[Liberia]
YELLOW FEVER DIAGNOSTICS REQUEST FORM

This template is for countries requesting Gavi support for procurement of yellow fever diagnostic reagents, supplies, and equipment under the Gavi Board-approved Yellow Fever Diagnostics initiative. The following are mandatory requirements to be submitted alongside this request form:

- Signatures required to endorse this request before submission to Gavi: i) Minister of Health, ii) Director of national yellow fever laboratory, and iii) Director of Finance for Ministry of Health. The signature of the Minister of Finance (or their delegated authorities) is recommended but not required.
- The Coordination Forum (ICC, HSCC or equivalent body) is recommended but not required to endorse this request before submission to Gavi. This can be done also through the ICC/HSCC endorsement of the Joint Appraisal (JA) and should be reflected in ICC/HSCC minutes.

Yellow fever diagnostic procurement support is provided to allow more timely, reliable identification and laboratory confirmation of yellow fever cases for more rapid containment of outbreaks and better prioritisation of preventive yellow fever vaccination efforts. Specifically, this support is intended to assist countries' efforts to follow World Health Organization (WHO) recommendations when conducting yellow fever diagnostic tests on all samples received from suspected yellow fever cases. The support is only available to Gavi-eligible countries in Africa that are classified as "high-risk" for yellow fever by WHO under the Eliminate Yellow Fever Epidemics (EYE) strategy[1]. The countries that currently meet those criteria are listed in the **Yellow Fever Diagnostics Support Guidelines**.

The request will be reviewed by members of the Independent Review Committee (IRC) who will make a recommendation to Gavi[2]. Following the independent review there will be a clarification period (30 working days) for countries to respond to any 'issues to be addressed' ahead of final Gavi approval and disbursement.

Submit this request form and the aforementioned requirements to: proposals@gavi.org

Countries requesting Gavi support for the introduction of yellow fever vaccine into the routine immunisation schedule or yellow fever preventive mass campaigns should consult the Application guidelines (section 5.3.8) for more information on the process and requirements. Countries requesting Gavi support for rapid outbreak response for yellow fever (via the International Coordinating Group (ICG)), should consult the yellow fever Application guidelines in the ICG site.

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[1] *The list of Gavi-eligible countries is provided in **Annex 1 Yellow Fever Diagnostics Guidelines**. For the full list of WHO classification, see 'World Health Organization. Eliminate Yellow Fever Epidemics (EYE): A Global Strategy, 2017-2026. Wkly Epidemiol Rec 2017;92:193-204."*

[2] *The requests for consumable reagents and supplies will be reviewed separately from requests for equipment, so support for requested consumables may be recommended even if support for requested equipment is not recommended.*

Gavi Grant Terms and Conditions

Gavi terms and conditions

The terms and conditions of the Partnership Framework Agreement (PFA) between Gavi and the Country, including those provisions regarding anti-corruption and anti-terrorism and money laundering, remain in full effect and shall apply to any and all Gavi support made pursuant to this application. The terms and conditions below do not supersede those of the PFA. In the event the Country has not yet executed a PFA, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.

GAVI GRANT APPLICATION TERMS AND CONDITIONS

SUPPLIES AND EQUIPMENT USED SOLELY FOR APPROVED PROGRAMMES

The applicant country ("Country") confirms that all material provided by Gavi will be used and applied for the sole purpose of fulfilling the programme(s) described in the Country's application. Any significant change from the approved programme(s) must be reviewed and approved in advance by Gavi. All decisions for the supply application are made at the discretion of Gavi and are subject to IRC processes and the availability of funds.

AMENDMENT TO THE APPLICATION

The Country will notify Gavi in its Joint Appraisal, or in any other agreed annual reporting mechanism, if it wishes to propose any change to the programme(s) description in its application. Gavi will document any change approved by Gavi according with its guidelines, and the Country's application will be amended.

CONFIRMATION OF LEGAL VALIDITY

The Country and the signatories for the Country confirm that its application, or any other agreed annual reporting mechanism, is accurate and correct and forms legally binding obligations on the Country, under the Country's law, to perform the programme(s) described in its application, as amended, if applicable.

COMPLIANCE WITH GAVI POLICIES

The Country confirms that it is familiar with all Gavi policies, guidelines and processes relevant to the programme(s), including without limitation the Transparency and Accountability Policy (TAP) and complies with the requirements therein. All programme related policies, guidelines and processes are available on Gavi’s official website and/or sent to the Country.

ARBITRATION

Any dispute between the Country and Gavi arising out of or relating to its application that is not settled amicably within a reasonable period of time, will be submitted to arbitration at the request of either Gavi or the Country. The arbitration will be conducted in accordance with the then-current UNCITRAL Arbitration Rules. The parties agree to be bound by the arbitration award, as the final adjudication of any such dispute. The place of arbitration will be Geneva, Switzerland. The languages of the arbitration will be English or French.

For any dispute for which the amount at issue is US$ 100,000 or less, there will be one arbitrator appointed by Gavi. For any dispute for which the amount at issue is greater than US $100,000 there will be three arbitrators appointed as follows: Gavi and the Country will each appoint one arbitrator, and the two arbitrators so appointed will jointly appoint a third arbitrator who shall be the chairperson.

Gavi will not be liable to the country for any claim or loss relating to the programme(s) described in the application, including without limitation, any financial loss, reliance claims, any harm to property, or personal injury or death. The Country is solely responsible for all aspects of managing and implementing the programme(s) described in its application.

REPORTING

The Country's national yellow fever laboratory will report information on yellow fever testing activity and performance as requested by the WHO yellow fever laboratory network in a timely and accurate manner, including on the number of samples received and tested, the results of that testing, the timeliness of the overall testing process and the different steps of that process, and problems encountered with performing yellow fever testing. To simplify reporting and avoid duplication, Gavi will be relying on information from WHO to inform future decisions on whether to renew support for procurement of yellow fever reagents, supplies, and equipment to individual countries.

1. Review and update country information

1.1. Country profile

1.1.1. Country profile

Eligibility for Gavi support

Yes

Date of Partnership Framework Agreement with Gavi

July 29, 2013

1.1.2. National customs regulations

Please describe local customs regulations that are instrumental for the delivery of imported laboratory supplies and equipment.

Currently, the Liberia Medicine and Health Products Regulatory Authority (LMHRA) and Liberia Revenue Authority (LRA) have granted Waiver for all vaccines, cold chain equipment, and laboratory equipment intended to be used by the immunization program of Liberia.

Please describe requirements for pre-delivery inspection of imported goods that are instrumental for the delivery of laboratory supplies and equipment.

In order for laboratory supplies and equipment to be delivered, the following pre-delivery documentations are needed: 1. The equipment should comply with WHO guidelines for health care equipment 2. the equipment must be of known reliability and meet the requirements of laboratory at each level 3. The supplier must have proven capacity to maintain and do emergency servicing, also ensuring the availability of spare parts 4. Procedure on disposal of redundant/unusable equipment

Please describe any special documentation requirements that are instrumental for the delivery of imported laboratory supplies and equipment.

In order for laboratory supplies and equipment to be delivered, the following pre-delivery documentations are needed: 1. Import permit 2. Dossier 3. Certificate of analysis, etc.

1.1.3. National Regulatory Agency

Please provide information on the National Regulatory Agency in the country, including status (e.g., whether it is WHO-certified).

The Liberia Medicine and Health Products Regulatory Authority (LMHRA) was established by an act in 2010 with five purposes namely:

1. To ensure that, in the national medicine supply system, safe, effective, good quality medicines reach the Liberia public.
2. To protect the Liberia public from the harmful effects of substandard and counterfeit medicines and health products
3. To ensure fair trade practices in medicine and health products.
4. To promulgate regulations to fight illegal trade in medicines, including counterfeit and adulterated medicines and health products
5. To conduct or facilitate necessary research and development, promote pharmacovigilance, and disseminate timely drug information.

Currently, the LMHRA is headed by Pharm. Keturah C. Smith, Managing Director. This institution is well functioning and WHO certified

Please identify at least one point of contact with phone number and e-mail address at the National Regulatory Agency. UNICEF will help work with regulatory processes where relevant and may need to communicate licensing requirements to laboratory supply manufacturers.

The point of contact Pharm. Keturah C. Smith as Managing Director. Cell number: +231770184007; email: keturah1@gmail.com

2. Yellow fever laboratory supplies and equipment

2.1. Number of samples from suspected yellow fever cases expected to be tested for which supplies will be needed

Number of samples received for testing in 2016	42
- Yellow fever outbreak in 2016?	Yes ☐ No ☒
Number of samples received for testing in 2017	171
- Yellow fever outbreak in 2017?	Yes ☒ No ☐
Number of samples received for testing in 2018	112
- Yellow fever outbreak in 2018?	Yes ☒ No ☐
Number of samples expected to undergo ELISA testing over a 12-month period[3]	180
Number of samples received for testing in 2016 that were collected ≤10 days after onset of illness	31
Number of samples received for testing in 2017 that were collected ≤10 days after onset of illness	138
Number of samples received for testing in 2018 that were collected ≤10 days after onset of illness	85
Currently testing for yellow fever with polymerase chain reaction (PCR)?	Yes ☐ No ☒
- If yes, what type of PCR machine is	

[3] *Number of samples expected to undergo ELISA testing over a 12-month period may be estimated to be equivalent to the largest number of samples received for testing in a single year over the last three years, excluding years with yellow fever outbreaks. For example, if no outbreaks occurred in 2016, 2017, and 2018 and more samples were received for testing in 2017 than in 2016 or 2018, the number of samples expected to be tested over a 12-month period can be estimated to be the same as the number of samples received for testing in 2017. If an outbreak occurred in 2017 and more samples were received for testing in 2018 than 2016, then the number of samples expected to be tested over a 12-month period can be estimated to be the same as the number of samples received for testing in 2018. Alternative approaches can be used if justification is provided.*

used?	
- If no, please describe any plans for starting testing for yellow with PCR in the next 12 months, including description of PCR testing already being done for other viruses	The lab has 2 technical staff that were in trained in Cameroon for Yellow Fever PCR sponsored by WHO and US CDC in 2019. The lab is currently conducting ELISA testing -serology IGM.and was assessed in 2018 and found to be capable and having the adequate space to carried out PCR testing for Yellow Fever The laboratory has demonstrated capacity for dealing with emerging and dangerous pathogen with more than 20,000 EVD samples tested with zero infection rate of staff. The NPHRL has vast experience in conducting PCR testing for Ebola virus diseases, Meningitides, Lassa Fever, Dengue, Buruli Ulcer, etc.
Number of samples expected to undergo PCR testing over a 12-month period[4]	100

2.2. Equipment

Does your laboratory receive at least 50 samples a year for yellow fever testing and need an enzyme-linked immunosorbent assay (**ELISA**) **reader** for yellow fever testing?	Yes ☒ No ☐
If yes: - Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.	The NPHRL tested 115 samples for Yellow fever in 2019, 112 in 2018, 171 in 2017 and 42 in 2016. This shows an increase in trend over the years. Data shows that Liberia had an outbreak of Yellow fever confirmed in 2017, two confirmed outbreaks in 2018 and one confirmed outbreak 2019. The frequency and consistency of outbreaks justify the need to have a robust laboratory surveillance system in place for Yellow fever. The Gavi assessment report from 2018 highlighted the implementation in quality control and biosafety practices at the laboratory. Participation in proficiency testing with 100% score. During the assessment it was observed

[4] If capacity to test for yellow fever with PCR is available, the number of samples expected to undergo PCR testing over a 12-month period may be estimated to be equivalent to the largest number of samples collected ≤10 days after onset of illness and received for testing in a single year over the last three years, excluding years with yellow fever outbreaks. For example, if no outbreaks occurred in 2016, 2017, and 2018 and more samples collected ≤10 days after onset of illness were received for testing in 2017 than in 2016 or 2018, the number of tests expected to be run over a 12-month period can be estimated to be the same as the number of samples collected ≤10 days after onset of illness and received for testing in 2017. If an outbreak occurred in 2017 and more samples collected ≤10 days after onset of illness were received for testing in 2018 than 2016, then the number of samples expected to be tested over a 12 month period can be estimated to be the same as the number of samples collected ≤10 days after onset of illness and received for testing in 2018. Alternative approaches can be used if justification is provided.

	that most of the gaps from the previous assessment have been addressed. These include validated assays, IHC, IHC OD plots, SOPs, document control system Levy-Jennings graphs, Westgard rules, temperature monitoring of all equipment posted, protocols posted, and assigning biosafety and quality managers. Daily equipment maintenance is documented and there is an SOP for turning off equipment at the end of the day, signed by one of the technicians. Laboratory technicians both monitor equipment, depending on who arrives first. The NPHRL Quality Officer reviews laboratories once a month with QA SOP. As per the WHO Lab Net QC program, the 10% of samples for IgM results are sent every 6 months for QC with 100% concordance. The Hygiene Department is notified to come pick up the biohazard waste and it is incinerated on-site.
- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.	The ELIZA reader and Washer were installed by the Country Biomedical Technicians, we do daily and monthly routine maintenance, however there have been no calibration since the installation. USB drive is used to export results from the ELIZA reader. There is no computer attached to the reader for smooth operation.
Does your laboratory receive at least 50 samples a year for yellow fever testing and need an **ELISA washer** for yellow fever testing?	Yes ☒ No ☐
If yes:	
- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.	The current ELISA Reader and washer his more than 13 years old. We have a single 8 channels ELIZA washer that is used for Measles/Rubella and Yellow fever and there is no backup of this machine
- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.	The ELISA Washer was installed by the Biomedical Engineering Team. The Technicians are trained in operating the washer and providing routine maintenance.
Does your laboratory receive at least 50 samples a year for yellow fever testing collected no more than 10 days after patients' onset of illness and need a **PCR machine** for yellow fever testing?	Yes ☒ No ☐

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.

The NPHRL tested 115 samples for Yellow fever in 2019, 112 in 2018, 171 in 2017 and 42 in 2016. This shows an increase in trend over the years. Data shows that Liberia had an outbreak of Yellow fever confirmed in 2017, two confirmed outbreaks in 2018 and one confirmed outbreak 2019. To be able to confirm presumptive positive from ELISA, PCR testing is needed. The turnaround time for confirmation of YF will greatly reduce if PCR for YF is introduce at the NPHRL.This is consistent with the recommendation by the consultant to introduce molecular testing for YF at the NPHRL from the assessment. One of the 2 ABI PCR provided in 2014 by DTRA is broken and the lab currently does not have a backup for testing.

- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.

There is currently capacity for maintaining the routine maintenance of the ELISA reader and the technicians are capable of operating. There is no capacity for PCR maintenance and installation.

Does your laboratory need a **biosafety cabinet**? Yes ☐ No ☒

If yes:

- Please provide justification, including referring to the findings from 2018 Gavi-funded yellow fever laboratory capacity assessment report or World Health Organization yellow fever laboratory capacity assessments.

- Please provide a description of the capacity for installing, operating, and maintaining the ELISA reader that will be available to your laboratory.

2.3. Logistics

2.3.1. Supply delivery

What is the address and, if available, geocoordinates of the national public health yellow fever reference laboratory that is the ultimate destination for yellow fever laboratory supplies and equipment?

Latitude 06.196997 Longitude -10.339500

What is the Port of Entry closest to the national public health yellow fever reference laboratory?

The Robert International Airport (RIA), Margibi County

How many shipments should the needed supplies be spread across and why?[5]

One shipment for the ELISA and PCR Machines. Supplies and consumables can be spread in two shipments over 6 month's period.

To facilitate timely delivery of supplies, laboratory staff will be responsible providing proof of customs clearance and other import authorizations prior to scheduling a shipment with UNICEF Supply Division. What is the laboratory's plan for securing the necessary customs clearance and any other import authorizations?

The National Public Health Institute of Liberia, National Public Health Reference Laboratory can secure a duty free clearance for the shipment once the packing list is send prior to the shipment from the Liberia Revenue Authority.

Please identify at least one point of contact with phone number and e-mail address at the laboratory. If the application is approved, UNICEF will reach out to that person to discuss delivery of supplies.

John B. Dogba , Director , National Public Health Reference Laboratory, The National Public Health Institute of Liberia

2.3.2. Logistical technical assistance

Does the laboratory staff need stock management training? If yes, please provide details

No

2.4. Strategic considerations

2.4.1. Rationale for the request

Briefly describe how yellow fever diagnostic capacity fits into your country's plan for eliminating yellow fever epidemics.

The National Public Health Reference Laboratory is the only laboratory in Liberia that conduct testing to confirm Yellow Fever.

2.4.2. Financial sustainability and budgeting of yellow fever laboratory

A cost sharing requirement will eventually be introduced for **yellow fever materials. This cost-sharing will not come into effect through at least the end of 2020. More information will be provided by your Gavi Senior Country Manager (SCM) as it becomes available. **

What is the current year's and, if available, the next year's domestic budget for yellow fever laboratory capacity needs, including yellow fever laboratory supplies and equipment?

Currently, in the national budget of Liberia, US $650,000 is allocated for the national immunization program to support the procurement of bundle vaccines and vaccine supplies. However, there are on going advocacy to consider other budget lines such as cold chain and laboratory equipment, routine supportive supervision.

[5] *Gavi will fund a maximum of three shipments for supplies used in routine yellow fever testing over a 12-month period (additional shipments are possible in response to outbreaks, if feasible). Exact shipment dates, times, and other details to be confirmed with UNICEF Supply Division.*

2.4.3. Anticipated future changes in yellow fever laboratory capacity

Aside from access to yellow fever diagnostic reagents, supplies, and equipment, does the laboratory expect its capacity to test for yellow fever to change over the next 2 years, e.g., new staff, training, new facility, etc.? If so, how?

Yes, there is a plan to scale up training for new staff and moving to the new laboratory under construction for the NPHRL. Once the laboratory gets accreditation, we hope to provide testing services for other countries in the sub region like Sierra Leone and Guinea.

Contacts

Person(s) who should be contacted in case Gavi needs to ask for more information regarding the application.

Name	Position	Phone Number	Email	Organisation
John B. Dogba	Director, National Public Health Reference Laboratory	+231777115681	directornrl2016@gmail.com	National Public Health Institute of Liberia

Comments

Please provide any comments you have about this application and how to improve it

Government signature form

The Government of (country) would like to expand the existing partnership with Gavi for the improvement of the immunisation programme of the country, and specifically hereby requests Gavi support for yellow fever diagnostics (that is, laboratory reagents, supplies and equipment) as outlined in this request form.

The Government of (country) commits itself to developing national immunisation services, including laboratory testing that helps guide immunisation services, on a sustainable basis in accordance with the national health and immunisation strategic plans. The Government requests that Gavi and its partners contribute financial and technical assistance to support immunisation of children as outlined in this application.

Please note that Gavi will not review this application without the signatures of the Minister of Health, the Director of the national yellow fever laboratory, and the Director of Finance for the Ministry of Health or their delegated authorities.

We, the undersigned, affirm that the objectives and activities in this request are fully aligned with the national health and immunisation strategic plans (or equivalent), and that funds for procuring yellow fever laboratory reagents, supplies, and equipment will be included in future annual budgets of the Ministry of Health, including funds for co-financing of future Gavi-supported procurement of supplies once the details of the Gavi co-financing requirements are available.

We, the undersigned, further affirm that the terms and conditions of the Partnership Framework Agreement between Gavi and the Country remain in full effect and shall apply to any and all Gavi support made pursuant to this application.[6]

Minister of Health (or delegated authority)	**Director of national yellow fever laboratory (or delegated authority)**
Name:	Name:
Date:	Date:
Signature:	Signature:

Director of Finance for Ministry of Health (or delegated authority)	**Minister of Finance (or delegated authority) (recommended but not required)**
Name:	Name:
Date:	Date:
Signature:	Signature:

[6] *In the event the Country has not yet executed a Partnership Framework Agreement, the terms and conditions of this application shall apply to any and all Gavi support made pursuant to this application.*