World Health Organization

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## Prequalification Unit - Inspection services

■ WHO/PQT: IVDs

***Notice of Concern***
*19 December 2025*

**NOTICE OF CONCERN**

**Meril Diagnostics Pvt. Ltd.**

**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)**

*Notice of Concern (NOC) issued pursuant to Resolution WHA57.14 read together with PQT Notice of Concern procedure of June 2008 (latest update of October 2024).*

Your attention is invited to the World Health Assembly Resolution WHA57.14 "*Scaling up treatment and care within a coordinated and comprehensive response to HIV/AIDS*" of 22 May 2004, which among other actions requests WHO: "*3. (4) to ensure that the prequalification review process and the results of inspection and assessment reports of the listed products, aside from proprietary and confidential information, are made publicly available*;"

Following the said resolution WHO, acting through its Prequalification Unit (PQT), implemented (June 2008) and updated (October 2024) a Notice of Concern procedure. That procedure is applied when, following the inspection of a manufacturing site of a product that is undergoing prequalification assessment or that has been prequalified by WHO, critical concerns are identified about a manufacturing site's compliance with specified standards such as those relating to Good Manufacturing Practices (GMP), Good Laboratory Practices (GLP) or Good Clinical Practices (GCP).

Based on these documents, WHO's Prequalification Unit hereby issues a Notice of Concern relating to the status of compliance with ISO 13485:2016 standard by Meril Diagnostics Pvt. Ltd. (the "manufacturer") at its manufacturing sites located at D1-D3, Meril Park, Survey No: 135/2/B & 174/2, Muktanand Marg, Chala Vapi, 396191 India (site 1) and at Block No- MD1, Survey No.- 1231, 1232 & 1228, Muktanand Marg, Balitha, Vapi, 396191 India (site 2).

The products in scope of this Notice of Concern (i.e., because they are manufactured at site 1 and/or site 2 mentioned above) are:

- Prequalified products:
  - One Step test for Malaria Pf/Pv Ag MERISCREEN Malaria Pf/Pv Ag (PQDx 0294-074-00)
  - One Step test for Malaria Pf HRP-II Ag MERISCREEN Malaria Pf HRP-II Ag (PQDx 0470-074-00)
  - MERISCREEN HIV 1-2 WB (PQDx 0464-074-00)
  - One Step test for Malaria Pf/Pan Ag MERISCREEN Malaria Pf/Pan Ag (PQDx 0330-074-00)

- Products under prequalification assessment:
    - Meriscreen HIV+ Syphilis Antibody Test (12387-074-00)
    - HIVFIND Whole Blood HIV 1/2 Antibody Detection Self-Test (PQDx 12642-074-00)
    - Meriscreen Malaria Pf HRP-ll/pLDH Ag (PQDx 13179-074-00)

On 14-16 October 2025, WHO's Inspection Services conducted a for-cause inspection of the manufacturing sites listed above to investigate potential data integrity issues identified during the review of the product dossiers for the products under prequalification assessment. The WHO Final Inspection Report for the sites and products listed above was sent to the manufacturer on 19 November 2025 together with a copy of the corresponding NOC.

Meril Diagnostics Pvt. Ltd. was requested by WHO, acting through the PQT Inspection Services Team, on 19 November 2025 to submit a written response to the inspection report. Following a review of the manufacturer's response, subsequent written exchanges of communication took place on 4 and 10 December 2025, during which it was indicated and acknowledged that several concerns remained outstanding, including, but not limited to, the following:

1. The requirements of **Clause 4.2.5 - Control of records** were not fully met, in that:
Several critical data integrity issues were observed, including what appears as data manipulation, misrepresentation of records, incomplete, unavailable and unretrievable data. Examples included, but were not limited to:

a. The details of the characterization of the syphilis specimens used for the analytical sensitivity study of the Meriscreen HIV+ Syphilis Antibody Test were not documented.

b. There was no record of the results of the in-process leak testing of pouched devices.

c. On 7 January 2024, 39 reports for the "Flex Study_HIVFIND WB Self-Test Rev 00" were signed by two staff members (operator and reviewer). However, the manufacturer could not provide objective evidence of those staff members entering the premises on that day.

d. The risk management plan for the Meriscreen Malaria Pf HRP-II/pLDH Ag product erroneously mentioned several times sickle cell and MPX Ab testing instead of malaria testing, indicating poor control of template documents.

e. The Meriscreen Malaria Pf HRP-ll/pLDH Ag product description mentioned pLDH to detect Pv, which was not part of the intended use.

f. The form to record results for accelerated stability QC studies did not include provisions to record invalid results and anomalies.

g. Analysis of photos in the memory card of the camera used to document experiments conducted in the QC laboratory revealed many critical issues with data integrity, including:

- Many instances of re-use of identical devices to document different experiments.
- Metadata of captured photos indicating significant difference with some of the claimed testing dates.

h. The in-process cleaning of the guillotine was not recorded.

i. The manufacturer could not objectively explain why the CoA of the syphilis QC specimens was dated 23 March 2021 when the order for these specimens was placed on 26 March 2021 given that the specimens were assembled based on the specifics of the order made by the manufacturer.

j. The original files of the CoAs of the syphilis specimens used for the analytical sensitivity study of the Meriscreen HIV+ Syphilis Antibody Test were not retrievable.

2. The requirements of **Clause 4.2.4 - Control of documents** were not fully met, in that:

a. The retention time of certain documents needed to be extended. For example, QC specimens were given a shelf-life of 5 years and were used to QC-release devices with a shelf-life of 2 years. Yet, CoAs of QC specimens were kept only for 5 years. This represented a risk that complaints would be received for devices that were QC-released using QC specimens for which the CoAs could not be retrieved, limiting the investigation into complaints.

3. The requirements of **Clause 7.1 - Planning of product realization** were not fully met, in that:

a. The Meriscreen Malaria Pf HRP-II/pLDH Ag product was in contact with the patient (e.g., lancet). Yet, the risk management file indicated otherwise.

b. The risk management plan and report for Meriscreen Malaria Pf HRP-II Ag was not properly performed and documented in that:

- There were many statements that the product was intended for screening, which was not part of the intended use.
- It stated that physicians would not diagnose just on the basis of IVD results alone but also on the basis of confirmatory test results and patient history, which was not aligned to WHO treatment guidelines.
- Working principle mentioned that the control line must appear. However, there was already a blue band at the control region before the test was used.

4. The requirements of **Clause 7.3.3 - Design and development inputs** were not fully met, in that:

a. Design inputs included a competitor product despite the fact that such inputs were not known by the manufacturer.

5. The requirements of **Clause 7.3.4 - Design and development outputs** were not fully met, in that:

a. Results of the performance testing for the Meriscreen Malaria Pf HRP-ll/pLDH Ag product were combined for the PfHRP2 and Pf LDH lines.

6. The requirements of **Clause 7.3.7 - Design and development validation** were not fully met, in that:

a. Experiments on a lot of HIVFIND Whole Blood HIV 1/2 Antibody Detection Self-Test that expired on 7 July 2025 (lot MI0723021) were photographed on 10 October 2025.

7. The requirements of **Clause 7.4.1 - Purchasing process** were not fully met, in that:

a. The specimen used in the “Flex Study_HIVFIND WB Self Test Rev 00 “ was collected from a hospital that was not listed as an approved supplier, and no supplier qualification records were available for that hospital.

b. The supplier scoring system allows suppliers with poor product quality performance to still achieve the minimum qualification threshold (40%).

8. The requirements of **Clause 7.5.1 - Control of production and service provision** were not fully met, in that:

a. The QC procedure was not documenting the possibility of the first and second readers disagreeing.

b. The procedure on the qualification of QC specimens did not document the possibility of the in-house device and competitor device yielding different results.

9. The requirements of **Clause 7.5.6 - Validation of processes for production and service provision** were not fully met, in that:

a. The shelf-life of QC specimens was validated neither for frozen nor for thawed specimens.

10. The requirements of **Clause 7.5.9 - Traceability** were not fully met, in that:

a. The reconciliation of the packing stage was inadequate in that some values were calculated and not counted. Also, there was no acceptance criteria for this reconciliation.

b. Some kit components with a direct impact on product quality and/or performance were not reconciled. For example, the desiccant was not.

c. The output of some processes (and therefore the input of next ones) were not known. For example, the number of assembled Dengue NS1 Ag devices was not known.

11. The requirements of **Clause 7.6 - Control of monitoring and measuring equipment** were not fully met, in that:

a. The procedure for the control of score cards used to score test and control line intensities was not documented. There was no certificate of conformity of score cards supplied by the vendor. As such, the manufacturer could not demonstrate that the score cards used to make quality decisions met specifications.

12. The requirements of **Clause 8.2.3 - Reporting to regulatory authorities** were not fully met, in that:

a. A second complaint reported by Mozambique for the Meriscreen Malaria Pf HRP-II Ag product was not reported to WHO in spite of 38 false negatives, and weak/faint test lines.

13. The requirements of **Clause 8.2.6 - Monitoring and measurement of product** were not fully met, in that:

a. Upon receipt, the syphilis QC specimens were tested using the in-house Syphiline test and an SD OneStep Syphilis anti-TP test. Some specimens showed largely different band intensities between the CoA and the specimens characterization record. This discrepancy had not been identified, and could not be explained, by the manufacturer.

Based on the nature of the observations, it was noted that:

- Meril Diagnostics Pvt. Ltd. presented analytical results and records with significant irregularities and what appears as data manipulation for products undergoing prequalification assessment at the time of inspection, as well as for products already prequalified at the time of inspection;
- Meril Diagnostics Pvt. Ltd. could not provide primary evidence supporting the origin of biological specimens used in analytical studies of the MERISCREEN HIV + Syphilis Antibody Test, and their certificates of analysis were not original documents and appear to have been manipulated.

It is the view of the WHO Prequalification Programme that these observations pose a risk to patient safety. On 4 December 2025, Meril Diagnostics Pvt. Ltd. was informed that they were considered as not operating in compliance with WHO standards (ISO 13485:2016) and the Inspection was closed.

Kindly be advised that further corrective and preventive actions are required by Meril Diagnostics Pvt. Ltd. for the purposes of removing this Notice of Concern from WHO's website. This Notice of Concern shall remain in effect and publicly available on WHO's website until such time as the World Health Organization has confirmed that all applicable requirements for WHO Prequalification of In Vitro Diagnostics have been fully met.

For further information please visit the WHO Prequalification Unit website at https://extranet.who.int/prequal or contact PQT directly at prequal@who.int

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