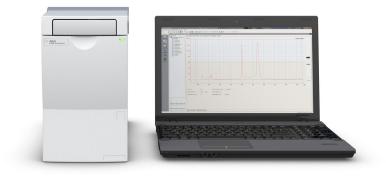Agilent

Trusted Answers

Agilent Bioanalyzer System Security Pack: Role Permissions

Security. Integrity. Compliance. The Agilent 2100 Expert Security Pack (p/n G2949CA) for the Agilent 2100 Bioanalyzer system (p/n G2939BA) enables fast and easy compliance with 21 CFR Part 11 regulations by providing:

- – Easy setup and use

- – Workflow management tools with multiple user levels (see Table 1 for full details)

- – Audit trails for full traceability

- – Electronic signature executed with two identification components

- – Enhanced data integrity through secured data storage

Table 1. In conformance with 21 CFR Part 11 standards, upon activating the Security Pack multiple user levels are preconfigured as operator roles with specific permissions according to this table.

		Administrator	Backup Operator	Standard Operator	Advanced Operator	Validation Operator	Unlock Operator	Guest
System	Set-Up Users	✓	✗	✗	✗	✗	✗	✗
	Assign Roles To Users	✓	✗	✗	✗	✗	✗	✗
	Disable Users	✓	✗	✗	✗	✗	✗	✗
	Change System Settings	✓	✗	✗	✗	✗	✗	✗
	Archive / De-Archive Files	✓	✓	✗	✗	✗	✗	✗
	Import / Export Multiple Data Files	✓	✓	✗	✓	✗	✗	✗
	View System Logbooks	✓	✓	✓	✓	✓	✓	✓
	View Previous System Logbooks	✓	✓	✗	✓	✗	✗	✗
Verification	Validate System	✗	✗	✗	✓	✓	✗	✗
	Validate Instruments	✗	✗	✗	✓	✓	✗	✗
	Open Previous Validation Files	✓	✓	✓	✓	✓	✓	✓
Methods	Open Existing Method	✓	✓	✓	✓	✓	✓	✓
	Create a New Method from Templates	✗	✗	✓	✓	✗	✗	✗
	Modify Properties (Study, Instrument, Reporting, and Configuration)	✗	✗	✓③	✓③	✗	✗	✗
	Add and Remove User from Workflow	✓③	✗	✓③	✓③	✗	✗	✗
	Modify "*Normal*" Setpoints	✗	✗	✓①	✓①	✗	✗	✗
	Modify "*Advanced*" Setpoints	✗	✗	✗	✓①	✗	✗	✗
	Modify Result Flagging Rules	✗	✗	✗	✓①	✗	✗	✗
Instruments	Select Instrument	✓	✓	✓	✓	✓	✓	✓
	Select Method	✓	✓	✓	✓	✓	✓	✓
	Start a Run	✗	✗	✓	✓	✗	✗	✗
	Stop a Run	✗	✗	✓	✓	✗	✗	✗
	Modify Run Parameters	✗	✗	✓	✓	✗	✗	✗
	View Raw Data	✗	✗	✓	✓	✗	✗	✗

① Only available if a user is a method owner or if set up in the "*Analysis*" workflow level. Settings of demo templates cannot be changed.

② Only available if set up in the current workflow level or if a data file is in "*Method Development.*"

③ Only available if a user is a method owner or if set up in one of the workflow levels of the data or method file.

		Administrator	Backup Operator	Standard Operator	Advanced Operator	Validation Operator	Unlock Operator	Guest
Data	Open Data Files	✓	✓	✓	✓	✓	✓	✓
	Close Data Files	✓	✓	✓	✓	✓	✓	✓
	Modify "*Normal*" Assay Setpoints	✗	✗	✓②	✓②	✗	✗	✗
	Modify "*Advanced*" Assay Setpoints	✗	✗	✗	✓③	✗	✗	✗
	Add or Modify Regions	✗	✗	✗	✓③	✗	✗	✗
	Print Reports	✓	✓	✓	✓	✓	✓	✓
	Apply Workflow Signature	✗	✗	✓②	✓②	✗	✗	✗
	Revert to Last Saved Versions	✗	✗	✓②	✓②	✗	✓	✗
	Perform Manual Integration	✗	✗	✗	✓③	✗	✗	✗
	Copy to Clipboard	✓	✓	✓	✓	✓	✓	✓
	Export	✓	✓	✓	✓	✓	✓	✓
	Add and Remove Users from Workflow	✓③	✗	✓③	✓③	✗	✗	✗
	View Data Logbooks	✓	✓	✓	✓	✓	✓	✓
General	Change User Password	✓	✓	✓	✓	✓	✓	✗
	Lock Application	✓	✓	✓	✓	✓	✓	✓
	Close Application	✓	✓	✓	✓	✓	✓	✓
	Log On to Application	✓	✓	✓	✓	✓	✓	✓
	Unlock Application of Other Users during a Workflow	✗	✗	✗	✗	✗	✓	✗

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