

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

<b>Inspected site/s</b>	
Name of Organization	AB Diagnostic Systems GmbH
Address/es of inspected manufacturing site/s	Sportfliegerstrasse 4 12487 Berlin Germany
<b>Inspection details</b>	
Start of inspection	02/04/2025
Inspection duration (in inspector days)	6
Type of inspection	Re-inspection
<b>Introduction</b>	
Brief description of manufacturing activities conducted at the site/s inspected	Purchasing, production, preservation, quality control.
General information about the organization	AB Diagnostic Systems GmbH is a contract manufacturer and critical supplier for RPC Diagnostic Systems, one of the Russian leaders in the field of immunodiagnostic tests production. RPC Diagnostic Systems is the legal manufacturer of the products in scope.
<b>Brief report of inspection activities undertaken – Scope and limitations</b>	
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	PQDx 0106-038-00: DS-EIA-HIV-AGAB-SCREEN PQDx 0120-038-00: DS-EIA-HBsAg-0,01 PQDx 12448-038-00: DS-EIA-ANTI-HCV
Criteria	<ul style="list-style-type: none"> <li>• All applicable clauses of ISO 13485:2016</li> <li>• WHO PQ requirements</li> <li>• Organization's own requirements</li> </ul>
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.

<b>Abbreviations</b>	<b>Meaning</b>
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**

### **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.

##### **4.2.4 Control of documents**

Documents required by the QMS were controlled. Records were a special type of document and were controlled according to the requirements given in Clause 4.2.5.

A documented procedure did define the controls needed to:

- a) review and approve documents for adequacy prior to issue;
- b) review, update as necessary and re-approve documents;
- e) ensure that documents remain legible and readily identifiable;
- g) prevent deterioration or loss of documents;

The organization did ensure that changes to documents were reviewed and approved either by the original approving function or another designated function that has access to pertinent background information upon which to base its decisions.

The organization did define the period for which at least one copy of obsolete documents was retained. This period did ensure that documents to which medical devices had been manufactured and tested were available for at least the lifetime of the medical device as defined by the organization, but not less than the retention period of any resulting record, or as specified by applicable regulatory requirements. The nonconformities identified were successfully addressed through a CAPA process.

#### ***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 nonconformities identified were successfully 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.

### **5.5 Responsibility, authority and communication**

#### ***5.5.1 Responsibility and authority***

Top management did ensure that responsibilities and authorities were defined, documented and communicated within the organization.

Top management did document the interrelation of all personnel who manage, perform and verify work affecting quality and did ensure the independence and authority necessary to perform these tasks.

### **5.6 Management review**

#### ***5.6.1 General***

The organization did document procedures for management review. Top management did review the organization's quality management system at documented planned intervals to ensure its continuing suitability, adequacy and effectiveness. The review did include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Records from management reviews were maintained.

The nonconformities identified were successfully addressed through a CAPA process.

### **5.6.2 Review input**

The input to management review did include, but was not limited to, information arising from:

- a) feedback;
- b) complaint handling;
- c) reporting to regulatory authorities;
- d) audits;
- e) monitoring and measurement of processes;
- f) monitoring and measurement of product;
- g) corrective action;
- h) preventive action;
- i) follow-up actions from previous management reviews;
- j) changes that could affect the quality management system;
- k) recommendations for improvement;
- l) applicable new or revised regulatory requirements.

### **5.6.3 Review output**

The output from management review was recorded and included the input reviewed and any decisions and actions related to:

- a) improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes;
- b) improvement of product related to customer requirements;
- c) changes needed to respond to applicable new or revised regulatory requirements;
- d) resource needs.

## **6 Resource management**

### **6.2 Human resources**

Personnel performing work affecting product quality were competent on the basis of appropriate education, training, skills and experience.

The organization did document the process(es) for establishing competence, providing needed training, and ensuring awareness of personnel.

The organization did:

- a) determine the necessary competence for personnel performing work affecting product quality;
- b) provide training or take other actions to achieve the necessary competence;
- c) evaluate the effectiveness of the actions taken;
- d) ensure that its personnel were aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives;
- e) maintain appropriate records of education, training, skills and experience.

The nonconformities identified were successfully addressed through a CAPA process.

### **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 nonconformities identified were successfully addressed through a CAPA process.

### **6.4 Work environment and contamination control**

#### ***6.4.1 Work environment***

The organization did document the requirements for the work environment needed to achieve conformity to product requirements.

If the conditions for the work environment could have an adverse effect on product quality, the organization did document the requirements for the work environment and the procedures to monitor and control the work environment.

The nonconformities identified were successfully addressed through a CAPA process.

## **7 Product realization**

### **7.1 Planning of product realization**

The organization did plan and develop the processes needed for product realization. Planning of product realization was consistent with the requirements of the other processes of the quality management system.

The organization did document one or more processes for risk management in product realization. Records of risk management activities were maintained.

The nonconformities identified were successfully addressed through a CAPA process.

### **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 established criteria for suppliers' evaluation and selection

a) based on the supplier's ability to provide product that meets the organization's requirements;

- c) based on the effect of the purchased product on the quality of 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.

The nonconformities identified were successfully 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.

Records of the verification were maintained.

The nonconformities identified were successfully addressed through a CAPA process.

## **7.5 Production and service provision**

### ***7.5.1 Control of production and service provision***

Production and service provision were planned, carried out, monitored and controlled to ensure that product conforms to specification. Production controls did include but were not limited to:

- a) documentation of procedures and methods for the control of production;
  - b) qualification of infrastructure;
  - c) implementation of monitoring and measurement of process parameters and product characteristics;
- The organization did establish and maintain a record for each medical device or batch of medical devices that provided traceability to the extent specified in Clause 7.5.9 and identified the amount manufactured and amount approved for distribution. The record was verified and approved. The nonconformities identified were successfully addressed through a CAPA process.

### ***7.5.6 Validation of processes for production and service provision***

The organization did validate processes for production and service provision where the resulting output cannot be or was not verified by subsequent monitoring or measurement and, as a consequence, deficiencies become apparent only after the product was in use or the service had been delivered. Validation did demonstrate the ability of these processes to achieve planned results consistently. The nonconformities identified were successfully addressed through a CAPA process.

### ***7.5.8 Identification***

The organization did document procedures for product identification and identify product by suitable means throughout product realization.

The organization did identify product status with respect to monitoring and measurement requirements throughout product realization. Identification of product status was maintained throughout production, storage, installation and servicing of product to ensure that only product that had passed the required inspections and tests or released under an authorized concession was dispatched, used or installed.

### ***7.5.9 Traceability***

#### ***7.5.9.1 General***

The organization did document procedures for traceability. These procedures did define the extent of traceability in accordance with applicable regulatory requirements and the records to be maintained. The nonconformities identified were successfully addressed through a CAPA process.

### ***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. If special conditions were required, they were controlled and recorded. The nonconformities identified were successfully addressed through a CAPA process.

## **7.6 Control of monitoring and measuring equipment**

The organization did determine the monitoring and measurement to be undertaken and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements.

The organization did document procedures to ensure that monitoring and measurement could be carried out and were carried out in a manner that was consistent with the monitoring and measurement requirements.

The organization did perform calibration or verification in accordance with documented procedures.

Records of the results of calibration and verification were maintained.

The nonconformities identified were successfully addressed through a CAPA process.

## **8 Measurement, analysis and improvement**

### **8.1 General**

The organization did plan and implement the monitoring, measurement, analysis and improvement processes needed to:

- a) demonstrate conformity of product;
- b) ensure conformity of the quality management system;
- c) maintain the effectiveness of the quality management system.

#### ***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 was 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 was maintained. The identity of the person authorizing release of product was recorded. As appropriate, records did identify the test equipment used to perform measurement activities.

### **8.3 Control of nonconforming product**

#### ***8.3.1 General***

The organization did ensure that product which did not conform to product requirements was identified and controlled to prevent its unintended use or delivery. The organization did document a procedure to define the controls and related responsibilities and authorities for the identification, documentation, evaluation and disposition of nonconforming product.

The nonconformities identified were successfully addressed through a CAPA process.

### **8.4 Analysis of data**

The organization did document procedures to determine, collect and analyse appropriate 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 include, at a minimum, input from:

- a) feedback;
- b) conformity to product requirements;
- c) characteristics and trends of processes and product, including opportunities for improvement;
- d) suppliers;
- e) audits;
- f) service reports, as appropriate.

Records of the results of analyses were maintained.

The nonconformities identified were successfully 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, **AB Diagnostic System GmbH** located at **Sportfliegerstrasse 4, 12487 Berlin, Germany** 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/](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.