EQP Name: Standard_EQP SW.02.04

Service Type: OQ

Company Name: _____

Customer Name/Title: _____

EQP Filename: Standard_EQP SW.02.04.eqp

EQP Release Date: October 18, 2019 10:14:00 AM

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Table of Contents

Scope and Purpose

Overview

The Equipment Qualification Plan (EQP) documents the activity program that is performed during the qualification services for the applicable systems. A complete description of the test specifications is provided for the supported services, including setpoints and acceptance criteria (or limits) for each test. The test specification section of this document is created directly from the EQP file name listed on the cover. This document is an abstraction of the EQP file used to perform the service and is generated directly from the electronic Agilent Equipment Qualification Plan (eEQP) Editor. The purpose of this document is to allow the user to review and record approval of the EQP that guides the delivery of compliance services provided by the Agilent Automated Compliance Engine.

CDS Software Pre-requisite for Hardware Qualifications

(Applies to hardware qualifications only) Agilent recommends that the customer data system (CDS) software used during the qualification has been qualified within the qualification period specified by the customer s software qualification SOP.

Statement of Intent

Unless otherwise requested, the qualification is delivered according to the standard test program described in the Agilent_Recommended EQP. Agilent defines variances as changes to the default recommended values (as stated in the Agilent Recommended EQP) that fall within a well-defined range. These changes are considered to be within the intended use range of the system under test.

Customizations are values that (a) subject the system to limits that exceed the typical operational range or (b) additional tests that are not considered part of the core program required for completion of the selected service. Because custom setpoints and limits may exceed the operational envelope of the equipment, Agilent reserves the right to warrant conformance only to the closest variance value. The user is notified of this stipulation at EQP setup time and the qualification report (EQR) will reflect this situation.

A set of ink signature fields, as determined by the creator of this document, can be included at the end of this document. All fields should be completed or a single set of fields, initialed by an appropriate approver, run through any signature fields that are not to be used. This is an optional process that allows a paper record of signoff by the appropriate reviewers where a hybrid (electronic/ink) signature SOP is followed. If this document will be saved electronically and digitally signed in a document management system, it should be generated without ink signature fields. Signing this document is for the customer's internal documentation purposes, to assist with the applicable regulatory requirements. It is available for customer review, but it is not a pre-requisite for the delivery. The delivery of the services is done according to the terms and conditions stated in the corresponding service exhibit. It is recommended that after approval, this EQP be archived with the electronic EQP file.

Understanding the Test Specification Section in Tabular Review Documents

(Applies to hardware qualifications only) For Agilent-recommended setpoints and limits, the range of allowable values (L for low, H for high) is included. As applicable, variances, customizations, and additional setpoints are listed beneath the Agilent recommended values and marked W (within range) or O (outside of range) in the left margin; values for added setpoints are also marked W or O and displayed after all configurations values. Dual limits are marked DW or DO. Agilent is NOT responsible for test failures for out of range setpoints and limits. Optional tests that are enabled are included and marked as such; required tests that are disabled by the customer are included and marked as such.

NOTE: Limit ranges must be more tightly managed than setpoint ranges because they often reflect physical measurement limits and are directly linked to the testing method. Therefore *within range* user limits are subject to best effort repairs if they cannot be met. In particular, Agilent will not be responsible for test failures for limits tighter (more demanding or challenging) than the recommended values.

Customer Responsibilities

o Safely store and archive this EQP
o Maintain change control and revision history
o Review and optionally sign the EQP, making sure the service delivery is what was approved
o Review and approve any of the following variances from the Agilent recommended:

-Within Variance Range: changes to the Agilent recommended that are identified by Agilent as within the operation ranges determined in our test development
-Outside of Variance Range: changes to the Agilent recommended that Agilent identifies as outside of the operational ranges determined in our test development. Agilent is not under any obligation to make the instrument pass the more stringent limits that fall in this range and this detail is called out in the EQP Test Specification
-Optional Tests: additional tests that are available but not part of the core testing suite and cost extra
-Disabled Tests: test for which all possible configurations have been disabled (tests are flagged in the test specification)

Agilent Responsibilities

o Deliver the services following the test programs described in the customer EQP
o Provide a locked and e-signed Qualification Report (EQR) upon completion of the service
o If requested, provide an optional ink-signed EQR CD to the customer

General Statements on the Testing Program

The recommended set of hardware OQ tests described in this EQP derives from Agilent's interpretation of authoritative expert literature issued by the FDA, USP, GAMP, ASTM 2500, and others. The OQ test design incorporates both modular and holistic testing, which is a proven approach, acceptable to regulators. As prescribed by the 4Q qualification methodology for Analytical Instrumentation Qualification (AIQ), the OQ step is separated from the PQ as recommended by the regulatory guidelines.

Agilent CrossLab Compliance uses a balanced selection of metrology and chemical tests to directly determine the performance of the systems without unnecessary reliance on inferred or derived results. For example, direct metrology is used to test pump flow rates and thermal-controlled column compartment and autosampler modules. Holistic chemical testing is used for the evaluation of the following critical instrument characteristics: linearity, precision, signal to noise, and carry over.

Agilent CrossLab Compliance Services

Agilent CrossLab is designed to fit traditional quality systems used by firms and recognized by regulatory agencies worldwide.

Note: Enterprise Edition has been renamed Agilent CrossLab Compliance; all functionality remains the same.

How Agilent CrossLab aligns with a traditional, paper-based methodology:

- Policy documents dictate the need for validation and qualification of GMP/GLP systems and usually mention the DQ/IQ/OQ/PQ model. The precise procedures for IQ and OQ for each type of equipment are prescribed in an approved SOP, perhaps called SOP #123: Qualification of HPLC Systems. In Agilent CrossLab, the equipment qualification plan (EQP) has the same role as the traditional qualification SOP.
- The traditional SOP provides lists of tests and limits for the range of system configurations found in the laboratory. The EQP follows this concept. The inventory of systems covered by an SOP or EQP changes over time, so this is kept as a separate record.
- The traditional qualification SOP typically has blank results forms as attachments to be photocopied for each IQ or OQ event–the results recorded in ink with manual calculations. In Agilent CrossLab, this execution process is streamlined and automated by use of Adobe forms and the Agilent Compliance Engine (ACE) delivery tool. It provides reports with no hand-writing errors; validated calculations; automated pass/fail report; traceability to raw data and the number of times a test was run. This automation provides efficiency and enforces compliance to procedure.
- The traditional qualification SOP is approved and released only once–replacing the need to author individual protocols for each chromatography system. This is the same concept for the EQP. The appropriate tests for each individual configuration are automatically selected by ACE from the list in the approved EQP–at time of delivery. The final reports are unique for each system and each qualification event–but the single approved EQP can cover a lab, department, or as wide a scope as desired.
- In the traditional qualification methodology, there is no convenient provision to record the actual workflow of the tests execution and results. In the event that a test is repeated during the Agilent CrossLab delivery, ACE maintains a counter per test which is automatically incremented for GxP compliant work, and the engineer generates a deviation note within the ACE report.

Design Qualification (DQ)

DQ for commercial lab instruments is recommended by some, but not all, guidances and procedures. Definitions of DQ found in guidances and firm-specific validation procedures vary widely around the world. Some firms require nothing more than a record (such as certificate) from the instrument manufacturer demonstrating that the lab system has been designed for purpose and manufactured to a quality standard. Others treat DQ as the development of a user requirement specification document (URS) which can be matched to the IQ and OQ specifications for a manufacturer. Other firms consider DQ as including the vendor selection activities.

USP Chapters literature definition of DQ:

Design qualification (DQ) is the documented collection of activities that define the functional and operational specifications of the instrument and criteria for selection of the vendor, based on the intended purpose of the instrument. Design qualification (DQ) may be performed not only by the instrument developer or manufacturer but also may be performed by the user. The manufacturer is generally responsible for robust design and maintaining information describing how the analytical instrument is manufactured (design specifications, functional requirements, etc.) and tested before shipment to users. Nonetheless, the user should ensure that commercial off-the-shelf (COTS) instruments are suitable for their intended application and that the manufacturer has adopted a quality system that provides for reliable equipment. Users should also determine capability of the manufacturer for support installation, services, and training.

For your reference, Agilent provides the following statements for DQ purposes:

1. All Agilent hardware and software laboratory products including the ACE software used to deliver qualification services, are designed, manufactured, and tested according to Agilent internal Quality Life-Cycle Development Procedures.
2. Certificates of Agilent testing, validation, and conformance to standards are provided with new Agilent instruments and similar certification is provided for ACE software. These documents are checked and recorded in Agilent CrossLab Compliance Services IQ.
3. Agilent maintains information describing how products are manufactured and maintains a problem and bug reporting program as required by international software quality guidelines.
4. The OQ specifications in this EQP can be used, as appropriate, by the user to prepare URS. The OQ specifications in this EQP represent the levels of performance acceptable to regulatory agencies for the technique; conform to typical specifications found in validation literature; are equally suitable for OQ at installation and on-going OQ throughout operational lifetime; are equivalent to the OQ specifications published in the legacy Agilent Classic OQPV protocols; and are suitable for most user requirements.
5. Agilent Technologies is capable of installation, support, preventive maintenance, on-going qualification, and re-qualification after repair and user training worldwide.

Installation Qualification (IQ)

IQ checks and tests for Agilent hardware and software products include the following:

1. Purchase Order Details: Allows the customer to verify that the instrument being qualified matches their design requirements (if available) and purchase order.
2. Preparation and Installation Details: Gathers and records information about preparation and installation documents.
3. Documentation: Gathers and records information about reference and user manuals for initial installations.
4. Product Quality Assurance Details: Collects and records certificates and other forms that verify that the vendor has developed and built the product according to internal standards.
5. Startup: Verifies that all modules start up properly.
6. Instrument Check (hardware only): Demonstrates that all modules of the instrument are correctly installed and connected. It does not test instrument performance as fully as OQ. This test is not necessary and therefore skipped if an OQ is to be performed by Agilent operator at installation after IQ.
7. Installation Verification (software only): Verifies the correctness of all installation-related files.

Operational Qualification (OQ)

Refer to the appropriate Test Definitions document for a detailed description of the testing program, setpoints, and acceptance limits for each system technique, category, and instrument configuration.

Dual-Acceptance Limits

(Applies to hardware qualifications only)

Within the EQP of Agilent CrossLab, each of the tests final result can be compared against two different limits if required. This allows customer-configured OQ to report against a User Limit (Limit 1) and the Agilent Recommended Limit (Limit 2) simultaneously.

In the standard EQP documents, Limit 1 and 2 values are the same – effectively de-activating this feature. Custom EQPs can also be prepared on request, making effective use of the two-limit feature of the Agilent Compliance Engine (ACE). In those cases, Limit 2 will always be the Agilent Recommended limit, and Limit 1 will be the limit requested by the user.

Agilent will not be under any obligation regarding the OQ testing results against user-requested limits that are more stringent than the Agilent Recommended ones.

Re-Qualification after Repair (RQ) Hardware

(Applies to hardware qualifications only)

In the event of a hardware breakdown followed by an engineering repair of a qualified instrument, it is necessary to re-qualify the system to an appropriate level before release back into operational use.

For some of the instrument techniques, Agilent offers a service contract to repair and re-qualify an instrument during the period between scheduled annual OQs.

The level of re-testing is prescribed in the RQ section of ACE: a form is displayed for the operator showing all types of repair possible and the re-testing required. Part of an example form is shown below.

Re-Qualification After Repair		
Pump Strategies		
Repair/Replace Strategy	Modules	OQ/PV Testing
Internal pump head parts, active inlet valve (or AIV cartridge), (parts of) check valves, reference valves, inlet manifold or pump drive, or taking pump head apart to clean (versus repair)	Any pump	Flow Accuracy & Precision
Pulse damper, pressure transducer	Any pump	Flow Accuracy & Precision
Multi-channel gradient valve	Quaternary	Flow Accuracy & Precision Gradient Composition

The full list of repair and re-test guidance is available for review by customers of the RQ service.

The RQ form in ACE prescribes which tests the operator must perform for each repair circumstance. The test procedure, setpoints, and limits will be an exact repeat of the previous OQ test (a regression-testing strategy).

Updated: June 2015 **www.agilent.com/crosslab/compliance-steps**

Overview

Agilent CrossLab qualification services offer flexible choices for the delivery method as descried below. The desired service delivery method is chosen according to the laboratory data integrity and general procedural requirements. To ensure complete data traceability, Agilent has devised two delivery methods that access data directly (default methods). An alternative method is also available that accesses data indirectly through a transfer location. If neither of the default methods is chosen, this document captures customer approval of the alternative delivery method.

Available Methods

Method	Definition
Preferred 1	Network-distributed ACE (NDA), where the ACE software is installed on a network node within the laboratory LAN infrastructure. Requires collaboration with the customer to load ACE behind the customer firewall. Raw data locations are always captured in the equipment qualification report (EQR), which provides end to end traceability and a fully characterized data workflow in the delivery.
Preferred 2	Dedicated spinning USB drive, where the ACE software resides on an independent drive that can be driven from the system controller, where the CDS resides. Because the USB spinning drive is connected to the CDS, the validity of this method is equivalent to the preferred 1 method. Raw data is imported directly into ACE by the Data Manager tool, with the data paths always captured in the report, which provides data traceability assurance. This is the most commonly used method.
Alternative	The ACE software is installed on and run from a PC not directly connected to the customer data system (CDS), such as the FSE's laptop. System data files are transferred indirectly from the CDS to the laptop instead of directly like preferred 1 and 2 methods. Requires customer pre-approval to remove later questions on data integrity.

Customer Approval of Alternative Method

Approved by/title:	
Comments:	

Updated: May 2017 **www.agilent.com/crosslab/compliance-steps**

Introduction

With heightened scrutiny of data integrity, Agilent's ACE (Automated Compliance Engine) software must be able to access instrument-generated raw data files one of two ways: (1) directly, using the connection between network nodes or with the server; (2) indirectly, through temporary storage in a transfer location. (In this document, data integrity refers to the who, what, and where of data used in generating an ACE equipment qualification report, or EQR.)

ACE includes three main service delivery use cases that address data integrity requirements; the rest of this document provides details to determine which one best fits a customer's needs.

Regardless of the delivery method, ACE features and delivery procedures are compatible.

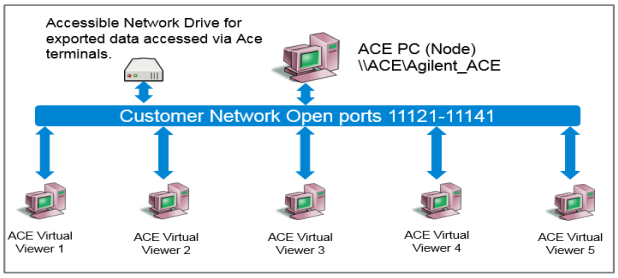
Preferred Method 1:	Network-distributed ACE (NDA)
Preferred Method 2:	Dedicated spinning USB drive (most commonly used method)
Alternative:	Service portable laptop or other PC not directly connected to customer data system (CDS)

Preferred Method 1: Network-Distributed ACE (NDA)

Overview

ACE software is installed on a network node within the laboratory LAN infrastructure, which requires collaboration with the customer to load ACE behind their firewall. Raw data locations are always captured in the EQR, which provides end-to-end traceability and a fully characterized data workflow in the delivery.

Details



Installing ACE in a separate node (a.k.a. the host PC) on the same network as the system controller offers data traceability that is equivalent to an installation on the system controller itself. The system controller (where the CDS resides) and the ACE host PC are identified and seen by the server and subject to the customer's data access controls and general IT policies. The CDS's audit trail records data movements between nodes or between the client and server, and ACE's data traceability features identify the original data directory and therefore ensures end-to-end data traceability

The ACE host PC has a separate/partitioned drive for ACE software. During ACE's installation, two services are setup on the operating system (OS): one for security and the other as a watchdog. Because the ACE host PC sits on the network as a shared drive, engineers access ACE through the networked drive: ACE is not installed on ACE Virtual Viewer PCs.

Requirements

Installation

- Install on a host PC with a separate drive (different from that of the OS)
- Attach to a network that clients can access
- 500 GB
- NTFS format
- User has local administration rights

Operational

- User has an ACE node logon with a minimum of power user rights permissions; user also has a personal ACE account and password added through the ACE licensing tool
- Up to 5 users with 3 open sessions each can access the NDA simultaneously
- Exception to ports 11121-11141 on ACE node, clients, and switch's/Smart Hubs to be open on the network

Preferred Method 2: Dedicated Spinning USB Drive

Overview

ACE software resides on an independent drive that can be driven from the system controller, where the CDS resides. Because the drive is connected to the CDS, this method's data integrity is equivalent to preferred 1 method's. Raw data is imported directly into ACE by ACE's Data Manager tool, and data paths are captured in reports to provide data traceability.

Details

A dedicated spinning USB drive can run ACE software without leaving a footprint on the host PC. Therefore, it can be connected directly to the system controller (where the CDS resides) without altering the system's qualification status. For additional protection, the drive can be driven by another host PC on the same network; also, the USB drive can remain on site with the customer for use by the Agilent FSE during service deliveries only.

Alternative Method

The ACE software is installed on and run from a PC not directly connected to the customer data system (CDS), such as the FSE's laptop. System data files are transferred indirectly from the CDS to the laptop instead of directly like preferred 1 and 2 methods.

Requires customer pre-approval to remove later questions on data integrity.

Updated: May 2017 **www.agilent.com/crosslab/compliance-steps**

Complete OQ Test Suite

This document describes the test program for qualifying software systems. All tests for all software types are listed in the following table; all tests are described in the Test Design and Rationale section; applicable tests by software type are included in

Security	General
Security Basic Access	Reporting and Calculation Algorithm Test
Security Advanced Access	Reporting and Calculation Report
Security User Interface Locking	Communication
User Traceability	Archive and Restore
Data Traceability	Acquisition Data Buffer
Data Integrity	Load Test
Client Connectivity	Spectral Evaluation
Server Connectivity	
Workflow	

ECM Base		ECM Optional (Clients/Workstations)
OpenLAB ECM File Operation	OpenLAB ECM Web Interface Add-on	OpenLAB ECM Generic Print Services
OpenLAB ECM Check-in Check-out	OpenLAB ECM Associate Files	OpenLAB ECM Distiller Print Services
OpenLAB ECM Mail Notification	OpenLAB ECM Archive	OpenLAB ECM Adobe E-Signature
OpenLAB ECM Content Basic Functions	OpenLAB ECM Query	OpenLAB ECM Adobe Template
OpenLAB ECM Content Filter Functions		OpenLAB ECM Desktop Integration
OpenLAB ECM Business Process Manager		OpenLAB ECM Scheduled Services

Analog to Digital Converter (ADC)	Setpoints (Each Channel Tested)			Limits
Height Accuracy				Accuracy ≤ 1.5%
Area, Height, and Retention Time Precision	31.25 mV	125.00 mV	500.00 mV	Area RSD, Height RSD < 1.00000%
	62.50 mV	250.00 mV	1000.00 mV	Retention Time RSD < 0.50000%
Height Linearity	N/A			Linearity ≥ 0.99900

Test Design and Rationale

Overview

Many GMP/GLP enforcement agency inspectors now ask firms to provide a risk assessment of their equipment and computer systems plus a science-based rationale for subsequent validation and qualification testing.

GENERAL RISK STATEMENT: Any chromatography or spectroscopy data system used for raw material testing or final drug product / medical device testing in GMP or used in formal GLP studies will likely fall into a HIGH RISK category. This risk assessment will imply the need for IQ & OQ & on-going qualification. ANY USER SPECIFIC RISK ANALYSIS SUPERCEDES THIS GENERAL RISK STATEMENT.

The rest of this section outlines the science-based rationale for each test in the Agilent OQ test design plus a brief test design and procedure description.

The recommended set of OQ tests described in this EQP derives from Agilent's interpretation of FDA, USP, and GAMP guidelines and other authoritative expert literature.

If calibrated equipment is used, calibration records will be provided.

Considering the number of setpoints, parameters, and conditions for some OQ tests, the proven concepts of worst case, range, and representative have been applied. If a property or characteristic is known to have its worst performance at one end of a range of use, this is the setpoint that should be tested and other setpoints are not required. If a property or characteristic has no known worst case, testing at the high and low points of the range of use is required. If there are too many possible use cases and conditions to realistically test (and none is a worst case), a representative sample for test is the best approach.

Preparation, Cleanup

These tests do not measure system performance. Preparation captures required user accounts, verifies software integrity, and (as applicable) performs other preparation required between tests; Cleanup restores the system to its pre-qualification state.

Security Tests

Security Basic Access

This test verifies that administration utilities and the software can only be accessed by valid user/password combinations.

Security Advanced Access

This test verifies that the password policy capabilities function properly.

Security User Interface Locking

This test uses interactive and/or time-based lockout of the application or session to verify that the software can prevent unauthorized access/impersonation by another user.

User Traceability

This test verifies that the software records the proper log information (electronic signature, dates and time stamp, and account information).

Data Traceability

This test checks that changes to the methods associated with data are properly maintained.

Data Integrity

This test verifies data integrity as files are stored, retrieved, and transferred. It also verifies that data can only be altered by authorized users.

Client Connectivity

This test verifies that the client used for the server qualification passed the Installation Qualification successfully and can connect to the server.

Server Connectivity

This test verifies the connection between the client and server using a workflow operation test.

Workflow

This test verifies software workflow that includes some or all of the following tasks depending on software configuration: creating and submitting a sequence; changing a method parameter; opening a result set; reprocessing data; printing reports; and verifying applicable audit trails for sequences, methods, and the system.

General Tests

Reporting and Calculation Algorithm Test

This automated test verifies the software's calculations.

Reporting and Calculation Report

This automated test verifies the software's calculations.

Communication

This test verifies that the software can communicate with all modules installed on the instrument.

Archive and Restore

This test verifies the server archive and restore capabilities.

Acquisition Data Buffer

This test verifies that data is buffered during network failure and sent to the system as soon as the network is recovered.

Load Test

This test stresses the client/server system with a predefined load of simultaneous data transfers from multiple clients.

Spectral Evaluation

This test verifies that you can create a library, add a compound to it, and then identify the compound and verify the identification.

ECM

OpenLAB ECM File Operation
This test verifies that an authorized user can log on, create a folder structure, and send, delete, and move files to and from the content management repository. The audit trail is used to verify performed steps.

OpenLAB ECM Check-in Check-out
This test verifies that an authorized user can check out a file and that the software forbids another user to check in the file when it is already checked out.

OpenLAB ECM Mail Notification
This test verifies that a notification e-mail is sent after deleting a file.

OpenLAB ECM Generic Print Services, Distiller Print Services
This test verifies that the print services send data to the content management repository.

OpenLAB ECM Adobe E-Signature
This test verifies that you can sign a document.

OpenLAB ECM Adobe Template
This test verifies that the system can extract information from Adobe documents to create keys in database.

OpenLAB ECM Associate Files
This test verifies that files can be associated and associations can be broken.

OpenLAB ECM Content Basic Functions
This test verifies that an authorized user can create, manipulate, and delete a content management structure.

OpenLAB ECM Content Filter Functions
This test verifies the system filter capabilities by running an automated test.

OpenLAB ECM Archive
This test verifies that repository data can be archived.

OpenLAB ECM Query
This test verifies that queries can find files and user-defined keys.

OpenLAB ECM Scheduled Services
This test verifies that data is uploaded to the repository as scheduled and that the uploaded and original data match.

OpenLAB ECM Desktop Integration
This test verifies that Microsoft applications can send files directly to ECM content.

OpenLAB ECM Business Process Manager
This test verifies the business process management operation.

OpenLAB ECM Web Interface Add-on
This test verifies the web interface add-on operation.

ADC (Analog to Digital Converter) Tests

Height Accuracy
This test uses a traceable peak output simulator to determine the height accuracy of the analog to digital convertor.

Area, Height, and Retention Time Precision
This test uses a traceable peak output simulator to determine the area, height, and retention time precision of the analog to digital conversion.

Height Linearity
This test uses a traceable peak output simulator to determine linearity of the analog to digital conversion.

Standard OQ Test Suite by Software Type

Core test	Included if a related package is installed	Not applicable

Note: The following tables list all available tests, required and optional, for each configuration.

OpenLAB CDS (2.x version)

Note: Security Advanced Access only applies to internal authentication provider configurations.

CM:	Content Management
OLSS:	OpenLAB Shared Services

Test	Standalone Workstation	OpenLAB ECM XT		OpenLAB Server (CDS) with ECM XT		Agilent Instrument Controller
		Server	Client	Server	Client	
Security Basic Access-OLSS	✓	✓		✓		
Security Advanced Access-OLSS	✓	✓		✓		
Security User Interface Locking-OLSS	✓	✓		✓		
User Traceability	✓			✓		
User Traceability-ECM XT		✓				
Data Traceability	✓			✓		
Data Traceability-ECM XT		✓				
Data Integrity	✓			✓		
Data Integrity-ECM XT		✓*				
Client Connectivity		✓		✓		
Server Connectivity			✓			
Workflow	✓			✓	✓	✓
Reporting and Calc. Algorithm Test	✓				✓	✓
Reporting and Calculation Report	✓**				✓**	✓**
Communication	✓					✓
Acquisition Data Buffer						Optional
Spectral Evaluation	✓***				✓***	✓***
OpenLAB ECM File Operation-CM		✓	✓	✓	✓	
OpenLAB ECM Checkin Checkout-CM		✓		✓		
OpenLAB ECM Content Basic Function-CM		✓		✓		
OpenLAB ECM Archive-CM		✓		✓		
OpenLAB ECM XT Import Services			✓		✓	
OpenLAB ECM XT Import Scheduler		✓	✓	✓	✓	
OpenLAB ECM XT PDF Data Extraction			✓		✓	

**MS Office Integration test option* ***GPC/SEC Data Analysis only* ****Scheduled only if NIST libraries are installed*

Test IMPORTANT! Before performing this qualification, scroll down to the OpenLAB ECM section and qualify the ECM server first.	OpenLAB CDS 2.4 Connected to OpenLAB ECM 3.x		
	OLSS Server	Client	Agilent Instrument Controller
Security Basic Access-OpenLAB ECM Client	✓		
Security Basic Access-OLSS	✓		
Security User Interface Locking-OLSS	✓		
Workflow		✓	✓
Reporting and Calc. Algorithm Test		✓	✓
Reporting and Calculation Report		✓*	✓*
Communication			✓
Acquisition Data Buffer			Optional
Spectral Evaluation		✓**	✓**

**GPC/SEC Data Analysis only* ***Scheduled only if NIST libraries are installed*

OpenLAB CDS ChemStation Edition

Note: Workflow only applies to A.02.02 and higher.

DS:	DataStore	ECM:	Enterprise content management	IR:	Intelligent Reporter	LCD:	LC Dissolution
Delta:	Delta qualification	Full:	Full qualification	LA:	Lab Applications	SFIO:	Secure File IO

Test	Workstation		Secure Workstation (w/ DS)		Networked Workstation		
	Base	w/ ECM	Full	Delta	Base	w/ECM	w/DS
Security Basic Access	✓	✓	✓				
Security Advanced Access	✓		✓				
Security User Interface Locking	✓	✓	✓		✓		
User Traceability	✓		✓				
Data Traceability			✓				
Data Integrity	SFIO	SFIO	✓		SFIO	SFIO	SFIO
Server Connectivity		✓			✓	✓	✓
Workflow		✓	✓	✓		✓	✓
Workflow (Add-on)			LA				LA
Reporting and Calc. Alg. Test	✓	✓	✓		✓	✓	✓
Reporting and Calc. Alg. Test (Add-on)		LCD	LCD	LCD		LCD	LCD
Reporting and Calculation Report	✓	✓	✓		✓	✓	✓
Communication	✓	✓	✓	✓	✓	✓	✓
OpenLAB ECM Generic Print Services		Optional				Optional	
OpenLAB ECM Distiller Print Services		Optional				Optional	
OpenLAB ECM Adobe E-Signature		Optional				Optional	
OpenLAB ECM Adobe Template		Optional				Optional	
OpenLAB ECM Scheduled Services		Optional				Optional	
OpenLAB ECM Desktop Integration		Optional				Optional	

Test	Client		Instrument Controller	
	w/ECM	w/DS	w/ECM	w/DS
Security Basic Access	✓			
Security User Interface Locking				
Data Integrity			SFIO	SFIO
Server Connectivity	✓	✓	✓	✓
Workflow			✓	✓
Workflow (Add-ons)		LA		
Reporting and Calc. Algorithm Test			✓	✓
Reporting and Calculation Report	IR		✓	✓
Communication			✓	✓
OpenLAB ECM Generic Print Services	Optional			
OpenLAB ECM Distiller Print Services	Optional			
OpenLAB ECM Adobe E-Signature	Optional			
OpenLAB ECM Adobe Template	Optional			
OpenLAB ECM Scheduled Services	Optional			
OpenLAB ECM Desktop Integration	Optional			

Test	Shared Services Server		
	Base	w/ECM	w/DS
Security Basic Access-OpenLAB ECM Client		✓	
Security Basic Access	✓	✓	✓
Security Advanced Access	✓		✓
Security User Interface Locking	✓	✓	✓
User Traceability	✓		✓
Data Traceability			✓
Data Integrity			✓
Workflow (Add-ons)			LA

OpenLAB ECM

BPM:	Business process manager
ECM:	Enterprise content management
WI:	Web interface add-on

Test	Server					Client
	Base	File Transfer	Application	BPM	WI	
Security Basic Access	✓					✓
Security Advanced Access	✓					
User Traceability	✓					
Client Connectivity	✓	✓	✓	✓	✓	
OpenLAB ECM File Operation	✓					✓
OpenLAB ECM Archive	✓					
OpenLAB ECM Query	✓					
OpenLAB ECM Check-in Check-out		✓				
OpenLAB ECM Mail Notification		✓				
OpenLAB ECM Associate Files		✓				
OpenLAB ECM Content Basic Functions		✓				
OpenLAB ECM Content Filter Functions			✓			
OpenLAB ECM Business Process Manager				✓		
OpenLAB ECM Generic Print Services	Optional	Optional	Optional	Optional		
OpenLAB ECM Distiller Print Services	Optional	Optional	Optional	Optional		
OpenLAB ECM Adobe E-Signature	Optional	Optional	Optional	Optional		
OpenLAB ECM Adobe Template	Optional	Optional	Optional	Optional		
OpenLAB ECM Scheduled Services	Optional	Optional	Optional	Optional		
OpenLAB ECM Desktop Integration	Optional	Optional	Optional	Optional		
Workflow					Optional	

OpenLAB CDS EZChrom Edition

Note: Workflow only applies to A.02.02 (A.04.07) and higher.

AFS:	Advanced file security
DS:	DataStore
ECM:	Enterprise content management
LA:	Lab Applications

Test	Workstation		Networked Workstation		
	Base	w/ ECM	Base	w/ECM	w/DS
Security Basic Access	✓	✓		✓	
Security Advanced Access	✓				
Security User Interface Locking	✓	✓	✓		
User Traceability	✓				
Data Traceability	✓		✓		
Server Connectivity		✓	✓	✓	✓
Workflow (Add-ons)	AFS		AFS		LA
Reporting and Calc. Algorithm Test	✓	✓	✓	✓	✓
Reporting and Calculation Report	✓	✓	✓	✓	✓
Communication	✓	✓	✓	✓	✓
OpenLAB ECM Generic Print Services		Optional		Optional	
OpenLAB ECM Distiller Print Services		Optional		Optional	
OpenLAB ECM Adobe E-Signature		Optional		Optional	
OpenLAB ECM Adobe Template		Optional		Optional	
OpenLAB ECM Scheduled Services		Optional		Optional	
OpenLAB ECM Desktop Integration		Optional		Optional	

Test	Client			Instrument Controller		
	File Server	w/ECM	w/DS	Base	w/ECM	w/DS
Security Basic Access		✓				
Security User Interface Locking	✓					
Server Connectivity	✓	✓	✓	✓	✓	✓
Workflow (Add-on)	AFS		LA			
Reporting and Calc. Algorithm Test	✓	✓	✓	✓	✓	✓

Test	Client			Instrument Controller		
	File Server	w/ECM	w/DS	Base	w/ECM	w/DS
Reporting and Calculation Report	✓	✓	✓			
Communication				✓	✓	✓
OpenLAB ECM Generic Print Services		Optional				
OpenLAB ECM Distiller Print Services		Optional				
OpenLAB ECM Adobe E-Signature		Optional				
OpenLAB ECM Adobe Template		Optional				
OpenLAB ECM Scheduled Services		Optional				
OpenLAB ECM Desktop Integration		Optional				

Test	Shared Services Server		
	Base	w/ECM	w/DS
Security Basic Access	✓	✓	✓
Security Advanced Access	✓		✓
Security User Interface Locking	✓	✓	✓
User Traceability	✓		✓
Data Traceability			✓
Data Integrity			✓
Workflow (Add-ons)			LA

MassHunter

CM:	OpenLAB ECM XT/Server (Content Management) 2.3 or later
DA:	F.xx MSD Data Analysis
DS:	DataStore
ECM:	Enterprise content management
OLSS:	OpenLAB Shared Services 4.5 or later
SDA:	Spectroscopy Database Administrator
UAC:	User access control 4.4 or earlier

Test	GC/&LC/MS (ACQ, QUANT, QUAL, and DA)			DS Server	ICPMS Workstation 4.4 or ealier			
	Base	Basic Security	ECM*		UAC	UAC w/ECM	UAC w/DS	UAC w/SDA
Security Basic Access		✓		✓	✓	✓	✓	✓
Security Advanced Access		✓		✓				
Security User Interface Locking		✓		✓	✓	✓	✓	✓
User Traceability		✓		✓				
Data Traceability		✓		✓				✓
Data Integrity		✓		✓				✓
Server Connectivity						✓	✓	✓
Workflow			✓					
Reporting and Calculation Report	✓	✓	✓		✓	✓	✓	✓
Communication	✓	✓	✓		✓	✓	✓	✓
Spectral Evaluation (GCMS only)	DA	DA	DA					
OpenLAB ECM Generic Print Services			Optional					
OpenLAB ECM Distiller Print Services			Optional					
OpenLAB ECM Adobe E-Signature			Optional					
OpenLAB ECM Adobe Template			Optional					
OpenLAB ECM Scheduled Services			Optional					
OpenLAB ECM Desktop Integration			Optional					

**For MSD ChemStation, DA in Compliance Mode will not function with ECM and is not a supported configuration.*

Test	ICPMS Workstation 4.5 or later			
	OLSS Only	OLSS w/ ECM	OLSS w/SDA	OLSS w/CM
Security Basic Access	✓	✓	✓	✓
Security Advanced Access	✓			
Security User Interface Locking	✓	✓	✓	✓
User Traceability				
Data Traceability			✓	

Test	ICPMS Workstation 4.5 or later			
	OLSS Only	OLSS w/ ECM	OLSS w/SDA	OLSS w/CM
Data Integrity			✓	
Server Connectivity		✓	✓	✓
Workflow				
Reporting and Calculation Report	✓	✓	✓	✓
Communication	✓	✓	✓	✓

MS ChemStation

ECM:	Enterprise content management

Test	Productivity ChemStation	Productivity ChemStation w/ECM	Security ChemStation
Security Basic Access	✓	✓	✓
Security Advanced Access			✓
Security User Interface Locking			✓
User Traceability			✓
Data Traceability			✓
Reporting and Calc. Algorithm Test	✓	✓	✓
Reporting and Calculation Report	✓	✓	✓
Communication	✓*	✓*	✓
Spectral Evaluation	✓		✓
OpenLAB ECM File Operation		✓	

** Not scheduled for Data Analysis only configurations*

ChemStation Family

CL:	ChemLaunch
CS:	ChemStore
CST:	ChemStation
ECM:	Enterprise content management
SP:	Security Pack

Test	CST Standalone	CST with CS Standalone w/ or w/o SP	CST Server w/o SP	CST w/ CS Client w/ and w/o SP	Healex CL CS Server w/ SP	Healex CL ChemStation Server w/ ECM	CST Client w/ ECM
Security Basic Access	✓	✓	✓	SP		✓	✓
Security Advanced Access		✓	✓			✓	✓
Security User Interface Locking		✓	✓			✓	✓
User Traceability		✓	✓			✓	✓
Data Traceability		✓	✓			✓	✓
Data Integrity		✓	✓			✓	✓
Client Connectivity			✓				
Server Connectivity				✓	✓		✓
Reporting and Calc. Algorithm Test	✓	✓		✓	✓	✓	✓
Reporting and Calculation Report	✓	✓		✓	✓	✓	✓
Communication	✓	✓		✓	✓	✓	✓
Archive and Restore			✓				
Load Test			✓				
OpenLAB ECM Generic Print Services						Optional	Optional
OpenLAB ECM Distiller Print Services						Optional	Optional
OpenLAB ECM Adobe E-Signature						Optional	Optional
OpenLAB ECM Adobe Template						Optional	Optional
OpenLAB ECM Scheduled Services						Optional	Optional
OpenLAB ECM Desktop Integration						Optional	Optional

EZChrom Elite

Test	Standalone
Security Basic Access	Security enabled
Security Advanced Access	Security enabled
Security User Interface Locking	Security enabled
User Traceability	Security enabled
Data Traceability	Security enabled
Data Integrity	Security enabled
Reporting and Calc. Algorithm Test	✓
Reporting and Calculation Report	✓
Communication	✓

MicroLab

Test	w/21 CFR 11 Module
Security Basic Access	✓
Security Advanced Access	✓
Security User Interface Locking	✓
User Traceability	✓
Workflow (Data Integrity, Data Traceability)	✓
Reporting and Calculation Report	✓
Communication	✓

Analog to Digital Converter

Test	35900E	SS420
Height Accuracy	✓	✓
Area, Height and Retention Time Precision	✓	✓
Height Linearity	✓	✓

UV-Visible ChemStation

ECM: Enterprise Content Management ECMC: ECM Compliance Pack SP: Security Pack

Test	Standalone	Standalone w/ SP	Standalone w/ ECM	Standalone w/ ECMC	Data Server w/ SP	Client w/ SP
Security Basic Access		✓				✓
Security Advanced Access		✓				
Security User Interface Locking		✓		✓		✓
Client Connectivity					✓	
Server Connectivity			✓	✓		✓
Workflow (Data Integrity, Data Traceability)		✓		✓		
Reporting and Calc. Algorithm Test	✓	✓	✓	✓		✓
Communication	✓	✓	✓	✓		✓

Dissolution Workstation

Test	Dissolution Workstation
Security Basic Access	✓
Security User Interface Locking	✓
User Traceability	✓
Communication	✓

Size-exclusion Chromatography Software (Bio-SEC and GPC/SEC)

Test	Bio-SEC and GPC/SEC
Reporting and Calc. Algorithm Test	✓
Communication	✓

Cary Software

CFR: 21 CFR Assistant
SCM/SDA: Spectroscopy Configuration Manager/ Database Administrator

Test	WinUV		UV WorkStation
	w/ CFR	w/ SCM/SDA	
Security Basic Access	✓	✓	
Security Advanced Access		✓	
Security User Interface Locking	✓	✓	
User Traceability		✓	
Data Traceability	✓	✓	
Data Integrity		✓	
Reporting and Calc. Algorithm Test	✓	✓	✓
Communication	✓	✓	✓

2100 Expert

SP: Security Pack

Test	w/o SP	w/ SP
Security Basic Access		✓
Security User Interface Locking		✓
Workflow		✓
Reporting and Calc. Algorithm Test	✓	✓
Communication	✓	✓

ICP Expert

SCM/SDA: Spectroscopy Configuration Manager/ Spectroscopy Database Administrator

Test	w/o SCM/SDA	w/ SCM/SDA
Security Basic Access		✓
Security Advanced Access		✓
Security User Interface Locking		✓
User Traceability		✓
Data Traceability		✓
Reporting and Calculation Report	✓	✓
Communication	✓	✓

SpectrAA

Test	w/o SCM/SDA	w/ SCM/SDA
Security Basic Access		✓
Security Advanced Access		✓
Security User Interface Locking		✓
User Traceability		✓
Data Traceability		✓
Data Integrity		✓
Reporting and Calc. Algorithm Test	✓	✓
Communication	✓	✓

Waters Empower

Test	Server w/ or w/o Security	LACE	Processing Client	Workstation w/ or w/o Security
User Traceability	Security enabled			Security enabled
Data Traceability	Security enabled			Security enabled
Data Integrity	Security enabled			Security enabled
Workflow	✓	✓	✓	✓
Communication		✓		✓
Acquisition Data Buffer		✓		

Updated: November 2019

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Report and Delivery Options

- Show header and footer on cover

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Status: EQP is not signed

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NOTE: The Revision History - EQP Editor document includes details for above and other available revisions.