Version: July 2019

[GHANA]
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.

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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

Gavi partnership framework Agreement (Agreement reference number :GHa-01). Additionally, Ghana is part of the Gavi eligible countries classified as yellow fever high risk under the EYE strategy.

Date of Partnership Framework Agreement with Gavi

11th-07-2014

1.1.2. National customs regulations

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

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

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

Air waybill

Letter of donation

Commercial 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 Food and Drugs Authority is a Ghanaian government agency responsible for inspection, certification and proper distribution of foods and products as well as drugs in Ghana. It is 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.

Food And Drugs Authority

Tel: +233302229794

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 959

- Yellow fever outbreak in 2016? Yes ☒ No ☐

Number of samples received for testing in 2017 825

Number of samples received for testing in 2018	1011
- Yellow fever outbreak in 2018?	Yes ☐ No ☒
Number of samples expected to undergo ELISA testing over a 12-month period[3]	1011
Number of samples received for testing in 2016 that were collected ≤10 days after onset of illness	846
Number of samples received for testing in 2017 that were collected ≤10 days after onset of illness	710
Number of samples received for testing in 2018 that were collected ≤10 days after onset of illness	874
Currently testing for yellow fever with polymerase chain reaction (PCR)?	Yes ☐ No ☒
- If yes, what type of PCR machine is 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	Personnel have been trained on YF molecular testing at Institute Pasteur Cameroon, July 2019. The lab has plans to start YF molecular testing when logistics, reagents and equipment are available. The lab is currently doing molecular testing for measles, rubella and bacterial meningitis.
Number of samples expected to undergo PCR testing over a 12-month period[4]	874

[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.*

[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.*

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.

From the Gavi Yellow Fever Laboratory Capacity Assessment report which was conducted by Gavi assessor Dr. Barbara W Johnson in 2018 it was discovered that:

1. The ELISA washer and reader are shared between all serology activities
2. Testing is scheduled and coordinated between the activities; however, sometimes both HIV and YF testing is conducted on the same day. The washer must be flushed and the buffer changed between tests.
3. The Ghana Demographics Health Survey (GDHS) research program funded procurement of the washer, reader, and pipettes.
4. The Clinical Engineering Unit provides limited repair services for refrigerators and freezers; the laboratory pays for transportation, parts, and other costs. However, NPHRL staff would like to be trained so that they can make minor equipment (eg: Washer, Plate reader, pipette) repairs.
5. There is no budget for equipment repairs.

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

The Ghana Health Service has a clinical engineering unit who has the mandate and capacity to install and maintain medical equipment. The staff in the laboratory have been trained to operate ELISA reader.

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.

From the Gavi Yellow Fever Laboratory Capacity Assessment report which was conducted by Gavi assessor Dr. Barbara W Johnson in 2018 it was discovered that:

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conducted on the same day. The washer must be flushed and the buffer changed between tests.
3. The Ghana Demographics Health Survey (GDHS) research program funded procurement of the washer, reader, and pipettes.
4. The Clinical Engineering Unit provides limited repair services for refrigerators and freezers; the laboratory pays for transportation, parts, and other costs. However, NPHRL staff would like to be trained so that they can make minor equipment (eg: Washer, Plate reader, pipette) repairs.
5. There is no budget for equipment repairs.

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

The Ghana Health Service has a clinical engineering unit who has the mandate and capacity to install and maintain medical equipment. The staff in the laboratory have been trained to operate ELISA Washer.

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.

1.PCR will be able to detect the antigen within the reporting date of 7 days from date of onset compared to ELISA IgM in which the antibodies peak after 10 days.

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

The Ghana Health Service has a clinical engineering unit has the mandate and capacity to install and maintain medical equipment. The staff in the laboratory have been trained to operate PCR machine.

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 is no biosafety cabinet in the serology laboratory and samples are prepared for testing on the benchtop as documented by the Gavi Yellow Fever Laboratory Capacity Assessment report which was conducted by Gavi assessor

Dr. Barbara W Johnson in 2018. An additional biosafety cabinet is needed for PCR testing since the volume of work will increase at the molecular lab.

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

The clinical engineering unit does not have the capacity to install and maintain biosafety cabinet. However, lab staff have been trained to operate biosafety cabinet.

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?

National Public Health and Reference Laboratory, Harley Street, Korle-Bu, Accra, Ghana
GPS: 5.32'19"N 0.13'43W
Ghana Post GPS number: GA-221-0392

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

Kotoka International Airport, Accra, Ghana

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

3

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?

A letter from the Minister of health requesting for a waiver will be sent to the Minister of Finance and Economic Planning for approval.

2.3.2. Logistical technical assistance

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

Yes. There is need to build the capacity of personnel on kit stock management for proper forecasting and utilization of reagents and consumables.

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.

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[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.*

From integrated disease surveillance and response from the country Yellow fever is a immediately reportable disease and it is targeted for elimination. Therefore, all suspected cases samples must be collected and sent to NPHRL for testing. However, there is always frequent shortage laboratory reagents and consumables. This corroborated in the assessment by Gavi in 2018, where in 2016, of 719 samples collected 219 were not tested. Furthermore, in 2017 all 961 suspected cases were not tested.

The incessant shortage of reagent has resulted in the country's ability to detect YF outbreaks early and contain rapidly. Patience care is however compromised. Again the country is unable to know its YF burden nationally and globally. Staff are demotivated in sending sample which are not tested. This is having a negative effect on the yellow fever surveillance in Ghana.

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?

200,000 US dollars

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. New staff who are posted to the lab must be oriented and trained. All staff will need structured refresher training.

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
Dr. David A Opare	Director of national yellow fever laboratory	+233-208-168-903	opared_60@yahoo.co.uk	NPHRL/GHS
Dr. George Bonsu	Director of EPI	+233-244-326-637	gybonsu@yahoo.com	EPI/GHS

Comments

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

1. The application form could have a section where items requested could be selected from a drop down menu.
2. The section on the country profile as it stands could be clarified better for ease of understanding

Government signature form

The Government of Ghana 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 Ghana 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: Nana Kwabena Adjei-Mensah	Name: Dr. David A. Opare
Date: 04-09-2019	Date: 01/09/2019
Signature:	Signature:

Director of Finance for Ministry of Health (or delegated authority)	**Minister of Finance (or delegated authority) (recommended but not required)**
Name: Ayindingo Daniel Nsabila	Name:
Date: 04-09-2019	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.*