World Health Organization

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Prequalification Unit - Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Abbott GmbH & Co. KG
In Vitro Diagnostic Product Manufacturer

Part 1	**General information**	
Manufacturers information		
Name and address of manufacturer	Abbott GmbH & Co. KG Max-Planck-Ring 2, Wiesbaden, Germany 65205	
Desk assessment details		
Dates of inspection	02 December 2019	
Type of inspection	Desk Assessment	
Products covered by this desk assessment	PQDx 0455- 180-00 Abbott RealTime High Risk HPV	
List of documents submitted	• MDSAP_Abbott Stage 2 Audit Report.pdf • MDSAP_LRQ0925480_AR_1702152_6252957_20180423125 2 (final).pdf	
Any documents missing?	No	
Part 2	**Summary of inspection evidence considered**	
Lloyd`s Register LRQ United Kingdom OU	Dates of inspection:	4-7 June 2018
	Type of inspection:	Initial
	Products covered:	Not listed
Part 3	**Summary of the last WHO inspection**	
Date and conclusion of most recent WHO inspection	WHO have not inspected the site in Germany but have previously inspected the site in Des Plaines, Illinois USA. A total of 3 inspections have been conducted at the Des Plaines site. All inspections have found the facility to be compliant and under the control of a well maintained effective quality management system.	
Areas inspected during the last WHO inspection	• Design and Development • Quality management system • Management responsibility • Purchasing • Production and Service Controls • Measurement, analysis and improvement • Adverse Events and Advisory Notices Reporting	
WHO product(s) covered by the	During the USA site inspections the below listed products were reviewed. Instruments were not manufactured at this site.	

last WHO inspection	Quantitative Assays: • PQDx 0083-027-00 Abbott Real Time HIV-1 (m24sp); List 02G31-090; • PDQx 0145-027-00 Abbott RealTime HIV-1 (m2000sp): List 02G31-090 and List 02G31-010: • PQDx 0146-027-00 Abbott Real Time HIV-1 (Manual); List 02G31-090: Qualitative Assays: • PQDx 0084-027-00 Abbott RealTime HIV-1 Qualitative; List 04N66-090; • PQDx 0151-027-00 Abbott RealTime HIV-1 Qualitative (Manual); List 04N66-090.
Additional product(s) to be covered by this desk assessment	PQDx 0455- 180-00 Abbott RealTime High Risk HPV
Abbreviations	**Meaning**
CoA	Certificate of analysis
IQ	Installation qualification
IVD	In vitro device
MR	Management Review
MSDS	Material safety data sheet
NC	Non-conformities
PPE	Personal Protective Equipment
OOS	Out-of-specifications test result
OQ	Operational qualification
PM	Preventive maintenance
PQ	PQ Performance qualification
PW	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

Part 4	Brief summary of the findings and comments

1. Quality Manual:

The MDSAP report concluded that the manufacture had a well-documented, effective quality management system. Quality objectives and policy were well established and measurable. There was a well-established risk management procedure that included product realization and monitoring that was clearly understood by staff. All aspects of the standard were reviewed at management review meetings including required inputs and outputs. Most of the measurable targets were being met.

2. Standard operating procedures for:

i. Complaint handling and vigilance:

The MDSAP report conclude that the manufacturer has a documented process in place for identifying device-related events that may meet reporting criteria as defined by participating regulatory authorities. Complaints were trended by assay type using appropriate statistical methods. The review contained an appropriate conclusion as to whether corrective or preventive action was required.

ii. Control of nonconforming goods/processes:

The MDSAP audit report found that the manufacturer had a feedback process that was in conformity with the audit criteria that included the control of nonconforming products.

iii. Risk management:

The manufacturer has a well-established process in place for risk management that followed ISO 14971:2007 and EN ISO 14971:2012 requirements. In addition, staff were found to be knowledgeable in the process. Appropriate investigations to determine root cause were planned or completed proportionate to the risk of the nonconformity. Detailed investigations were conducted and documented to identify the underlying cause of potential nonconformities. It was found that investigations were proportionate to the risk of the potential nonconformity.

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

There was a procedure available for the evaluation of suppliers including data analysis that was fed back into the management review process. Risk management was considered throughout the process.

3. List of changes t product and processes (since prequalification submission to WHO and since the last external certification for this desk assessment):

Not applicable

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

The site has been inspected and reports provided from

- Lloyd's Register Quality Assurance Inc. (LRQA) – June 2018
- LRQ United Kingdom OU – April 2018

Part 5	Conclusion – Inspection outcome

Based on the previous WHO inspections and on the MDSAP evidence received and reviewed, it is considered that a desk assessment is acceptable in lieu of a WHO onsite inspection. The site ***Abbott GmbH & Co. KG*** located at ***Max-Planck-Ring 2, Wiesbaden, Germany 65205*** 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 for 3 years, 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. 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.