

Operational Qualification/Performance Verification of Agilent ChemStation Software

Agilent Technologies' operational qualification/performance verification (OQ/PV) procedures for Agilent ChemStation software include tests for security, communication and internal verification. These services use a written protocol and software qualification procedure to ensure that Agilent ChemStation software operates within pre-defined acceptance limits, challenges any breach of security and reports chromatographic results accurately.

The ChemStation OQ/PV services are also applicable for ChemStations configured for data analysis only, such as for use with Agilent networking solutions.

All tests and fully documented. This documentation verifies that the Agilent ChemStation software meets Agilent functional test specifications and can be used to assist you in meeting regulatory requirements such as FDA 21 CFR Part 11.

OQ/PV Requirement for the Agilent ChemStation Software

• ChemStation software version A.06.01 and later

Supported Software

Agilent ChemStation software OQ/PV services cover Agilent chemical analysis software versions A.06 and later. This includes:

- LC (G2170AA), GC (G2070AA), CE (G1601AA) and analog-to-digital (A/D) converter (G2072AA) single instrument modules
- LC (G2171AA), GC (G2071AA), CE (G2172AA) and A/D (G2073AA) additional modules
- LC data and spectroscopy data evaluation module (G2190AA)
- Diode array detector spectral module (G2180AA)
- LC/MSD single instrument (G2710AA) and ChemStation add-on (G2715AA) modules as well as the data evaluation ChemStation (G2730AA)
- Chromatography data evaluation module (G2090AA)
- LC (G2175AA), GC (G2075AA), A/D (G2077A) and spectral evaluation (G2185AA) licenses

ChemStation 0Q/PV Tests

- Communication. This test interactively determines correct communication between the software and the analytical instrument that is being controlled by the application. The test does not perform an OQ/PV on the analytical instrument.
- Security. This procedure interactively tests direct challenges to the security of ChemStation logon. It does not challenge your NT or network logon.
- Internal Verification. This test verifies the structural and functional integrity for data analysis components used in determining quantitation*, integration* (including time-based integration functions), reporting*, system suitability*, library searching and peak purity for spectral analysis.
- * Our tests have been designed using devices that are traceable to national standards such as the National Institute for Standards Testing (NIST) and the United Kingdom National Measurement and Accreditation Service (NAMAS)

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