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)
In vitro Medical Devices

Part 1	**General information**
Inspected laboratory details	
Name of Manufacturer	AccuBio Ltd
Address of inspected manufacturing site	Unit 1-12 Hillfoots Business Village, Alva, FK 12 5DQ, United Kingdom
Inspection details	
Dates of inspection	24-25 April 2023
Type of inspection	On-site Follow-up inspection
Introduction	
Brief description of manufacturing activities	The facility was responsible for design and development, production (sub-assembly and final device assembly), and final release of the product.
General information about the manufacturer	Omega Diagnostics Ltd was founded in 1987 and manufactures a wide range of immunoassay products, in three segments: Allergy and autoimmune diseases, Food intolerance, and Infectious disease. In early 2022, Omega Diagnostics Ltd (Alva site) went into a business venture with AccuBio Ltd., with the infectious disease division now operating under the AccuBio Ltd license.
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Production Warehouse Quality Control Laboratory
Restrictions	Nil
Out of scope	Nil
WHO prequalified /submitted products covered by the inspection	PQDx 0384-077-00 VISITECT CD4 Advance Disease
Abbreviations	**Meaning**
CoA	Certificate of analysis
IQ	Installation qualification
IVD	In-vitro medical device
MR	Management review
MSDS	Material safety data sheet
NC	Non conformity
PPE	Personal protective equipment
OOS	Out-of-specifications test result

OQ	Operational qualification
PM	Preventive maintenance
PQ	Performance qualification
PW	Purified water
QA	Quality assurance
QC	Quality control
QCL	Quality control laboratory
QMS	Quality management system
QRM	Quality risk management
RA	Risk assessment
RCA	Root cause analysis
SOP	Standard operating procedure

Part 2	**Summary of the findings and comments**

1. Quality management system:

1.1. General requirements

The organization and management structure of the facility were clearly documented and defined within the organisational chart. Roles and responsibilities were available with the overall reporting structure available with clear delineation for the release of the product.

There were no outsourcing processes occurring at the site.

1.2. Documentation requirements

1.2.1. Quality manual and Management Commitment

The manufacturer`s Quality Manual adequately addressed and reflected the intended practices of the laboratory, with a clear commitment from top management for the continual improvement and support of the QMS.

1.2.2. Medical device file

The manufacturer had a Medical Device file available for the above-listed product.

1.2.3. Control of documents and records

Although at the time of the inspection, the manufacturer was still in the transitional stages of the acquisition and there were a number of documents that still reflected the Omega logo. Staff were well aware of the transition and were able to locate documents in a timely manner. The manufacturer had recently upgraded their document management system (Q-Pulse 7) since the previous WHO inspection. The upgrade provided the manufacturer with more flexibility and control over their process.

2. Management responsibility

2.1. Quality policy

Top management had an established Quality Policy. The inspectors verified that the manufacturer had established processes that mostly met the requirements of ISO 13485:2016 (the standard) and other applicable regulations (notwithstanding the nonconformities identified during this inspection).

2.2. Management review

2.2.1. General

The manufacturer had an established process for regular management reviews that met the requirements of the standard. The inspection team were able to verify review inputs and outputs, complaint communication with top management and trending of monitoring and measurement processes and product.

3. Resource management

3.1. Provision of resources

During the initial acquisition between Omega Diagnostics Ltd and AccuBio Ltd, additional resources were on hold. However, at the time of inspection, this had been lifted and all required resources, including personnel, were in the process of being filled.

3.2. 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, there was a willingness to learn and were open to exploring new ideas.

The manufacturer had an established and well-documented training procedure, including refresher training for staff. Training files for staff were maintained and available for review during the inspection.

3.3. 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. The facility was well maintained, clean and orderly and clearly signposted. The Pest control management procedure was available.

3.4. Work environment and contamination control

3.4.1. Work environment

All rooms were temperature and humidity monitored with recordings available. In general, all staff observed were wearing appropriate PPE, with access to appropriate coats, shoes, masks, and hair nets that were provided and laundered by the manufacturer. There were pictorials when entering an area on the gowning requirements. A mirror was available to ensure hair was secured. The use of shoe covers when entering the production areas were required and were available.

3.4.2. Contamination control

A procedure for the cleaning of the facility was available. Cleaning validations were available.

4. Product realization

4.1. Planning of product realization

The manufacturer’s approach to the control and planning of production and service provision was adequately documented in the QMS, with procedures for document management, risk management, product production, material verification, process validation, monitoring, inspection, and test activities, incorporating an adequate device master record.

4.2. Design and development

4.2.1. General

The manufacturer had an established process for design and development. This was not reviewed at this inspection as the product was prequalified in 2021 and reviewed in detail at the initial inspection.

4.3. Purchasing

4.3.1. Purchasing process

The manufacturer had an established and well-documented process for the purchasing of materials, that included a traceable inventory, release, and verification of all 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 had been revised and clarity relating to requirements and the process was available.

4.3.2. Control of design and development changes

The manufacturer had an established and well-documented procedure for the control of design and development that incorporated informing WHO of such changes as per the WHO requirements. At the time of inspection, there had been no changes to the design of the product.

4.4. Production and service provision

4.4.1. Control of production and service provision

The manufacturer had a documented process for the control of production that included but was not limited to the qualification of infrastructure and monitoring and measuring equipment. Temperature mapping was performed, and reports were available. All maintenance tasks, equipment registers, and scheduling were available within the Q-pulse system. Designated staff were responsible for the maintenance of equipment.

4.4.2. 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.

4.4.3. Preservation of product

There was a well-established procedure for the preservation of the product that ensured that the product was shipped with suitable shipping containers and maintained at the appropriate temperature throughout the process.

4.5. Control of monitoring and measuring equipment

The manufacturer had a well-documented system for the calibration, maintenance, and use of equipment with individual procedures available for all equipment. Regular maintenance and calibration of equipment were performed.

5. Measurement, analysis and improvement

5.1. Monitoring and measurement

5.1.1. Feedback

The manufacturer had a procedure for assessing and reporting to WHO the safety and performance throughout the lifecycle of the product. The procedure for post-market surveillance had been revised and continued to meet the WHO requirements. The PMS plan was available.

Marketing of the product was conducted by a Global Salesforce team with Product managers and Sales directors appointed as appropriate and required.

Notification of the change in the legal manufacturer was underway with a detailed and documented procedure to communicate with customers, including a leaflet in the kit. The only change to the labelling was to the logo and legal manufacturer details. Notification of the change in legal manufacture to the country was underway. Difficulties were expected as some countries were slow in acknowledging this and had to approve the product although no change to the actual product was planned. There was concern that would delay the product from being distributed into the country.

5.1.2. Complaint handling

The manufacturer had a well-established procedure for customer complaints that included monthly trending of complaints and post-market surveillance. Reporting to regulatory authorities was available.

5.1.3. Internal audits

The manufacturer had implemented an internal audit program including documented requirements. This document described the requirements for independent auditors. Training records were reviewed and found appropriate. All nonconformities identified were captured as corrective actions and were followed using the manufacturer`s CAPA process.

5.1.4. Monitoring and measurement of processes and product

Trending and regular review of monitoring and measurement of processes and products were verified at the time of inspection. Detailed reports were available for the management review meetings and other relevant meetings.

5.2. Control of nonconforming product

5.2.1. General

The manufacturer had a process in place for the segregation of nonconforming products that met the requirement of the standard. There was clear labelling and traceability of nonconforming products throughout the various stages of production, and post-delivery.

5.3. Improvement

5.3.1. General

Handling and disposition of non-conformity events, as well as a related CAPA plan, took place in accordance with the procedure. All CAPAs were controlled within Q-Pulse with responsible personnel, action, and completion dates, with regular review of implementation.

Part 3	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, ***AccuBio Ltd,*** located at ***Unit 1-12 Hillfoots Business Village, Alva, FK 12 5DQ, United Kingdom*** was considered to be operating at an acceptable level of compliance with WHO GPPQCL Guidelines.

All the non-compliances observed during the inspection that were listed in the full report as well as those reflected in the WHOPIR, were addressed by the manufacturer, to a satisfactory level, prior to the publication of the WHOPIR

This WHOPIR will remain valid for 3 years, provided that the outcome of any inspection conducted during this period is positive.

Part 5	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. ISO 9001:2015 Quality management systems - Requirements

4. WHO Post-market surveillance of in vitro diagnostics 2015 (ISBN 978 92 4 150921 3)

5. Medical devices - Application of risk management to medical devices - ISO14971:2007

6. GHTF/SG3/N19:2012 “Quality management system – Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange”

7. GHTF/SG4/(99)28 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 1: General Requirements

8. GHTF/SG4/N30R20:2006 'Guidelines for Regulatory Auditing of Quality Systems of Medical Device Manufacturers - Part 2: Regulatory Auditing Strategy

9. 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