World Health Organization

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WHO Prequalification Team - Inspection services
WHO PUBLIC INSPECTION REPORT (WHOPIR)
In vitro Diagnostic product

Inspected site/s	
Name of Organization	Abbott Diagnostics Korea Inc.
Address/es of inspected manufacturing site/s	HAGAL site: 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do BORA site: 46, Hagal-ro 15beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do
Inspection details	
Start of inspection	11/06/2025
Inspection duration	6 inspector-days
Type of inspection	For cause
Introduction	
Brief description of manufacturing activities conducted at the site/s inspected	Abbott Diagnostics Korea Inc. offers a variety of rapid immunodiagnostic products for point-of-care testing. The company specializes in hepatitis B, HIV, HCV, syphilis, and malaria tests.
General information about the organization	The site was founded in 1999 as Standard Diagnostics, Inc., acquired by Alere in 2010 and then by Abbott in 2017. Its legal name changed to Abbott Diagnostics Korea Inc. in 2019. The Bora site hosts the reagent production, the assembly and packing of final products, and the QC of finished products. The Hagal site hosts the production and QC of semi-finished products (uncut sheets).
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	• Bioline Malaria Ag P.f (HRP2/pLDH) (formerly SD BIOLINE Malaria Ag P.f (HRP2/pLDH)) - PQDx 0209-012-00 • Bioline Malaria Ag P.f/P.v (formerly SD BIOLINE Malaria Ag P.f/P.v) - PQDx 0125-012-00 • Bioline Malaria Ag P.f/Pan - PQDx 0030-012-01 • Bioline Malaria Ag P.f (formerly SD BIOLINE Malaria Ag P.f) - PQDx 0031-012-01 • NxTek Eliminate Malaria Ag P.f (formely Alere Malaria Ag P.f) - PQDx 0349-012-00 • Bioline Malaria Ag P.f/P.f/P.v (formerly SD BIOLINE Malaria Ag P.f/P.f/P.v) - PQDx 0297-012-00

Criteria	• All applicable clauses of ISO 13485:2016 • WHO PQ requirements • Organization's own requirements
Objective(s)	Verify continued compliance to the inspection criteria and investigate specific aspects linked to complaints received for some of the products manufactured at this site.
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
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure

Summary of the findings and comments

4 Quality management system

4.2 Documentation requirements

4.2.1 General

The quality management system documentation did include:

a) documented statements of a quality policy and quality objectives;

b) a quality manual;

c) documented procedures and records required by the Standard;

d) documents, including records, determined by the organization to be necessary to ensure the effective planning, operation, and control of its processes;

e) other documentation specified by applicable regulatory requirements.

4.2.2 Quality manual

The organization did document a quality manual that included:

a) the scope of the quality management system, including details of and justification for any exclusion or non-application;

b) the documented procedures for the quality management system, or reference to them;

c) a description of the interaction between the processes of the quality management system.

The quality manual did outline the structure of the documentation used in the quality management system.

4.2.5 Control of records

Records were maintained to provide evidence of conformity to requirements and of the effective operation of the quality management system.

The organization did document procedures to define the controls needed for the identification, storage, security and integrity, retrieval, retention time and disposition of records.

Records did remain legible, readily identifiable and mostly retrievable. Changes to a record did remain identifiable.

The nonconformities identified were adequately addressed through a CAPA process.

5 Management responsibility

5.1 Management commitment

Top management did provide evidence of its commitment to the development and implementation of the quality management system and maintenance of its effectiveness by:

a) communicating to the organization the importance of meeting customer as well as applicable regulatory requirements;

b) establishing the quality policy;

c) ensuring that quality objectives were established;

d) conducting management reviews;

e) ensuring the availability of resources.

6 Resource management

6.3 Infrastructure

The organization did document the requirements for the infrastructure needed to achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure included, as appropriate:

a) buildings, workspace and associated utilities;

b) process equipment (both hardware and software);

c) supporting services (such as transport, communication, or information systems).

The organization did document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, could affect product quality. As appropriate, the requirements did apply to equipment used in production, the control of the work environment and monitoring and measurement.

Records of such maintenance were maintained.

7 Product realization

7.2 Customer-related processes

7.2.1/2 Determination and review of requirements related to product

The organization committed to determine requirements not stated by the customer but necessary for specified or intended use, as known, as well as applicable regulatory requirements related to the product. The organization committed to review the requirements related to product and ensure that product requirements are defined and documented, applicable regulatory requirements are met, and the organization has the ability to meet the defined requirements.
The nonconformities identified were adequately addressed through a CAPA process. Those commitments will be verified following an approved timeline and their effective implementation may be verified at the next inspection.

7.3 Design and development

7.3.3 Design and development inputs

Inputs relating to product requirements were determined and records maintained. These inputs did include:

a) functional, performance, usability and safety requirements;
b) applicable output(s) of risk management;
c) as appropriate, information derived from previous similar designs;
d) other requirements essential for design and development of the product and processes.

The nonconformities identified were adequately addressed through a CAPA process.

7.3.4 Design and development outputs

The outputs of design and development were in a form suitable for verification against the design and development inputs and were approved prior to release.
Records of the design and development outputs were maintained.

7.3.6 Design and development verification

Design and development verification were performed in accordance with planned and documented arrangements to ensure that the design and development outputs had met the design and development input requirements. The organization did document verification plans that include methods, and acceptance criteria. Records of the results and conclusions of the verification and necessary actions were maintained.
The nonconformities identified were adequately addressed through a CAPA process.

7.3.7 Design and development validation

Design and development validation were performed in accordance with planned and documented arrangements to ensure that the resulting product was capable of meeting the requirements for the specified application.
As part of design and development validation, the organization largely did perform clinical evaluations or performance evaluations of the medical device in accordance with applicable regulatory requirements. Records of the results and conclusion of validation and necessary actions were maintained.
The nonconformities identified were adequately addressed through a CAPA process.

7.3.8 Design and development transfer

The organization did document procedures for transfer of design and development outputs to manufacturing. These procedures did ensure that design and development outputs were verified as suitable for manufacturing before becoming final production specifications and that production capability could meet product requirements.
Results and conclusions of the transfer were recorded.

7.3.9 Control of design and development changes

The organization did document procedures to control design and development changes. The organization did determine the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.
Design and development changes were identified. Before implementation, the changes were:

a) reviewed;
b) verified;
c) validated, as appropriate;
d) approved.

The review of design and development changes did include evaluation of the effect of the changes on constituent parts and product in process or already delivered, inputs or outputs of risk management and product realization processes.
Records of changes, their review and any necessary actions were maintained.

7.3.10 Design and development files

The organization did maintain records generated to demonstrate conformity to the requirements for design and development and records for design and development changes.

7.4 Purchasing

7.4.1 Purchasing process

The organization did document procedures to ensure that purchased product conforms to specified purchasing information.
The organization did establish criteria for the evaluation and selection of suppliers. The criteria were:

a) based on the supplier's ability to provide product that meets the organization's requirements;
b) based on the effect of the purchased product on the quality of the medical device;
c) proportionate to the risk associated with the medical device.

The organization did plan the monitoring and re-evaluation of suppliers. Supplier performance in meeting requirements for the purchased product were monitored.
Records of the results of evaluation, selection, monitoring and re-evaluation of supplier capability or performance and any necessary actions arising from these activities were maintained.
The nonconformities identified were adequately addressed through a CAPA process.

7.4.2 Purchasing information

Purchasing information did describe or reference the product to be purchased, including as appropriate:

a) product specifications;
b) requirements for product acceptance, procedures, processes and equipment;
c) quality management system requirements.

Purchasing information did include, as applicable, a written agreement that the supplier notify the organization of changes in the purchased product prior to implementation of any changes that affect the ability of the purchased product to meet specified purchase requirements.
To the extent required for traceability given in Clause 7.5.9, the organization did maintain relevant purchasing information in the form of documents and records.
The nonconformities identified were adequately addressed through a CAPA process.

7.4.3 Verification of purchased product

The organization did establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements. The extent of verification activities were proportionate to the risks associated with the purchased product.
Records of the verification were maintained.

7.5 Production and service provision

7.5.11 Preservation of product

The organization did document procedures for preserving the conformity of product to requirements during processing, storage, handling, and distribution. Preservation did apply to the constituent parts of a medical device.
The organization did protect product from alteration, contamination or damage when exposed to expected conditions and hazards during processing, storage, handling, and distribution by:
a) designing and constructing suitable packaging and shipping containers;
b) documenting requirements for special conditions needed if packaging alone cannot provide preservation.
The nonconformities identified were adequately addressed through a CAPA process.

8 Measurement, analysis and improvement

8.2 Monitoring and measurement

8.2.2 Complaint handling

The organization did document procedures for timely complaint handling in accordance with applicable regulatory requirements.
These procedures did include at a minimum requirements and responsibilities for:

a) receiving and recording information;
b) evaluating information to determine if the feedback constitutes a complaint;
c) investigating complaints;
d) determining the need to report the information to the appropriate regulatory authorities;
e) handling of complaint-related product;
f) determining the need to initiate corrections or corrective actions.

Any correction or corrective action resulting from the complaint handling process were documented.
If an investigation determines activities outside the organization contributed to the complaint, relevant information were exchanged between the organization and the external party involved.
Complaint handling records were maintained.
The nonconformities identified were adequately addressed through a CAPA process.

8.2.3 Reporting to regulatory authorities

If applicable regulatory requirements required notification of complaints that met specified reporting criteria of adverse events or issuance of advisory notices, the organization did document procedures for providing notification to the appropriate regulatory authorities. Records of reporting to regulatory authorities were maintained.

8.2.6 Monitoring and measurement of product

The organization did monitor and measure the characteristics of the product to verify that product requirements had been met. This were carried out at applicable stages of the product realization process in accordance with the planned and documented arrangements and documented procedures.
Evidence of conformity to the acceptance criteria were maintained. The identity of the person authorizing release of product were recorded. As appropriate, records did identify the test equipment used to perform measurement activities.
Product release and service delivery did not proceed until the planned and documented arrangements had been satisfactorily completed.
The nonconformities identified were adequately addressed through a CAPA process.

8.3 Control of nonconforming product

8.3.3 Actions in response to nonconforming product detected after delivery

When nonconforming product was detected after delivery or use has started, the organization did take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken were maintained.
The organization did document procedures for issuing advisory notices. Records of actions relating to the issuance of advisory notices were maintained.
The nonconformities identified were adequately addressed through a CAPA process.

8.4 Analysis of data

The organization did document procedures to determine, collect and analyse data to demonstrate the suitability, adequacy and effectiveness of the quality management system.
The analysis of data did include data generated as a result of monitoring and measurement and from other relevant sources and included input from conformity to product requirements.
Records of the results of analyses were maintained.
The nonconformities identified were adequately addressed 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, ***Abbott Diagnostics Korea Inc.*** located at ***65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do, Republic of Korea*** 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.