

Agilent TapeStation Platform Compliance Solution



Feel confident in laboratory environments

The Agilent TapeStations compliance solution provides an integrated and reliable tool for quality control of nucleic acids. It supports the validation process from start to finish, enabling users to run the Agilent TapeStation systems in regulated lab environments. The Agilent TapeStation compliance solution comprises the 4150 and 4200 TapeStation instrument, software, services, as well as application-specific consumables. With Installation Qualification (IQ) and Operational Qualification (OQ) services the TapeStation system can easily be made GLP/GMP compliant.

An integrated compliance solution

- 4150 and 4200 TapeStation instruments and TapeStation software
- RNA and DNA ScreenTape devices and reagents
- Design qualification documentation
- Compliance services (TapeStation system IQ and OQ service)

Key features

- Reproducible results: System with prepackaged reagents and ScreenTape devices, standardized protocols and optimized assays
- Objective information regarding sample concentration, size and integrity
- Compliance services: Software and hardware IQ and OQ can be purchased at any time. A certified engineer will test and verify the functionality of the hardware and software, thereby qualifying the system
- Design qualification: Functional and operational specifications are defined by the declaration of conformity for the TapeStation instruments, ScreenTape devices as well as the TapeStation Test Tape, certificate of conformance for the reagents and the declaration of system validation for the Agilent TapeStation software

GLP/GMP Compliance

Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP) are guidelines to ensure minimal requirements are met for quality management or research facilities

and/or manufacturer of food and pharmaceutical products. These practices ensure uniformity, consistency, reliability, reproducibility, quality, and integrity of laboratory tests.

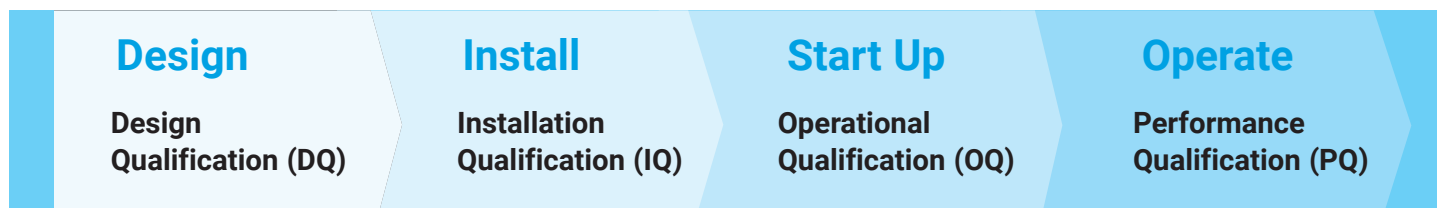


Figure 1. Validation process

The Agilent TapeStation system compliance solution supports the validation process regardless of whether you are analyzing RNA or DNA samples.

Design Qualification (DQ)

The customer is responsible to define the functional and operational specifications for the intended purpose. With the declaration of conformity Agilent guarantees all specifications and ensures that the individual system components passed all Agilent quality criteria.

Documents provided:

- Declaration of System Validation for the TapeStation software
- Declaration of Conformity for the 4150 and 4200 TapeStation instrument
- Declaration of Conformity for all ScreenTape devices
- Declaration of Conformity for the TapeStation Test Tape
- Certificate of conformance for the TapeStation reagents

Installation Qualification (IQ)

IQ ensures that the Agilent 4150 and 4200 TapeStation instruments and the TapeStation software are installed correctly and all electrical connections are correct – from

the moment the components are unpacked to the point the system is ready for operation – documenting the completeness of shipping, the operating environment, and the components of the system. The correct installation of the software is checked in the TapeStation system diagnostics of the controller software. Audit-ready documentation will be supplied for both the TapeStation instrument and software.

Operational Qualification (OQ)

OQ is performed to verify and document the TapeStation system's ability to meet specified performance criteria ensuring basic accuracy after it is installed in the selected environment. OQ should be performed after hardware or software updates, repair, or relocation and at regular intervals during routine use. Agilent recommends performing preventive maintenance prior to an OQ. Audit-ready documentation confirms that TapeStation hardware and software perform according to operational specifications.

Performance Qualification (PQ)

PQ confirms that the system functions according to the needs of the application.

Defining the PQ is the customers responsibility: Standard Operating Procedures (SOPs) can be put in place for sample processing and analysis.

	Part number	Option code IQ	Option code OQ
4150 TapeStation system	SYS-TS-4150	R26N091	R26J091, Multiyear: R26J00x (x= 1-5)
		combined Agilent Instrument Qualification (AIQ): R26H091	
4200 TapeStation system	SYS-TS-4200B	R26N091	R26J091, Multiyear: R26J00x (x= 1-5)
		combined Agilent Instrument Qualification (AIQ): R26H091	
TapeStation Software	SYS-SW-CS	R26N091	R26J091, Multiyear: R26J00x (x= 1-5)
		combined Agilent Instrument Qualification (AIQ): R26H091	

Table 1. TapeStation Compliance Service Part Numbers

www.agilent.com/genomics/tapestation

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