World Health Organization

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WHO Prequalification Team - Inspection services

WHO PUBLIC INSPECTION REPORT (WHOPIR)

In vitro Diagnostic product

Part 1	**General information**
Company information	
Name of manufacturer	BD Life Sciences – Integrated Diagnostics Solution (IDS)
Corporate address of manufacturer	Becton, Dickinson and Company 7, Loveton Circle, Sparks, MD 21152 USA
Manufacturing site(s) under assessment	
Address of manufacturing site if different from that given above	**Design & Development** 7 Loveton Circle, Sparks, MD 21152 USA **Raw materials, Assembly of device, Primary packaging, Secondary packaging, Final product warehouse** 52 Loveton Circle, Sparks, MD 21152 USA **In-process quality control (QC) including lot release** 54 Loveton Circle, Sparks, MD 21152 USA
Desk assessment details	
Date of review	28 January 2026
Inspection record number	INSP-IVD-2024-0070 (I-04760) INSP-IVD-2025-0044 (I-05104) INSP-IVD-2025-0043 (I-05103)
General information about the manufacturer	Becton, Dickinson and Company (BD) is a global medical technology company that develops, manufactures, and markets medical devices, instrument systems, and reagents. The company was founded in 1897 and headquartered in Franklin Lakes, New Jersey, with operation in about 50 countries. BD Integrated Diagnostic Solutions (referred to as IDS) is headquartered in Sparks, Maryland, and employs approximately 7,500 associates worldwide.
Scope	Products included in the scope of this desk assessment include: PQDx 12411-045-00 BD Onclarity HPV Assay for the BD COR System PQDx 12315-045-00 BD Onclarity HPV Assay for the BD Viper LT System
Last WHO inspection	WHO PQ had not inspected the above listed sites previously. The manufacturer holds MDSAP certification.
Criteria	ISO 13485:2016 and WHO Prequalification specific requirements
Objective(s)	To assess the manufacturers compliant with the inspection criteria

Limitations	None
Abbreviations	**Meaning**
NC	Non-Conformity
NCR	Non-Conformity Report
OOS	Out-of-specification
QA	Quality Assurance
QC	Quality Control
QMS	Quality Management System
Part 2	**Summary of the assessment of ISO evidence submitted (most recent to oldest)**
Inspection Report 1	
Competent authority	BSI Group America Inc., for MDSAP
Dates of inspection	8 – 11 APRIL 2025
Type of inspection	Surveillance 1, Hybrid
Products(s) covered:	The report did not detail the products in scope. However, the certificate covered the design, development, manufacture, service and distribution of in-vitro diagnostic medical devices and microbiological products. These devices and products included equipment, in-vitro diagnostic test kits and reagents, prepared media products, dehydrated culture media, collection and transport, antimicrobial susceptibility tests, sample preparation, cytology devices, cytopathology auto-imaging devices with computerized microscopy, telepathology devices, lab automation, ancillary devices and instrument software for use in the screening and diagnosis of diseases, transmissible and sexually transmissible agents, and autoimmune status. As such, it can be reasonably assumed that the BD Onclarity HPV Assay for the BD COR System and for the BD Viper LT System in scope of this desk assessment have been covered by the MDSAP report.
Inspected areas	Raw materials, Assembly of device, Primary packaging, Secondary packaging and In-process quality control (QC)
A summary of major areas of deficiency observed	No major deficiencies were raised in the report. However, 2 minor NCs were still open at the time of the audit from the previous audit.
Description of CAPAs	Not applicable.
Final conclusion of the inspection report	The manufacturer provided objective evidence of MDSAP certification and provided a copy of the report. The sites were certified against MDSAP requirements by bsi Group America Inc who were a MDSAP recognize auditing authority. All medical device activities for this manufacturer were included in the Scope of Certification.
Part 3	**Summary of the last WHO inspection**
Date and conclusion of most recent WHO inspection	The sites listed above have never been inspected by WHO.

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 established to achieve IDS' quality policy and prescribed the requirements of the quality management system in relation to the design, development, manufacture, and sales of reagents for in vitro diagnostic medical devices and other products manufactured by the company. The manual was updated regularly 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.

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 contained a commitment to establishing and reviewing quality objectives with the vision of continual improvement. The high-level quality objectives were measurable, with a commitment to be monitored and communicated.

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.

5.5. 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.

5.5.3. Internal communication

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

6. Resource management

6.1. Provision of resources

It had been established 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 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.

7. Product realization

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

Final acceptance testing was to be completed before design transfer. Risk was to be reviewed at all stages of development. A regulatory check conducted by the Core Team Leader and members would be performed to ensure all laws and regulations were addressed in each of the marketed countries. 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. Steps were identified for impact assessments to be conducted at the various stages of the change. Various levels of changes were clearly identified. Change control monitoring was conducted by the coordinator or Quality team.

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

The supplier management procedure described the ongoing qualification of suppliers as well as the process if supplied goods did not meet the established acceptance criteria as per the purchase specifications. According to the procedure, annual review of all suppliers was performed and maintained with clear criteria for selection, evaluation, approval, and re-evaluation of suppliers.

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

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

According to the MDSAP report 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.

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.

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.

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

The manufacturer audits complaint handling, CAPA process, adverse event reporting and the pharmacovigilance system annually and all other processes are audited bi-annually. Independence of the audit team was assured. All critical nonconformities were addressed as per the CAPA procedure and major nonconformities were addressed according to the Corrective and Preventive Action initiation Determination procedure.

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. Recall

and customer notification of released product was clearly documented. All product subject to recall was reviewed by the Material Review Board and this team were responsible for the maintenance of the product quality and prevention of occurrence.

Conclusion – Inspection outcome

Based on the MDSAP report and on the QMS evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***BD Life Sciences – Integrated Diagnostics Solution (IDS)*** located at ***7 Loveton Circle, Sparks, MD 21152 USA, 52 Loveton Circle, Sparks, MD 21152 USA*** and ***54 Loveton Circle, Sparks, MD 21152 USA*** is considered to be operating at an acceptable level of compliance with ISO 13458:2016 and WHO requirements.

This WHOPIR will remain valid until April 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