World Health Organization

20, AVENUE APPIA – CH-1211 GENEVA 27 – SWITZERLAND – TEL CENTRAL +41 22 791 2111 – FAX CENTRAL +41 22 791 3111 – WWW.WHO.INT

Prequalification Team Inspection Services

WHO PUBLIC INSPECTION REPORT (WHOPIR)

Desk Assessment of In Vitro Diagnostic Product Manufacturer

Part 1	**General information**	
Manufacturers information		
Name and address of manufacturer	ACON Biotech (Hangzhou) Co., Ltd. No.2 Qiancheng Road of Fengdu Village Pingyao Town Yuhang District Hangzhou, 311115 China	
Desk assessment details		
Dates of inspection	25 October 2024	
Type of inspection	Initial	
Products covered by this desk assessment	PQDx 12343-021-00 "Flowflex SARS-CoV-2 Antigen Rapid Test (Self-Testing)"	
List of documents submitted	MDSAP Audit Report SH2310605 CAPAs BC-24006/7/8/9/10 Audit Finding List Site information	
Any documents missing?	No	
Part 2	**Summary of inspection evidence considered**	
Tuv Sud America Inc, for MDSAP	Dates of inspection:	29-31 January 2024
	Type of inspection:	Initial - Onsite
	Products covered:	The COVID-19 Self-Test product in scope of this desk assessment was covered in this MDSAP inspection that pertained to IVD test kits and reagents for the detection of infectious diseases.

Part 3	Summary of the last WHO inspection
Date and conclusion of most recent WHO inspection	N/A. Initial inspection.
Brief description of the manufacturing activities	Warehousing
Areas inspected during the last WHO inspection	N/A. Initial inspection
Out of scope and restrictions (last WHO inspection)	N/A. Initial inspection
WHO product(s) covered by the last WHO inspection	N/A. Initial inspection
Additional product(s) to be covered by this desk assessment	N/A. Initial inspection
General information about the company and site	ACON Biotech (Hangzhou) Co., Ltd. was founded in 1995. It provides a broad range of medical diagnostic and healthcare products, including lateral flow devices. ACON strives to make better clinical outcomes accessible to patients around the globe through the development of innovative products.

Part 4	Brief summary of the findings and comments

1. Quality Manual:

The manufacturer had implemented a quality manual set out in accordance with ISO 13485:2016 with references to other international laws and regulations. Endorsement from top management on the effectiveness and maintenance of the QMS was available within the manual with top management being committed to the development and continual improvement of the QMS. Roles and responsibilities were clearly defined. There was reference within the manual to the Medical Device file. The Quality Manual described the company's quality policy, quality objective and the processes of QMS as well as the interrelationship between them. It was the responsibility of each department to establish and monitor and measure quality objectives that were in line with the manufacturer's objectives. The quality control and Manufacture/Technical departments were independent of each other with different reporting lines.

2. List of current quality management procedures:

The Documents Distribution Control List contained the document number, responsible department, document name, version and effective date.

3. Standard operating procedures for:

i. Compliant handling and vigilance:

The Customer Complaint Procedure described the complaint process and when complaints were notifiable to governing agencies, including the process for notifying WHO of any complaints received that involved a WHO prequalified product. The Vigilance System procedure contained extracts from the WHO "Guidance for Post-market Surveillance of In Vitro Diagnostics" document with reporting timelines clearly identified.

ii. Control of nonconforming goods/processes:

The Nonconforming Product Control Procedure described the segregation of nonconforming or OOS product/material. Investigation was initiated by the QA department. For high level nonconformities, an investigation was to the completed within 10 working days.

iii. Risk management:

Risk management files were created for all medical devices and the full life cycle of the product was considered. The manufacturer had also considered the benefit-risk. If the risk could not be reduced, a benefit risk analysis would have to demonstrate that the medical benefits outweighed the residual risks. Once the evidence supported this conclusion and the medical benefit outweigh the overall residual risk, the overall residual risk could be judged acceptable. The procedure was detailed and met the requirements of the standards (ISO 13485:2016 and ISO 14971:2019).

iv. Supplier evaluation and control, verification of purchased product:

Suppliers were classified according to the risk of the material supplied and if they were directly related to the performance of the product and internal quality. An initial audit was conducted for class A suppliers (highest risk), and annual evaluation was performed including annual on-site audits. For lesser risk suppliers, annual evaluation was performed that involved review of quality, price, delivery time, service performance, etc. If the quality score was below 60% of the full quality score, the supplier would be notified and would be required to submit a written report within 30 days of how the deficiency would be corrected. The supplier would be cancelled if they failed. Annual review of approved suppliers was documented within the Purchasing Control Procedure.

4. Audit report of the most recent full regulatory audit and all subsequent surveillance audits:

A copy of the MDSAP Audit Report SH2310605 following an onsite inspection performed from the 29th to the 31st of January 2024 was provided and reviewed. Responses to the nonconformities identified were accepted on the 29th of February 2024.

Part 5	Conclusion – Inspection outcome

Based on the evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***ACON Biotech (Hangzhou) Co., Ltd located at No.2 Qiancheng Road of Fengdu Village, Pingyao Town, Yuhang District, Hangzhou, 311115, China*** is considered to be operating at an acceptable level of compliance with ISO 13485: 2016 and WHO *Information for Manufacturers on Prequalification Inspection Procedures for the Sites of Manufacture of Diagnostics* (PQDx_014).

This WHOPIR will remain valid until the 31st of January 2027 (i.e., 3 years after the MDSAP report reviewed), provided that the outcome of any inspection conducted during this period is positive.

Part 6	List of Standards and 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 - ISO14971:2007

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.