

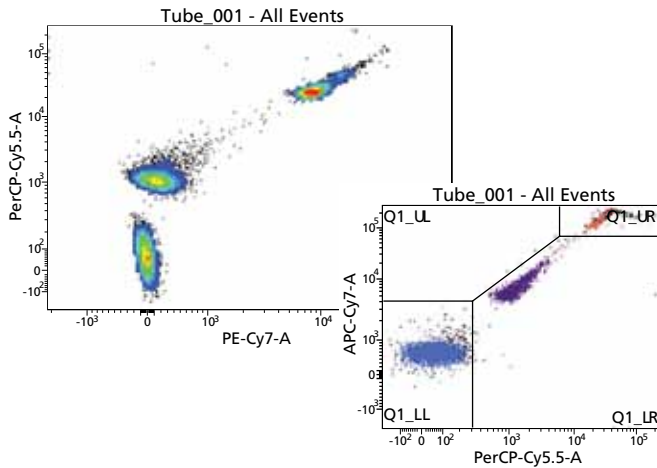
BD FACSuite™ Data Security

Information security overview for the BD FACSuite™ System

Features

User access controls, audit trails, and electronic signatures support FDA's Electronic Records and Electronic Signatures Rule (21 CFR Part 11)

Encrypted data storage and file checksum help protect data integrity and confidentiality



Signature:

REPORT NOT SIGNED

Comments:

CS&T Assay w Report UD

Signature:

Donald Johnson
4/21/2011 2:36:19 PM

Comments:

CS&T Assay w Report UD

Figure 1. Electronic signatures

Researchers can electronically sign assay reports after reviewing results by entering their user ID and password.

The ability to manage, store, and exchange information securely can be critically important when conducting basic research or drug development in flow cytometry laboratories. BD FACSuite™ software, used with BD FACSuite™ systems, includes user access controls, audit trails, and electronic signatures that may support the US Food and Drug Administration's Title 21 CFR Part 11 Rule, covering electronic records and signatures.

In addition to these software control features, BD FACSuite software also offers barcoding support, keyword management, data encryption, and file checksum. Together, they comprise a security solution that helps researchers protect proprietary research results.

Supports electronic records and signatures

BD FACSuite software's user and workflow controls help to improve data security and workflow efficiency.

User access controls

BD FACSuite software's user and password administration facility protects against unauthorized access. The design requires that users must log in with unique IDs and passwords, and are locked out if their passwords have expired or if they exceed the set limit of failed login attempts. Users may choose to make their assays, tube settings, worklists, and experiments private or shared.

Audit trails

Researchers can enable an audit trail for any or all entries in a worklist. When an audit-enabled entry is modified, such as changing a gate or adding a plot, the software records the date and time of the change and prompts the user to enter a reason.

Electronic signatures

From the BD FACSuite Library, users can require electronic signatures for individual assays and their reports. An e-signature consists of a unique user ID and password. When the system completes acquisition of an assay that requires an e-signature, a signature request appears on the worklist entry. Once an entry or report is signed, any modification of the report automatically removes its e-signature.

Visit bdbiosciences.com for more information.

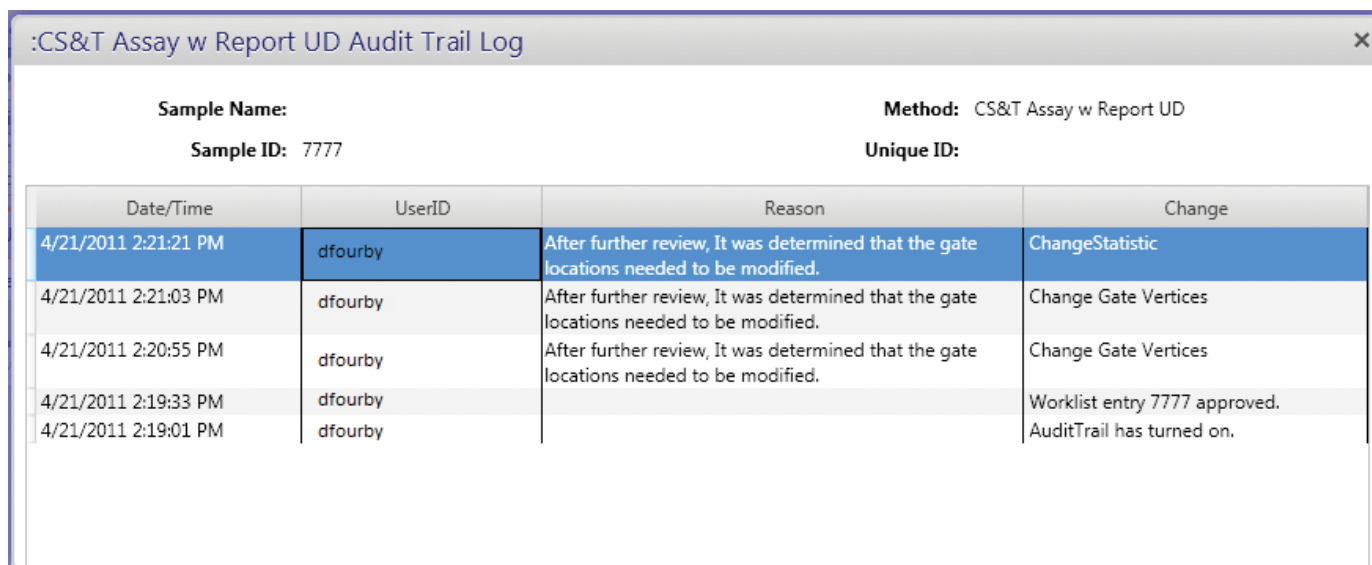


BD FACSuite™ Data Security

Helps protect data integrity and confidentiality

Protecting and safeguarding data from unauthorized use and disclosure is essential. BD FACSuite software helps secure file storage for proprietary information. The database and associated BD FACSuite files are encrypted for added security.

When a file is exported, the software attaches a checksum value, which is programmed to change if the file is modified. Before it can be imported, BD FACSuite software checks the value to prevent import if the value has changed. These built-in security functions promote data integrity and protect against accidental or malicious alteration of the data files imported into BD FACSuite software.



Date/Time	UserID	Reason	Change
4/21/2011 2:21:21 PM	dfourby	After further review, It was determined that the gate locations needed to be modified.	ChangeStatistic
4/21/2011 2:21:03 PM	dfourby	After further review, It was determined that the gate locations needed to be modified.	Change Gate Vertices
4/21/2011 2:20:55 PM	dfourby	After further review, It was determined that the gate locations needed to be modified.	Change Gate Vertices
4/21/2011 2:19:33 PM	dfourby		Worklist entry 7777 approved.
4/21/2011 2:19:01 PM	dfourby		AuditTrail has turned on.

Figure 2. Audit trail log

Audit trail logs provide complete records showing what changes were made, when, by whom, and why.



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