

Quality Assurance Information Notice for Health Products

IN N° 2025-89 Version 1 2026-05-28	Precautionary measures: Suspension of WHO Prequalification status of all In-Vitro Diagnostics medical devices (IVDs) manufactured by Meril Diagnostics Pvt. Ltd.
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Addressees

- Through Health Product Management (HPM) specialists, all Principal Recipients (PR) procuring products manufactured by Meril Diagnostics Pvt. Ltd. (Meril) and financed by The Global Fund.
- Any procurer and buyer procuring products manufactured by Meril and financed by The Global Fund.
- Any procurers, buyers with a pending order.
- Any person having products in stock, in transit or under custom clearance.
- Any person using the products for clinical decision making.

Purpose

The Global Fund Quality Assurance and Compliance Team is issuing this QA Information Notice to provide recommendations and advice following the WHO Inspection services Notice of Concern (NoC), the delisting of WHO Prequalified products and the WHO information notice for IVD manufactured by Meril Diagnostics Pvt. Ltd. located second floor, D1-D3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi 396191, Gujarat, India and Meril Academy, Block No- MD1, Survey No.- 1231, 1232 & 1228, Muktanand Marg, Balitha, Vapi, 396191 India.

This notice is for internal and external dissemination, and country teams are expected to communicate this information to their relevant stakeholders.

Identification of the product(s) and manufacturer

Name of Manufacturer(s)	Meril Diagnostics Pvt. Ltd. (Meril)
Commercial / Brand Name(s)	All in vitro diagnostic medical devices (IVDs) manufactured by Meril at D1-D3, Meril Park, Survey No: 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191 India and Meril Academy, Block No- MD1, Survey No.- 1231, 1232 & 1228, Muktanand Marg, Balitha, Vapi, 396191 India, including but not limited to: <ul style="list-style-type: none"> - Prequalified products delisted by WHO PQ: <ul style="list-style-type: none"> i. One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag (PQDx 0294-074-00) [MFLRPD-05,

	<p>MFLRPD-02, MFLRPD-03, MFLRPD-04, MFLRPD-06, MFLRPD-07, MFLRPD-08]</p> <p>ii. One Step test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag (PQDx 0470-074-00) [RPWMPH-02, RPWMPH-03, RPWMPH-04, RPWMPH-05, RPWMPH-06, RPWMPH-07]</p> <p>iii. MERISCREEN HIV 1-2 WB (PQDx 0464-074-00) [HVWRPD-01, HVWRPD-02, HVWRPD-06, HVWRPD-07, HVWRPD-08, HVWRPD-09, HVWRPD-10, HVWRPD-11, HVWRPD-12]</p> <p>iv. One Step test for Malaria Pf/Pan Ag MERISCREEN Malaria Pf/Pan Ag (PQDx 0330-074-00) [MHLRPD-02, MHLRPD-03, MHLRPD-04, MHLRPD-05, MHLRPD-06, MHLRPD-07, MHLRPD-08]</p> <p>- Products under WHO pre-qualification assessment:</p> <p>i. Meriscreen HIV+ Syphilis Antibody Test (12387-074-00) [RPDHIS-01, RPDHIS-02, RPDHIS-03, RPDHIS-04, RPDHIS-05, RPDHIS-06, RPDHIS-07, RPDHIS-08, RPDHIS-09, RPDHIS-10]</p> <p>ii. HIVFIND Whole Blood HIV 1/2 Antibody Detection Self-Test (PQDx 12642-074-00) [HIVWBS-01, HIVWBS-02, HIVBS-03, and HIVWBS-04]</p> <p>iii. Meriscreen Malaria Pf HRP-II/pLDH Ag (PQDx 13179-074-00) [RWPFDH-09, RWPFDH-01, RWPFDH-02, RWPFDH-03, RWPFDH-04, RWPFDH-05, RWPFDH-06, RWPFDH-07, RWPFDH-08, RWPFDH-10, RWPFDH-11, RWPFDH-12, RWPFDH-13, and RWPFDH-14]</p>
Product code:	See above
Formulation	N/A
Packaging & Pack size & Type	All
Batch(es)	All
Expiry Date	All

Background

On the 14-16th October 2025, Inspection Services of the WHO Prequalification Unit conducted a for-cause inspection of the manufacturer Meril Diagnostic Pvt. Ltd.

Based on this, WHO published the Notice of Concern (NoC) on 19th December 2025 relating to the status of compliance with ISO 13485:2016 standard of Meril (<https://extranet.who.int/prequal/inspection-services/notices-concern-nocs-vitro-diagnostics>). The WHO Prequalification Unit delisted on 5th January 2026 all four prequalified products and suspended review of three products under prequalification assessment from Meril.

In addition, WHO issued an Information Notice for IVD User (2026/01) with advice on actions to be taken by stakeholders, including possible actions that could be taken by Users (including control programmes, their implementing partners and procurement agencies), and by national regulatory authorities (NRAs) (<https://www.who.int/news/item/16-03-2026-medical-product-alert-n-1-2026--who-information-notice-for-in-vitro-diagnostic-medical-devices>).

Nature of defect(s)

Details of defect or problem.	Critical nonconformities across the quality management system at the manufacturing sites
Is there any evidence or suspicion of a risk to public health?	Per the WHO NoC, the WHO Prequalification Programme's view is that there are risks to patient safety. This could be potential misdiagnosis leading to inappropriate or missed treatment.
Extent of the problem (eg. No. of batches).	All products manufactured by Meril
Extent of distribution of the product / batch (es).	Worldwide distribution of malaria Rapid Diagnostic Tests (RDTs) to Global Fund Principal Recipients. One country reported to have received 7'400 MERISCREEN HIV 1-2 WB RDTs. No products assessed by the Global Fund's Expert Review Panel have been reported to be procured.
Number of users and / or patients potentially impacted	No impacted patients reported to the Global Fund to date.
Other products potentially impacted	None.

Action taken

- Delisting of the affected products from the Global Fund QA List of eligible products on 22nd December 2025.
- Communication to Global Fund Country Teams.

- Request to the Global Fund Procurement Service Agent on 22nd December 2025 to request the PR to place affected products which were in transit in quarantine on arrival in the country
- All procurement activities through Global Pooled Procurement Mechanism were immediately suspended following the publication of the WHO Notice of Concern.
- All orders placed through Global Fund Pooled Procurement Mechanism with the manufacturer and not yet fulfilled were cancelled and reallocated, with no financial prejudice incurred.

Recommendations

Based on the information available to date and until further notice, the following actions are recommended by the Global Fund Quality Assurance and Compliance Team:

For Principal Recipients:

- Stop any new procurement of above referenced products as these products became ineligible for procurement when delisted by WHO PQ according to the QA Policy of Medical Devices (including IVDs) and core PPE and choose eligible products. Please refer to Global Fund list of eligible Malaria and HIV RDTs available at: <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/in-vitro-diagnostics/> .
- Together with in-country stakeholder, follow the WHO Information Notice for IVD Users 2026/01, including any specific measures appropriate in the country context.
- Liaise with the NRAs to reinforce the importance of vigilance activities in their respective market.
- In case of programmatic concerns (excluding new orders), requests for case-by-case assessment can be addressed to the respective Country Team / HPM specialist for discussion with the Quality Assurance and Compliance Team.
- Request advice from The Global Fund Quality Assurance and Compliance Team in case of doubt.

As a reminder, PR have the possibility to make a complaint about the product with the manufacturer by using for example the "Complaints and Product Alerts" form available on the following Global Fund website <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/in-vitro-diagnostics/>. The PR shall copy The Global Fund Quality Assurance and Compliance Team on any customer complaints communicated to the manufacturer.

For Procurement Service Agents

- Stop any new procurement of above referenced products as these products became ineligible for procurement when delisted by WHO PQ according to the QA Policy of Medical Devices (including IVDs) and core PPE, and choose eligible products. Please refer to GF list of eligible Malaria and HIV RDTs available at: <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/in-vitro-diagnostics/> .
- Follow the WHO Information Notice for IVD Users 2026/01, including any specific measures appropriate in the country context.
- Request advice from the Global Fund Quality Assurance and Compliance Team in case of doubt.

For IVD Users and/or Patients

- Revisit the Global Fund QA Information Notice 2025-03: Advice regarding the use of all Rapid Diagnostic Tests (RDT) for malaria concerning faint positive test lines for patients with confirmed malaria infection available on the Global Fund website <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/information-notice/>.
- IVD users and / or patients who have experienced any adverse reaction or quality problems with the use of the impacted product shall report this to the relevant National Regulatory Authorities, manufacturer and the Global Fund Health Product Management (HPM) Specialist.

Transmission of QA Information Notice

This QA Information Notice needs to be passed on to all those who need to be aware within your organization and/or to any organization where the potentially affected products have been transferred.

Please maintain awareness of this QA Information Notice and resulting action(s) for an appropriate period to ensure effectiveness of the corrective action(s).

Validity

The QA Information Notice will be valid from date of publication on the Global Fund Information Notice webpage <https://www.theglobalfund.org/en/sourcing-management/quality-assurance/information-notice/> until it is either removed or superseded.

Contacts

This QA Information Notice does not require a specific written response from PR. PR should copy the Global Fund Quality Assurance and Compliance Team of any correspondence regarding the matter for follow-up.

Please direct the respective questions about this matter to the technical contact listed below.

Organization	Name / Function	E-mail address
Global Fund	Your respective Country Team/ HPM specialist for the portfolio	County Team / HPM Specialist Email
Global Fund	René Becker-Burgos, QA Specialist Medical Devices (including In-Vitro Diagnostic Products) and core Personal Protective Equipment	Rene.Becker-Burgos@theglobalfund.org

Annex



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WHO INFORMATION NOTICE FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES

Products: In vitro diagnostic medical devices (IVDs) manufactured by Meril Diagnostics Pvt. Ltd at the Manufacturing Sites (as defined below) and listed in Annex 1, (collectively the “Products”).

WHO-identifier: 2026/01-02

Type of action: Information for national regulatory authorities (NRAs), and users¹ including control programmes, their implementing partners and procurement agencies (collectively the “Users”).

Date: 16 March 2026

Attention: National malaria, HIV, and sexually transmitted infection (STI) control programme managers and their implementing partners, procurement agencies, national regulatory authorities for IVDs and clinical testing sites.

Purpose: To alert Users and NRAs of malaria, HIV, and HIV/syphilis rapid diagnostic tests (RDTs) of concerns for Products manufactured by Meril Diagnostics Pvt. Ltd. at specified Manufacturing Sites located at: D1-D3, Meril Park, Survey No: 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191 India (site 1) and Meril Academy, Block No- MD1, Survey No.- 1231, 1232 & 1228, Muktanand Marg, Balitha, Vapi, 396191 India (site 2) (collectively, the “Manufacturing Sites”).

Description of the situation:

As part of the WHO pre- and post-prequalification product review process², WHO’s Prequalification Unit conducted a special (for-cause) inspection of the quality management system (QMS) at the Manufacturing Sites from 14 to 16 October 2025. A for-cause inspection is a non-routine inspection triggered by specific concerns or evidence of potential non-compliance or product quality issues.

During that inspection, critical nonconformities across the QMS at the Manufacturing Sites were identified that may pose a risk to patient safety for the Products. As a result:

- WHO issued a Notice of Concern on 19 December 2025, which is available at: https://extranet.who.int/prequal/sites/default/files/document_files/NOC_MerilDiagnostics_19December2025.pdf. The Notice of Concern will remain active on the WHO website until WHO confirms that all applicable requirements for WHO Prequalification of In Vitro Diagnostics have been met.
- Products that had been prequalified by WHO were subsequently delisted from the list of prequalified IVDs on 5 January 2026.: <https://extranet.who.int/prequal/vitro-diagnostics/prequalified/in-vitro-diagnostics>.

¹ in the context of adverse event reporting to include patients, operators, and any other persons affected by a medical device incident.

² <https://www.who.int/teams/regulation-prequalification/incidents-and-SF/safety-information-for-medical-devices-including-in-vitro-diagnostics>

In addition to the WHO Prequalification Unit inspection findings, the WHO Malaria Rapid Diagnostic Test (RDT) Lot Testing Laboratory at the Research Institute for Tropical Medicine in the Philippines assessed 29 lots of Meril Diagnostics malaria RDTs over the past year. The RDT lot testing did not report any failures.

Advice on actions to be taken by stakeholders

Below is a non-exhaustive list of possible actions that Users and NRAs may consider in light of the situation. Decisions regarding the procurement, acceptance, deployment, distribution or continued use of the Products remain the sole responsibility of NRAs and Users (including disease programmes, procurers and implementing partners) based on such factors as: national regulatory requirements, operational needs, availability of alternative products, risk-benefit assessment in the local context, and other relevant considerations. WHO is not responsible for any of these assessments or decisions.

Users are encouraged to follow the advice of relevant national regulatory authorities, particularly those responsible for the regulation of medical devices including in vitro diagnostics.

Possible actions that could be taken by Users:

1. Following consideration of the risks and benefits of continued use or not:
 - for Products in health facilities, if suitable alternative is available in-country inside the supply chain, strongly consider switching to alternative products.
 - for Products in country but not yet deployed, if suitable alternative is available in-country inside the supply chain, strongly consider switching to alternative products.
 - review all orders of Products, including in process, in production, pending shipment, in transit, in country but not yet accepted, if suitable alternative is available, strongly consider switching to the alternative products.
2. Review the WHO list of prequalified in vitro diagnostic products, and WHO programmatic guidance and technical resources such as the WHO Toolkit to optimize HIV testing algorithms for HIV RDTs³.
3. Report if any product problem and/or adverse event is detected with respect to the Products (see definitions in table below).

<p>A product problem is something that happens to the IVD itself.</p>	<p>The following product problems should be reported:</p> <ul style="list-style-type: none"> • Packaging (e.g. foil pouch, buffer vial/bottle, desiccant, shipping container) – damaged, defective, suspect tampered; • Labelling (e.g. pouch label, instructions for use) – insufficient, illegible, missing; • Components (e.g. specimen transfer device) – defective, incorrect, or missing; • Unexpected increase in invalid results, for example more than one invalid test per box of 25 tests. <p><i>Note: this list is non-exhaustive.</i></p>
<p>An adverse event is the health effect on the patient, user or other person.</p>	<p>The following adverse events should be reported:</p> <ul style="list-style-type: none"> • A false negative test result confirmed by another reliable testing method; • A series of false positive test results (more than two) confirmed by another reliable testing method and; • Non-reproducible results. <p><i>Note: this list is non-exhaustive.</i></p>

³ <https://www.who.int/tools/optimizing-hiv-testing-algorithms-toolkit>

Reporters should without delay:

- a. Send a user feedback form to the manufacturer (e-mail: diagnostics@merillife.com)
 - Preferably using WHO form at the following web address https://cdn.who.int/media/docs/default-source/substandard-and-falsified/pms_user_feedback_form.docx?sfvrsn=3856959_19
- b. Copy the same user feedback form to WHO (e-mail rapidalert@who.int).

Special consideration for malaria Products:

4. If malaria RDTs are already in a country where there are no suitable alternatives, strongly consider requesting WHO lot testing prior pre or post deployment.
5. Consider the risk-benefit profile of continuing to use malaria RDTs that are currently deployed, on order or in stores.

In the case that the risk-benefit profile favours continued use until product replacement is achieved: if the RDT results are negative and no alternative diagnosis is available, advise patients to return for re-evaluation or re-testing⁴ if their symptoms worsen or their condition does not improve. All cases of suspected severe malaria should be treated empirically, and health workers should be reminded to treat all faint/weak test lines as positive results.

Possible actions that could be taken by national regulatory authorities:

1. Review the information provided through this information notice and the associated Notice of Concern in the context of their regulatory responsibilities.
2. Consider whether actions or communication strategies require tailoring according to local approvals or recommendations for product use, such as for product use by health facilities versus product use by the public for self-testing.
3. For malaria Products:
 - Consider whether additional verification, market surveillance activities, or communication with national stakeholders is appropriate within their jurisdiction.
 - Determine if any regulatory actions - such as enhanced monitoring, temporary restrictions, or requests for manufacturer clarification - are warranted based on national legislation and risk assessment.
 - Communicate relevant outcomes to all Users.

Transmission of this WHO Information Notice:

This notice should be communicated to all those who need to be aware within an organization or to any organization where the potentially affected Products have been deployed and used.

Contact details for further information:

Market Surveillance and Control Team, Regulation and Safety Unit, Regulation and Prequalification Department, World Health Organization, e-mail: rapidalert@who.int

⁴ re-testing may be with the same or alternative RDT or by microscopy.

Annex 1. Implicated Product names

The following Products manufactured by Meril Diagnostics Ltd. at the Manufacturing Sites that are listed in the WHO Information Notice, located at: D1-D3, Meril Park, Survey No: 135/2/B & 174/2, Muktanand Marg, Chala, Vapi, 396191 India (site 1) and Meril Academy, Block No- MD1, Survey No.- 1231, 1232 & 1228, Muktanand Marg, Balitha, Vapi, 396191 India (site 2):

Product names
One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag
One Step test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag
One Step test for Malaria Pf/Pan Ag MERISCREEN Malaria Pf/Pan Ag
MERISCREEN HIV 1-2 WB
Meriscreen HIV+ Syphilis Antibody Test
HIVFIND Whole Blood HIV 1/2 Antibody Detection Self-Test
Meriscreen Malaria Pf HRP-II/pLDH Ag