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	InTec Products, Inc.
Address/es of inspected manufacturing site/s	308-8 & 51 Wengjiao Road, Xinyang Industrial Area, Haicang Fujian Province Xiamen 361022 China
Inspection details	
Start of inspection	17/03/2025
Inspection duration	6 inspector-days
Type of inspection	Re-inspection
Introduction	
Brief description of manufacturing activities conducted at the site/s inspected	Design and development, Production (including purchasing and quality control), Preservation, Regulatory Affairs
General information about the organization	InTec Products, Inc. was founded in 1989 by Ms Dr Wang Kaihua. The product portfolio includes ELISA tests and IVDs for infectious diseases.
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	PQDx 0627-017-00 ONE STEP Malaria (Pf/Pv) Tri-line Test PQDx 0371-017-00 Rapid Anti-HCV Test PQDx 0372-017-00 ONE STEP Anti-HIV (1&2) Test PQDx 0626-017-00 ONE STEP Malaria (Pf) Test PQDX 0372-017-01 Advanced Quality HIV Self Test
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
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

4.2.2 Quality manual

The organization did document a quality manual that included:

a) the scope of the QMS, 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 QMS.

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

The nonconformities identified were successfully addressed through a CAPA process.

4.2.4 Control of documents

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

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 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.

5.5.2 Management representative

Top management did appoint a member of management who, irrespective of other responsibilities, had responsibility and authority that included:

a) ensuring that processes needed for the quality management system were documented;
b) reporting to top management on the effectiveness of the quality management system and any need for improvement;
c) 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 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.

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 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 did establish criteria for the evaluation and selection of suppliers. The criteria were:

a) based on the supplier's ability to provide product that met requirements;
b) based on the performance of the supplier;
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.
The nonconformities identified were successfully addressed through a CAPA process.

7.4.2 Purchasing information

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. The organization did maintain relevant purchasing information in the form of documents and records.

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.

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. The organization did establish and maintain a record for each medical device or batch of medical devices that provided traceability 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 any 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.

7.5.9 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.

8 Measurement, analysis and improvement

8.2 Monitoring and measurement

8.2.1 Feedback

As one of the measurements of the effectiveness of the quality management system, the organization did gather and monitor information relating to whether the organization had met customer requirements. The methods for obtaining and using this information were documented.
The organization did document procedures for the feedback process

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.

Complaint handling records were maintained.
The nonconformities identified were successfully addressed through a CAPA process.

8.2.3 Reporting to regulatory authorities

If applicable regulatory requirements require notification of complaints that meet 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.

8.2.4 Internal audit

The organization did conduct internal audits at planned intervals to determine whether the quality management system:

a) conforms to planned and documented arrangements, requirements of the Standard, quality management system requirements established by the organization, and applicable regulatory requirements;
b) was effectively implemented and maintained.

The organization did document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.

An audit program were planned, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods were defined and recorded. The selection of auditors and conduct of audits did ensure objectivity and impartiality of the audit process. Auditors did not audit their own work.
Records of the audits and their results, including identification of the processes and areas audited and the conclusions, 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 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, segregation, evaluation and disposition of nonconforming product.
Records of the nature of the nonconformities and any subsequent action taken, including the evaluation, any investigation and the rationale for decisions were maintained.

8.3.2 Actions in response to nonconforming product detected before delivery

The organization did deal with nonconforming product by one or more of the following ways:

a) taking action to eliminate the detected nonconformity;
b) taking action to preclude its original intended use or application;
c) authorizing its use, release or acceptance under concession.

8.3.3 Actions in response to nonconforming product detected after delivery

When nonconforming product was detected after delivery or use had started, the organization did take action appropriate to the effects, or potential effects, of the nonconformity. Records of actions taken were maintained.
The nonconformities identified were successfully addressed through a CAPA process.

8.5 Improvement

8.5.2 Corrective action

The organization did take action to eliminate the cause of nonconformities in order to prevent recurrence. Any necessary corrective actions were taken without undue delay.
Records of the results of any investigation and of action taken 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, ***InTec Products, Inc.*** located at ***308-8 & 51 Wengjiao Road, Xinyang Industrial Area, Haicang, Fujian Province, Xiamen 361022, China*** 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.