

# Agilent Life Sciences and Chemical Analysis Support Services: Qualification Services

## Exhibit 21V

Agilent Technologies' Life Sciences and Chemical Analysis Qualification Services are governed by this Exhibit and the Agilent Service Terms.

### A. Services

Agilent performs Qualification Services using standard Agilent test protocols and performance specifications based on sound metrological practice to verify and qualify instrument performance, at installation and at periodic intervals. The measurements made in conjunction with the services are traceable to the appropriate national or international standards organization, where applicable. Customer is responsible for ensuring compliance with regulatory requirements. The chemical performance test kits, parts, labor and travel to deliver the qualification service are included. The service is available for Agilent and non-Agilent instruments as well as Agilent software.

**a. Operational Qualification** (also referred to as **Performance Verification**) (**R-22B for Classic Edition or R-26J for Enterprise Edition**). Determines

operational performance using a chemical test sample kit of known concentration on chromatography instruments. Service is provided annually.

**b. Documentation.** Complete documentation of tests, test results (pass or fail) and a copy of test protocol with the specified values are provided to Customer. Such documentation is also provided for optional services, if applicable. A sticker, including the date of the test, is placed on the instruments that have passed the test.

### B. Optional Services

Upon request, Agilent may additionally provide the following optional services for an additional charge:

- a. Basic ChemStation Qualification (R-22C).** Agilent performs operational tests, including log-on security, the ChemStation software, calculation, reporting and integration algorithms within the application, of the named ChemStation application software.
- b. Part 11-Compliant CDS Qualification (R-22E).** Agilent provides functional check, including log-on security

and calculation, reporting and integration algorithms within software on named Agilent NDS/Security Pack software. Software features important to 21CFR Part 11 compliance are also tested.

### c. Instrument Repair Qualification (R-22F for Classic Edition or R-26E for Enterprise Edition).

Agilent performs Repair Qualification (RQ) service to test that system performance is returned to Agilent's operational specifications after a repair event. For selected user performed maintenance, test procedures are available for the user to perform the re-qualification.

**d. Extra tests for Classic Edition compliance (R-22K):** Can be used for any of the following two tests (for both use quantity two):

- **FID Response Qualification:** Agilent qualifies the linearity of Flame Ionization Detectors (FID).
- **Thermal Performance Qualification:** Agilent tests the temperature accuracy of the heated zones, such as inlets, detectors and oven, of the specified products.



**e. Extra tests for Enterprise Edition compliance (R-26B):** Can be used for any one of the following tests:

- **Extra OQ test from menu:** This covers extra tests beyond the core tests specified by the Enterprise Edition OQ protocol, or repeated tests with different setpoints. Customer-requested set points and limits are available with a Custom EQP. Additional charges may apply. Use multiple quantities when applicable.
- **FID Response Qualification:** Agilent qualifies the linearity of Flame Ionization Detectors (FID).
- **Thermal Performance Qualification:** Agilent tests the temperature accuracy of the heated zones, such as inlets, detectors and oven of the specified products.

### C. Prerequisites

- a. Minimum Configuration.** The serviced Agilent system must include at least the minimum configuration or other configuration specified in the appropriate calibration or OQ procedure.
- b. Preventive Maintenance.** A preventive maintenance procedure, when recommended by manufacturer may be performed prior to qualification services at Customer's expense.

**c. Equipment Qualification Plan.** Prior to the delivery of Enterprise Edition Qualification services, customer must review and verbally approve the standard Enterprise Edition equipment qualification plan (EQP) or make arrangement for a Custom EQP with Agilent.

### D. Customer Responsibilities and Service Limitations

- a. Operating and Maintenance Procedures.** Customer must follow the operating and maintenance procedures specified in the applicable Agilent documentation. These procedures include routine operational maintenance and other routine maintenance associated with the operation of an Agilent Instrument. Equipment tests are performed to determine the system operational performance and can yield pass or fail results.
- b. Guaranteed Pass OQ.** Agilent does not guarantee that instruments will pass operational qualification except when the OQ service is purchased as option to Agilent Advantage Silver or Gold service plans. See Exhibit 21X. Agilent Life Sciences and Chemical Analysis Support Services: Warranty Extension and Advantage Service Plans
- c. Access.** Customer must provide Agilent access to the instruments, adequate working space and use

of all information and facilities necessary to service the instrument at Customer's site.

- d. Rescheduled Services.** Customer will be responsible for costs incurred by Agilent as a result of postponing or rescheduling any qualification service.
- e. Business decisions.** Business decisions or actions taken by Customer as a result of any qualification service procedure are sole responsibility of Customer.
- f. Proprietary Information.** Any Agilent copyrighted materials may not be copied unless Agilent agrees to such copying in writing.
- g. Product Eligibility.** Unless otherwise stated, eligibility for qualification services is limited to select Agilent and non-Agilent instruments only and is subject to local availability. Any service not covered by the contractual service ordered, including but not limited to Software Support, is subject to Agilent's standard service rates.
- h. Service Availability.** Coverage hours will be Agilent's normal business hours (08:00am to 17:00pm), Monday through Friday, excluding local holidays.
- i. Travel Zones.** The standard At-Your-Site service price includes travel to sites located within 100 miles or 160 kilometers of an Agilent office. Additional charges will be included for travel beyond this distance.

**j. Obsolete Instruments.** Agilent standard services do not cover Instruments or Products that are beyond their specified support period. For Products or Instruments that are obsolete, Agilent cannot guaranty that parts will be available. Agilent will use commercially reasonable efforts to effect the service, however, Agilent does not warrant that such services will be successful.

**k. Contamination.** Services for parts and instruments that become contaminated when operated in hazardous environment or are used to analyze hazardous materials, may be subject to additional charges. Customer is responsible for proper disposal of all contaminated material that cannot be returned to Agilent in a safe manner.

**l. Consumables, Supplies and Parts.** All parts, supplies, and consumables specified by the Agilent qualification protocol are provided by Agilent. Any additional parts for maintenance or repair needed to affect qualification will be billed

to customer unless otherwise covered by Agilent service and support agreement.

**m. Notification of Out-of-Tolerance Conditions and Retesting.** Agilent notifies Customer in writing if the test and measurement equipment used to perform the qualification test has been found to have any, in Agilent's evaluation, significantly out-of-tolerance conditions. Agilent will offer to recalibrate or test the affected Agilent instrument at no charge.

#### **E. Cancellation or Deletion**

Notwithstanding the provisions of the Terms of Service to which this Exhibit applies, upon sixty (60) days written notice, Customer may delete Product from or cancel in its entirety a remedial Service Agreement to which this Exhibit applies that includes but is not limited to such Services as return to bench, on-site support, response centre, application and technical assistance and Software Updates. Customer will receive a refund that is prorated over

the term of the Service Agreement. Cancellation of a scheduled Service Agreement, or deletion of a Product from a Service Agreement including but not limited to such Services as calibration and preventive maintenance, will be subject to a fee in the amount of 10% of the price of the Service so cancelled or deleted. Customer will also pay for all Service rendered under the scheduled Service Agreement. Information regarding applicable Service charges is available upon request. A Service Agreement that contains more than one type of Service may only be cancelled in its entirety. Customer may not cancel a portion of or an individual Service offered under such Service Agreement.

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