

**Decision Letter
KENYA**

Yellow Fever Diagnostics and Laboratory Consumables Procurement Support

This Decision Letter forms part of the Partnership Framework Agreement (PFA) and together with the PFA sets out the Terms of the Programme. Any term used in this Decision Letter but not defined shall have the meaning given to such term in the PFA. The English language version of this Decision Letter shall prevail in the case of any conflict with terms expressed in other language(s).

1. Country: Republic of Kenya
2. Grant number: KEN-YF-DIAG
3. Date of Decision Letter: 24 July 2023
4. Date of the Partnership Framework Agreement (the "PFA"): 25 November 2014
5. Programme Title: Gavi Support for Yellow Fever Diagnostic Capacity
<p>6. Programme description:</p> <p>The Programme offers a procurement mechanism to improve availability of yellow fever (YF) diagnostic reagents, test kits, equipment, and laboratory supplies in African countries that are at high or moderate risk for Yellow Fever and eligible for Gavi support.</p> <p>The commodities offered under this Decision Letter are:</p> <ul style="list-style-type: none"> • Yellow Fever IgM MAC-HD ELISA test kits • Consumable bundles for the Yellow Fever IgM MAC-HD ELISA test kits • Yellow Fever IgM RDT test kits • Yellow Fever PCR test kits • Viral RNA extraction kits for use with Yellow Fever PCR test kits • PCR consumable supplies <p>There is no cash component to the support offered by Gavi under this Programme.</p> <p>Final destination for shipment of goods: Kenya Medical Research Institute, Off Mbagathi Way, P.O. Box 54628-00200, Nairobi, Kenya</p> <p>For further information about the Programme please refer to:</p> <ul style="list-style-type: none"> • Gavi Yellow Fever Diagnostics Procurement Support guidelines and application form available by contacting your Gavi country manager or on the Gavi website at: https://www.gavi.org/our-support/guidelines • Country's approved Yellow Fever Diagnostics procurement support application together with the Gavi Independent Review Committee's (IRC's) report on that application and any requests for clarifications from the IRC.

7. Programme Duration: 2020-2023**8. Joint Investment Classification:** Gavi – 100% investment; Country – 0% investment**9. Programme Budget** (indicative): This is the amount of an estimated budget endorsed by Gavi under the Programme.

Note: The value of the commodities granted to the country includes costs of shipping and delivery, exclusive of taxes and duties, and may be more or less than these endorsed amounts, subject to the terms of the PFA and Gavi's Policies.

	2020	2021	2022	2023	Total
Gavi Programme Budget (\$USD)	\$56,750.22	\$26,204.34	\$5,606.00	\$21,568.41	\$110,128.97

10. Indicative amounts of Yellow Fever diagnostic testing supplies provided to the country via this Decision Letter:

Items eligible to be purchased with Gavi funds under this Programme	Total number approved for 2023
YF IgM MAC-HD ELISA Test Kits ¹	1
Consumable Bundle A for MAC- HD ²	1
Consumable Bundle B for MAC- HD ³	1
YF IgM RDT Test Kits ⁴	5
YF PCR test kits ⁵	4
Viral RNA extraction kits (for YF PCR test kits) ⁶	1
Consumable set for YF PCR test kits ⁷	1

¹ One ATCC YF MAC-HD test kit is sufficient to test 240 samples.

² Bundle A contains reagent reservoirs, required pipette tips and standard microtube racks.

³ Bundle B contains sample dilution tubes and cryogenic storage tubes.

⁴ One YF RDT test kit contains 25 tests/kit.

⁵ One YF PCR test kit is sufficient to test 96 samples.

⁶ One viral RNA extraction kit is sufficient for 250 reactions.

⁷ Consumable sets for PCR tests contain pipette tips, PCR microtubes, PCR optical caps, conic tubes, and biohazard bags.

11. Additional supplies: The quantities of approved supplies are based on the number of samples expected to be tested over a 12-month period based on the needs foreseen at the time of issuance of this Decision Letter. In line with recommendations from the Gavi Independent Review Committee, Gavi has also approved \$83,742 for procurement of additional yellow fever IgM testing supplies and \$57,638 for procurement of additional yellow fever PCR testing supplies for use in response to yellow fever outbreaks if needed.

These supplies shall be made available to all countries receiving Gavi support for the procurement of yellow fever diagnostics in the event of yellow fever outbreaks during the time period covered by this Decision Letter. If WHO notifies Gavi of a new or expanded lab confirmed Yellow Fever outbreak in a country, that country will be eligible to request some or all of the supplies from an additional allotment of Yellow Fever testing supplies beyond the volumes notified in this Decision Letter for supplies expected to be used outside an outbreak setting. Each additional allotment consists of:

- 4 YF IgM ELISA MAC-HD Test Kits
- 4 consumable Bundles A for MAC-HD
- 1 consumable Bundles B for MAC-HD
- 24 YF IgM RDT Test Kits
- 5 YF PCR test kits
- 1 Viral RNA extraction kits
- 1 Consumable set for YF PCR test kits

While Gavi has approved this additional funding, its availability is subject to the approved funding for procurement of outbreak supplies not having been exhausted by other countries facing a WHO declared Yellow Fever outbreak at the date the country submits its request for additional outbreak supplies to Gavi.

12. Procurement agency: UNICEF Supply Division (SD) is the sole procurement agency for the YF Diagnostic procurement support Programme. Gavi shall release the funding approved for the procurement of the supplies by the country to UNICEF SD each year.

13. Reporting Requirements:

The country's national yellow fever laboratory will report information on yellow fever testing activity and performance within the timelines and manner as requested by the WHO yellow fever laboratory network, including 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. The country's national yellow fever laboratory will also report information on shipment conditions, such as temperature monitoring results during shipment, as requested by UNICEF SD. To simplify reporting and avoid duplication, Gavi will rely on information from WHO and UNICEF to inform future decisions on whether to renew support for procurement of yellow fever reagents, test kits, and supplies to individual countries.

14. Other conditions: In addition to the terms of the PFA, the following terms and conditions shall apply to the Programme:

The country is reminded that it is responsible for the reception at the port of entry, customs clearance, and provision of a waiver (or in the absence of a waiver, paying) for any taxes or duties for such consignment of all Yellow Fever test kits and associated consumables. The Government must provide UNICEF SD with confirmation of such waivers or payments of taxes and duties, as well as country specific requirements for importation, prior to UNICEF SD arranging shipping for yellow fever diagnostic test kits, supplies, and equipment. The country is advised to pay special attention to proposed delivery modes and schedules agreed with UNICEF SD, its designated supplier(s) and local agent(s) when initiating the deployment and commissioning of goods. If the country needs to make unplanned variations to the delivery schedules, such as cases of force majeure, the Government must develop a deviation protocol to document such cases and include any cost implications of such variations. The Government will be responsible for such costs.

Based on information in the country's Yellow Fever Diagnostics procurement support application, Gavi shall indicate to UNICEF SD that the final destination for shipment of goods is that listed under point 6 of this Decision Letter, unless the country identifies a different final destination within 75 km of a port of entry within 14 calendar days from the notification of this Decision Letter.

Country public health yellow fever reference laboratories should request from UNICEF SD only the amounts of supplies needed for testing the samples they actually receive, up to the allotted amounts authorized for Gavi funding. If fewer supplies than expected are adequate for testing the actual number of samples received, country public health laboratories should not request the full amount of yellow fever diagnostic consumable supplies authorized for Gavi funding from UNICEF SD.

Utilisation of Gavi support stated in this letter will be subject to performance monitoring.

For Gavi

Signed By

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Colette Selman

Director, Core Countries