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. (formerly Standard Diagnostics, Inc.)
Address/es of inspected manufacturing site/s	• Hagal site: 65, Borahagal-ro, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea • Bora site: 46, Hagal-ro 15beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, Republic of Korea • Warehouse: 48, Dongtanmullyu-ro, Hwaseong-si, Gyeonggi-do 18465, Republic of Korea
Inspection details	
Start of inspection	10/05/2023
Inspection duration (in inspector days)	6
Type of inspection	Re-inspection
Introduction	
Brief description of manufacturing activities conducted at the site/s inspected	The Hagal site hosts production and QC activities for urine strips, ELISAs, and semi-finished products. The Bora site hosts the R&D center, the QA, QC, and RA departments, as well the production of reagents, and the assembly and packing of finished products. The warehouse hosts the logistics and materials departments.
General information about the organization	Abbott Diagnostics Korea Inc. was founded as Standard Diagnostics, Inc. in 1999. In 2010, it was acquired by Alere and extended to new facilities. In October 2017, it was acquired by Abbott and, on 12 July 2019, changed its legal entity name to Abbott Diagnostics Korea Inc. Abbott Diagnostics Korea Inc. aims to be the leading manufacturer of infectious diseases lateral flow tests and contribute to global healthcare industry.
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 HBsAg WB (formerly SD BIOLINE HBsAg WB) - PQDx 0219-012-00 • Bioline HCV (formerly SD BIOLINE HCV) - PQDx 0257-012-00 • 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 • Bioline HIV1/2 3.0 (formerly SD BIOLINE HIV-1/2 3.0) - PQDx 0027-012-00 • Bioline Malaria Ag P.f/Pan (formerly SD BIOLINE Malaria Ag P.f/Pan) - PQDx 0030-012-00 • Bioline Malaria Ag P.f (formerly SD BIOLINE Malaria Ag P.f) - - PQDx 0031-012-00 • NxTek Eliminate Malaria Ag P.f (formely Alere Malaria Ag P.f) - PQDx 0349-012-00 • Bioline HIV/Syphilis Duo (formerly SD BIOLINE HIV/Syphilis Duo) - PQDx 0179-012-00 • 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.
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 organization`s Quality Manual adequately addressed and reflected the intended practices of the laboratory. The non-conformities identified were successfully addressed by 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. The document control system had been implemented to manage QMS documentation, including procedures, work instruction, records, CAPAs, 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 non-conformity identified was successfully addressed by a CAPA process.

5. Management responsibility

5.5. Responsibility, authority and communication

5.5.1. Responsibility and authority

Responsibilities and authorities were defined, documented, and communicated within the organization. The interrelation of all personnel who managed, performed, and verified work affecting quality were documented and ensured the independence and authority necessary to perform these tasks.

5.5.2. Management representative

Mr TJ Lee, Head of the Quality Department, was the management representative. Their responsibility and authority included ensuring that processes needed for the quality management system are

documented; reporting to top management on the effectiveness of the quality management system and any need for improvement; and ensuring the promotion of awareness of applicable regulatory requirements and quality management system requirements throughout the organization.

5.6. Management review

5.6.1. General

The organization had an established process for regular management reviews that appeared to meet the requirements of the standard. 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. The nonconformity identified was successfully addressed by a CAPA process.

5.6.2. Review input

The input to management review included feedback, complaint handling, reporting to regulatory authorities, audits, monitoring and measurement of processes and product,corrective and preventive actions, changes that could affect the QMS, recommendations for improvement, and applicable new or revised regulatory requirements. The non-conformity identified was successfully addressed by a CAPA process.

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 quality management system 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 ensured the QMS was implemented, and its effectiveness maintained, and that applicable regulatory and customer requirements were met (notwithstanding the nonconformities identified during the inspection).

6.2. Human resources

The facility was staffed with personnel who had the necessary education, training, technical knowledge, and experience for their assigned functions. Staff questioned were open and forthcoming with information. The organization had established a training procedure. Training files for staff were maintained and available for review during the inspection. The non-conformity identified was successfully addressed by 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, orderly, and clearly sign-posted. The non-conformities identified were successfully addressed by a CAPA process.

6.4. Work environment and contamination control

6.4.1. Work environment

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 that were provided. There were pictorials when entering an area on the gowning requirements. A mirror was available to ensure appropriate PPE was properly downed.

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 organization had documented a procedure for risk management that involved a risk assessment committee that included medical expertise if and when needed. The non-conformity identified was successfully addressed by a CAPA process.

7.2. Customer-related processes

7.2.1. Determination of requirements related to product

The organization had determined the requirements for post-delivery activities, as well as the applicable regulatory requirements related to the product.

7.2.3. Communication

The organization was collecting customer feedback via different means, including some appropriate to resource-constrained settings. Where relevant, advisory notices, recalls, and other communication with customers were documented.

7.4. Purchasing

7.4.1. Purchasing process

The organization had an established and 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. The non-conformities identified were successfully addressed by a CAPA process.

7.4.2. Purchasing information

The quality agreements with relevant suppliers of materials and services reviewed indicated that the supplier must 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.

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 risks associated with the purchased product. Records of these activities were maintained.

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 and records were verified and approved. The non-conformity identified was successfully addressed by 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 qualification of equipment and personnel; the use of specific methods, procedures, and acceptance criteria; the criteria for revalidation; and the approval of changes to the processes. The non-conformities identified were successfully addressed by a CAPA process.

7.5.8. Identification

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

7.5.11. Preservation of product

There was a documented 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. Retained samples were kept in their final packaging. The non-conformities identified were successfully addressed by 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, against measurement standards; and had identification indicating its calibration status. Calibration records were available, and a sample was reviewed.

8. Measurement, analysis and improvement

8.1. General

The organization planned the monitoring, measurement, analysis and improvement processes needed to demonstrate conformity of the product, ensure conformity and maintain the effectiveness of the QMS. The non-conformity identified was successfully addressed by a CAPA process.

8.2. Monitoring and measurement

8.2.1. Feedback

The organization had procedures in place to gather and monitor information relating to whether the organization has met customer requirements. Data were gathered from production as well as post-production activities.

8.2.2. Complaint handling

The organization had implemented a procedure for the 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.

8.2.3. Reporting to regulatory authorities

The organization had documented procedures for providing notification of adverse events or issuance of advisory notices to the WHO. Records of reporting to the WHO were maintained.

8.2.4. Internal audits

The organization had implemented an internal audit program and was conducting internal audits at planned intervals. The audit program was planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval, and methods were defined and recorded. Auditors were selected to ensure objectivity and impartiality of the audit process. Auditors did not audit their own work. The non-conformities identified were successfully addressed by a CAPA process.

8.2.6. Monitoring and measurement of product

The organization had implemented procedures to monitor and measure the characteristics of the product to verify that product requirements had been met. This was carried out at applicable stages of the product realization process. Evidence of conformity to the acceptance criteria were maintained. The identity of the person authorizing release of product was recorded. Product release did not proceed until the planned and documented arrangements had been satisfactorily completed. The non-conformities identified were successfully addressed by a CAPA process.

8.3. Control of nonconforming product

8.3.1. General

The organization 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. The non-conformity identified was successfully addressed by a CAPA process.

8.4. Analysis of data

The organization had documented procedures to 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.

8.5. Improvement

8.5.2. Corrective action

The organization had procedures in place to take action to eliminate the cause of nonconformities to prevent recurrence. Any necessary corrective actions were to be taken without undue delay. Records of investigation and actions taken were maintained.

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. Records of investigation and actions taken were maintained.

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 ***46, Hagal-ro 15beon-gil, Giheung-gu, Yongin-si, Gyeonggi-do 17099, 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.