World Health Organization

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WHO Prequalification Team - Inspection services

WHO PUBLIC INSPECTION REPORT (WHOPIR)

In vitro Diagnostic product

Inspected site	
Name of Manufacturer	bioLytical Laboratories Inc
Address of inspected manufacturing site	Head Quarters: 406-13251 Delf Place Richmond, BC, V6V 2A2 Canada Latitude/Longitude: 49.181243, –123.076699
Inspection details	
Dates of inspection	31 December 2025 – 7 January 2026
Type of inspection	Desk Assessment
Introduction	
Brief description of manufacturing activities	bioLytical Laboratories, Inc. headquarters was responsible for the Design and development, manufacturing, and distribution of near patient in-vitro diagnostic medical devices for HIV, Syphilis, HCV, HBsAg, Multiplex HIV/Syphilis, SARS-COV-2 and in-vitro medical devices for self-test used as an aid in the diagnosis of HIV and SARS COV-2 status. Activities at the site also included management review, document and record control, human resources, customer support and complaint handling as well as CAPA. At the additional site located on Worster Court, manufacturing, QC raw material inspection, in process and finished products release, raw material storage, finished good storage and shipping were performed for the iStatis product line only.
General information about the manufacturer	bioLytical Laboratories Inc. ("bioLytical") is a medical device manufacturer engaged in the design, development, and commercialization of single-use rapid, flow through in vitro qualitative immunoassays used in the diagnosis of HIV, Hepatitis C (HCV), Hepatitis B (HBsAg), Syphilis infection, and for the detection of SARS-CoV-2 Nucleocapsid protein.
History	The site was previously inspected by WHO (April 2012, November 2016 and November 2022).
Brief report of inspection activities undertaken – Scope and limitations	
Areas inspected	Design and Development Quality management system Management responsibility Purchasing Production and Service Controls Measurement, analysis and improvement Adverse Events and Advisory Notices Reporting WHO pre-qualification-specific requirements

Scope	PQDx 0002-002-00 – INSTI HIV-1/HIV-2 Antibody Test (prequalified) PQDx 0002-002-01 - INSTI HIV Self Test (prequalified) PQDx 12634-002-00 - iStatis Syphilis Antibody Test (under assessment at the time of the desk assessment) PQDx 13489-002-00 - iStatis Hepatitis B Surface Antigen Test (under assessment at the time of the desk assessment)
Criteria	ISO 13485:2016 and WHO Prequalification specific requirements
Objective(s)	To assess the manufacturers compliant with the inspection criteria
Limitations	None
Abbreviations	**Meaning**
CoA	Certificate of analysis
IQ	Installation qualification
IVD	In vitro 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

Summary of the findings and comments

The inspection findings are listed below, following the numbering of the clauses of the ISO 13485:2016 standard for easy reference.

4. Quality management system

4.1 General requirements

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

4.2 Documentation requirements

4.2.1 General

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 was an established quality policy and quality objectives available. Procedures and records were available as per the requirements of the standard.

4.2.2. Quality manual

The organization's Quality Manual was updated regularly and continued to reflect the intended practices of the manufacturer. The quality manual described the interaction between the processes of the Quality Management System (QMS), it defined the structure of the documentation system and listed/excluded non-applicable clauses of ISO13485:2016 with appropriate justifications.

4.2.3. Medical device file

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

4.2.4. Control of documents

The procedures for document control were available that met the requirements of the standard.

4.2.5. Control of records

The procedures for document control of records were available that met the requirements of the standard.

5. Management responsibility

5.1. Management commitment

There was sufficient evidence to support claims that Top management were commitment to the development and implementation of the quality management system and maintenance of its effectiveness by communicating to the organization the importance of meeting customer as well as applicable regulatory requirements.

5.3. Quality policy

The quality policy was applicable to the purpose of the organization with clear commitment from top management in ensuring effectiveness was maintained with regular review of the quality objectives and continued review for suitability.

5.4. Planning

5.4.1. Quality objectives

Quality objectives were available that included those needed to meet applicable regulatory requirements and requirements for product. Quality objectives were measurable and consistent with the quality policy.

5.4.2 Quality management system planning

There was evidence that the planning of the QMS was carried out to meet the requirements of the standard as well as the quality objectives.

5.5. Responsibility, authority, and communication

5.5.1. Responsibility and authority

Responsibilities and authorities were defined, documented, and communicated within the organization. The interrelation of all personnel who managed, performed, and verified work affecting quality were documented and ensured the independence and authority necessary to perform these tasks.

5.5.2. Management representative

The appointed management representative had clear roles and responsibilities defined within the quality manual.

5.5.3. Internal communication

There was sufficient evidence to ensure that communication processes were well established and available.

5.6. Management review

5.6.1. General

Management review was not reviewed at the time of this desk assessment. However, this had been reviewed at previous WHO inspections and was found to meet the requirements of the standard.

6. Resource management

6.1. Provision of resources

It had been established from the previous WHO inspections and from the MDSAP report provided that the facility was well resourced, with trained personnel and adequate facilities for the function and activities that were performed. This largely ensured the QMS was implemented, and its effectiveness maintained, and that applicable regulatory and customer requirements were met.

6.2. Human resources

From the previous WHO inspections and information available within the MDSAP report, that the facility was staffed with personnel who had the necessary education, training, technical knowledge, and experiences for their assigned functions.

6.3. Infrastructure

The previous WHO inspections reported that the infrastructure was well maintained, with the appearance of being clean and tidy. The organization had documented requirements for the maintenance activities that applied to equipment used in production, to the control of the work environment, and to monitoring and measuring equipment.

6.4. Work environment and contamination control

6.4.1. Work environment

From the previous WHO inspections, it was reported that production was planned and carried out in rooms with controlled environments.

6.4.2. Contamination control

The previous WHO inspections verified that there were procedures for the cleaning of the facility and infrastructure to prevent contamination of the work environment, personnel, or product.

7. Product realization

7.1. Planning of product realization

Product realization was not reviewed in detail at the time of this desk assessment. However, this had been reviewed at previous WHO inspections and was found to meet the requirements of the standard. There was evidence that the organization's approach to the planning of production and service provision was adequately documented in the QMS and met the requirements of the standard.

7.2. Customer-related processes

7.2.1. Determination of requirements related to product

The organization had documented customer requirements that included applicable regulatory requirements that were related to the product.

7.3. Design and development

7.3.1. General

The Design and development procedure was available. The procedure clearly described the phases of the product life cycle with a review of risk performed at each stage.

7.3.3. Design and development inputs

The Design and development procedure adequately identified the requirements for design inputs.

7.3.4. Design and development outputs

The Design and development procedure adequately identified the requirements for design outputs.

7.3.6. Design and development verification

As reviewed at the previous WHO inspection, design and development verification was verified and found that the design and development outputs met the design and development input requirements. There was adequate evidence that design and development verification met the requirements of the standard.

7.3.9. Control of design and development changes

The organization had an established and well documented procedure for the control of design and development changes that incorporated a determination of any necessary regulatory affairs actions as well as WHO requirements for reporting such changes.

7.4. Purchasing

7.4.1. Purchasing process

The organization had an established and documented process for the purchasing of materials and services, that included verification of critical incoming material. Supplier management and qualification procedures were available and implemented. Criteria for selection, evaluation, approval, and re-evaluation of suppliers were available.

7.4.2. Purchasing information

Supplier management and qualification procedures were available and implemented with supplier agreements for critical suppliers. Criteria for selection, evaluation, approval, and re-evaluation of suppliers was available.

7.4.3. Verification of purchased product

The organization had implemented processes for the verification of purchased products to ensure that they met specified purchasing requirements. The extent of verification activities was proportionate to the risks associated with the purchased product.

7.5. Production and service provision

7.5.1. Control of production and service provision

Production and service provision was not reviewed in detail at the time of this desk assessment. However, the control of production was reviewed at the previous WHO inspections and there was evidence within the MDSAP report there was adequate control of production to meet the requirements of the standard.

It was found that there was sufficient evidence that production was planned, carried out, monitored, and controlled to ensure that product conformed to documented specifications. The organization had a documented process for the control of production that included, but was not limited to, qualification of infrastructure and monitoring and measuring equipment. Batch manufacturing records were available and identified the amount manufactured and amount approved for distribution.

7.5.6. Validation of processes for production and service provision

The organization had validated processes for production and service provision that followed procedures that included equipment and personnel qualification, the use of specific methods, procedures, and acceptance criteria, the criteria for revalidation and the approval of changes to the processes. This was verified at the previous WHO inspections.

7.5.8. Identification

There was a documented procedure for product identification and segregation for the life cycle of the product including released and nonconforming products.

7.5.9. Traceability

7.5.9.1. General

The organization had procedures available that supported full traceability of components, materials, work environments used that were in accordance with applicable regulatory requirements.

7.5.11. Preservation of product

There were adequate and suitable processes available to ensure the preservation of product to requirements during processing, storage, handling, and distribution. This had been reviewed at previous WHO inspections and was found to meet the requirements of the standard.

7.6. Control of monitoring and measuring equipment

The control of monitoring and measuring equipment was not reviewed at the time of this desk assessment. However, the control of production was reviewed at the previous WHO inspections and was found to meet the requirements of the standard. The organization had implemented procedures for the control of monitoring and measuring equipment. Measuring equipment was calibrated and/or verified, at specified intervals, or prior to use, there was adequate identification indicating its calibration status and was safeguarded from adjustments that would invalidate the measurement result.

8. Measurement, analysis, and improvement

8.2. Monitoring and measurement

8.2.1. Feedback

The organization had procedures in place to gather and monitor information relating to whether the organization has met customer requirements in the form of post market surveillance and customer feedback. Data were gathered from production as well as post-production activities and served as input into the risk management for monitoring and maintaining the product requirements as well as the product realization or improvement processes.

8.2.2. Complaint handling

The organization had implemented a procedure for the timely handling of customer complaints. The procedures included requirements and responsibilities for investigating complaints, determining the need to report the information to the appropriate regulatory authorities, including WHO, handling of complaint-related products and determining the need to initiate corrections or corrective actions.

8.2.3. Reporting to regulatory authorities

There was a procedure available for reporting and providing the necessary notifications to the appropriate regulatory authorities.

8.2.4. Internal audits

Internal audits were not reviewed at the time of this desk assessment.

8.3. Control of nonconforming product

8.3.1. General

The organization had a process in place for the segregation of nonconforming product.

8.3.2. Actions in response to nonconforming product detected before delivery

The organization had procedures available for taking action to eliminate nonconforming property before delivery.

8.3.3. Actions in response to nonconforming product detected after delivery

The organization had implemented a procedure to deal with nonconforming product detected after delivery by taking appropriate action to the effects, or potential effects, of the nonconformity.

8.4. Analysis of data

The organization had a procedure available to determine, collect and analyse appropriate data to demonstrate the suitability, adequacy, and effectiveness of the QMS. This was verified during the previous WHO inspections.

8.5. Improvement

8.5.1 General

The MDSAP report found there was sufficient evidence available to ensure that the manufacturer could identify and implement any changes necessary to maintain the continued suitability, adequacy, and effectiveness of the QMS, incorporating medical device safety and performance through the use of the

quality policy, quality objectives, audit results, post-market surveillance, analysis of data, corrective and preventive actions, and through the management review.

8.5.2. Corrective action

The MDSAP report found that the organization had procedures in place to take action to eliminate the cause of nonconformities to prevent recurrence. The procedures defined the requirements for reviewing nonconformities (including complaints), determining the causes of nonconformities, evaluating the need for corrective action, planning and documenting actions needed and implementing such actions, including, as appropriate, updating documentation and reviewing the effectiveness of corrective actions taken.

Conclusion – Inspection outcome

Based on the QMS evidence received and reviewed, it was considered that a desk assessment was acceptable in lieu of a WHO onsite inspection. The site ***bioLytical Laboratories Inc*** located at ***406-13251 Delf Place Richmond, BC, V6V 2A2 Canada*** was considered to be operating at an acceptable level of compliance with ISO 13458:2016 and WHO *Information for Manufacturers on Pre-qualification Inspection Procedures for the Sites of Manufacture of Diagnostics* (PQDx_014).

This WHOPIR will remain valid until February 2028, 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. Inspection Services – In Vitro Diagnostics and Male Circumcision Devices (https://extranet.who.int/prequal/inspection-services/vitro-diagnostics-and-male-circumcision-devices)

2. Overview of WHO's prequalification procedure for in vitro diagnostics (ISBN 978-92-4-011802-7)

3. ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

4. ISO 9001:2015 Quality management systems - Requirements

5. Guidance for post-market surveillance and market surveillance of medical devices, including in vitro diagnostics. (ISBN 978 92 4 001531-9)

6. Reportable changes to WHO prequalified and emergency use listed in vitro diagnostics – Application guide (ISBN 978 92 4 010984-1)

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

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

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

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

11. 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