Version: July 2019

[Ethiopia]
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 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.

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

Ethiopia is one of the landlocked countries and the second-most populous country of Africa after Nigeria with a population estimate (2019) of 112.08 million. The surface area is 1,104,300 km² (or 426,372.6137 miles square) and population density is 83 people per square mile (214/square mile), which ranks 123rd in the world.

Ethiopia is located within the geographic "yellow fever belt" and had frequent outbreaks of yellow fever at different times. Outbreaks of 1960-62, 1966, 2013 and 2018 have made remarkable impacts to public health. According to the WHO classification, Ethiopia is categorized as high risk country for Yellow Fever.

Ethiopia is one of the eligible countries for diagnostic support by GAVI. The national laboratory situated in Ethiopian Public Health Institute is equipped with trained man power, facility and dedicated management to host laboratory testing of clinical samples from yellow fever suspected patients. Laboratory personnel are trained and have scored full in the WHO provided proficiency testing in July 2019, Cameroon.

Date of Partnership Framework Agreement with Gavi

1.1.2. National customs regulations

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

The Government Customs Authority will be responsible for the clearance of imported goods, including medical equipment, drugs and supplies. The Food and drugs Administration is responsible for control and approval of the quality of medical equipment and medicines. Hence the laboratory equipment to be procured by GAVI support from market outside the country will pass the process to be applied by the above stated Authorities.

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

Product description, export permit from country of origin, import permit from Ethiopian customs, custom's invoice are necessary for delivery of reagents and supplies to the national laboratory.

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

Product description, export permit from country of origin, import permit from Ethiopian customs, custom's invoice.

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 Ethiopian (national) Food and Drugs Authority is a regulatory body for regulating reagents and supplies importation to the country.

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.

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	21
- Yellow fever outbreak in 2016?	Yes ☐ No ☒
Number of samples received for testing in 2017	4
- Yellow fever outbreak in 2017?	Yes ☐ No ☒
Number of samples received for testing in 2018	45
- Yellow fever outbreak in 2018?	Yes ☒ No ☐
Number of samples expected to undergo ELISA testing over a 12-month period[3]	40
Number of samples received for testing in 2016 that were collected ≤10 days after onset of illness	0
Number of samples received for testing in 2017 that were collected ≤10 days after onset of illness	21
Number of samples received for testing in 2018 that were collected ≤10 days after onset of illness	35
Currently testing for yellow fever with polymerase chain reaction (PCR)?	Yes ☒ No ☐
- If yes, what type of PCR machine is used?	ABI 7500

[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.*

- 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

Number of samples expected to undergo PCR testing over a 12-month period[4] 35

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.

  We have 1 ELISA reader but a back-up is a must in the laboratory for use in cases of dysfunction. So, we need one more reader.

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

  We have been using automated ELISA reader to see the absorbance/OD of the solution. We also have biomedical engineers for general services as needed. The national Lab at EPHI has good experience of virological testing for, like Dengue, Yellow fever, Chikungunya, and other arboviruses using ELISA.

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

  We test many samples every year and we need a back-up ELISA washer since we have only one.

[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.*

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.

We are already using ELISA washer for our routine activities. We also have equipment engineers in our institute who are in charge of maintaining all medical equipment of the institute.

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.

We have 3 functional PCR machines in our laboratory. So, we may not need extra machines as far as they are functional.

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

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.

There are 2 functional biosafety cabinets in the laboratory.

- 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?

Ethiopian Public Health Institute, Arbegnoch Street, PO BOX 1242, Gulelle, Addis Ababa, Ethiopia,

Coordinate:
Latitude: 9.04723, Longitude: 38.73038

What is the Port of Entry closest to the national public health yellow fever reference laboratory?
Addis Ababa Bole International Airport

How many shipments should the needed supplies be spread across and why?[3]
Once a year, because our laboratory is expected to test 150 samples for PCR and 150 samples for ELISA on average per year from routine surveillance and hence we less likely to consume much of the supplies shorter than that frequency.

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 laboratory will facilitate necessary documentations in order the supplies be cleared from Ethiopian customs for quick delivery to the laboratory.

2.3.2. Logistical technical assistance

Does the laboratory staff need stock management training? If yes, please provide details
Yes, because as yellow fever testing needs careful utilization of those limited resources to ensure continuation of yellow fever surveillance, laboratory staff must be trained in managing supplies and communication mechanisms with suppliers and donors. The training will primary focus on new staff recruited and to address new developments on the related laboratory technology as well as staff turnover issues.

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.
As Ethiopia is a yellow Fever high risk country, the country has adopted the Global/Regional EYE strategy and developed National EYE strategy in 2018, The FMOH is preparing to introduce Yellow Fever New vaccine in to routine immunization and Preventive mass vaccination for the general population. NITAG has recommended introducing Yellow Fever vaccine and conducting PMVC; and application documents are being prepared to be applied in next window. Laboratory based surveillance of the disease is crucial to implement and ensure elimination. Hence, testing capacity for acute phase and convalescent samples is a must to follow the disease. In the national EYE strategic plan the strengthening of laboratory capacity for Yellow Fever testing has be included as one component.

[3] *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, sizes, and other details to be confirmed with UNICEF Supply Division.*

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?

The government of Ethiopia will cover the costs of supplies through its financing system to achieve the country's sustainable development goal to the health sector. Partners will also play in sustaining the capacity through providing financial and technical support.

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?

All the staffs working in the national yellow fever laboratory are trained in molecular and serological testing of samples for yellow fever. So, it is reliable that the laboratory has a capacity to test samples. If und support is available, the national Yellow fever Capacity can be upgraded to conduct confirmatory testing.

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
Desalegn Belay	Team lead	+251911721521	desalegnpapa@gmail.com	Ethiopian Public Health Institute
Hiwot Amare	Lab expert	+251913661058	Hiwotamare20@gmail.com	Ethiopian Public Health Institute

Comments

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

Based on the WHO AFRO yellow fever laboratory testing algorithm, we need to test other viruses like West Nile, Dengue and Zika as differential diagnosis. These tests will need to have sustainable laboratory reagents and supplies as well. Therefore, we want to be supplied with the reagents for the differential diagnoses.

Government signature form

The Government of Ethiopia 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 Ethiopia 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.*