



**EQP Name:** Standard\_EQP FTIR.01.02

**Service Type:** OQ

**Company Name:** \_\_\_\_\_

**Customer Name/Title:** \_\_\_\_\_

**EQP Filename:** Standard\_EQP FTIR.01.02.eqp

**EQP Release Date:** July 2016

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# 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

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## Overview

Agilent CrossLab qualification services offer flexible choices for the delivery method as described 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:

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**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)

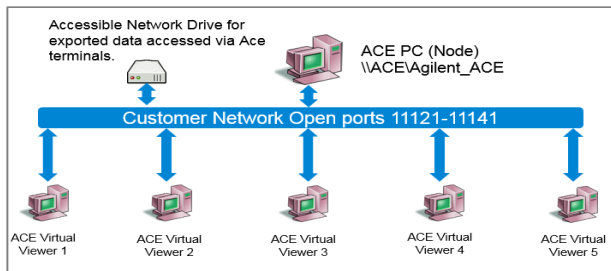
**Preferred Method 1: Network-Distributed ACE (NDA)**

**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**

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## Standard OQ Test Suite

This document describes the test program for qualifying Agilent FTIR spectrometer systems. All automated tests are run from the instrument control software.

**Note:** In the test tables, WN is short for wavenumber.

## Setpoints, Parameters, and Limits

Test setpoints, parameters, and limits are integrated in the instrument control software and cannot be changed.

## Cary 630 Models

For these models, multiple interchangeable sample accessories can be purchased, and all accessories can be tested in a single qualification. The Diagnostic Verification test is run for all accessories; all other tests, which are referred to as engine specific, are only run on the accessory configured as primary in the instrument control software and ACE.

Test	Setpoints and Parameters	Limits
Diagnostic Verification	N/A	Instrument's energy levels and temperatures are checked; adjustments are made if the energy level is too high or low.
Signal to Noise Ratio (KBR optics)	Range: 1142 - 1042 $\text{cm}^{-1}$	Ratio > 20,000:1 (Transmission) Ratio > 9,600:1 (DialPath, TumbIIR) Ratio > 8,500:1 (1B Diamond ATR, 1B ZnSe ATR) Ratio > 2,620:1 (1B Germanium ATR)
Signal to Noise Ratio (ZnSe optics)		Ratio > 25,000:1 (Transmission) Ratio > 12,000:1 (DialPath, TumbIIR, 1B Diamond ATR, 1B ZnSe ATR) Ratio > 3,275:1 (1B Germanium ATR)
Stability	Tested: 1000 $\text{cm}^{-1}$ region of the infrared spectrum	Stability < 1%
Wavenumber Accuracy and Repeatability (Transmission, DialPath, TumbIIR)	WN 1: 1028.50 $\text{cm}^{-1}$ WN 2: 1583.35 $\text{cm}^{-1}$ WN 3: 1601.35 $\text{cm}^{-1}$ WN 4: 3082.10 $\text{cm}^{-1}$	Accuracy < 0.3 $\text{cm}^{-1}$ (WN 1, 3, 4) Accuracy < 0.1 $\text{cm}^{-1}$ (WN 2) Repeatability: < 0.05 $\text{cm}^{-1}$ (WN 1-4)
Wavenumber Accuracy and Repeatability (1B Diamond ATR, 1B ZnSe ATR, 1B Germanium ATR)	WN 1: 904.9 $\text{cm}^{-1}$ WN 2: 1026.4 $\text{cm}^{-1}$ WN 3: 1599.4 $\text{cm}^{-1}$	Accuracy: < 1 $\text{cm}^{-1}$ (WN 1-3) Repeatability: < 0.2 $\text{cm}^{-1}$ (WN 1-3)

**4500 / 5500 Models**

For these models, all tests are run on the single built-in sample accessory.

Test	Setpoints and Parameters	Limits
Diagnostic Verification	N/A	Instrument's energy levels and temperatures are checked; adjustments are made if the energy level is too high or low.
Signal to Noise Ratio	Range: 1142 - 1042 $\text{cm}^{-1}$	Ratio > 12,000:1 (DialPath, TumbllR) Ratio > 9,600:1 (1B Diamond ATR, 3B Diamond ATR)
Stability	Tested: 1000 $\text{cm}^{-1}$ region of the infrared spectrum	Stability < 1%
Wavenumber Accuracy and Repeatability (DialPath, TumbllR)	WN 1: 1028.50 $\text{cm}^{-1}$ WN 2: 1583.35 $\text{cm}^{-1}$ WN 3: 1601.35 $\text{cm}^{-1}$ WN 4: 3082.10 $\text{cm}^{-1}$	Accuracy < 1 $\text{cm}^{-1}$ (WN 1-4) Repeatability: < 0.2 $\text{cm}^{-1}$ (WN 1-4; 5500 only)
Wavenumber Accuracy and Repeatability (1B Diamond ATR, 3B Diamond ATR)	WN 1: 904.9 $\text{cm}^{-1}$ WN 2: 1026.4 $\text{cm}^{-1}$ WN 3: 1599.4 $\text{cm}^{-1}$	Accuracy: < 2 $\text{cm}^{-1}$ (WN 1-3) Repeatability: < 0.2 $\text{cm}^{-1}$ (WN 1-3; 5500 only)

**Test Design and Rationale****Diagnostic Verification**

Description: This test verifies that the accessory is recognized and that the spectrometer functions properly and has an appropriate gain setting.

Procedure: Run the automated test; a pass/fail status is determined automatically and included in the report.

**Signal to Noise Ratio**

Description: This test measures the signal to noise ratio from 1142 – 1042  $\text{cm}^{-1}$ . The ratio is defined as the reciprocal of the RMS noise in the defined region for a blank sample measured with a blank background.

Procedure: Run the automated test; a pass/fail status is determined automatically and included in the report.

**Stability**

Description: This test measures the short-term stability of the 1000  $\text{cm}^{-1}$  region of the infrared spectrum. Stability is calculated as the baseline differences observed over the selected time period.

Procedure: Run the automated test; a pass/fail status is determined automatically and included in the report.

**Wavenumber Accuracy and Repeatability**

Description: This test measures the accuracy and precision of the wavenumber scale. For accuracy, wavenumbers from a spectrum of a polystyrene film are determined and compared to wavenumbers set by an NIST SRM 1921b traceable polystyrene film. Repeatability is calculated as the standard deviation of the test.

Procedure: Run the automated test; a pass/fail status is determined automatically and included in the report.

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## Report and Delivery Options

- Show chromatograms
- Show header and footer on cover

## Selected Signature Options

Status: EQP is not signed

- Setpoint/Limit variance is allowed in this EQP
- Reporting variance is allowed in this EQP

## Customer Approval

Name:

Title:

Date:

Signature:

Name:

Title:

Date:

Signature:

Name:

Title:

Date:

Signature:

Name:

Title:

Date:

Signature:

## Legal Notice

Agilent CrossLab Compliance and its primary components (ACE software tool, procedures, test design, metrology tools, chemical reference standards, and operator training materials) have been designed, tested, validated, and released for commercial use following Agilent's Life-Cycle Development Quality Assurance methodology.

Date: June 2019

Agilent CrossLabs Group R&D VP and Dir. of Technology: Neil Cook. Santa Clara, California USA.

Agilent CrossLabs Group Quality Manager: Julio Hector. Santa Clara, California USA.

Agilent CrossLab Compliance is endorsed by Dr. Ludwig Huber on behalf of labcompliance.com.

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## Protocol Details

**Protocol Revision Used for this Document**

**Protocol Revision Release Date**

FTIR.01.02

July 2016

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