

## 21 CFR Part 11 Compliance Matrix for FCS Express

This table shows how De Novo Software's FCS Express can help you with the requirements of 21 CFR Part 11.

Section	Summary of Rule	Compliance Strategy
11.10	<b>Controls for Closed Systems</b>	FCS Express is designed to run as a closed system: it can only be accessed via the FCS Express user interface.
11.10(a)	<b>Validation</b>	De Novo Software has validated FCS Express. De Novo can assist your laboratory with preparation of a validation plan to meet your unique requirements.
11.10(b)	<b>Record Generation and Copying</b>	FCS Express stores its layout files and results in a format that is both human readable and machine-readable.
11.10(c)	<b>Record Protection</b>	Records are saved in an encrypted and locked format, with checksum measures in place to detect tampering. De Novo Software advises that you save your FCS Express files in a secure folder.
11.10(d)	<b>Access Limitation</b>	FCS Express contains security features that limit access to authorized individuals.
11.10(e)	<b>Audit Trails</b>	Audit trails are secure and time-stamped. They record the date and time of actions that modify any aspect of your analysis, along with the name of the person who made the change.
11.10(f)	<b>Operational System Checks</b>	This does not apply to FCS Express.
11.10(g)	<b>Authority Checks</b>	User credentials are required to access FCS Express. FCS Express also features a comprehensive set of permissions that you can set on an individual user basis.
11.10(h)	<b>Device/Terminal Checks</b>	FCS Express applies checks to determine if it has received a valid flow cytometry data file.
11.10(i) and (j)	<b>Training and User Accountability</b>	De Novo Software can assist your laboratory with preparation of a training plan so that your scientists understand how to use FCS Express as well as the implications of Part 11 on their work.
11.10(k)	<b>System Document Control</b>	De Novo Software follows change control and life cycle management procedures for document control.
11.30	<b>Controls for Open Systems</b>	Does not apply to FCS Express, which is designed to operate as a Closed System.
11.100(a), 11.200(b)	<b>Uniqueness of Electronic Signatures</b>	FCS Express ensures that all user IDs are unique; therefore, all electronic signatures are unique.
11.100(b)	<b>Verification of Identity</b>	You must verify the identity of your FCS Express users.
11.100(c)	<b>Certification</b>	You must certify with the FDA that you intend to use electronic signatures.
11.200(a)(1)	<b>Two-Component Signing</b>	FCS Express requires entry of username and password to sign layout files and results.
11.200(a) (2) and (a)(3)	<b>Signature Authenticity and Collaboration to Falsify</b>	To gain access to FCS Express and to sign a layout file or result, users must have a valid username and password.
11.200(b)	<b>Biometric Signatures</b>	Not required for FCS Express which operates as a Closed System.
11.300(b)	<b>Password Aging</b>	FCS Express has a configurable password-aging feature.
11.300(d)	<b>Controls to Prevent Unauthorized Credential Use</b>	FCS Express disables accounts after a configurable number of failed login attempts.