nCounter® Pro Analysis System: Support of 21 CFR Part 11

This document explains how the nCounter® Pro Analysis System can help your laboratory comply with the regulations in U.S. 21 CFR Part 11.

Background

Part 11 of the 21 CFR (Title 21 – Food and Drugs of the Code of Federal Regulations) covers the use of electronic records and electronic signatures. In 1997, the regulation became effective with the goal of preventing fraud in the generation and signing of electronic records.

The regulation describes 5 key elements necessary to support a compliant environment:

- System validation
- Audit trail
- Electronic signatures
- Copies of records
- Record retention

Although no one system on its own can claim to be 21 CFR Part 11-compliant itself, it is important to work with a system that helps enable such an environment holistically at the laboratory-level.

nCounter Validation Summary

The nCounter Pro Analysis System has been validated for meeting all the key elements of the applicable sections of the 21 CFR Part 11 regulation, as summarized in the following table:

Key Element	Assessment of Compliance
System Validation	Validation and verification has been done for the software systems, and it meets the requirements and user needs.
Audit Trail	Evidence shows that the software has been designed and verified to meet this requirement. It is possible to determine which users interacted with the system at any given time, and there is traceability in the software for determining when errors occurred and what actions were taken.
Electronic Signatures	Not applicable - There is no identified need to have an electronic signature produced for the various steps in the nCounter workflow. The system does not produce electronic batch records or document control software. Records can be produced that show the identity of the users that interacted with the system, and the proper login protections are in place. Given the intended use, no gap is identified.
Copies of Records	The system is capable of producing paper copies of records for use in audits. The system can also export data files to other formats, and the integrity of this process has been verified.
Record Retention	The software system stores records within the system and also has the capacity to allow admins or other authorized users to copy data files to other locations for long-term storage. Verification of the integrity of this transfer process has been verified and validated.

For more details on 21 CFR Part 11, visit www.fda.gov

NanoString values the diverse needs of its customers and is dedicated to working with them to help them meet their regulatory needs wherever possible.

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