Operational Qualification Procedure

cobas p 680

Version 5.0

Instrument Serial Number: _____

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Preface

Revision History

Version	Revision Date	Revision Information
0.1	30-Jan-2014	1. This is the first pre-launch issue of this document
1.0	07-May-2014	1. Section 3 Changed “Calibration Weight 20g” to “Calibration Weight”. 2. IOQ changed to mandatory upon installation or move.
2.0	06-Jan-2015	1. General, Corrected general terminology. 2. Section 3 Tool Calibration Certificates, consolidated with IQ naming and terminology. Added TOOL WEIGHING ONBOARD SYSTEM 3. Screenshots of all performed macros replaced by trace files printouts of performed macros, printouts will be performed if required by customers. 4. Calibration documents and other documents will be attached to the end of the OQ document. 5. Consolidated format of Instrument Check macros and Instrument Verification checkups.
3.0	17-May-2015	1. Section 1 Principal Systems Information and section 2 Document Verification, corrected description and removed the conclusion part. 2. Section 6 Handheld barcode reader, added barcodes to be checked. 3. Section 7 Pool Communication Test Run, added list of materials required to perform the procedure.
4.0	29-Jan-2016	1. Section 7 Pool Communication Test Run updated the procedure.
5.0	20-Sep-2016	1. Section 2 added **cobas**® 6800/8800 iSDoc. 2. Section 6 renamed Handheld scanner to Scanner Barcode Hand Held to keep terminology from **cobas**® 6800/8800. 3. Section 6 Handheld scanner configuration procedure moved to **cobas** p 680 iSDoc. 4. Section 7 Pool Communication Test Run procedure refers now to **cobas**® 6800/8800 iSDoc to reduce redundancies.

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About this Document

This document is to be used to perform an Operational Qualification on a **cobas p** 680, operated with **cobas p** 680 software on a Pooling Instrument Manager.

The Operational Qualification must be performed by trained Roche personnel only.

Documentation of Deviations

All deviations occurring during this qualification procedure must be logged in the Deviation Log and finally commented in the Deviation Report.

Abbreviations

GRIPS	Global Repository of Information about Products and Services
ID	Identification
iSDoc	Integrated Systems Documentation
IQ	Installation Qualification
IVD	In vitro diagnostics
LAN	Local Area Network
N/A	Not Applicable
PIM	Pooling Instrument Manager
OQ	Operational Qualification
S/N	Serial Number
STAR	Sequential Transfer and Aliquoting Robot
USB	Universal Serial Bus

General Information

Customer Information

Company: _____

_____

Address: _____

_____

_____

_____

System location and department: _____

_____

Contact person: _____

_____

Roche Representative

Installation Qualification performed by: _____

Job title: _____

Company: _____

_____

Address: _____

_____

_____

_____

Operational Qualification Procedure

1 Principal Systems Information

Objective

Record the principal **cobas p** 680 information and the used version of each component.

Procedure

- Record the required information of the components in the table below

Results

Component	Model, Version or S/N
Hardware components	
cobas p 680	S/N
PIM (Control Unit)	Model: S/N:
Software components	
cobas p 680 OS Win7 Recovery	Version:
cobas p 680 SW Installation Disc	Version:
Microlab® STAR Service SW	Version:
Microlab® STAR Maintenance & Verification SW	Version:

2 Document Verification

Objective

Record the versions (according to GRIPS) of all listed documents below available during the Operational Qualification

Procedure

- Record the available versions of the listed documents in the table below.

Results

Document	Version
cobas® 6800/8800 SW Installation Manual	Version:
cobas p 680 IQ OQ Guidelines	Version:
cobas p 680 iSDoc	Version:
cobas® 6800/8800 iSDoc	Version:
cobas p 680 Operator's Manual	Version:

3 Tool Calibration Certificates

Objective

The tools used for the Operational Qualification of the. **cobas p** 680 must be calibrated according to manufacturers' instructions.

Acceptance Criteria

The valid calibration certificates for the tools are available

Procedure

- Record the valid calibration ID the tool calibration certificates in the table below
- Record the corresponding calibration date of the tools in the table below
- Make copies of the calibration certificates and attach them to this document.

Results

Calibration Tool	Calibration ID	Availability Cal. Certificate		Calibration Dates
Mettler Toledo Balance Included in VFV Balance &Accessories Box Material number: 05527350001 for Type WXS 04640560001 for Type SAG (110V) 04640578001 for Type SAG (230V) 05411025001 for Type OWS		☐ Yes	☐ No	Last Calibration Valid through:
Mettler Toledo Weight Included in VFV Balance &Accessories Box Material number: 05527350001		☐ Yes	☐ No	Last Calibration Valid through:
TESTO Humidity meter Included in VFV Balance &Accessories Box Material number: 05527350001		☐ Yes	☐ No	Last Calibration Valid through:
Torque Wrench ¼" Material number: 04635892001		☐ Yes	☐ No	Last Calibration Valid through:
WIKA Pressure transmitter Material number: 04636228001		☐ Yes	☐ No	Last Calibration Valid through:

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

4 Instrument Check Procedure

The **cobas p** 680 Instrument check procedure has to be performed using Microlab® STAR Service SW.

Acceptance Criteria

The **cobas p** 680 instrument must pass the Instrument Check Procedure without errors.
The values are within specifications as defined in the respective Microlab® STAR Service SW macro and the **cobas p** 680 iSDoc procedure.

Procedure

- Perform the Instrument Check Procedure according to the **cobas p** 680 iSDocs.
- Verify that the acceptance criteria are met and confirm it in the table below.
- If required, print trace files of macros performed. Trace file to can be found on the control unit under: **C:\ProgramData\HAMILTON\StarService\Macros\Traces.**
- Attach printouts of the trace files to this document.

Results

Tests	Performed
cobas p 680 **Adjust_Arm_Z_using_PIP.mcr** passed	☐ Done
cobas p 680 **Check _X-Arm X Diff.mcr** passed	☐ Done
cobas p 680 **Adjust_PIP_Manual.mcr** passed	☐ Done
cobas p 680 **Adjust_PIP.mcr** passed	☐ Done
cobas p 680 **Check_PIP.mcr** passed	☐ Done
cobas p 680 **Check_PIP_Tightness.mcr** passed	☐ Done
cobas p 680 **Adjust_PIP_Pressure.mc** passed	☐ Done
cobas p 680 **Check_PIP_Pressure.mc** passed	☐ Done
cobas p 680 **Adjust_Autoload.mcr** passed	☐ Done

cobas p 680 **Check_Autoload.mcr** passed	☐ Done
cobas p 680 **Read_Barcodes_and_TubePresence.mcr** passed	☐ Done
cobas p 680 **ADJUST RD5 Handler** passed	☐ Done
cobas p 680 **Check RD5 Handler** passed	☐ Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

5 Instrument Verification

Objective

The **cobas p** 680 Instrument Verifications has to be performed using Microlab® STAR Maintenance & Verification program.

Acceptance Criteria

The **cobas p** 680 must pass all Instrument Verification checkups according to Microlab® STAR Maintenance & Verification program.

Procedure

- Perform all checkups from table below.
- Verify that the acceptance criteria are met and record the result in the table below.
- Attach printouts of all checkups to this document.

Results

Tests	Performed
cobas p 680 Weekly Maintenance passed	☐ Done
cobas p 680 Channel Position Verification passed	☐ Done
cobas p 680 Barcode Verification passed	☐ Done
cobas p 680 Cover Safety Verification passed	☐ Done
cobas p 680 Volume Verification passed	☐ Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

6 Scanner Barcode Hand Held

Objective

Verify the handheld barcode reader has been installed and configured correctly.

Acceptance criteria

Verify the acceptance criteria in the iSDoc procedure.

Procedure

Perform the Check Scanner Barcode Hand Held procedure according to the **cobas p** 680 iSDoc.

Results

Test	Performed
Scanner Barcode Hand Held	☐ Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

7 Pool Communication Test Run

Objective

Verification of the **cobas p** 680 communication of sample pool data with the **cobas**® 6800/8800. The sample pool data consists of the barcode identifications from the sample tubes which are included in the pool tube.

Acceptance Criteria

The sample pool data shown on the **cobas p** 680 must be the same as the sample pool data shown on the **cobas**® 6800/8800.

Procedure

Perform the Pool Communication Test Run according to the **cobas**® 6800/8800 iSDoc.

Results

Tests	Performed
cobas p 680 pool communication test run	☐ Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

8 Notes

Signature: _____ Date: _____

9 Conclusion

Conclusion A:

All Acceptance Criteria have been met. The Operational Qualification of the respective equipment was performed successfully	☐ Yes	☐ No
If No è continue with conclusion B		

Conclusion B:

All deviations or non-conformities observed have been recorded on the Deviation Log (see Appendix) and a corresponding Deviation Report (separate document) has been filled out. The deviations or non-conformities were resolved satisfactorily. Consequently the Operational Qualification of the respective equipment was performed successfully.	☐ Yes	☐ No

Comments:

Authorized Roche Representative:

Signature: _____ Date: _____

Reviewed and acknowledged by the customer:
(2 signatures required)

Signature: _____ Date: _____

Signature: _____ Date: _____

Appendix

Deviation Log

Record all deviations noticed during the Operational Qualification in the list below:

Number	Description	Reference Page No.
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		

Performed by Roche representative: _____

Signature: _____ Date: _____

Reviewed and approved by customer: _____

Signature: _____ Date: _____

Attach all required documents.