facilities of CERMEL.

MINUTES OF MEETINGS
BETWEEN
THE JAPANESE DETAILED PLANNING SURVEY TEAM
AND
THE AUTHORITIES CONCERNED OF
THE GOVERNMENT OF THE GABONESE REPUBLIC
ON
THE JAPANESE TECHNICAL COOPERATION PROJECT
FOR
"IDENTIFICATION OF UNKNOWN PATHOGENS AND ESTABLISHMENT OF ON-SITE RAPID DIAGNOSTIC SYSTEM FOR VIRAL DISEASES IN GABON"

Japan International Cooperation Agency (hereinafter referred to as "*JICA*") organized the Detailed Planning Survey Team (hereinafter referred to as "*the Team*"), headed by Dr. Kaname KANAI, which visited the Gabonese Republic (hereinafter referred to as "*Gabon*") from September 21 to October 2, 2015 for the purpose of discussing the framework of the technical cooperation project entitled "*Identification of Unknown Pathogens and Establishment of On-site Rapid Diagnostic System for Viral Diseases in Gabon*" (hereinafter referred to as "*the Project*").

During its stay in Gabon, the Team had a series of discussions and exchanged views on this Project with the authorities concerned of Gabon.

As a result of the discussions, the Team and Gabonese authorities concerned agreed on the matters referred to in the document attached hereto.

Libreville, October 2, 2015

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THE ATTACHED DOCUMENT

I. OBJECTIVES OF THE DETAILED PLANNING SURVEY

The objectives of the survey were to confirm background and contents of the collaborative research project between Gabon and Japan and to agree upon a cooperation plan (project design) through discussions with the Gabonese authorities concerned.

The Team also collected and analyze necessary information for ex-ante evaluation.

The main contents of the survey were as follows:

1. To confirm the contents of the collaborative research project of the Institute of Tropical Medicine ,Nagasaki University (hereinafter referred to as "*NEKKEN*") and the Center of Medical Research Lambaréné (hereinafter referred to as "*CERMEL*") under the cooperation of the International Center for Medical Research Franceville (hereinafter referred to as "*CIRMF*");
2. To have discussions on the scope and framework of this Project such as a Project Design Matrix (hereinafter referred to as "*PDM*"), a tentative Plan of Operation (hereinafter referred to as "*PO*"), and an implementing structure with the Gabonese implementing organizations such as CERMEL and CIRMF, followed by the agreement on the framework with the Gabonese authorities such as the Ministry of Higher Education and Scientific Research (hereinafter referred to as "*MoHESR*") and the Ministry of Health, Social Welfare and National Solidarity (hereinafter referred to as "*MoH*");
3. To confirm the current situation on ethical aspect, procedure of research approval and research;
4. To confirm actions and schedule up to this Project's commencement; and
5. To exchange the Minutes of Meetings (hereinafter referred to as "*M/M*") containing project scope and framework and a draft version of the Record of Discussions (hereinafter referred to as "*R/D*"), which is to be signed on commencement of this project as a token of confirmation of result of the discussions.

II. BASIC FRAMEWORK OF THE PROJECT

1. Project Implementation Scheme

1-1. Scheme

Both sides confirmed that this Project should be implemented under the 'Science and Technology Research Partnership for Sustainable Development*' promoted by JICA in collaboration with the

Japan Agency for Medical Research and Development (hereinafter referred to as "*AMED*").

JICA will take necessary measures for the technical cooperation such as dispatch of experts, provision of equipment and training of personnel, and other supports related to this Project in Gabon. AMED will support NEKKEN for this project activities implemented in Japan.

CERMEL will take necessary measures for technical cooperation such as preparation of research facilities, equipment and materials, personnel, utilities, and other support related to this Project.

* "Science and Technology Research Partnership for Sustainable Development" aims to develop new technology and its applications, and also aims at capacity development of researchers and research institutions in both countries.

1-2. Organizations

Although the request form of this Project was submitted by the Ministry of Foreign Affairs of Gabon with the recommendation letter from MoH, it is agreed that MoHESR, which has jurisdiction over the area of research, to be a responsible agency of this Project as the result of the discussion with MoHESR and MoH.

In addition, CIRMF was listed as one of the implementation agencies in the request form of this Project but the role of CIRMF is limited to the provision of the opportunity of using its facilities only when needed. Therefore, it is agreed that CIRMF is not included in this Project as an implementation agency.

When the case happens in this Project, CERMEL will request cooperation to other research organizations including CIRMF each time.

2. Project Title

It is appropriate to modify the title of the Project from the one indicated in the application entitled "*Identification of Unknown Pathogens and Establishment of On-site Rapid Diagnostic System for Viral Diseases in Gabon*" to "*The Project for Identification of Pathogens and Development of On-site Diagnostic Methods for Viral Diseases of Public Health Concern including Viral Hemorrhagic Fever*" so that the agreed contents of the Project are accurately reflected.

Both sides agreed that the above change and will propose the title modification to authorities concerned of each government and, if approved, the title will be changed officially through diplomatic procedure.

3. Duration

The duration of the Project will be five (5) years from the date, which will be indicated in the R/D.

4. Administration of the Project

4-1. Administration

Both sides agreed that the administration of the Project would be organized as shown in Annex I and as follows.

There will be:

(1) Project Director (who will bear overall responsibility for the administration and implementation of the Project): Director General of Scientific Research and Innovation , MoHESR;

(2) Project Manager (who will be responsible for the managerial and technical matters of the Project): Co-Director or compatible position or higher, CERMEL;

(3) Gabonese counterpart researchers and personnel, as shown in Annex II;

(4) Chief Advisor (who will provide necessary recommendations and advice to the Project Director and the Project Manager on any matters pertaining to the implementation of the Project);

(5) Project Coordinator (who will coordinate the Project, supporting the Chief Advisor and other experts); and

(6) Other JICA Experts (who will give necessary guidance and advice to Gabonese counterpart researchers and personnel on technical matters pertaining to the implementation of the Project).

4-2. Joint Coordinating Committee

For the effective and successful implementation of the Project, a Joint Coordinating Committee will be established of which functions and composition are described as follows:

(1) Functions

1) To formulate and authorize the annual activity plan of the Project;
2) To endorse major achievements and products of the Project;
3) To monitor and review overall progress and supervise the Project; and
4) To review and discuss on major issues arising from or concerning the Project.

(2) Composition

- Chairperson: Director General of Scientific Research and Innovation, MoHESR, Gabon (Project Director)

1) Members:

a. The Gabonese side
   - Project Manager
   - Research Group Leaders
   - Representative(s) from MoHESR

b. The Japanese side
   - Chief Advisor, Project Coordinator, and other JICA Experts

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- Representative(s) from the JICA Gabon Office

2) Observing members

a. The Gabonese side**

- Representative(s) from MoH
- Representative(s) from the National Laboratory of Public Health

**: The two members above are not determined as of the time of signing the M/M. MoHESR will take necessary procedures to obtain commitment of MoH to be an observing member of JCC, and the implementation structure of the Project should be determined in advance of the time of signing the R/D.

b. The Japanese side

- Representative(s) from Embassy of Japan in Gabon
- Representative(s) from AMED

c. Other stakeholders appointed by the Chairperson

4-3. Project Steering Committee

A Project Steering Committee will be established and convened every six (6) months. Its function and composition are as follows:

(1) Functions

1) To review progress and outcomes of research activities;
2) To coordinate and exchange information; and
3) To discuss issues including technical, ethical, safety and any matters, arising from or concerning the Project.

(2) Composition

1) Chairperson:
   - Project Manager
2) Co-chairpersons: and
   - Chief Advisor
3) Members:
   - Research Group Leaders, Researchers of CERMEL
   - JICA Experts (Researchers)
   - Project Coordinator
   - Other stakeholders appointed by the Chairperson such as representatives from MoHESR, JICA and AMED

4-4. Annual Scientific Meeting

In order to ensure effective monitoring of the research progress and timely feedback of the technical advice from the experts, researchers and personnel engaged in the Project will have opportunities for exchanging and monitoring research outcomes as well as administrative matters by holding Annual Scientific Meeting at least once a year. Reports and/or minutes will be prepared in English and will be shared with the relevant researchers and personnel.

5. Project Design Matrix and Tentative Plan of Operation

The basic framework of the Project is shown in the PDM in Annex III. The tentative PO is as shown in Annex IV.

6. Inputs

The inputs from each side are as follows:

6-1. The Japanese side

(1) Chief Advisor;

(2) Project Coordinator;

(3) Other researchers with the expertise of rapid diagnostics, viral experiments, research management and other designated areas;

(4) Project assistant(s) and driver(s);

(5) Training in Japan and/or third country/-ies for Gabonese counterpart personnel;

(6) Necessary research instruments, equipment and devices for research and development activities, as shown in Annex V; and

(7) Running expenses necessary for implementation of the project activities other than that borne by the Gabonese side.

6-2. The Gabonese side

(1) Project Director

(2) Project Manager

(3) Research staff and laboratory technicians;

(4) Office space and laboratory space in CERMEL;

(5) Existing research instruments, equipment and devices in CERMEL;

(6) Available data, information and specimens related to the Project; and

(7) Running expenses necessary for implementation of the project activities such as personnel costs of staff, research activity costs including travel expenses, consumables and supplies, maintenance costs for research instruments, equipment and devices and laboratory facilities, utility costs such as water, electricity and communication.

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(8) Support to project activities will be made available in accordance with the laws and regulations in force in Gabon, and subject to the availability of resources.

7. Special Issues

7-1. Memorandum of Understanding between research institutes

Both sides agreed that NEKKEN and CERMEL should reach an agreement to execute the collaborative research in accordance with the project design at the timing around signing the R/D. The document (e.g. Memorandum of Understanding) will contain the following items of the collaborative research:

a. Objective and Plan;
b. Implementation;
c. Confidentiality and Intellectual Property Rights;
d. Access to Genetic Resources;
e. Publication of Results;
f. Dispute Resolution;
g. Duration of the Agreement;
h. Compliance with Laws and Regulations; and
i. Other items concerning both sides.

7-2. Intellectual Property Rights

Both sides confirmed that matters related to intellectual property rights should follow the Memorandum of Understanding to be signed between the two organizations.

7-3. Exclusion of Clinical Trials

Both sides agreed that clinical trials would not be included in the Project.

JICA is indemnified for any and all liabilities, losses, and expenses on claims for injury or damages arising out of or resulting from the actions or omissions by NEKKEN and CERMEL with respect to the clinical trials.

Therefore, JICA will not bear any expenses or honorarium for implementing clinical trials.

7-4. Ethical Approval of the Project

All research activities of the Project involving human subjects shall be approved by the ethical committee of NEKKEN and/or Gabonese authorities concerned, as applicable.

7-5. Biosafety

Both sides agreed that all laboratory activities should follow the international biosafety regulations

stipulated by the World Health Organization. The CERMEL institutional biosafety committee will be established to be charged with ensuring that all project activities in CERMEL, involving infectious biological agents, are conducted in a safe manner and in conformity with generally accepted standards.

7-6. Approval of Specific Activities

Both sides agreed that clearance of material transfer (import/export) from relevant ministry/authority should be obtained. The materials may include microbiological pathogens, clinical specimens, animal materials, and so on.

7-7. Construction of BSL-2/3 laboratory in CERMEL

As a result of direct observation on existing facilities and discussions between the Team and CERMEL, both sides confirmed that it is necessary for some project research activities to be done in BSL-3 laboratory; nevertheless, CERMEL have neither such laboratory nor sufficient space for renovation. In addition, there is not sufficient space to use for the Project in the existing BSL-2 laboratory of CERMEL. On the basis of the confirmation, CERMEL and NEKKEN requested the Team to construct BSL-2/3 laboratory as an input of the Japanese side to the Project.

On the other hand, the Japanese side express the concern over the feasibility of constructing BSL-2/3 laboratory in CERMEL for following reasons: 1) necessity of land evaluation for its foundations; 2) CERMEL's capacity and experiences for selection of reliable local constructor(s) and for proper monitoring of construction work; 3) budget allocation and possibility of easy procurement process of the construction by the Japanese side; and 4) appropriation of maintenance costs for BSL-2/3 laboratory and research instruments, equipment and devices.

Under such circumstances, the Team acknowledged that it is difficult to decide the construction of BSL-2/3 laboratory with such limited information at this detailed planning survey. In order to examine whether the construction of BSL-2/3 laboratory can be included as a Project Component or not, both sides, nonetheless, agreed that CERMEL and NEKKEN, in consultation and support with JICA and AMED, will start a prior assessment of the feasibility of the construction of BSL-2/3 laboratory as early as possible on the basis of land evaluation as well as solvency evaluation for maintenance costs. On the basis of the examination results, JICA will judge the feasibility for the construction no later than the date of signing of the R/D.

III. WAY FORWARD

1. Based on this M/M and the draft R/D as shown in Annex VI, Gabon and Japanese sides will

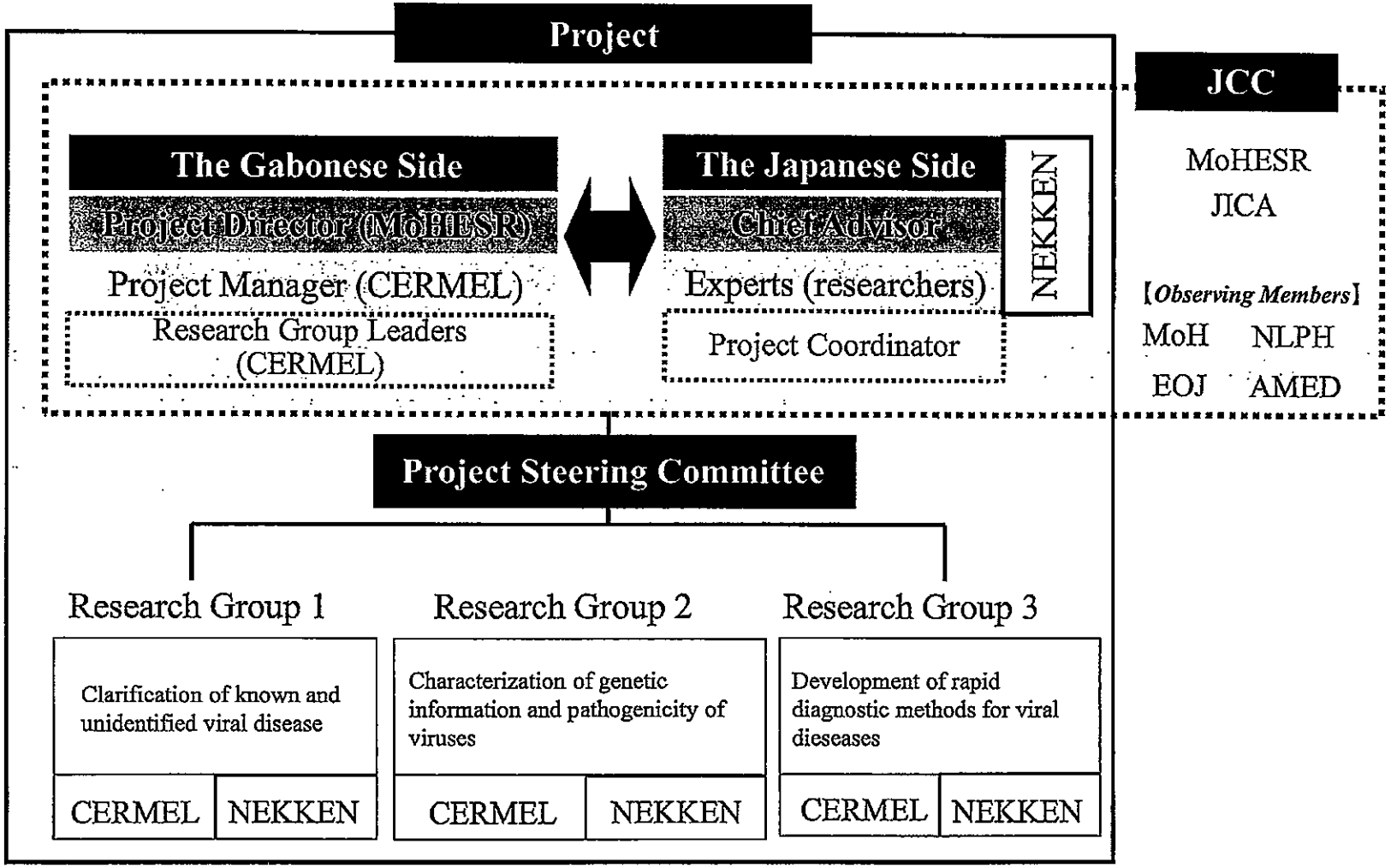
prepare the final version of the R/D.

2. Before starting the Project, NEKKEN and CERMEL should take necessary measures including the application to relevant ethical committees, if necessary, and allocation of the budget.
3. Based on the mutual agreement reached, the R/D should be signed by both sides as soon as possible aiming at the end of January 2016 but not later than end of March 2016.
4. The Memorandum of Understanding between NEKKEN and CERMEL will be finalized by January 2016.
5. The Project is expected to start in April 2016.
6. The schedule is subject to change in accordance with approval processes of the Project.

LIST OF ANNEXES

Annex I	Project Implementation Structure
Annex II	Research Contents and Organizations in Charge
Annex III	PDM Version 0
Annex IV	Tentative PO Version 0
Annex V	Tentative List of Equipment
Annex VI	Draft of the R/D

Annex I. Project Implementation Structure



Abbreviations: EOJ: Embassy of Japan, **JCC**: Joint Coordinating Committee, **JICA**: Japan International Cooperation Agency, **AMED**: Japan Agency for Medical Research and Development, **MoH**: Ministry of Health, , Social Welfare and National Solidarity, **MoHESR**: Ministry of Higher Education and Scientific Research, , **NEKKEN**: the Institute of Tropical Medicine, the Nagasaki University, **NLPH**: National Laboratory of Public Health

Annex II

Research Contents and Organization in Charge

Research Subjects	The Gabonese side	The Japanese side
To clarify known and unidentified viral diseases in the areas around Lambaréné.	Hansjorg Fotouri Albert Scheweitzer Hospital Director	Jiro Yasuda NEKKEN Professor
	Bertrand Lell CERMEL Co-director	Yohei Kurosaki NEKKEN Assistant Professor
	Selidji Agnandji Todagbe CERMEL Co-director	Shuzo Urata NEKKEN Assistant Professor
	Marguerite Massinga Loembe CERMEL Responsible for laboratory researches	Saori Sakabe NEKKEN Assistant Professor
	Jose Francisco Fernandes CERMEL Research Physician	Olamide Oloniniyi NEKKEN Ph.D student
	Abraham Alabi Sunday CERMEL Senior Biologist	*A NEKKEN Assistant Professor
		*B NEKKEN Researcher
To characterize genetic information and pathogenicity of viruses that are regarded as public health concern and newly identified in Gabon.	Bertrand Lell CERMEL Co-director	Jiro Yasuda NEKKEN Professor
	Selidji Agnandji Todagbe CERMEL Co-director	Yohei Kurosaki NEKKEN Assistant Professor
	Marguerite Massinga Loembe CERMEL Responsible for laboratory researches	Shuzo Urata NEKKEN Assistant Professor
		Saori Sakabe NEKKEN Assistant Professor
		Olamide Oloniniyi NEKKEN Graduate Student (MD)
		*A NEKKEN Assistant Professor
		*B NEKKEN Researcher
To develop rapid diagnostic methods for viruses of public health concern and/or newly identified ones.	Bertrand Lell CERMEL Co-director	Jiro Yasuda NEKKEN Professor
	Selidji Agnandji Todagbe CERMEL Co-director	Yohei Kurosaki NEKKEN Assistant Professor
	Marguerite Massinga Loembe CERMEL Responsible for laboratory researches	Shuzo Urata NEKKEN Assistant Professor
		Saori Sakabe NEKKEN Assistant Professor

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		Olamide Oloniniyi NEKKEN Graduate Student (MD)
		*A NEKKEN Assistant Professor
		*B NEKKEN Researcher

*A and *B will be assigned from April 2016.

Annex III

Project Design Matrix

Title of Project (Prpposed Title) : The Project for Identification of Pathogens and Development of On-site Diagnostic Methods for Viral Diseases of Public Health Concern Including Viral Hemorrhagic Fever

Version 0

Date: October 2, 2015

Implementing Agency: Administrative officers, doctors and researchers engaged in the control, treatment and diagnosis of infectious diseases of public health concern including viral hemorrhagic fever
[Minister of Higher Education and Scientific Research of Gabon]: 5 persons
[Center of Medical Research Lambaréné (CERMEL)]: 10 persons
Target Group: Residents at risk of viral diseases in Gabon: Approx. 1.6 million
Period of Project: 5 years from the date indicated in the Record of Discussions
Project Site: The area around Lambaréné in the Moyen-Ogooué province in the Gabonese Republic

Narrative Summary	Objectively Verifiable Indicators	Means of Verification	Important Assumption	Achievement	Remarks
Project Purpose					
The research and development capacity of the Gabonese research center is enhanced through the collaborative research with Japanese research institute regarding identification of pathogens of known and unidentified infectious diseases an well as development of rapid diagnostic methods for viral diseases of public health concern.	1.By six (6) months before the termination of the Project, at least six (6) research papers are published in peer-reviewed international journals with the themes of the prevalence of viral diseases in the areas around of Lambaréné, the characteristics analyses of the target viruses and/or rapid diagnostic methods (or kit).	(1) Project reports (2) The report submitted to governmental organizations concerned (3) Research articles published in international scientific journals			
	2. By six (6) months before the termination of the Project, the discussions are commenced with governmental organizations concerned for future clinical application of the rapid diagnostic methods developed by the Project (registration of the methods as standard methods in Gabon, commercialization of the kit, etc.).				
	3. By six (6) months before the termination of the Project, a comprehensive report of research outcomes including policy recommendations such as viral diseased to be monitored in the target area is submitted to governmental organizations concerned.				

Annex III

Outputs					
1. The prevalence of known and unidentified viral diseases is clarified in the areas around Lambaréné.	1-1. Within one (1) year after the commencement of the Project, the operation of the library of specimens is commenced at CERMEL for the research of viral diseases. 1-2. By six (6) months before the termination of the Project, research outcomes regarding the prevalence of infectious diseases caused by known and/or newly-identified viruses in the areas around Lambaréné gained from the viral and serological investigations is compiled in a report and/or scientific articles.	(1) Project reports	1. Cooperation from governmental organizations concerned is gained for the practical application of research outcomes to the society (implementation of discussion for it, etc.)		
2. Characteristics such as genetic information and pathogenicity of viruses that are regarded as public health concern and newly identified in Gabon is defined.	2-1. By two and a half (2.5) years after the commencement of the Project, public health-concerned and newly-identified viruses (if detected) are isolated and identified. 2-2.By six (6) months before the termination of the Project, research outcomes regarding genetic information, pathogenicity, etc. of the target viruses are compiled in a report and/or scientific articles. 2-3. By six (6) months before the termination of the Project, the results of risk assessment for newly-identified virus(es) are compiled in a report and/or scientific articles insofar as it is identified.	(1)Rapports de Projet			
3. Rapid diagnostic methods for viral diseases of public health concern and/or newly identified ones are developed.	3-1. By two and a half (2.5) years after the commencement of the Project, rapid diagnostic methods for the selected viruses are developed. 3-2. Within three and a half (3.5) years after the commencement of the Project, serological testing methods for the selected viruses are developed at CERMEL. 3-3. By six (6) months before the termination of the Project, the clinical utilities of the rapid diagnostic methods are evaluated. 3-4. By six (6) months before the termination of the Project, clinical performance evaluation as well as cost analysis of the rapid diagnostic test kit that can detect multiple pathogens simultaneously are performed.	(1)Rapports de Projet			

Annex III

Activities	Inputs		Important Assumption
	The Japanese Side	**The Gabonese Side**	
1. The prevalence of known and unidentified viral diseases is clarified in the areas around Lambaréné. 1-1. To develop a library of specimens (blood, urine, throat swab, etc.) in CERMEL, collected from malaria-negative febrile patients who visited medical facilities such as the Albert Schweitzer Hospital. 1-2. To conduct PCR screening for known viruses such as Chikungunya virus, Dengue virus, Rift Valley Fever virus and West Nile virus in the specimens. 1-3. To investigate the possibility of unidentified virus(es) by detecting viral genes exhaustively using next-generation sequencer from the specimens that demonstrated negative for the tested viruses, followed by matching them with the known gene sequences registered in the database. 1-4. To investigate the possibility of unidentified virus(es) by detecting viral genes exhaustively using next-generation sequencer from the specimens that demonstrated negative for the tested viruses, followed by matching them with the known gene sequences registered in the database. **2. Characteristics such as genetic information and pathogenicity of viruses that are regarded as public health concern and newly identified in Gabon is defined.**	Dispatch of JICA Experts (1) A chief advisor (short-term expert) (2) Project coordinator(s) (long-term expert) (3) An expert with the expertise of rapid diagnostics (short-term expert) (4) Experts with the expertise of viral experiments (short-term experts) (5) A local research manager (long-term expert) (6) A researcher (long-term expert) (7) Other researcher(s) with designated expertise (short-term expert) Training in Japan and/or third country/-ies (1) Virology (2) Laboratory diagnosis (3) Other necessary training Provision of Equipment and materials Necessary research instruments, equipments and/or devices activities for project research activities Local costs Running expenses necessary for implementation of the project activities other than those that borne by the Gabonese side.	Allocation of Counterpart Personnel (1) Project Director (2) Project Manager (3) Researchers in CERMEL (4) Medical doctors in CERMEL (5) Other designated personnel when necessary Land, Facilities, Equipment and Materials (1) Office space in CERMEL (2) Laboratory space in CERMEL (3) BSL-2 laboratory in CERMEL (4) BSL-4 laboratory in other research and/or testing institute(s) (when necessary) (5) Clinical specimens form patients Local costs Running expenses necessary for implementation of the project activities such as personnel costs of researchers, research activity costs including travel expenses, consumables, and supplies, maintainance costs for researech instruments, epuipment and devices and laboratory facilities, utility costs such as water, electricity and communication,.	1. Gabonese counterparts do not leave their position so as to affect the output of the project. 2. Necessary cooperation is gained by health facilities and relevant agencies for the project activities.

2-1. To perform the isolation of public health-concerned and/or newly-identified viruses with cultured cells, in parallel with the gene analyses under the Activities 1.
Note: In case that a virus is suspected to be handled in BSL-4 laboratory, isolation of the virus is supposed to be done in the said laboratory in other research and/or testing institute(s))

2-2. To accumulate virological findings through detailed gene analyses such as evolution (molecular) phylogenetic analyses for public health-concerned and/or newly-identified viruses.

2-3. To perform risk assessment of newly-identified virus(es) as pathogen(s) on the basis of characteristics analyses such as proliferativity, cytotoxicity (pathogenicity) and host/tissue specificity by inoculating them various types of host-derived cultured cells.

3. Rapid diagnostic methods for viral diseases of public health concern and/or newly identified ones are developed.

3-1. To select at least five (5) viral diseases that are supposed to have the needs for the development of rapid diagnostic methods on the basis of the information regarding the endemic infectious diseases in Gabon and its neighboring countries together with the results from the Activities 1.

3-2. To develop rapid diagnostic methods for the detection of the selected viruses using gene amplification technologies with a focus on the LAMP method.

3-2-1. To determine the genetic sequences with high specificity for the target pathogens base on the genome information of the pathogens of the target infectious diseases as well as that for differential diagnosis.

3-2-2. To design the primers for the LAMP or other nucleic acid amplification methods and develop the diagnostic test that specifically detect target viruses.

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3-2-3. To evaluate the clinical utility of the newly-developed rapid diagnostic methods by conducting comparative studies with existing diagnostic methods in its performance such as sensitivity, specificity and reagent stability as well as the cost for testing. 3-3. To develop a rapid diagnostic test kit that can detect multiple pathogens simultaneously. 3-3-1.To develop rapid diagnostic method(s) using LAMP method for the pathogens other than that developed under the Activity 3-2 through the same procedure. 3-3-2. To develop rapid diagnostic method(s) using LAMP method for the pathogens other than that developed under the Activity 3-2 through the same procedure. 3-3-3. To prepare a rapid diagnostic test kit that detect at least five (5) pathogens simultaneously by panelizing the rapid diagnosing methods developed under the Activities 3-2 and 3-4-2. 3-3-4. To evaluate the clinical utility and the testing cost of the kit. 3-4. To develop serological testing methods for the viruses selected under the Activity 3-2. 3-4-1. To determine the viral antigen for ELISA followed by the development of its mass-expressing system in eukaryotic cells or E. coli as well as purification methods at the Institute of Tropical Medicine, the Nagasaki University (NEKKEN). 3-4-2. To develop IgG-ELISA for the target viruses using sera from infected persons and/or animals at CERMEL.			**Pre-Conditions** 1. Approval is obtained by the Ethical Committee(s) of CERMEL for the research subjects conducted in the Project. 2. The agreement for the provision of clinical specimens to the Project for research purpose is gained from relevant hospitals. **Issues and countermesures**

[Abbreviations] LAMP: Loop-mediated Isothermal Amplification, ELISA: Enzyme-Linked ImmunoSorbent Assay, NEKKEN: Institute of Tropical Medicine, Nagasaki University

ANNEX IV

Tentative Plan of Operation

Version 0
Date 2015/10/2

Project Title (New Title): The Project for Identification of Pathogens and Development of On-site Diagnostic Methods for Viral Diseases of Public Health Concern Including Viral Hemorrhagic Fever

Inputs	Year	2016				2017				2018				2019				2020				Remarks	Monitoring: Issue	Monitoring: Solution
		I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV			
Expert																								
Chief Advisor	Plan																							
	Actual																							
Expert 1	Plan																							
	Actual																							
Expert 2	Plan																							
	Actual																							
Expert 3	Plan																							
	Actual																							
Expert 4	Plan																							
	Actual																							
Expert 5	Plan																							
	Actual																							
Equipment																								
Laboratory equipment	Plan																							
	Actual																							
Training in Japan																								
Training for handling viruses	Plan																							
	Actual																							
In-country/third country Training																								
Training for working in biosafety level-2/3 facilities	Plan																							
	Actual																							

Activities / Sub-Activities	Year	2016				2017				2018				2019				2020				Responsible Organization: Japan	Responsible Organization: GOGR	Achievements	Issue & Countermeasures
		I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV				
Output 1:																									
1-1. To develop a library of specimens (blood, urine, throat swab, etc.) in CERMEL, collected from malaria-negative febrile patients who visited medical facilities such as the Albert Schweitzer Hospital,	Plan																								
	Actual																								
1-2. To conduct PCR screening for known viruses such as Chikungunya virus, Dengue virus, Rift Valley Fever virus and West Nile virus in the specimens.	Plan																								
	Actual																								
1-3. To investigate the possibility of unidentified virus(es) by detecting viral genes exhaustively using next-generation sequencer from the specimens that demonstrated negative for the tested viruses, followed by matching them with the known gene sequences registered in the database.	Plan																								
	Actual																								
1-4. To clarify the antibody prevalence rate of residents in the area around Lambaréné by conducting serological investigation of public health-concerned viruses for the patients visited to the Albert Schweitzer Hospital using the testing methods developed in the Activity 3-4.	Plan																								
	Actual																								
Output 2:																									
2-1. To perform the isolation of public health-concerned and/or newly-identified viruses with cultured cells, in parallel with the gene analyses under the Activities 1. Note: In case that a virus is suspected to be handled in BSL-4 laboratory, isolation of the virus is supposed to be done in the said laboratory in other research and/or testing institute(s))	Plan																								
	Actual																								
2-2. To accumulate virological findings through detailed gene analyses such as evolution (molecular) phylogenetic analyses for public health-concerned and/or newly-identified viruses.	Plan																								
	Actual																								
2-3. To perform risk assessment of newly-identified virus(es) as pathogen(s) on the basis of characteristics analyses such as proliferativity, cytotoxicity (pathogenicity) and host/tissue specificity by inoculating them various types of host-derived cultured cells.	Plan																								
	Actual																								
Output 3:																									
3-1. To select at least five (5) viral diseases that are supposed to have the needs for the development of rapid diagnostic methods on the basis of the information regarding the endemic infectious diseases in Gabon and its neighboring countries together with the results from the Activities 1.	Plan																								
	Actual																								
3-2. To develop rapid diagnostic methods for the detection of the selected viruses using gene amplification technologies with a focus on the LAMP method.	Plan																								
	Actual																								
3-2-1. To determine the genetic sequences with high specificity for the target pathogens base on the genome information of the pathogens of the target infectious	Plan																								
	Actual																								
3-2-2. To design the primers for the LAMP or other nucleic acid amplification methods and develop the diagnostic test that specifically detect target viruses.	Plan																								
	Actual																								
3-2-3. To evaluate the clinical utility of the newly-developed rapid diagnostic methods by conducting comparative studies with existing diagnostic methods in its performance such as sensitivity, specificity and reagent stability as well as the cost for testing.	Plan																								
	Actual																								
3-3. To develop a rapid diagnostic test kit that can detect multiple pathogens simultaneously.	Plan																								
	Actual																								

ANNEX IV

3-3-1. To select infectious diseases that have the needs for the Point-of Care (POC) testing with the focus on viral diseases (add other diseases such as malaria if needed).	Plan	
	Actual	
3-3-2. To develop rapid diagnostic method(s) using LAMP method for the pathogens other than that developed under the Activity 3-2 through the same procedure.	Plan	
	Actual	
3-3-3. To prepare a rapid diagnostic test kit that detect at least five (5) pathogens simultaneously by panelizing the rapid diagnosing methods developed under the Activities 3-2 and 3-4-2.	Plan	
	Actual	
3-3-4. To evaluate the clinical utility and the testing cost of the kit.	Plan	
	Actual	
3-4. To develop serological testing methods for the viruses selected under the Activity 3-2.	Plan	
	Actual	
3-4-1. To determine the viral antigen for ELISA followed by the development of its mass-expressing system in eukaryotic cells or E. coli as well as purification methods at the Institute of Tropical Medicine, the Nagasaki University (NEKKEN).	Plan	
	Actual	
3-4-2. To develop IgG-ELISA for the target viruses using sera from infected persons and/or animals at CERMEL.	Plan	
	Actual	
Duration / Phasing	Plan	
	Actual	

Monitoring Plan	Year	1st Year				2nd Year				3rd Year				4th Year				5th Year				Remarks	Issue	Solution
		I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV	I	II	III	IV			
Monitoring																								
Joint Coordinating Committee	Plan	■				■				■				■				■						
	Actual																							
Set-up the Detailed Plan of Operation	Plan	■				■				■				■				■						
	Actual																							
Submission of Monitoring Sheet	Plan		■		■		■		■		■		■		■		■		■					
	Actual																							
Monitoring Mission from Japan	Plan										■								■					
	Actual																							
Joint Monitoring	Plan		■		■		■		■		■		■		■		■		■		■			
	Actual																							
Post Monitoring	Plan																							
	Actual																							
Reports/Documents																								
Project Completion Report	Plan																				■			
	Actual																							
Public Relations																								
To hold symposium of project results for ministries	Plan														■									
	Actual																							

Annex V

Tentative list of equipment

Category	Articles
Biosafety	BSL-2/3 laboratory, container/prefabricated lab (not determined, JICA will make a final decision)
	Biosafety cabinet, biohazard class II
	Autoclave
Identification of the viral gene sequences	Next generation sequencer
	DNA sequencer
Molecular biology for viral identification	LAMP detection device
	High speed refrigerated microcentrifuge
	Nanodrop
	Chemiluminescent detection and image capture system
	Protein & DNA electrophoresis system
Cell culture for virus isolation	CO_2 incubator
	Inverted routine microscopy
	Fluorescence microscopy
Sample storage	-80 ℃ deep freezer
	-30 ℃ biomedical freezer
	Refrigerator
Sample data management	Laptop Computer
Production of the ultrapure water	Milli-Q integral system
Others	Vehicle for Transportation

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Annex VI

[DRAFT]

RECORD OF DISCUSSIONS

ON

THE PROJECT FOR IDENTIFICATION OF PATHOGENS AND DEVELOPMENT OF ON-SITE DIAGNOSTIC METHODS FOR VIRAL DISEASES OF PUBLIC HEALTH CONCERN INCLUDING VIRAL HEMORRHAGIC FEVER

IN

THE GABONESE REPUBLIC

AGREED UPON BETWEEN

THE MINISTRY OF HIGHER EDUCATION AND SCIENTIFIC RESEARCH

AND

JAPAN INTERNATIONAL COOPERATION AGENCY

Libreville, January XX, 2016

Mr. Nobuyuki Yamaura
Representative Chief
JICA Gabon Office
Japan International Cooperation Agency
Japan

Ministry of Higher Education and Scientific Research
Gabonese Republic

Based on the minutes of meetings on the Detailed Planning Survey on the "Identification of Unknown Pathogens and Establishment of On-site Rapid Diagnostic System for Viral Diseases in Gabon" (hereinafter referred to as "this Project") signed on October 2, 2015 between the Ministry of Higher Education and Scientific Research (hereinafter referred to as "MoHESR"), relevant organizations and the Japan International Cooperation Agency (hereinafter referred to as "JICA") held a series of discussions with Center of Medical Research Lambaréné (hereinafter referred to as "CERMEL") and other relevant organizations to develop the detailed plan of this Project.

Both parties agreed to the details of this Project and the main points discussed as described in Appendix 1 and Appendix 2, respectively.

Both parties also agreed that CERMEL will be responsible for the implementation of this Project in cooperation with JICA, coordinate with other relevant organizations and ensure that the self-reliant operation of this Project is sustained during and after the implementation period in order to contribute toward both social and economic development of the Gabonese Republic (hereinafter referred to as "Gabon").

This Project will be implemented within the framework of the Agreement on Technical Cooperation signed on March 21, 2008 and the Note Verbales exchanged on XX XX, 2015 between the Government of Japan (hereinafter referred to as "GOJ") and the Government of Gabon (hereinafter referred to as "GOGR").

Appendix 1: Project Description
Appendix 2: Minutes of Meetings on the Detailed Planning Survey for the "Identification of Unknown Pathogens and Establishment of On-site Rapid Diagnostic System for Viral Diseases in Gabon"

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Appendix 1

PROJECT DESCRIPTION

Both parties confirmed that there is no change in this Project Description in the Minutes of Meetings for the Detailed Planning Survey on this Project signed on October 2, 2015 (Appendix 2).

I. BACKGROUND

The infectious diseases account for a large part of the cause of death in Gabon (56% 2011, WHO), in particular, Malaria is the largest cause of under-5 mortality and the Infection rate of HIV and the prevalence rate of tuberculosis are higher than the average rate of Sub-Saharan Africa. In addition to these three major infectious diseases, a variety of Infectious diseases such as Dengue fever, Chikungunya fever and Ebola virus disease have occurred in Gabon. Moreover, Gabon is geographically close to Nigeria, where Lassa virus is endemic, and the Democratic Republic of Congo, which has experienced the repeated Ebola virus disease outbreak, so that Gabon is also exposed to the risk of viral diseases. However, the ability of Gabon to take measures to cope with the emerging and reemerging infectious diseases is not sufficient.

In this situation, Gabon has set the construction of a monitoring system for infectious diseases control in the national development strategy, "President Strategic Plan 2011-16" and positioned infection control measures as a particular problem to be solved preferentially.

This project aims to enhance the research and development capacity of the Gabonese research center through collaborative research by the Institute of Tropical Medicine, Nagasaki University (hereinafter referred to as "NEKKEN") and CERMEL about identification and characterization analysis of known and identified pathogenic viruses based on the survey. The result of this project is expected to benefit to the countermeasures against viral diseases in Gabon and also in the Central Africa region in the future.

II. OUTLINE OF THE PROJECT

The Details of this Project are described in this Project Design Matrix (hereinafter referred to as "PDM") (Annex I) and the tentative Plan of Operation (hereinafter referred to as "PO") (Annex II).

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1. Title of the Project

The title of the Project is modified from the one indicated in the application entitled "The Project for Identification of Unknown Pathogens and Establishment of On-site Rapid Diagnostic System for Viral Diseases in Gabon" to "The Project for Identification of Pathogens and Development of On-site Diagnostic Methods for Viral Diseases of Public Health Concern Including Viral Hemorrhagic Fever" (hereinafter referred to as "the Project"), so that the agreed contents of the Project are accurately reflected.

2. Project Purpose

The research and development capacity of the Gabonese research center is enhanced through the collaborative research with Japanese research institute regarding identification of pathogens of known and unidentified infectious diseases as well as development of rapid diagnostic methods for viral diseases of public health concern.

3. Outputs

(1) The prevalence of known and unidentified viral diseases is clarified in the areas around Lambaréné.
(2) Characteristics such as genetic information and pathogenicity of viruses that are regarded as public health concern and newly identified in Gabon is defined.
(3) Rapid diagnostic methods for viral diseases of public health concern and/or newly identified ones are developed.

4. Inputs

(1) Inputs by the Japanese Side
(a) Dispatch of Experts
- Chief Advisor
- Project Coordinator
- Other Experts with the expertise of rapid diagnostics, viral experiments, research management and other designated areas

(b) Training
(c) Machinery and Equipment
- Necessary research instruments, equipment and devices for research and development activities, as shown in Annex Ⅲ

In case of importation, the machinery, equipment and other materials under II-4

(1) (c) above will become the property of the Gabonese side upon being delivered C.I.F. (cost, insurance and freight) to the Gabonese authorities concerned at the ports and/or airports of disembarkation.

Input other than indicated above will be determined through mutual consultations between JICA and CERMEL during the implementation of the Project, as necessary.

(2) Inputs by the Gabonese Side

The MoHESR and CERMEL will take necessary measures to provide at their own expense:

(a) Services of the Gabonese side counterpart personnel and administrative personnel as referred to in II-5;
(b) Suitable office space with necessary equipment;
(c) Supply or replacement of machinery, equipment, instruments, vehicles, tools, spare parts and any other materials necessary for the implementation of the Project other than those provided by JICA;
(d) Information as well as support in obtaining medical service;
(e) Credentials or identification cards;
(f) Available data (including maps and photographs) and information related to the Project;
(g) Running expenses necessary for the implementation of the Project;
(h) Expenses necessary for operation and maintenance of the equipment referred to in II-5 (1).

5. Implementation Structure

The Project Implementation Structure is shown in Annex Ⅳ. The roles and assignments of both sides are as follows:

(1) The Gabonese side will assign:

(a) Project Director (who will bear overall responsibility for the administration and implementation of the Project);
(b) Project Manager (who will be responsible for the managerial and technical matters of the Project); and
(c) Research staff and laboratory technicians.

(2) The Japanese side will dispatch:

(a) Chief Advisor (who will provide necessary recommendations and advice to the Project Director and the Project Manager on any matters pertaining to the implementation of the Project);
(b) Project Coordinator (who will coordinate the Project, supporting the Chief Advisor and other experts); and

(c) Other JICA Experts (who will give necessary guidance and advice to Gabonese counterpart researchers and personnel on technical matters pertaining to the implementation of the Project).

(3) Joint Coordinating Committee

Joint Coordinating Committee (hereinafter referred to as "JCC") will be established in order to facilitate inter-organizational coordination. JCC will be held at least once a year and whenever deems it necessary. JCC will review the progress, revise the overall plan when necessary, approve an annual work plan, conduct evaluation of the Project, and exchange opinions on major issues that arise during the implementation of the Project. A list of proposed members of JCC is shown in the Annex V.

6. Project Site(s), Implementers and Beneficiaries

(1) Project Target Area: The area around Lambaréné in the Moyen-Ogooué province in the Gabonese Republic

(2) Project Implementers: Ministry of Higher Education and Scientific Research and Center of Medical Research Lambaréné

(3) Beneficiaries: Residents at risk of viral diseases in Gabon

7. Duration

The duration of the technical cooperation for the Project will be five (5) years starting in April 2016.

8. Reports

The Gabonese and Japanese sides will jointly prepare the following reports in French with English translation:

(1) Progress Report on bi-annual basis until the project completion; and

(2) Project Completion Report at the time of project completion.

9. Environmental and Social Considerations

MoHESR, CERMEL, and NEKKEN agreed to abide by 'JICA Guidelines for Environmental and Social Considerations' in order to ensure that appropriate considerations will be made for the environmental and social impacts of the Project.

10. Management of Safety for Construction Works

For construction works, which will be carried out in the Project, CERMEL and

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JICA will assure the management of safety in accordance with the "Safety Plan" and "Method Statements of Safety"submitted by contractors based on the Guidance for the Management of Safety for Construction Works in Japanese ODA Projects.

III. UNDERTAKINGS OF GOGR

The GOGR will take necessary measures to:

(1) ensure that the technologies and knowledge acquired by the Gabon nationals as a result of Japanese technical cooperation contributes to the economic and social development of Gabon, and that the knowledge and experience acquired by the personnel of Gabon from technical training as well as the equipment provided by JICA will be utilized effectively in the implementation of the Project; and

(2) grant privileges, exemptions and benefits to JICA Experts referred to in II-5 above and their families, which are no less favorable than those granted to experts and members of the missions and their families of third countries or international organizations performing similar missions in the Gabonese Republic.

IV. MONITORING AND EVALUATION

JICA and CERMEL will jointly and regularly monitor the progress of the Project through the Monitoring Sheets based on the Project Design Matrix (PDM) and Plan of Operation (PO). The Monitoring Sheets will be reviewed every six (6) months.

Also, the Project Completion Report will be drawn up one (1) month before the termination of the Project.

JICA will conduct the following evaluations and surveys to verify sustainability and impact of the Project. CERMEL is required to provide necessary support for them.

(1) Ex-post evaluation three (3) years after the project completion, in principle

(2) Follow-up surveys on necessity basis

V. PROMOTION OF PUBLIC SUPPORT

For the purpose of promoting support for the Project, the Gabonese side will take appropriate measures to make the Project widely known to the people of Gabon.

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VI. MISCONDUCT

If JICA receives information related to suspected corrupt or fraudulent practices in the implementation of the Project, CERMEL and relevant organizations will provide JICA with such information as JICA may reasonably request, including information related to any concerned official of the government and/or public organizations of the Gabon.

CERMEL and relevant organizations will not unfairly or unfavorably treat the person and/or company, which provided the information related to suspected corrupt or fraudulent practices in the implementation of the Project.

VII. MUTUAL CONSULTATION

JICA and CERMEL will consult each other whenever any major issues arise in the course of project implementation.

VIII. AMENDMENTS

The Record of Discussions may be amended by the minutes of meetings among JICA, CERMEL and MoHESR. However, PO may be amended in the Monitoring Sheets. The minutes of meetings will be signed by authorized persons of each side who may be different from the signers of the Record of Discussions.

Annex I	PDM version 0 (M/M Annex III)
Annex II	Tentative PO version 0 (M/M Annex IV)
Annex III	Tentative List of Equipment (M/M Annex V)
Annex IV	Project Implementation Structure (M/M Annex I)
Annex V	List of Proposed Members of Joint Coordinating Committee

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ANNEX V

LIST OF PROPOSED MEMBERS OF JOINT COORDINATING COMMITTEE

1. Functions

The JCC will be held at least once a year and whenever deems it necessary. The functions of JCC are as follows:

(1) To formulate and authorize the annual activity plan of the Project;
(2) To endorse major achievements and products of the Project;
(3) To monitor and review overall progress and supervise the Project; and
(4) To review and discuss on major issues arising from or concerning the Project.

2. Chairperson:

Director General of Scientific Research and Innovation, MoHESR, Gabon (Project Director)

3. Members:

a. The Gabonese side
- Project Manager
- Research Group Leaders
- Representative(s) from MoHESR

b. The Japanese side
- Chief Advisor, JICA Project Coordinator, and other JICA Experts
- Representative(s) from the JICA Gabonese Office

4. Observing Members

a. The Gabonese side
- Representative(s) from MoH
- Representative(s) from the National Laboratory of Public Health

b. The Japanese side
- Representative(s) from Embassy of Japan in Gabon
- Representative(s) from AMED

c. Other stakeholders appointed by the Chairperson

Audit on biosafety

Table 1.Basic Laboratory-BSL1

Place: CERMEL Joint Research Laboratory / Nagasaki University	Date: 30 April 2018				
Head of laboratory: Dr Marguerite Massinga Lombe					
Person (s) audited and post: Dr Haruka Abe, Assistant Prof / Dr Yuri Ushijima, Post-doc					
controlled points	**Yes**	**No**	**Partial**	**Means of verification**	**Observations**
1. Laboratory					
1.1. Is signalling appropriate: hazardous substances?		✓		**Visual verification, MSDS and / or implementation cards**	• No adequate marking to know biological hazard pictogram on all rooms, appliances, autoclaves, centrifuges
1.2. Are biosecurity guidelines existing and known?		✓		**Visual Verification (Pictogram), Biosafety Manual (read and signed)**	• No copy of the biosecurity manual on site • Guidelines for hand hygiene are not displayed
1.3. Are laboratory equipment properly marked (biological hazard, radioactivity, toxicity, etc.)?		✓		**Visual verification (Pictogram)**	
Access and good practice code: *The international pictogram of biological hazard must be affixed to the doors of rooms where micro-organisms belonging to risk group 2 or higher groups are handled.* *A biological hazard sign on the laboratory door should indicate the level of biosecurity and the name of the laboratory manager responsible for access to the premises* ***WHO Biosafety Manual, 2010, pages 10 and 22*** ***Biosecurity management:*** *The laboratory must have a copy of the laboratory manual or health and safety guide.* *The staff must be aware of the risks specific to the laboratory's activities and read the manual* ***WHO Biosafety Manual, 2010, page 12***					
2. Laboratory design					
2.1. Are the shelves securely fixed?	✓			**Visual verification**	
2.2. Is bench top coating waterproof and resistant to acids, bases, organic solvents and heat?	✓			**Visual verification**	
Coating of the benches: *Countertop work surfaces must be waterproof, resistant to disinfectants, acids, alkalis and organic solvents and be able to withstand moderate heat.* ***WHO Biosafety Manual, 2010, page 14***					
2.3. Are the rooms adequately lighted?	✓			**Visual verification**	Lighting in each room
Norm: *The laboratory space must be sufficient to ensure the quality of work, the safety of staff and the ability of staff to carry out quality control and documentation procedures. The laboratory must be clean and well organized, free from congestion, well ventilated, well-lit and within acceptable temperature ranges.* ***ISO 15190: 6.3.1***					

2.4. Are storage spaces adequate and properly used?		✓		**Visual verification and related documentation (Reagent storage sheets)**	Congestion: presence of devices on ways, and laboratory equipment on laboratory instruments
Storage spaces: *The storage spaces must be able to receive the current equipment, so as to avoid the bulk of the benches and the passage areas.* ***WHO Biosafety Manual, 2010, page 15***					
3. Chemicals					
3.1. Are flammable products stored in appropriate cabinets?				**Visual verification and related documentation (Reagent storage sheets)**	Limited quantity chemical (eg bleach, EtOH) No stock on site Provide secure cabinet for large quantity storage
3.2. Are the products properly separated?	✓			**Visual verification and related documentation (Reagent storage sheets)**	
3.3. Are dangerous products stored above eye level?		✓		**Visual verification**	
3.4. Are products stowed on the ground?		✓		**Visual verification**	
3.5. Do chemical containers remain open during and after use?		✓		**Visual verification**	
3.6. Are the solutions correctly labelled?			✓	**Visual verification**	Bleach: lack of initials, date of preparation and expiration Missing danger marking
Labelling of chemicals: *All hazardous chemicals must be Labelled with the chemical name and clearly marked hazard markings.* ***ISO 15190: 17.1 et 17.3***					
3.7. Are flammable products stored in secure or explosion proof units?				**Visual verification and related documentation (Reagent storage sheets)**	NA: No stock of chemicals in the lab
Norm: *Flammable chemicals should be stored away from solar radiation and below their flash point, preferably in a well-ventilated area. Flammable and corrosive agents must be separated from each other. Special care must always be taken to manage the safety of hazardous chemicals in the workplace.* ***ISO 15190: 17.1 et 17.3***					
4. Refrigerators, freezers, cold rooms					
4.1. Are foods for human consumption stored in refrigerators and freezers?			✓	**Visual verification**	No food in the laboratory. However, no signage prohibiting the storage of food in refrigerators
Norm: *Personnel foodstuffs must be stored in separate areas reserved for this purpose, and not in the laboratory storage areas, especially in the cold room. Laboratory reagents and blood products should be stored separately when refrigerated or frozen.* ***ISO 15190: 11.1***					
4.2. Are carcinogenic, radioactive or biohazardous substances indicated by an external mark?				**Visual verification (Pictogram)**	NA: Absence of chemicals in the laboratory

Norm:** All hazardous chemicals must be labelled with the chemical name and clearly marked hazard markings.* ***ISO 15190: 17.1 et 17.3					
4.3. Is there a temperature management system?			✓	**Visual verification and documentation (temperature log)**	Presence of thermometers in each room Log of temperature monitoring not systematically informed
Norm:** ISO 15189: 5.2.5 «The laboratory shall monitor, control and record environmental conditions in accordance with the corresponding specifications or where they are likely to influence the quality of the results»* ***CERMEL SOP: Monitoring temperatures fridges and freezers(L-G-029-V04-EN)					
4.4. Is there a preventive or annual maintenance of the devices?		✓		**Visual verification and documentation (equipment maintenance log, annual maintenance labels)**	**Note**: No maintenance to date, newly installed laboratory Equipment installation documentation not available in the laboratory
Norm:** Preventive maintenance should be performed by operators on all equipment used for testing, including centrifuges, autoclaves, microscopes and safety cabinets* ***ISO 15189: 4.2.5, 5.3.2 ***CERMEL SOP: General usage and maintenance of microscopy (L-G-027-V06-EN)***					
5. Electrical equipment					
5.1. Are extension cords properly placed in theatres?		✓		**Visual verification**	Many extensions passing crossing areas, high accident risk
5.2. Are there electric cables on the ground?	✓			**Visual verification**	
5.3. Are the wafers connected to the floor?	✓			**Visual verification**	
5.4. Are outlets and other connections near sinks, under showers, etc... ?		✓		**Visual verification**	
5.5. Are plugs or inserts with connections overloaded?		✓		**Visual verification**	
5.6. Do outlets close to water supply comply with local regulations?				**Visual verification**	NA
5.7. Are there device protections against power interruptions and / or overloading?	✓			**Visual verification**	Generator + UPS
Norm:** Cords, plugs, extension cords and electrical outlets must be kept in good condition and used appropriately. Any congestion should be avoided and cords should be kept out of areas of passage.* ***ISO 15190: 19.7 et 9.3					
6. Personal protective equipment					
6.1. Are there eye rinses in the laboratory?		✓		**Visual verification and related documentation (Biosafety Manual)**	
ISO 15190: 12.10					
6.2. Are there safety showers?		✓		**Visual verification and related documentation (Biosafety Manual)**	
6.3. Are personal protective equipment (gloves, gowns, safety glasses) present and properly used?	✓			**Visual verification and related documentation (Biosafety Manual)**	

6.4. Are overalls, coveralls, lab coats, gloves and other protective clothing or accessories worn outside the laboratory?			✓	**Visual verification and related documentation (Biosafety Manual)**	No but no note the signifier
6.5. Is there personal protective clothing for cryogenic storage?				**Visual verification**	Unverified, appliance out of order
Norm: *It is the responsibility of the laboratory management to ensure that the laboratory is equipped with standard safety equipment ... Hand washing stations must be designed and equipped and eye wash stations (or other acceptable methods of rinsing eyepiece) must be available and functional. Spill control equipment and first aid kits must be kept in a well-defined place and their functional status regularly checked.* ***ISO 15190: 5.1***					
7. Waste management					
7.1. Are there signs for waste disposal?		✓		**Related signs and documentation**	In implementation
7.2. Is the waste sorted and collected in the appropriate containers?		✓		**Visual verification (pictogram)**	Only garbage cans for household waste are available No bin for infectious waste or sharps waste, sharp, sharp.
Norm: *The waste must be separated according to biological risk; infectious and non-infectious waste being disposed of in separate containers. Infectious waste must be placed in receptacles that do not leak and be clearly marked with a biological hazard symbol. Sharp instruments and needles should be placed in puncture-resistant containers. Infectious waste and sharps receptacles must be autoclaved prior to disposal to decontaminate any potentially infectious material. To avoid injury from exposed waste, infectious waste must be incinerated, burned in a pit or buried* ***ISO 15190 :22***					
7.3. Are Chemical Waste Containers Properly Labelled?		✓		**Visual verification (pictogram)**	Not available
7.4. Are hazardous chemicals disposed of properly?				**Visual verification and documentation related (Waste sorting sheets)**	N/A: Laboratory not used yet
Norm: *All hazardous chemicals must be labelled with the chemical name and clearly marked hazard markings. Flammable chemicals should be stored away from solar radiation and below their flash point, preferably in a well-ventilated area. Flammable and corrosive agents must be separated from each other. Special care must always be taken to manage the safety of hazardous chemicals in the workplace.* ***ISO 15190: 17.1 et 17.3***					
7.5. Are sharp, sharp or sharp objects containers properly used and disposed of?		✓		**Visual verification and related documentation (Biosafety Manual)**	Not available
Norm: *All syringes, needles, lancets or other bleeding devices capable of transmitting an infection must be disposable and disposed of in puncture-resistant containers that are not filled to the brim. Sharps containers must be clearly marked to warn operators of the potential hazard and should be located in areas where sharps are commonly used.* ***ISO 15189: 5.2.10;***					
7.6. Do we find rubbish on the floor?		✓		**Visual verification**	
7.7. Is there a poster for the procedure for waste disposal?		✓		**Visual verification and related documentation (display etc.)**	Not available
8. Existence of occupational health and safety programs at work					
8.1. Risk Communication: Biosafety Manual		✓		**Related documentation (manual, display, etc.)**	Copy not available in the lab

Norm: *The laboratory must have a safety manual that is easily accessible in work areas and is required for all employees to read. The manual must be adapted to the specific needs of the laboratory, it must be reviewed and updated at least once a year by the laboratory management.* ***ISO 15190: 7.4***					
8.2. Staff reads, reviews and follows instructions on practices and techniques, especially those contained in the Safety Manual or Laboratory Manual (mandatory once a year for all staff)		✓		**Related documentation (signature pages)**	Copies of manuals not available in the laboratory
8.3. Medical prevention: vaccinations or necessary examinations offered to staff according to the infectious agents handled: HBV, PEP HIV	✓			**Related documentation (manual, posting, skills assessment sheet, etc.)**	Vaccination of current staff (HR file)
Norm: *Laboratory staff should be offered appropriate vaccinations, particularly for hepatitis B. Staff may refuse to receive the vaccination but must sign a refusal form which will be kept in the employee's personal file.* ***ISO 15190: 11.3*** ***CERMEL SOP : G-023 Accidental Exposure To Potentially Infectious Material V06***					
8.4. Competent medical services contacted for check-ups, medical surveillance and treatment in case of occupational exposure				**Related documentation (manual, display, etc.)**	
Norm: *The laboratory should have a procedure for monitoring known and percutaneous exposures to HIV, HBV, or HCV, mucous membranes, or skin scrapes. The procedure should include clinical and serological evaluation and appropriate prophylaxis.* ***ISO 15190: 9*** ***CERMEL SOP: G-023 Accidental Exposure To Potentially Infectious Material V06***					
9. Technical control systems					
9.1. Is the water distiller in good condition?	✓			**Visual check maintenance sheet**	
Norm: *Preventive maintenance should be performed by operators on all equipment used for testing, including centrifuges, autoclaves, microscopes and safety cabinets.* ***ISO 15189: 4.2.5, 5.3.2***					
9.2. Is the disposal of products in the sink controlled?		✓		**Poster for the disposal of products in washbasins Biosafety Manual**	Miss note indicating the type of waste to be disposed of in the sink Security manual not available
9.3. Is there an arthropod and rodent control program?		✓		**Deratting reports**	
10. General practices and rules					
10.1. Is there a formal ban on eating, drinking, smoking or putting on makeup in the laboratory?		✓		**Visual verification and related documentation (Pictogram, Biosafety Manual)**	No display
10.2. Mechanical pipetting devices, pro pipettes, etc. are they provided and used?	✓			**Visual verification**	
Pipetting and pipetting devices: *Mouth pipetting is strictly prohibited. Pipetting devices, to replace mouth pipetting.* ***WHO Biosafety Manual, 2010, pages 11 and 16***					
10.3. Planning for Staff training course on biosafety		✓		**Related documentation (Training schedule)**	

Norm: *In accordance with national laboratory training plans, each laboratory must have functional training policies and procedures that meet the needs of laboratory personnel through internal and external training.*					
CERMEL SOP : Staff training (L-G-019-V03-EN)					***ISO 15189: 4.12.5, 5.1.6, 5.1.9***
11. General holding of the laboratory					
11.1. Are glass containers placed on the floor?		✓		**Visual verification and related documentation**	
11.2. Are there obvious risks of stumbling?	✓			**Visual verification**	Electrical cables crossing the passages
Norm: *Any clutter should be avoided and the cords should be kept out of the passage areas.*					***ISO 15190: 19.7 et 9.3***
11.3. Is paper towel available on the work surfaces?	✓			**Visual verification and related documentation (SOP: L-CL-002-V04-EN)**	
11.4. Is there a procedure for mechanical handling of glass debris (shovel and brush, pliers, etc...?)	✓			**Visual verification**	
12. Fire safety					
12.1. Are the traffic aisles at least 1m wide?		✓		**Visual verification and related documentation (SOP: Conducting Fire Drills, Emergency Actions and Evacuation Procedure (L-G-028-V01-EN)**	Restricted traffic areas
Norm: *The laboratory should be designed to support high quality work, staff safety and operational efficiency.*					***ISO 15189: 5.2.2***
12.2. Are objects stored on ducts or on electrical appliances?	✓			**Visual verification**	
12.3. Do the devices have frayed wires or are they damaged??		✓		**Visual verification**	
Norm: *Cords, plugs, extension cords and electrical outlets must be kept in good condition and used appropriately. Any congestion should be avoided and cords should be kept out of areas of passage.*					***ISO 15190: 19.7 et 9.3***
13. Heating baths at constant temperature					
13.1. With low water level and overheating switch				**Related documentation (SOP: Immersion thermostat A100 and water bath (L-RL-013-V03-EN) or Machine instructions**	NA
13.2. Constructed of non-combustible material					

Table 2. Basic Laboratory- BSL2

Place:	Date:				
Head of laboratory:					
Person (s) audited					
Controlled Points	**Yes**	**No**	**Partial**	**Means of verification**	**Observations**
1. Microbiological safety station (MSS)					
1.1 Is there certification or validation during the previous year?		✓		**Visual verification and related documentation**	MSS not yet operational
Norm:** A biosafety cabinet must be used to prevent exposure to aerosols from specimens or contagious organisms. To ensure proper operation and complete protection, biological safety cabinets require periodic maintenance and must be maintained accordingly.* ***ISO 15190: 16 ***CERMEL SOP: Use of Microbiological Safety Stations (L-G-045-V01-FR)***					
1.2 Is the surface of the MSS cleaned with a suitable disinfectant at the beginning and end of each manipulation?		✓		**Visual verification and related documentation (maintenance log)**	MSS not yet operational
1.3 Is there a front grille and an unobstructed drain filter on the MSS?	✓			**Visual verification**	
1.4 Can open flames be used in the MSS enclosure?	✓				In deflection with the norm in force and SOP CERMEL
Use of biosafety cabinets in the laboratory *Open flames: Avoid the presence of any open flame in the near-sterile environment inside the enclosure. Flames disrupt the flow of air and can be dangerous if volatile substances are also used. To sterilize bacteriological loops, there are micro burners that are preferable to open flames.* ***WHO Biosafety Manual, page 66*** ***CERMEL SOP: Use of Microbiological Safety Stations (L-G-045-V01-FR)***					
1.6 Is the effectiveness of MSS compromised by ambient air or location?		✓		**Visual verification**	
Use of biosafety cabinets in the laboratory: *BSCs must be installed in locations that are remote from the waypoints and drafts that could interfere with their operation. If possible, a clearance of about 30 centimeters should be provided behind the enclosure and on each side to facilitate access in the event of maintenance operations.* ***WHO Biosafety Manual, page 67***					
1.7 Is MSS used when there is a risk of aerosol formation?				**Visual verification of practices**	N / A laboratory not yet used
Norm:** A biosafety cabinet must be used to prevent exposure to aerosols from specimens or contagious organisms. To ensure proper operation and protection, biosafety cabinets require periodic maintenance and must be serviced accordingly.* ***ISO 15190: 16					
2. Laboratory					

2.1 Is access restricted to authorized personnel?	✓			**Visual verification and related documentation (display)**	Existence of an access code to the main door
Norm: *Unauthorized access to the laboratory must be strictly limited to avoid unnecessary contact with contaminated areas, reagents or equipment. Unnecessary traffic should not disrupt workflow or distract staff members.* ***ISO 15189: 5.2.7***					
2.2 Biological hazard sign affixed to the laboratory door		✓		**Visual verification and related documentation (display)**	
2.2.1 Exact and up-to-date panel information: ✓ Biosafety level ✓ Anticipated risks (Pathogens) ✓ Researcher in charge ✓ N° to call in case of emergency (day and night):		✓			
2.2.2 Panel readable and in good condition?		✓			
2.3 Are all doors constantly closed?		✓			P3 doors Open
3. Decontamination					
3.1 Are there any disinfectants specific to the microorganisms involved??	✓			**Visual verification and related documentation**	Bleach available
Norm: *The work area should be inspected regularly for cleanliness and leakage. An appropriate disinfectant should be used. At a minimum, all benches and work surfaces must be disinfected at the beginning and end of each work cycle. All accidental spills must be immediately controlled and disinfected work surfaces.* ***ISO 15189: 5.2.10; ISO 15190 :13*** ***SOP CERMEL: Cleaning and disinfection of surfaces (L-ML-039-V01-FR)***					
3.2 Is the laboratory supervisor notified if infectious material is widespread or involved in an accident?		✓		**Tools: Exposure report (L-G-023-T3-V03-EN)**	No documentation on site
3.3 Are work plans cleaned before and after each handling, daily or if a product has been spilled?				**Visual verification and related documentation (maintenance log)**	
Plans de travail: *Work plans must be decontaminated if they have been contaminated with potentially dangerous products and at the end of the working day.* ***WHO Biosafety Manual: Laboratory Design page 12*** ***CERMEL SOP: Cleaning of CERMEL Facilities and Laboratories (L-G-040-V02-EN)*** ***CERMEL SOP: Accidental exposure to potentially infectious material (L-CL-002-V04-EN)***					
4. Handling of contaminated waste					
4.1 Good use of contaminated waste containers?			✓	**Visual verification**	Waste are autoclaved but no bins available for biomedical waste
4.2 No bins filled up to the brim?				**Visual verification**	NA: no bins
4.3 Trash bins properly labelled and closed?				**Visual verification**	NA: no bins

4.4 Crops and other wastes subject to regulation properly decontaminated before disposal?	✓			**Visual verification and related documentation (Waste management)**	Autoclave available in the room
Norm**: Infectious waste and sharps receptacles must be autoclaved prior to disposal to decontaminate any potentially infectious material. To avoid injury from exposed waste, infectious waste must be incinerated, burned in a pit or buried.* ***ISO 15190 :22					
4.5 Transport in sealed, solid and sealed containers of decontaminated material outside the laboratory, in accordance with local regulations	✓			**Visual verification**	
5. Individual protection					
5.3 Wearing gloves for handling infectious biological material or contaminated equipment			✓	**Visual verification and related documentation (Biosafety Manual)**	Gloves available but laboratory still not operational
5.4 Facial protection when working on infectious material outside MSS				**Visual verification and related documentation (Biosafety Manual)**	N/A
Norm:** It is the responsibility of the laboratory management to ensure that the laboratory is equipped with standard safety equipment. The list above is a partial list of the necessary items.* ***ISO 15190: 5.1					
5.5 Wash hands after removing gloves and before leaving the laboratory		✓		**Visual verification and related documentation (tool: hand washing L-G-041-R2-V01-EN)**	No display for this purpose
Norm:** Hand washing stations should be designed and equipped and eyewash stations (or other acceptable eye washing methods) should be available and functional.* ***ISO 15190: 5.1					
6. Practice					
6.1 Are auto-disable or disposable syringes used for work on infectious agents?				**Visual verification of practices**	NA
Aerosol production: *All techniques used must minimize the formation of aerosols and droplets.* ***WHO Biosafety Manual: Procedure page 11***					
6.2 Infectious specimens are transported out of PSM in approved containers in accordance with the transport regulations for this type of product	✓			**Visual verification and related documentation (Biosafety Manual, SOP)**	
Transport of samples**:* *To avoid leaks or accidentally spilled material, secondary containers, such as boxes, with racks should be used so that the container containing the sample does not spill, in accordance with national or international regulations.* ***WHO Biosafety Manual: pages 12 and 77					
7. Convenience					
7.1 Are sinks installed near the exit of the laboratory?	✓			**Visual verification**	
Norm:** Hand washing stations should be designed and equipped and eyewash stations (or other acceptable eye washing methods) should be available and functional.* ***ISO 15190: 5.1					

Table 3. Containment laboratory -BSL3

Place:	Date:				
Head of laboratory:					
Controlled Points	**Yes**	**No**	**Partial**	**Means of Verification**	**Observations**
Overview: *Containment Laboratory - Biosafety Level 3 is designed and planned for work involving risk group 3 microorganisms and high volumes or concentrations of Risk Group 2 microorganisms that are more susceptible to handling. to cause the diffusion of aerosols.* ***WHO Biosafety Manual, page 22***					
1. Laboratory design					
1.1. Is the laboratory separated from the normal crossing points of the building?	✓			Visual verification	
1.2. Does access to the laboratory through a vestibule have self-closing doors?	✓			Visual verification	• Door not operational on the day of the audit
1.3. Are gaskets installed or can be installed at all crossings for laboratory decontamination?	✓			Visual verification	
2. Room air not recycled and evacuated from occupied areas	✓			Visual verification	• Non-operational ventilation system on the day of the audit
2.1. Regulated ventilation system to control the direction of air circulation	✓			Visual verification (manometer)	• Non-operational ventilation system on the day of the audit
Design and layout of the laboratory: *Laboratory to be separated from unregulated passage areas* *The vestibule doors must be self-closing and interlocked so that only one door can be opened at a time* *The laboratory must be able to be hermetically closed to be decontaminated* *The ventilation system must create a stream of air directed from the access area to the interior of the room. A visual control device, whether or not equipped with an alarm, shall be installed so that personnel can ensure that the airflow is always correctly directed* *The ventilation system must be constructed in such a way that the air leaving the containment laboratory - Biosafety Level 3, is not recycled in other areas of the building* ***WHO Biosafety Manual, page 23***					
3. Individual protection					
3.1. Wearing closed blouses on the front in the laboratory		✓		Visual verification	
3.2. Wear protective clothing limited to laboratory premises		✓		Visual verification and related documentation (display)	No display
3.3. Pedestal, elbow or self-operated washbasin		✓		Visual verification	No washbasin in the room
Norm: *It is the responsibility of management to provide appropriate personal protective equipment (gloves, gowns, goggles, etc.) in a usable condition. Laboratory personnel must at all times use PPE in the laboratory. Protective clothing should not be worn outside the laboratory. Torn or contaminated gloves should be replaced immediately and not washed for reuse.* ***ISO 15190: 12***					

Code of good practice *It is forbidden to wear protective clothing outside the laboratory.* *A washbasin that can be controlled without the help of the hands will be placed near each exit door.* *Protective clothing to be worn in the laboratory must be of the following type: aprons, gowns, lab coats, cleaning suits, overalls, headdresses and, where appropriate, shoe covers and special shoes. Regular lab coats that button in front are not suitable, as well as sleeves that do not fully cover the forearms.* ***WHO Biosafety Manual, page 22***					
4. **Hands protections**					
4.1. Wearing double gloves for working with infectious material and equipment or worktops that may be contaminated				**Visual verification of practices**	N / A non-operational laboratory
5. Respiratory protection					
5.1. Wearing respiratory protection by all laboratory personnel when aerosols are not safely contained in a MSS	✓			**Visual verification of practices**	N95 masks available
Code of good practice *Wearing a respirator may be necessary for some handling or when working on animals carrying certain pathogens* ***WHO Biosafety Manual, page 22***					
6. **Practice**					
6.1. Staff warned of specific risks related to the agent or infectious agents		✓		**Visual verification of practices and related documentation (biosecurity manual, display)**	Manual not available No display
Norm: *The laboratory must have a safety manual that is easily accessible in work areas and* ***is required for all employees to read****. The manual must be adapted to the specific needs of the laboratory, it must be reviewed and updated at least once a year by the laboratory management.* ***ISO 15190: 7.4***					
6.2. Annual updates to staff or additional training if changes are made to certain techniques				**Related documentation (skills assessment sheet, training plan)**	
6.3. Autoclaving of all waste before disposal	✓			**Visual verification of practices and related documentation (Biosafety Manual,)**	Autoclave available in the room
Norm: *The waste must be separated according to biological risk; infectious and non-infectious waste being disposed of in separate containers. Infectious waste must be placed in receptacles that do not leak and be clearly marked with a biological hazard symbol. Sharp instruments and needles should be placed in puncture-resistant containers. Infectious waste and sharps receptacles must be autoclaved prior to disposal to decontaminate any potentially infectious material. To avoid injury from exposed waste, infectious waste must be incinerated, burned in a pit or buried.* ***ISO 15190 :22***					
7. **Health surveillance**					
7.1. Staff warned of specific risks related to the agent or infectious agents		✓		**Visual verification of practices and related documentation (biosecurity manual, display)**	Manual not available No display

Medical and health surveillance

1. The medical examination is mandatory for all laboratory personnel working in the containment laboratory. It should include an anamnesis in search of medical history and a physical examination to check if the person is medically fit to perform this type of professional activity.

2. If the medical check-up is satisfactory, the person concerned will receive a medical card attesting that he / she is employed in an establishment where a level 3 biological safety containment laboratory is located. This card, which the card holder must always wear, will include the holder's photograph and must be stowed in a wallet or card holder. It should also indicate the name of the person or persons to contact in case of problems, who will be designated locally, but who could be for example, the director of the laboratory, the medical adviser or the delegate for biosafety.

WHO Biosafety Manual, page 26

Auditor's Name & Signature: Hutch-l'herbner Nzenguélé [signature]

Auditor's Name & Signature: thierry GANZI SOUNDA [signature]

End Date of control 30th April 2018

cermel

Rapport - Mesures correctives pour l'audit interne: Laboratoire BSL2/3 Avril 2018

	CERMEL- REPORT/ MESURES CORRECTIVES/ AUDIT INTERNE		
Departement	Laboratoire BSL2/3		
Date d'audit	~~30 Avril~~ 14 Decembre 2018		
Auditeurs	Hutch-L'herbier NZENGUELE, Thierry GANZI,		
Définitions de statut :	**C = Résultat Critique** Un résultat critique est une déviation compromettant une conduite d'étude et quand la validité / l'intégrité des données sont affectées. Cet écart peut nécessiter que d'autres opérations cessent jusqu'à ce que des mesures correctives soient prises	**M = Résultat Majeur** Une découverte majeure est un écart par rapport aux principes de la bonne pratique de laboratoire clinique (GCLP) ou d'étudier la procédure ou d'autres procédures opérationnelles standard (SOP) applicables à l'activité auditée. Cette déviation est majeure ou fréquente ou a un impact important sur l'activité. Les mesures correctives doivent être complétées au plus tard 6 semaines après la réception de ce rapport ou à une date d'échéance indiquée.	**O = "Other" (Autre)** "Autre "est un écart par rapport aux principes de la bonne pratique de laboratoire clinique (GCLP) ou pour étudier des procédures ou d'autres procédures opérationnelles standard (SOP) applicables à l'activité auditée. Cette déviation a un impact indirect sur l'activité ou est considérée comme moins significative que "Majeur". Les mesures correctives liées à chaque conclusion «autre» doivent être complétées dans un délai convenu par l'audité principal / la personne responsable et le vérificateur.
INSTRUCTIONS: **Veuillez insérer votre réponse d'action corrective à chaque constatation dans la colonne D ainsi que la personne responsable dans la colonne E et la date d'échéance pour la résolution dans la colonne F. NOTE: La date d'échéance peut être déjà donnée par l'auditeur. Le statut peut être mis à jour dans la colonne G, c'est-à-dire que l'action corrective est en cours ou terminée au moment de la soumission du modèle d'action corrective à l'auditeur.**			

Hutch-L'herbier NZENGUELE

牛島由理

Laboratoire de base-BSL1: contrôle sécurité

Sécurité Biologique						
1. Laboratoire						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai d'execution**	**Statut (En attente / Complet)**
1.1.	Pas de marquage adéquat: - Pictogramme de danger biologique sur l'ensemble des salles, appareils, autoclaves, centrifugeuses…	O	Coller les pictogrammes de danger biologique, de risque électrique et chimique sur les appareils le nécessitant	Hutch	01/08/2018	C
1.2.	Pas de copie du manuel de sécurité biologique sur place Les directives relatives à l'hygiène des mains ne sont pas affichées.	O	Se rapprocher de Rodrigue, afin d'obtenir une copie du manuel de sécurité biologique	Yuri	15/09/2018	C
1.3.	Cf 1.1	O	Voir 1.1	Hutch	01/08/2018	C

2. Conception du laboratoire						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
2.4.	Encombrement : - Présence d'appareils sur les voies de circulation, - Matériel de laboratoire sur les instruments de laboratoire	O	Déplacer les appareils des voies de passage Installer des étagères afin de plus entreposer du matériel sur les appareils	Yuri Abe	15/09/2018	C C

3. Produits chimiques						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
3.1.	Produits chimiques en quantité limitée (ex eau de javel, EtOH): - Prevoir armoire sécurisée pour stockage de grande quantité	M	Pas de grandes quantités de produits stockées en laboratoire. Toutefois, mise en place d'une armoire pour les petites quantités de produits	Yuri Abe	15/09/2018	C

	de produits chimiques					
3.6.	Etiquetage de solution: - Absence d'initial, date de préparation et d'expiration sur le flacon d'eau de javel	M	Identification de toutes les preparations du laboratoire	Yuri Abe	15/09/2018	C

4. Réfrigérateurs, congélateurs, chambres froides						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
4.1.	- Pas d'aliments dans le laboratoire mais absence de note ou pictogrammes interdisant le stockage d'aliments dans les réfrigérateurs	O	Coller sur les appareils (frigo, congélateurs) ainsi que sur les portes des pictogrammes et/ou notes interdisant de metre à manger ou à boire dans les frigo ou congélateurs	Yuri Abe	15/09/2018	C

5. Equipement électrique						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
5.1.	- Rallonges électriques tranversant les voies de passage, risques d'accidents élévés	M	Rétirer les rallonges éléctriques du sol (des voies de passage et les fixer au mur et au plafond	Yuri Abe Arnold	05/08/2018	C

6. Equipement de protection individuelle						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
6.1	- Pas de rinces-yeux dans le laboratoire	M	Demander à Dr Josiane un rince-yeux et remettre à Yuri ou Abe. Constituer également un kit de déversement biologique	Hutch	25/08/2018	C
6.4.	- EPI non porté hors du laboratoire mais aucune	O	Rédiger et afficher une note et si possible un pictogramme interdisant	Hutch	05/09/2018	C

	note le signifiant		le port des EPI hors du laboratoire			

7. Gestion des déchets						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
7.2.	Tri des déchets: - Inexistant pour les déchets infectieux	M	Identifier les poubelles, coller la fiche d'élimination des déchets et remettre la sop "gestion des déchets biomédicaux"	Hutch	03/08/2018	C
7.3.	Recipients pour déchets chimiques: - Non disponible	M		Yuri Abe		
7.5.	Recipients pour objets coupant, piquants, tranchants: - Non disponible	M	Metre à disposition du laboratoire des "sharps containers"	Hutch	15/07/2018	C
7.7.	Marche à suivre pour l'élimination des déchets: - Non disponible	M	Coller les affiches sur l'élimination des déchets	Hutch	15/07/2018	C

8. Existence de programmes de santé et sécurité au travail						
A	**B**	**C**	**D**	**E**	**F**	**G**
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
8.1.	Communication du risque : - Copie de manuel de sécurité biologique, non disponible dans le laboratoire	M	Cf 1.2	Rodrigue	15/09/2018	C
8.2.	- Cf 8.1.	O		Rodidrigue		C

9. Systèmes de contrôle technique						
A	**B**	**C**	**D**	**E**	**F**	**G**
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
9.2.	Elimination des déchets dans lavabo : - Manque la note indiquant le type de déchets à éliminer dans l'évier	M	Traduire, faire implémenter et coller les fiches circuit évacuation des déchets traduites et implementées	Hutch	15/07/2018	C

9.3.	Programme de lutte contre les arthropodes et rongeurs : - Inexistence du programme de lutte	M	Rédiger une procédure de lutte contre les arthropodes et les rongeurs	Hutch	10/08/2018	P

10. Pratiques et règles générales						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
10.1.	- Pas de note ou pictogrammes interdisant de manger, boire dans le laboratoire ou consommer la glace de la machine à glace	M	Rediger et coller une note interdisant de boire et manger ansi que de consommer la glace de la pondeuse à glace	Yuri Abe	15/09/2018	C
10.3.	Planning de formation du personnel: - Pas de documentation à cet effet	M	A metre en place	Yuri Abe	15/09/2018	P

11. Tenue générale du laboratoire						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
11.2.	Risque de trébuchement : - Câbles électriques traversant les voies de passage	M	Cf 5.1	Yuri Abe	15/09/2018	C

12. Sécurité incendie						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
12.1.	- Espaces de circulation restreint	O	Pas de solution à l'heure actuelle. Construction faite ainsi.	Yuri Abe	15/09/2018	P

Laboratoire de base-BSL2 : contrôle sécurité

1. Poste de sécurité microbiologique (PSM)						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
1.4.	- Flammes nues utilisées dans l'enceinte du PSM, en déviation avec la norme en vigueur et SOP CERMEL	M	Hotte adaptée à l'utilisationn des flames nues.	Yuri Abe	15/09/2018	C

2. Laboratoire						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
2.2.	- Pas de panneau de danger biologique apposé sur la porte du laboratoire	M	Coller les pictogrammes de "danger biologique" sur les portes.	Yuri Abe	15/09/2018	C
2.3.		M		Yuri	15/09/2018	C

	- Les portes ne sont pas constamment fermées		Mettre en action le systeme de fermeture automatique des portes	Abe		

3. Décontamination						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
3.2.	Matériel infectieux répandu ou impliqué dans un accident : - Pas de documentation attestant que le chef du laboratoire doit être prévenu	M	S'inspirer du manuel de sécurité biologique du laboratoire de recherche	Rodrigue		P

4. Manipulation des déchets contaminés						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
4.1.	Usage des conteneurs des déchets contaminés : - Déchets autoclavés	M	Commander les poubelles auprès de l'administration	Hutch	10/08/2018	C

	mais pas de poubelles disponibles pour déchets biomédicaux					

5. Protection individuelle						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
5.5.	Hygiène des mains : - Pas de documentation ou note à cet effet	O	Coller les affiches d'hygiène des mains	Thierry	05/08/2018	C

6. Pratiques						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
6.2.	Pas de manuel de sécurité biologique.	M	Cf 8.1	Yuri Abe	15/09/2018	C

7. Commodités						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	Observations / Recommandations	Niveau de risque	Reponse du Laboratoire	Personne responsable	Délai	Statut (En attente / Complet
7.1.	- Lavabos pas installés près de la sortie	O	Non pris en compte lors de la construction du laboratoire		15/09/2018	P

Laboratoire de confinement-BSL3: contrôle sécurité

1. Conception du laboratoire						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	Observations / Recommandations	Niveau de risque	Reponse du Laboratoire	Personne responsable	Délai	Statut (En attente / Complet)
1.2.	Fermeture automatique du vestibule : - Système non opérationnel le jour de l'audit	M	Activer le sytème de fermeture du vestibule	Yuri Abe	15/09/2018	C
2	Air du local : - Système de ventilation non opérationnel le jour de l'audit	M	Activer le système d'air du local	Yuri Abe	15/09/2018	C

2.1	Système de ventilation : - Système de ventilation non opérationnel le jour de l'audit	M	Activer le système de ventilation	Yuri Abe	15/09/2018	C

3. Protection individuelle						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
3.2	Aucun affichage interdisant le port de blouses hors du laboratoire	M	Rediger et coller la note interdisant le port de blouse hors du laboratoire	Yuri Abe	15/09/2018	C
3.3	Pas de lavabo actionne par le pied ou à déclenchement automatique :	M	En reflexion	Yuri Abe	15/09/2018	P

6. Pratiques						
A	B	C	D	E	F	G
Section de la liste de contrôle d'évaluation	**Observations / Recommandations**	**Niveau de risque**	**Reponse du Laboratoire**	**Personne responsable**	**Délai**	**Statut (En attente / Complet)**
6.1.	Risques liés aux agents pathogènes : - Manuel non disponible - Pas d'affichage	M	Recuperer une copie de l'analyse situationnelle par Hutch	Yuri Abe	15/09/2018	C
6.2.	Planning de formation du personnel: - Pas de documentation à cet effet	M	Cf 10.3	Yuri Abe	15/09/2018	P
6.3.	Autoclavage des déchets : - Pas d'autoclave disponible dans la salle	M	Installer un autoclave dans le laboratoire	Yuri Abe	15/09/2018	C

Report of Social and Environmental Monitoring

Institute: Centre de Recherches Médicales de Lambaréné (CERMEL)

Department: Laboratoire mixte de recherches CERMEL / Nagasaki University

Monitoring Period: 01/01/2019 – 30/06/2019

Responsible Person: Rodrigue Bikangui (CERMEL)

Haruka Abe, Yuri Ushijima (Nagasaki University)

#	Monitoring Points	Jan 2019					Feb 2019					Mar 2019					Apr 2019					May 2019					Jun 2019				
		1/4	1/11	1/18	1/25	X	2/1	2/8	2/15	2/22	X	3/1	3/8	3/15	3/22	3/29	4/5	4/12	4/19	4/26	X	5/3	5/10	5/17	5/24	5/31	6/7	6/14	6/21	6/28	X
1	UPS operation check	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
2	Personal protective equipment (PPE) stocks	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
3	Water stocks	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
4	Laboratory cleaning	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
5	Appropriate waste separation	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
6	Compliance with the "Solid-Waste-Disposal-Circuit" rule of CERMEL	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
7	Compliance with the "Liquid-Waste-Disposal-Circuit" rule of CERMEL	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
8	Autoclaving of laboratory wastes	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
9	Waste collection 3 times a week by CERMEL	✓	✓	✓	✓		✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	
10	Generator operation check	1/25					2/22					3/29					4/26					5/31					6/28				
11	Washing or Replacing the pre-filter	1/25					2/22					3/29					4/26					5/31					6/28				
12	Monitoring the condition of the middle-efficiency air filter	1/25					2/22					3/29					4/26					5/31					6/28				
13	Replacing the HEPA filters every year	December 2019																													
14	Professional check of laboratory machines every year	September 2019																													

SIGNATURE / DATE

12/07/2019

(CERMEL)

1/7/2019

(Nagasaki University)

Report of Social and Environmental Monitoring

Institute: Centre de Recherches Médicales de Lambaréné (CERMEL)

Department: Laboratoire mixte de recherches CERMEL / Nagasaki University

Monitoring Period: 01/07/2019 – 31/12/2019

Responsible Person: Rodrigue Bikangui (CERMEL)

Haruka Abe, Yuri Ushijima (Nagasaki University)

#	Monitoring Points	Jul 2019					Aug 2019				Sep 2019				Oct 2019					Nov 2019				Dec 2019			
		7/3	7/10	7/17	7/24	7/31	8/7	8/21	8/28		9/4	9/11	9/18	9/25	10/2	10/9	10/16	10/23	10/30	11/6	11/13	11/20	11/27	12/4	12/11	12/18	
1	UPS operation check	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
2	Personal protective equipment (PPE) stocks	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
3	Water stocks	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
4	Laboratory cleaning	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
5	Appropriate waste separation	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
6	Compliance with the "Solid-Waste-Disposal-Circuit" rule of CERMEL	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
7	Compliance with the "Liquid-Waste-Disposal-Circuit" rule of CERMEL	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
8	Autoclaving of laboratory wastes	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
9	Waste collection 3 times a week by CERMEL	✓	✓	✓	✓	✓	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	
10	Generator operation check	7/31 ✓					8/28				9/25				10/30					11/27				12/18			
11	Washing or Replacing the pre-filter	7/31 ✓					8/28				9/25				10/30					11/27				12/18			
12	Monitoring the condition of the middle-efficiency air filter	7/31 ✓					8/28				9/25				10/30					11/27				12/18			
13	Replacing the HEPA filters every year	December 13																									
14	Professional check of laboratory machines every year	September 20																									

SIGNATURE / DATE

Rodrigue BIKANGUI 18/12/2019

(CERMEL)

牛島由理 18/12/2019

(Nagasaki University)

Report of Social and Environmental Monitoring

Institute: Centre de Recherches Médicales de Lambaréné (CERMEL)

Department: Laboratoire mixte de recherches CERMEL / Nagasaki University

Monitoring Period: 01/01/2020 – 30/06/2020

Responsible Person: Rodrigue Bikangui (CERMEL)

Haruka Abe, Yuri Ushijima (Nagasaki University)

#	Monitoring Points	Jan 2020				Feb 2020				Mar 2020				Apr 2020					May 2020				Jun 2020			
		1/17	1/24	1/29		2/5	2/12	2/19	2/26	3/4	3/11	3/18	3/25	4/1	4/8	4/15	4/22	4/29	5/6	5/13	5/20	5/27	6/3	6/10	6/17	6/24
1	UPS operation check	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓		✓
2	Personal protective equipment (PPE) stocks	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
3	Water stocks	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
4	Laboratory cleaning	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
5	Appropriate waste separation	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
6	Compliance with the "Solid-Waste-Disposal-Circuit" rule of CERMEL	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
7	Compliance with the "Liquid-Waste-Disposal-Circuit" rule of CERMEL	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
8	Autoclaving of laboratory wastes	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
9	Waste collection 3 times a week by CERMEL	✓	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
10	Generator operation check	1/17				2/12				3/18				4/1					5/20				6/24			
11	Washing or Replacing the pre-filter	1/17				2/12				3/18				4/1					5/20				6/24			
12	Monitoring the condition of the middle-efficiency air filter	1/17				2/12				3/18				4/1					5/20				6/24			
13	Replacing the HEPA filters every year	December 2020																								
14	Professional check of laboratory machines every year	September 2020																								

SIGNATURE / DATE

Rodrigue BIKANGUI 24/06/2020

(CERMEL)

24/06/2020

(Nagasaki University)

■ Coherence

対ガボン共和国の国別援助方針（2019 年 4 月）においては、ガボンは，GNI が高い一方，経済指標と人間開発指数との乖離が大きく、この是正を図るバランスの取れた国造りの支援を行うこととしている。「事業展開計画、開発課題への対応方針」の中の「社会格差の是正に貢献するため、地球規模課題対応国際科学技術協力（SATREPS）を通じて医療の基礎研究のレベルアップを支援する」に合致しており、整合性はとれる。

■ Performance

本プロジェクトは、長崎大学にとってガボン共和国における初めての国際共同研究であり、フランス語圏ということもあり、事務関連では非常に困難な場面に直面することが多かった。このような場面において、本部およびガボン支所の JICA 関係者の方々による支援によって問題が解決することが多々あり、貢献は大変大きかった。特に、BSL-2/3 実験棟の建設にあたり、土地所有権や土地利用権を巡る問題に対して、シュバイツァー病院や財団に働きかけていただいたことにより、当初のスケジュールより若干遅れたものの無事実験棟は建設され、その後も所有権等を巡る問題が発生することもなかった。また、資機材の輸送や免税手続きに関しても JICA 関係者の支援をいただいたことで、荷物の未着や不可解な高額支払いなどのトラブルに巻き込まれることは一度もなかった。新規検体採取を開始するにあたって、国家倫理審査委員会からの承認に時間を要していた状況においては、ガボン支所長に委員会の幹部へ直接働きかけていただき、無事承認を得ることができ、研究を大きく推進することが出来た。さらに、大統領選挙時の暴動および新型コロナウイルスのパンデミック時の緊急退避においては、ガボン支所関係者の方々の大変迅速な対応により、安全を確保しながら、長崎大学の職員だけが孤立することもなく無事帰国することができ、大変感謝している。

■ Additionality

JICA 関係者によるガボンおよび日本国内向けの非常に積極的な広報活動は、プロジェクト研究員だけではなし得なかった大きな成果である。特に、BSL-2/3 実験棟完成時の式典は、ガボン国内の重要人物のみならず、隣国カメルーンや本部の JICA 関係者の方々も多く参加して頂いたことによって、本プロジェクトが日本を代表して行われているという意識をプロジェクト、CERMEL、ガボン側関係者と共有することができ、大変効果的であったと考えている。また、新型コロナウイルス感染の対策に向けて、防護服・マスク・アルコールなどの緊急支援をガボン全土に行ったことは、国際協力における日本の重要な役割をガボン側に再認識してもらう良い機会であり、プロジェクトが再度現地での活動を再開する上でガボン側からの協力を得る大きな後押しとなった。