20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

WHO Prequalification Team - Inspection services

WHO PUBLIC INSPECTION REPORT (WHOPIR)

In vitro Diagnostic product

Inspected site/s	
Name of Organization	Premier Medical Corporation Pvt. Ltd.
Address/es of inspected manufacturing site/s	A1-302 and 3704-05, GIDC Sarigam INA Sarigam, Gujarat 396155 India
Inspection details	
Start of inspection	22/09/2024
Inspection duration (in inspector days)	6
Type of inspection	Re-inspection
Introduction	
Brief description of manufacturing activities conducted at the site/s inspected	Premier Medical Corporation Pvt. Ltd. designs, manufactures, and distributes rapid diagnostic tests for human infectious diseases based on lateral flow technology.
General information about the organization	Premier Medical Corporation Pvt. Ltd. aims at being one of the world leaders in developing cost effective point-of-care tests. The organization has experience in the development, manufacturing and distribution of RDTs designed to be affordable, high-quality, and easy to use. The organization has a market presence in African, European, Asian, and Middle East markets.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	As detailed below, the areas inspected were sampled from the areas of activities performed on site that were relevant to the products in scope. The sampling was performed using a risk-based approach considering, for example, the impact of the area inspected on the product, as well as past inspection findings.
Products in scope	• First Response Malaria Antigen P. falciparum (HRP2) Card Test PQDx 0283-010-00 • First Response Syphilis Anti-TP Card Test PQDx 0471-010-00 • First Response Malaria Ag. P.f. / P.v. Card Test PQDx 0329-010-00 • First Response Malaria Ag. pLDH/HRP2 Combo Card Test PQDx 0285-010-00 • First Response HIV 1-2.O Card test Version 2.0 PQDx 0363-010-00

	• First Response HIV1+2/Syphilis Combo Card Test PQDx 0364-010-00 • First Response HCV Card Test PQDx 0469-010-00 • First Response HIV 1-2.O Card Test (Self-Test) PQDx 0705-010-00 • Sure Status COVID-19 Antigen Card Test (Nasal Swab) PQDx 12362-010-00
Criteria	• All applicable clauses of ISO 13485:2016 • WHO PQ requirements • Organization's own requirements
Objective(s)	Verify continued compliance to the inspection criteria.
Limitations	None.
Out of scope	Any processes or activities not related to the products in scope were considered out of scope of this inspection.

Abbreviations	**Meaning**
CAPA	Corrective and Preventive Action
CoA	Certificate of analysis
IQ	Installation qualification
IVD	In vitro device
MR	Management review
MRM	Management review meeting
MSDS	Material safety data sheet
NC	Non-conformity
PPE	Personal protective equipment
OOS	Out-of-specifications test result
OQ	Operational qualification
PM	Preventive maintenance
PMS	Post Market Surveillance
PQ	Performance qualification
PW	Purified water
QA	Quality assurance
QC	Quality control
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure

Summary of the findings and comments (where applicable)

4. Quality management system

4.1 General requirements

The organization and management structure of the facility was documented and defined within the organisational chart. Roles and responsibilities were available with the overall reporting structure available with clear delineation for release of product.

4.2 Documentation requirements

4.2.2. Quality manual

The Quality Manual adequately addressed and reflected the intended practices of the organization, with commitment from top management for the continual improvement and support of the QMS. The nonconformity identified was successfully resolved through a CAPA process.

4.2.4/5. Control of documents and records

There were documented procedures for document and record control that appeared to meet the requirements of the standard. There were no significant changes to the previously inspected document control system that had been implemented to manage QMS documentation, including procedures, work instruction, records, CAPAs including quality incidents and NCs and other documents. Document control practices were compliant where the procedures and the records reviewed provided evidence of conformity and completion of requirements. Generally, records and documents were readily available. The nonconformity identified was successfully resolved through a CAPA process.

5. Management responsibility

5.6. Management review

5.6.1. General

The organization had an established process for regular management reviews. Records from management reviews were maintained. The review included assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

5.6.2. Review input

The input to management review included feedback, complaint handling, reporting to regulatory authorities, audits, monitoring and measurement of processes, monitoring and measurement of product, corrective action, preventive action, follow-up actions from previous management reviews, changes that could affect the QMS, recommendations for improvement, and applicable new or revised regulatory requirements.

5.6.3. Review output

The output to management review were documented and included decisions and actions related to improvement needed to maintain the suitability, adequacy, and effectiveness of the QMS and its processes, improvement of product related to customer requirements, changes needed to respond to applicable new or revised regulatory requirements, and resource needs.

6. Resource management

6.1. Provision of resources

The facility was well resourced, with trained personnel and adequate facilities for the function and activities that were performed. This aimed to ensure the QMS was implemented, and its effectiveness maintained, and that applicable regulatory and customer requirements were met.

6.2. Human resources

The facility was staffed with personnel who had the necessary education, training, technical knowledge, and experiences for their assigned functions. Staff questioned were open and forthcoming with information. The organization had an established and documented training procedure. Training files for staff were maintained and available for review during the inspection. The nonconformities identified were successfully resolved through a CAPA process.

6.3. Infrastructure

The facility was well maintained with a logical workflow with segregation of activities with rooms of suitable size and design to suit the functions and to perform the operations to be conducted in them. This prevented product mix-up and ensured orderly handling of product.
The facility was well maintained, clean and orderly and clearly sign posted. Pest control management procedure was implemented.
The organization had documented requirements for the maintenance activities that applied to equipment used in production, to the control of the work environment, and to monitoring and measurement.
The nonconformities identified were successfully resolved through a CAPA process.

6.4. Work environment and contamination control

6.4.1. Work environment

All production rooms were controlled and monitored for temperature and relative humidity with recordings available. Staff were observed to be wearing appropriate PPE, with access to appropriate coats, shoes, masks, and hair nets. There were pictorials when entering an area on the gowning requirements. A mirror was available to ensure appropriate PPE was properly downed.

6.4.2. Contamination control

Procedures for the cleaning of the facility and infrastructure were available to prevent contamination of the work environment, personnel, or product.

7. Product realization

7.1. Planning of product realization

The organization’s approach to the planning of production and service provision was documented in the QMS, with procedures for document management, risk management, product production, material verification, process validation, monitoring, inspection, and test activities. The nonconformity identified was successfully resolved through a CAPA process.

7.4. Purchasing

7.4.1. Purchasing process

The organization had an established and well documented process for the purchasing of materials and services, that included a traceable inventory, release, and verification of critical incoming material. Supplier management and qualification procedures were available and implemented with supplier agreements for critical suppliers available. Criteria for selection, evaluation, approval, and re-evaluation of suppliers were documented and based on the supplier's ability to provide product that met the organization's requirements, the performance of the supplier, and the effect of the purchased product on the quality of the medical device. The nonconformity identified was successfully resolved through a CAPA process.

7.4.3. Verification of purchased product

The organization had implemented processes for the verification of purchased products to ensure that they met specified purchasing requirements. The extent of verification activities was based on the supplier evaluation results and proportionate to the risks associated with the purchased product. Records of these activities were maintained. The nonconformity identified was successfully resolved through a CAPA process.

7.5. Production and service provision

7.5.1. Control of production and service provision

Production and service provision was carried out, monitored, and controlled to ensure that product conformed to specifications. The organization had a documented process for the control of production that included, but was not limited to, qualification of infrastructure and monitoring and measuring equipment. Batch manufacturing records were available. Records were verified and approved. The nonconformities identified were successfully resolved through a CAPA process.

7.5.6. Validation of processes for production and service provision

The organization had validated processes for production and service provision that followed procedures that included the equipment qualification and qualification of personnel; the use of specific methods, procedures, and acceptance criteria; the criteria for revalidation; and the approval of changes to the processes. The nonconformities identified were successfully resolved through a CAPA process.

7.6. Control of monitoring and measuring equipment

The organization had implemented procedures for the control of monitoring and measuring equipment. Measuring equipment was calibrated and/or verified, at specified intervals, or prior to use, had identification indicating its calibration status, and was safeguarded from adjustments that would invalidate the measurement result. Calibration records were available, and a sample was reviewed. The nonconformity identified was successfully resolved through a CAPA process.

8. Measurement, analysis and improvement

8.2. Monitoring and measurement

8.2.2. Complaint handling

The organization had implemented a procedure for the timely handling of customer complaints. The procedures included requirements and responsibilities for evaluating information to determine if the feedback constitutes a complaint, investigating complaints, determining the need to report the information to the appropriate regulatory authorities, handling of complaint-related product, and determining the need to initiate corrections or corrective actions. Corrections and corrective actions were documented. Complaint handling records were maintained. The nonconformities identified were successfully resolved through a CAPA process.

8.4. Analysis of data

The organization had documented procedures to determine, collect, and analyse appropriate data to demonstrate the suitability, adequacy, and effectiveness of the QMS. Data analysed were gathered from customer feedback, quality control, supplier performance, and audits. The nonconformity identified was successfully resolved through a CAPA process.

8.5. Improvement

8.5.3. Preventive action

The organization had procedures in placed to determine action to eliminate the causes of potential nonconformities to prevent their occurrence. These procedures described the requirements for determining potential nonconformities and their causes; evaluating the need for action to prevent occurrence of nonconformities; planning and documenting action needed and implementing such action, including, as appropriate, updating documentation, and verifying that the action does not adversely affect the ability to meet applicable regulatory requirements or the safety and performance of the medical device. Records of investigation and actions taken were maintained. The nonconformity identified was successfully resolved through a CAPA process.

Conclusion – Inspection outcome

Based on the areas inspected, the people met, and the documents reviewed, and considering the findings of the inspection, including the observations listed in the Inspection Report the company, ***Premier Medical Corporation Pvt. Ltd.*** located at ***A1-302 and 3704-05, GIDC Sarigam INA, Sarigam, Gujarat 396155, India*** was considered to be operating at an acceptable level of compliance with ISO 13485:2016 and WHO *Information for Manufacturers on Pre-qualification Inspection Procedures for the Sites of Manufacture of Diagnostics* (PQDx_014).

All the non-compliances observed during the inspection that were listed in the full report were addressed by the organization to a satisfactory level prior to the publication of the WHOPIR.

This WHOPIR will remain valid for 3 years, provided the outcome of any WHO pre-qualification inspection or other audit from regulatory authorities that WHO relies on conducted during this period provides evidence of current compliance with the audit criteria.

List of WHO Guidelines referenced in the inspection report

1. WHO Information for Manufacturers on Prequalification Inspection Procedures for the Sites of Manufacture of Diagnostics (PQDx_014). (https://www.who.int/diagnostics_laboratory/evaluations/en/)
2. ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes
3. WHO Post-market surveillance of in vitro diagnostics 2020 (ISBN 978 92 4 001532 6)
4. Medical devices - Application of risk management to medical devices - ISO14971:2019
5. GHTF/SG3/N19:2012 “Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange”
6. GHTF/SG4/(99)28 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements
7. GHTF/SG4/N30R20:2006 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy
8. GHTF/SG4(pd1)/N33R16:2007 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 3: Regulatory Audit Reports ISO 13485:2016, Commitments to WHO PQ.