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Prequalification Unit - Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
Abbott Molecular Inc
In Vitro Diagnostic Product Manufacturer

Part 1	**General information**	
Manufacturers information		
Name and address of manufacturer	Abbott Molecular, Inc 1300 East Touhy Avenue, Des Plaines, Illinois, 60018, United States of America	
Desk assessment details		
Dates of inspection	19 September 2019	
Type of inspection	Desk Assessment	
Products covered by this desk assessment	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; New product: • PQDx 0450- 027-00 Abbott RealTime HCV • PQDx 0461- 027-00 Alinity m HCV • PQDx 0462- 027-00 Alinity m HIV-1	
List of documents submitted	Abbott Molecular 2018 1A MDSAP Report.pdf	
Any documents missing?	No	
Part 2	**Summary of inspection evidence considered**	
UL LLC	Dates of inspection:	25-27 September 2018
	Type of inspection:	Surveillance
	Products covered:	Alinity m HCV Assay

Part 3	**Summary of the last WHO inspection**
Date and conclusion of most recent WHO inspection	The site was first inspected by WHO in June 2011. Since then a total of 3 inspections have been conducted. All inspections have found the facility to be compliant and under the control of a well maintained effective quality management system. Last WHO inspection (D-INS-0206) found the site compliant.
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 last WHO inspection	The below listed products are manufactured at the Des Plaines facility. Instruments were not manufactured at this site. 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 0450- 027-00 Abbott RealTime HCV • PQDx 0461- 027-00 Alinity m HCV • PQDx 0462- 027-00 Alinity m HIV-1
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 manual. Quality objectives and policy were well established and measurable. There was a documented procedure for the control of documents that included review and approval prior to issue, update when required and re-approval of documents, including prevention from deterioration or loss of records and documents.

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. Based on the output of the complaint process, there was a mechanism to reviewing each complaint to determine if a report to a regulatory authority was required. The report did not list the authorities. However, as the last WHO inspection was in September 2018, the requirements to report to WHO were present. These processes do meet the timeframes required by each regulatory authority where the product is marketed.

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 an established process in place for risk management that followed ISO 14971:2007 and EN ISO 14971:2012 requirements. Evidence of a risk management plan, risk evaluation, risk control and a risk management report was available. Risk acceptability criteria were established throughout the design and development process. Any residual risk was evaluated and, where appropriate was communicated to the customer (e.g., labelling, service documents, advisory notices, etc.).

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.

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 report provided from

- UL, LLC – September 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 Molecular, Inc*** located at ***1300 East Touhy Avenue, Des Plaine, Illinois, 60018, United States of America*** 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.