World Health Organization

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Prequalification Team Inspection services
WHO PUBLIC INSPECTION REPORT
(WHOPIR)
In Vitro Diagnostic Product Manufacturer

Part 1	**General information**	
Manufacturers information		
Name and address of manufacturer	**Roche Diagnostics GmbH** Sandhofer Strasse 116, Mannheim, 68305 Germany	
Desk assessment details		
Dates of inspection	04 December 2019	
Type of inspection	Desk Assessment	
Products covered by this desk assessment	• PQDx 0373-118-00 cobas® HIV-1 Quantitative nucleic acid test for use on the cobas® 4800 System • PQDx 0200-118-00 COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 (TaqMan 96) • PQDx 0221-118-00 COBAS® AmpliPrep/COBAS® TaqMan® HIV-1 Qualitative Test, version 2.0 (TaqMan 48) • PQDx 0465-118-00 cobas® HCV (Quantitative nucleic acid test for use on the cobas® 6800/8800 Systems) • PQDx 0365-118-00 cobas® HIV-1 Quantitative nucleic acid test for use on the cobas® 6800/8800 Systems	
List of documents submitted	• MDSAP Audit Report Mannheim TUV.pdf • MDSAP Audit Report_Rotkreuz_TUV.pdf • MDSAP Cert Aug2018 BBG LRQA.pdf • MDSAP Cert Aug2018 PLS LRQA.pdf • MDSAP Cert Aug2018 TUV.pdf • MDSAP Report BBG&PLS August 2018	
Any documents missing?	No	
Part 2	**Summary of inspection evidence considered (from most recent to last)**	
TUV SUD America, Inc **Mannheim facility**	Dates of inspection:	20-21 March 2018
	Type of inspection:	Recertification
	Products covered:	Not listed
TUV SUD America, Inc **Rotkreuz facility**	Dates of inspection:	3-9 March 2018
	Type of inspection:	Recertification
	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 Branchburg, New Jersey USA site in 2011 and 2016. Both inspections have found the Branchburg 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 last WHO inspection	• PQDx 0200-046-00 COBAS®Ampliprep/COBAS® TaqMan®HIV-1 Qualitative Test, version 2.0 (TaqMan 96) • PQDx 0221-046-00 COBAS®Ampliprep/COBAS® TaqMan®HIV-1 Qualitative Test, version 2.0 (TaqMan 48) • PQDx 0126-046-00 COBAS®Ampliprep/COBAS® TaqMan®HIV-1, version 2.0 (TaqMan 48) • PQDx 0147-046-00 COBAS®Ampliprep/COBAS® TaqMan®HIV-1 version 2.0 (TaqMan 96)
Additional product(s) to be covered by this desk assessment	• PQDx 0373-118-00 cobas® HIV-1 Quantitative nucleic acid test for use on the cobas® 4800 System • PQDx 0465-118-00 cobas® HCV (Quantitative nucleic acid test for use on the cobas® 6800/8800 Systems) • PQDx 0365-118-00 cobas® HIV-1 Quantitative nucleic acid test for use on the cobas® 6800/8800 Systems
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 (where applicable)

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. Regular management review meetings were conducted that incorporated all aspects of the standard.

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 complaints and a process for ensuring they were directed to the correct department. For example, complaints regarding product were forwarded to the quality management/complaint handling units by the complaint investigation and resolution department. The complaints were reviewed and CAPA may be instigated depending if an impact on the product was considered. Complaints are trended using appropriate statistical methods.

ii. Control of nonconforming goods/processes:
The MDSAP audit report found that the manufacturer had a 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 assessing risk throughout the full life cycle of the product. Appropriate investigations were observed to determine root cause.

iv. Supplier evaluation and control, verification of purchased product:
There was a procedure available for the evaluation of suppliers. A global Operations Direct Procurement department were responsible for the sites covered in the MDSAP reports.

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

4. Audit report of the most recent full regulatory audit and all subsequent surveillance audits:
The site has been inspected and reports provided from

- MDSAP - 3-9 March 2018
- MDSAP - 20-21 March 2018

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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 ***Roche Diagnostics GmbH*** located at ***Sandhofer Strasse 116, Mannheim, 68305 Germany*** 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.