cobas® 6800/8800 Systems

Operational Qualification (OQ)

Version 4.0

Instrument Serial Number: _____

Instrument Type:

- ☐ **cobas**® 6800
- ☐ **cobas**® 6800 movable
- ☐ **cobas**® 8800

Sample Supply Module Serial Number: _____

Instrument Gateway Serial Number: _____

Platform Serial Number (movable only): _____

Instructions to locate serial numbers are described in the iSDoc.

Roche

This page intentionally left blank.

Table of Contents

Preface

Revision history

Version	Revision Date	Revision Information
1.0	10-Jun-2014	This is the first issue of this document
1.1	01-Dec-2014	Chapter 4.4, Material required corrected. Chapter 10, Check Run material corrected according the new CHK ASAP Over all, change Instrument into Systems
1.2	27-Aug-2015	Chapter 1 and 2, Changed from “verify” to “record” for recording the relevant document information. Removed Acceptance Criteria and Conclusion accordingly. Chapter 7.3 Added the caution information. Chapter 8.2 Added the barcodes to be checked.
2.0	10-Jun_2016	New handheld barcode scanner check Editorial Changes
3.0	01-Aug-2017	Adaption to divergent DSS SW Versions Document name changed from *Operational Qualification Procedure* to *Operational Qualification (OQ* Removed numbering for consistency reasons Editorial Changes
4.0	See GRIPS	Editorial Changes

Published by Roche Diagnostics International Ltd, a subsidiary of F. Hoffmann-La Roche Ltd, 4070 Basel, Switzerland.

Questions or comments regarding the content of this document can be directed to your Roche representative.

Every effort has been made to ensure that all the information contained in this document is correct at the time of printing.

However, Roche Diagnostics International Ltd reserves the right to make any changes necessary without notice as part of ongoing product development.

Copyrights and Trademarks

The following trademark is acknowledged:

About this document

This document has to be used to perform an Operational Qualification (OQ) on a **cobas**® 6800/8800 System.

The OQ must be performed by trained Roche personnel only.

This Operational Qualification (OQ) document has to be filled out completely and truthfully. Where required it has to be signed by the RSR or by the customer respectively.

All checks performed in the specific product in the DSS Software (OQ cobas 6800 or OQ cobas 8800) have to be completed successfully.

The DSS Software records all results and generates an Operational Qualification Certificate which has to be printed out and added to this document. The DSS Software tests all required specifications and returns a “Passed” or “Failed”.

A “Failed” test has to be followed by the appropriate correction/repair. It has to be documented in the deviation log in the Appendix of this document. Additionally, each deviation has to be described in detail in a separate Deviation Report.

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

ASAP	Assay Specific Analysis Package
DSS	Diagnosis and Service
IC	Instrument Control
ID	Identification
IG	Instrument Gateway Server
IM	Instrument Manager
IPC	Industrial Personal Computer
N/A	Not Applicable
NC	Negative Controls
MGP	Magnetic Glass Particles
OQ	Operational Qualification
OWS	Tool Kit Onboard Weighing System
S/N	Serial Number
SW	Software

General Information

Customer Information

Company: _____

_____

Address: _____

_____

_____

_____

System location and department: _____

_____

Contact person: _____

_____

Roche Representative

Installation Qualification performed by: _____

Job title: _____

Company: _____

_____

Address: _____

_____

_____

_____

Operational Qualification (OQ)

Document Verification

Objective

Make sure that the latest version of the respective document is used during the Installation and the OQ. All documents are available on GRIPS.

Procedure

- Record the document versions of the used documents in the table below.

Results

Document	Version
cobas® 6800/8800 Systems iSDoc	
cobas® 6800/8800 Systems User Guide	

Software Information

Objective

Record the system software release versions, the Check Run ASAP version, the Sample Supply Module software version and DSS Software version.

Procedure

- Record the version of the components into the table below.

Results

Component	Version
System Software release	
Check Run ASAP	
Sample Supply Module Software	
DSS Software	

Tool Calibration Certificates

Objective

Verify that the tool certificates are valid.

In order to ensure proper function of the OWS, Roche recommends the following maintenance procedures for the OWS equipment:

- Calibration of the OWS balance once a year
- Calibration of the 10g weight every two years

Attention

- The OWS needs to be shipped in its original packaging.
- Calibration intervals are based on the frequency of use and local regulations. Therefore, Roche only provides recommendations for initial calibration intervals.

Acceptance Criteria

Valid calibration certificates for the tools are available and the tools are currently within calibration.

Tools Required

- Tool Kit Onboard Weighing System

Procedure

- Record the corresponding serial / identification numbers, calibration certificate numbers and the calibration date of the tools used in the table below.
- Verify that the acceptance criteria are met.

Results

Calibration Tool	Model & Serial Number	Calibration ID	Calibration Dates
Tool Kit Onboard Weighing System			Last calibration: Valid until:
External calibration weight (10g)			Last calibration: Valid until:

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

DSS OQ checks for cobas® 6800/8800

The DSS checks are specified in the **cobas**® 6800/8800 Systems Qualification Specifications document. The checks can differ substantially between DSS SW releases.
The DSS SW guides the RSR through the checks.
For a detailed description consult the according section in iSDoc.

Objective

The OQ checks in the DSS verify the functionality, accuracy and precision of the installed instrument.

Acceptance criteria

All OQ checks have to be passed according to the detailed Acceptance Criteria in the **cobas**® 6800/8800 Systems Qualification Specifications document.

Procedure

Perform all checks in the DSS SW in the respective OQ product.

Caution

1. The **cobas omni** training kit and the **cobas omni** training control kit used in the *Main Handler Handling Check* expire due to *On-board stability (cumulative time on board outside refrigerator)*.
In order to have these reagents valid for the Check Run, make sure that you follow **one** of the procedures listed below:

-Execute the Reagent Storage Check
-Load and unload the reagents as soon as possible via the UI on a system in status *Standby*
-Make sure that you start the Check Run within 8 hours after this test.

2. The transfer module hood has to be **opened** during the *Instrument Teach* because the main handler performs a rotational movement going outward of the instrument.
A closed hood can damage the handler.

Material Required

- Calibration rack
- Pre-teach Tool
- Teach Tool
- 2 (4 for **cobas**® 8800) **cobas omni** Specimen Diluent Bottles
- 2 (4 for **cobas**® 8800) **cobas omni** Lysis Reagent Bottles
- 3 (6 for **cobas**® 8800) **cobas omni** Wash Reagent containers
- 1 (2 for **cobas**® 8800) **cobas omni** MGP Reagent cassette
- 1 (2 for **cobas**® 8800) **cobas omni** training kit
- 1 Kit Tool Optical Verification Cassette
- 2 (4 for **cobas**® 8800) **cobas omni** Processing
- 4 (6 for **cobas**® 8800) **cobas omni** Pipette Tips
- 4 (6 for **cobas**® 8800) **cobas omni** Amplification Plate
- 1 Tool Kit Onboard Weighing System
- Mettler Toledo Tweezers.
- External calibration weight (10g).
- Tool Holder for Balance
- Tool Weigh Boat
- Reagent storage adjustment tool
- 1 **cobas omni** training control kit

Results

DSS Product	Performed
cobas 6800 OQ	☐ N/A ☐ Done
cobas 8800 OQ	☐ N/A ☐ Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

Handheld barcode reader

Objective

Verify the handheld barcode scanner has been correctly 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**® 6800/8800 Systems iSDoc.

Results

Test	Performed
Check Scanner Barcode Hand Held	☐ Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

Sample Supply Module

Objective

Verify the sample supply module is within specification and perform the time synchronization.

Acceptance Criteria

The sample supply time must be synchronized and all module checks must pass successfully according to the Qualification Specifications document.

Precondition

The sample supply module should have been leveled and aligned according to the Installation Manual.

Procedure

- Perform the time synchronization of the sample supply module according to the procedure in iSDoc.
- Perform the sample supply module checks according to the procedure in iSDoc.
- Verify that the acceptance criteria are met.

Material Required

- Calibration rack
- 1 MPA Rack 13mm navy blue 6201-6250
- 1 **cobas omni** secondary tubes 13x75

Results

Test	Performed
Sample supply module time synchronization	☐ Done
Sample supply module checks under OQ mode	☐ Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

Check Run

Objective

Verify that the **cobas**® 6800/8800 Systems can perform a complete run and results are available on the screen.

Acceptance criteria

The initialization and check run must complete without any hardware error and without any liquid leakage. The Overflow Container has to be checked before and after performing the Check Run to ensure that the fluidic system is working correctly.
The following results must be available after completion of the Check Run:
cobas® 6800: 50 Check Run sample results, one negative and one positive Check Run control result.
cobas® 8800: 100 Check Run sample results, two negative and two positive Check Run control results.

Procedure

Perform the Check Run according to the **cobas**® 6800/8800 Systems iSDoc.

Results

Test	Performed
Initialization and Check Run	☐ Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

Certificates

Objective

Add the Operational Qualification Certificate to this document.

Acceptance Criteria

The Operational Qualification Certificate is attached to the OQ documentation.

Procedure

- Generate a Certificate on the DSS SW.
- Follow the instruction in iSDoc how to get the DSS Certificate.
- Print and attach the Operational Qualification Certificate to this document.
- Verify that the acceptance criteria are met.

Results

Test	Performed
Print and attach the Operational Qualification Certificate	☐ Done

Conclusion

Do the results meet the specified Acceptance Criteria?

Yes: ☐ No ☐

Signature: _____ Date: _____

Notes

Signature: _____ Date: _____

Conclusion

Conclusion A:

All Acceptance criteria have been met. The Operational Qualification of the respective equipment was performed successfully	☐ Yes	☐ No
If No ➔ 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	☐ N/A

Comments:

Authorized Roche Representative: _____

Date: _____ _____

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

Date: _____ _____

_____

Date: _____ _____

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: _____