World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
In vitro Medical Devices

Part 1	**General information**
Inspected laboratory details	
Name of Manufacturer	Abbott Rapid Diagnostics Jena GmbH
Address of inspected manufacturing site	Orlaweg 1, Jena, 07734, Germany
Inspection details	
Dates of inspection	27-28 April 2023
Type of inspection	Routine inspection
Introduction	
Brief description of manufacturing activities	The facility was responsible for design and development, production (sub-assembly and final device assembly), final release of product.
General information about the manufacturer	The company was founded in 1986 as CLONDIAG and was acquired by Inverness Medical Inc. In 2010, following a merger with Alere, Alere Technologies were formed and the company is now part of the Abbott Group. The manufacturer holds a valid ISO 13485 and CE Certificate.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Production Warehouse Quality Control Laboratory
Restrictions	Nil
Out of scope	Nil
WHO prequalified /submitted products covered by the inspection	• PQDx 0359-032-00 - Alere q HIV 1/2 plasma/ m-PIMA HIV-1/2 VL • PQDx 0099-032-00 - Pima CD4 test • PQDx 0226-032-00 - m-PIMA HIV-1/2 Detect • PQDx 0480-032-00 - Panbio HIV Verification Test (former name : Maxure HIV-1/2) -– not manufactured at this site • PQDx 0481-032-00 - CheckNOW HIV SELF TEST – not manufactured at this site • PQDx 0564-032-00 - Panbio COVID-19 Ag Rapid Test Device (Nasopharyngeal) – out of scope • PQDx 0587-032-00 - Panbio COVID-19 Ag Rapid Test Device (Nasal) – out of scope
Abbreviations	**Meaning**
CoA	Certificate of analysis

IQ	Installation qualification
IVD	In-vitro medical device
MR	Management review
MSDS	Material safety data sheet
NC	Non conformity
PPE	Personal protective equipment
OOS	Out-of-specifications test result
OQ	Operational qualification
PM	Preventive maintenance
PQ	Performance qualification
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure

Part 2	**Summary of the findings and comments (where applicable)**

1. Quality management system:

1.1. General requirements

The organization and management structure of the facility was clearly 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.

1.2. Documentation requirements

1.2.1. Quality manual and Management commitment

The manufacturer`s Quality Manual adequately addressed and reflected the intended practices of the laboratory, with clear commitment from top management for the continual improvement and support of the QMS.

1.2.2. Medical device file

The manufacturer had a Medical Device file available for the above listed product.

1.2.3. Control of documents and records

There were documented procedures for document and record control which met 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. Record retention was confirmed as being at least equivalent to the lifetime of the device.

2. Management responsibility

2.1. Quality policy

Top management had an established Quality Policy. The inspectors verified that the manufacturer had established processes that mostly met the requirements of ISO 13485:2016 (the standard) and other applicable regulations (notwithstanding the nonconformities identified during this inspection).

2.2. Management review

2.2.1. General

The manufacturer had an established process for regular management reviews that met the requirements of the standard. The quality policy and objectives were reviewed at the last management meeting and no changes were implemented. The manufacturer monitored and measured the ability of the quality management system processes to meet planned results. The inspection team were able to verify review inputs and outputs, complaint communication with top management and trending of monitoring and measurement processes and product.

3. Resource management

3.1. Provision of resources

The facility was well resourced, with trained personnel and adequate facilities for the function and activities that were performed.

3.2. 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 manufacturer had an established and well documented training procedure, including re-fresher training for staff. Training files for staff were maintained and available for review during the inspection.

3.3. 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. The facility was well maintained, clean and orderly and clearly sign posted. The Pest control management procedure was available.

3.4. Work environment and contamination control

3.4.1. Work environment

All rooms were temperature and humidity monitored with recordings available. In general, all staff observed were wearing appropriate PPE, with access to appropriate coats, shoes, masks, and hair nets that were provided and laundered by the manufacturer. There were pictorials when entering an area on the gowning requirements. A mirror was available to ensure hair was secured.

3.4.2. Contamination control

A procedure for the cleaning of the facility was available. Cleaning validations were available.

4. Product realization

4.1. Planning of product realization

The manufacturer's approach to the control and planning of production and service provision was adequately documented in the QMS, with procedures for document management, risk management, product production, material verification, process validation, monitoring, inspection, and test activities, incorporating an adequate device master record.

4.2. Design and development

4.2.1. General

The manufacturer had an established process for design and development. This was not reviewed at this inspection as the products were reviewed in detail at the initial inspection.

4.3. Purchasing

4.3.1. Purchasing process

The manufacturer had an established and well documented process for the purchasing of materials, that included a traceable inventory, release, and verification of all 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 had been revised and clarity relating to requirements and the process was available.

4.3.2. Control of design and development changes

The manufacturer had an established and well documented procedure for the control of design and development that incorporated informing WHO of such changes as per the WHO requirements.

4.4. Production and service provision

4.4.1. Control of production and service provision

The manufacturer had a documented process for the control of production that included but was not limited the to qualification of infrastructure and monitoring and measuring equipment. Temperature mapping was performed, and reports were available. All maintenance tasks, equipment register, and scheduling were available. Designated staff were responsible for the maintenance of equipment.

4.4.2. Identification

There was a documented procedure for the product identification that was suitable throughout product realization. There was clear segregation of released and nonconforming product within the facility.

4.4.3. Preservation of product

There was a well-established procedure for the preservation of product that ensured that the product was shipped with suitable shipping containers and maintained at the appropriate temperature throughout the process.

4.5. Control of monitoring and measuring equipment

The manufacturer had a well-documented system for the calibration, maintenance, and use of equipment with individual procedures available for all equipment. Regular maintenance and calibration of equipment was performed.

5. Measurement, analysis and improvement

5.1. Monitoring and measurement

5.1.1. Feedback

The manufacturer had a procedure for assessing and reporting to WHO the safety and performance throughout the lifecycle of the product. The procedure for post market surveillance had been revised and continued to meet the WHO requirements. The PMS plan was available.

5.1.2. Complaint handling

The manufacturer had a well-established procedure for customer complaints that included regular trending of complaints and post market surveillance. Reporting to regulatory authorities was available.

5.1.3. Internal audits

The manufacturer had implemented an internal audit program including documented requirements. This document described the requirements for independent auditors. Training records were reviewed and found appropriate. All nonconformities identified were captured as corrective actions and were followed using the manufacturer`s CAPA process.

5.1.4. Monitoring and measurement of processes and product

Trending and regular review of monitoring and measurement of processes and product was verified at the time of inspection. Detailed reports were available for the management review meetings and other relevant meetings.

5.2. Control of nonconforming product

5.2.1. General

The manufacturer had a process in place for the segregation of nonconforming product that met the requirement of the standard. There was clear labelling and traceability of nonconforming product throughout the various stages of production, and post-delivery.

5.3. Improvement

5.3.1. General

Handling and disposition of non-conformity events, as well as a related CAPA plan took place in accordance with the procedure.

Part 3	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, ***Abbott Rapid Diagnostic Jena GmbH*** located at ***Orlaweg 1, Jena, 07734, Germany*** was considered to be operating at an acceptable level of compliance with WHO requirements and ISO 13485:2016.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 5	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. ISO 9001:2015 Quality management systems - Requirements

4. WHO Post-market surveillance of in vitro diagnostics 2015 (ISBN 978 92 4 150921 3)

5. Medical devices - Application of risk management to medical devices - ISO14971:2007

6. GHTF/SG3/N19:2012 "Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange"

7. GHTF/SG4/(99)28 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements

8. GHTF/SG4/N30R20:2006 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy

9. 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