Data Sheet

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Agilent Fragment Analyzer Portfolio Compliance Solution

Achieve Confidence in Laboratory Settings

The Agilent Fragment Analyzer systems employ automated parallel capillary electrophoresis to ensure reliable quality control of nucleic acid molecules. The Fragment Analyzer controller and Agilent ProSize data analysis software facilitate streamlined data acquisition, review, and reporting.

The Fragment Analyzer portfolio includes the 5200, 5300, and 5400 Fragment Analyzer instruments, along with software, services, and application-specific consumables. With Installation Qualification (IQ) and Operational Qualification (OQ) services available for hardware and software, along with the Fragment Analyzer security module, the systems support compliance-enabling requirements for GLP/GMP laboratories.

Key Features

- Reproducible results: Validated consumables with standardized protocols and optimized assays
- Sample analysis: Objective information on sample size, concentration, and integrity
- Compliance services: Software and hardware IQ and OQ for purchase at any time, with a certified engineer testing and verifying functionality to ensure system qualification
- Design qualification: Functional and operational specifications are outlined in the declaration of conformity for the Fragment Analyzer consumables

GLP/GMP Compliance

Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP) are guidelines to ensure the minimum requirements for quality management are met by research facilities and/or food and pharmaceutical product manufacturers. These practices ensure uniformity, consistency, reliability, reproducibility, quality, and integrity of laboratory tests.

Figure 1. System validation workflow.

Design Qualification (DQ)

The customer is responsible for defining the functional and operational specifications for their intended purpose. With the declaration of conformity, Agilent guarantees all specifications and ensures that each system component meets Agilent's stringent quality criteria.

Documents provided:

- Declaration of System Validation for the Fragment Analyzer software (Fragment Analyzer controller and ProSize data analysis software)
- Declaration of Conformity for the 5200, 5300, and 5400 Fragment Analyzer instrument
- Declaration of Conformity for all Fragment Analyzer consumables and reagents

Installation Qualification (IQ)

IQ ensures that the 5200, 5300, and 5400 Fragment Analyzer instrument and software are installed correctly, and all connections are correct. From the moment the components are unpacked to the point the system becomes operational, we document the completeness of shipping, the operating environment, and all system components.

Operational Qualification (OQ)

OQ is conducted to verify and document that the Fragment Analyzer systems meet specified performance criteria, ensuring basic accuracy after installation in the selected environment. OQ should be performed following hardware or software updates, repairs, relocations, and at regular intervals during routine use. Agilent recommends conducting preventive maintenance prior to an OQ. Audit-ready documentation confirms that Fragment Analyzer hardware and software operate according to operational specifications.

Performance Qualification (PQ)

PQ verifies that the system operates according to the specific requirements of the application. It is the customer's responsibility to define the PQ. Standard Operating Procedures (SOPs) can be established for sample processing and analysis to ensure consistent and reliable results.

For detailed information and pricing, please contact your Agilent local representative.

Learn more at
www.agilent.com/genomics/fragment-analyzer-security-module

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