

[UGANDA]

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) strategy¹. 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 Gavi². 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](#).

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

1.1. 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.

1.1.1.1. 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.

2. Review and update country information

2.1. Country profile

2.1.1. Country profile

Eligibility for Gavi support

Eligible

Date of Partnership Framework Agreement with Gavi

28 June 2013

2.1.2. National customs regulations

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

National Drugs Authority (NDA) regulations

Register all test kits and supplies into the NDA online platform using the commercial invoice accompanying the shipment. A payment of 2% is charged per item shipped. Accompanying the commercial invoice is usually a letter of donation.

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

Commercial invoice, NDA invoice

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

Commercial invoice, NDA Pre-verification certificate, Air Way Bill

2.1.3. National Regulatory Agency

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

NDA which 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.

Mr Umar Hassan Nkuutuat, unkuutu@iavi.or.ug

+256772722382

Mr. Nkuutuat is the pharmacist representative for UVRI

3. Yellow fever laboratory supplies and equipment

3.1. 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 417

- Yellow fever outbreak in 2016?

Yes No

Number of samples received for testing in 2017	
- Yellow fever outbreak in 2017?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Number of samples received for testing in 2018	565
- Yellow fever outbreak in 2018?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>
Number of samples expected to undergo ELISA testing over a 12-month period ³	666 – includes samples from other countries including South Sudan
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	62
Number of samples received for testing in 2018 that were collected ≤10 days after onset of illness	274
Currently testing for yellow fever with polymerase chain reaction (PCR)?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
- If yes, what type of PCR machine is used?	ABI 7500 Fast Real-Time PCR System, MX Pro 3000 Stratagen PCR Machine
- 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	274 – includes samples from other countries including South Sudan

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

3.2. 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.

UVRI Arbovirus laboratory routinely uses the BioTek ELx 800 for reading ELISA plates

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

Currently have a service contract with F&S Scientific in Kenya who are the certified engineers for BioTek equipment in the region

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.

UVRI Arbovirus laboratory routinely uses the BioTek 405 TS ELISA washer

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

Currently have a service contract with F&S Scientific in Kenya who are the certified engineers for BioTek equipment in the region

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

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.

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.

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.

3.3. Logistics

3.3.1. 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?

Uganda Virus Research Institute, Plot 51-59 Nakiwogo Road, P.O. Box 49, Entebbe

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

Entebbe International Airport

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

Three (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?

The UVRI laboratory does not require importation permits for laboratory supplies apart from the NDA pre-verification certificate which confirms to customs that clearance fees have been paid to NDA.

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.

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 Kayiwa, +256774313662, jkayiwa@yahoo.com

3.3.2. Logistical technical assistance

Does the laboratory staff need stock management training? If yes, please provide details
Yes. Two participants, the store manager and laboratory manager would benefit from the training in stock management. All relevant topics to store management would be beneficial to the participants and UVRI in general.

3.4. Strategic considerations

3.4.1. Rationale for the request

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

It's the mandate of UVRI to report all its results directly to the Ministry of Health and all other international partners like WHO and US CDC. This happens through various ways like the National Task Force meetings which take place once every end of the month and every week on Fridays during outbreaks. In the National Task Force meeting various ministries and organizations are involved mainly from the human, animal and environment ministries. Through these National Task Force meetings, updates on the disease situations/outbreaks are consolidated and reported. Also, UVRI reports results to the Ministry of Health through the Emergency Operating Center. Here data/results are shared in real-time. The UVRI also hosts a committee of Members of Parliament (MPs) who visit the institute at least once a year and get acquainted and updates on the procedures and notifiable diseases being tested. Information gathered from all these different platforms is used by Ministry of Health in decision making. For example, the Ministry of Health recently decided to introduce yellow fever vaccine into routine immunization in Uganda and to apply to the ICG for yellow fever vaccine for an outbreak based on UVRI laboratory results showing multiple yellow fever cases in northeastern Uganda.

3.4.2. 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?

\$1,500.00

3.4.3. 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?

No

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 Julius Lutwama	Head Department	0752650251	jilutwama03@yahoo.com	UVRI
Mr John Kayiwa	Lab Manager	0774313662	jkayiwa@yahoo.com	UVRI
Annet Nankya	Lab Technologist	0704891743	a.nankya@yahoo.com	UVRI

1.1.1.2. Comments

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

Not applicable

Government signature form

The Government of **Uganda** 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 **Uganda** 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: Dr Julius Lutwama
Date:	Date: 23/Dec/2019
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.*