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	Pacific Biotech Co., Ltd.
Address/es of inspected manufacturing site/s	42 Moo 4, Petchaboon-Chalianglub Road, Napa, Muang Petchaboon 67000 Thailand
Inspection details	
Start of inspection	13/01/2025
Inspection duration	4 inspector-days
Type of inspection	Re-inspection
Introduction	
Brief description of manufacturing activities conducted at the site/s inspected	Purchasing, Production, Monitoring and Measurement, and Preservation of the products in scope.
General information about the organization	The site is manufacturing the products in scope for OraSure Technologies, Inc., a US-based company. Pacific Biotech CO. LTD is an affiliate of BRIA that manufactures a range of rapid test kits. It has multiple manufacturing sites in Thailand.
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 0244-055-00 - OraQuick Hepatitis C Self-Test PQDx 0159-055-00 - OraQuick HIV 1/2 Rapid Antibody Test PQDx 0159-055-01 - Oraquick 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
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

4.2.2 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 QMS.

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

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.

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;

c) ensure that the current revision status of and changes to documents were identified;

d) ensure that relevant versions of applicable documents were available at points of use;

e) ensure that documents remain legible and readily identifiable;

f) ensure that documents of external origin, determined by the organization to be necessary for the planning and operation of the quality management system, were identified and their distribution controlled;

g) prevent deterioration or loss of documents;

h) prevent the unintended use of obsolete documents and apply suitable identification to them.

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 resolved 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.

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

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.

The nonconformities identified were successfully resolved 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 resolved 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 resolved through a CAPA process.

7.4 Purchasing

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. 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;
d) availability and use of monitoring and measuring equipment;
e) implementation of defined operations for labelling and packaging;
f) implementation of product release, delivery and post-delivery activities.
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 resolved 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.
The nonconformities identified were successfully resolved 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 and storage 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.
The nonconformities identified were successfully resolved 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, and handling. 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 resolved through a CAPA process.

8 Measurement, analysis and improvement

8.2 Monitoring and measurement

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.
The nonconformities identified were successfully resolved through a CAPA process.
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.

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, ***Pacific Biotech Co., Ltd.*** located at ***42 Moo 4, Petchaboon-Chalianglub Road, Napa, Muang, Petchaboon 67000, Thailand*** 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.