BD FACS™ Workflow Manager System User's Guide

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For US patents that may apply, see bd.com/patents

Regulatory information

BD FACSDuet™, BD FACSLyric™, and BD FACSVia™ are in vitro diagnostic medical devices bearing a CE Mark

In the EU, the BD FACSVia[™] Flow Cytometer is no longer available for sale.

Laser safety information

BD FACSDuet[™], BD FACSLyric[™], and BD FACSVia[™] are Class 1 Laser Products.

EC information

The BD FACS™ Workflow Manager system flow cytometer isin vitro diagnostic medical devices bearing a CE Mark.

NOTICE: For a patient/user/third party in the European Union and in other countries with identical regulatory regime: if, during the use of this device or as a result of its use, a serious incident has occurred, please report it to BD and/or its authorized representative and to your national authority managing health products.

Electromagnetic Compliance

The BD FACS™ Workflow Manager system complies with standard EN 61326-2-6:2013, Section 9.3 (emission and immunity requirements). This equipment has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference. The electromagnetic environment should be evaluated prior to operating the device. Do not use this device in close proximity to sources of strong electromagnetic radiation (e.g., unshielded intentional radio frequency sources), as these can interfere with the proper operation.

History

Revision	Date	Change made
23-21509(01)	2021-09	Initial release
23-21509(02)	2023-05	Release of new version 1.1

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Introduction

This chaptersection covers the following topics:

- About this guide (page 8)
- Abbreviations (page 9)
- Technical support (page 10)

About this guide

This guide provides information for setting up and running the BD FACS™ Workflow Manager system for using BD FACSLyric™, BD FACSVia™ and/or BD FACSLyric™ physically and data integrated with BD FACSDuet™.

In addition to becoming familiar with the instructions outlined in the guide, operators must receive appropriate training on the BD FACS $^{\text{\tiny{TM}}}$ Workflow Manager system before attempting to operate the system.

This guide includes:

- An overview of the BD FACS™ Workflow Manager system.
- Navigation Instructions for the BD FACS™ Workflow Manager software.
- The different workflows for processing panel requests on BD FACSLyric[™], BD FACSVia[™] and BD FACSLyric[™] physically and data integrated with BD FACSDuet[™].
- A system reference providing a detailed explanation of functionalities of the BD FACS™ Workflow Manager system.

Additional information

This User Guide can be viewed by clicking the Help button from the user menu of the navigation panel in the BD FACS $^{\text{\tiny{TM}}}$ Workflow Manager software. Internet access is not required to access the Help system.

Abbreviations

The following table lists the abbreviations used in this guide.

Abbreviation	Meaning	
CRO	Contract Research Organisation	
ERP	Entry Run Package	
FACSDuet™	BD FACSDuet™ Sample Preparation System	
FACSDuet™ Software	BD FACSDuet™ Software on BD FACSDuet™ Sample Preparation System	
FACSLyric™	BD FACSLyric™ Flow Cytometer	
FACSuite™	BD FACSuite™ application on BD FACSLyric™ Flow Cytometer	
FACSVia™	BD FACSVia™ Flow Cytometer	
FACSVia™ Software	BD FACSVia™ Software on BD FACSVia™ Flow Cytometer	
FWM	BD FACS™ Workflow Manager	
LIS	Laboratory Information System	
SOP	Standard Operating Procedure	
UD	User Defined Assay	

Technical support

Technical support contact

If assistance is required, contact your local BD Biosciences technical support representative or BD distributors. Go to our website bdbiosciences.com, for up-to-date contact information.

The following information is required while contacting BD Biosciences:

- · Product name and license number
- · Any error messages

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About the system

This chapter section covers the following topics:

• BD FACS™ Workflow Manager system (page 12)

BD FACS™ Workflow Manager system

BD FACS™ Workflow Manager (FWM) is a standalone laboratory software solution that provides data management and workflow management functionalities across locations where clinical diagnostic activities occur. The software combines clinical results, operational data, and patient and sample data from the following sources:

- Automation (BD FACSDuet™ Sample Preparation System)
- Diagnostic Instrumentation (BD FACSVia[™] and BD FACSLyric[™] Flow Cytometers)
- External software such as Laboratory Information Systems (LIS)

The data collected from the above sources is aggregated, evaluated, and disseminated subsequently.

Getting started

This chaptersection covers the following topics:

- Launching and Logging in to the FWM Software (page 14)
- FWM Software navigation panel (page 15)

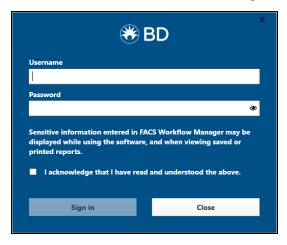
Launching and Logging in to the FWM Software

To launch the FWM software double-click the Desktop icon of the application.



Logging in

- Once the FWM software is launched, the user is prompted to enter the credentials for signing in as a defined user.
- Select the Eye icon on the right side of the Password tab for viewing the password.
- The user must select the check box "I acknowledge that I have read and understood the above" to enable the "Sign in" button.



FWM Software navigation panel

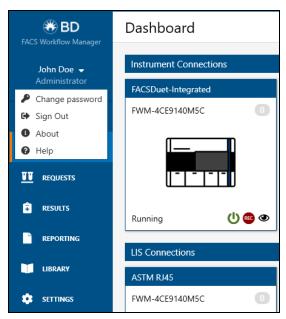
Overview

The navigation panel is located on the left side of the application. The various functions associated with the navigation panel are described below:

Navigation panel		SI. No.	Function
	ℰ BD FACS Workflow Manager Admin →	1	User Menu (your name): Change your password Sign out About Help
(2)	Administrator	2	Notifications: View current and archived notifications (New notifications are indicated with a counter)
3	DASHBOARD TT REQUESTS	3	Dashboard: View connection status of available Instruments and LIS connections
5	RESULTS	4	Requests: View, Create and Edit Requests
(b	REPORTING	5	Results: Review and process Results
7	LIBRARY	6	Reporting: View the Audit log
	** SETTINGS	7	Library: Manage system configuration
		8	Settings: Manage system settings

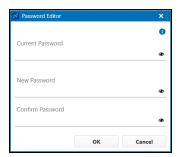
Accessing the user menu

Clicking the User name drop-down provides the following options: Change password, Sign Out, About and Help.



Change the Password

Click **Change password** to edit the password for the current user. Type the Current Password and provide the New Password, then type the New Password again to confirm it and click **OK**.



Signing Out

Click **Sign out** for signing out as the current user.

About

Click **About** to display the About FACS Workflow Manager dialog that contains information related to the software versions of the FWM software and related services and drivers.



Help

Click **Help** to access the BD FACS™ Workflow Manager system User's Guide.

Operating the system

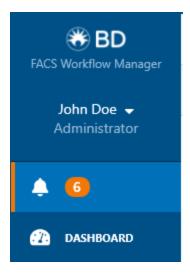
This chaptersection covers the following topics:

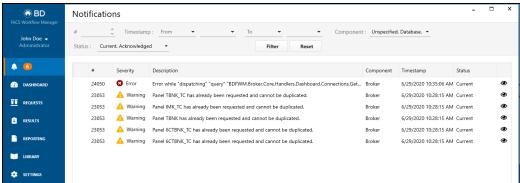
- Notifications workspace (page 20)
- Dashboard workspace (page 22)
- Requests workspace (page 24)
- Managing requests (page 27)
- Results workspace (page 33)

Notifications workspace

Overview

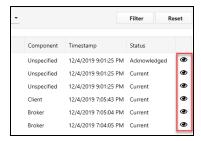
Click the Notification icon in the navigation menu to access the Notifications Workspace. The number of unread notifications is displayed in the orange notification counter.





Details

Details of each notification can be viewed by either double-clicking the entry in the list or by clicking the Eye icon on the right side of the corresponding notification.

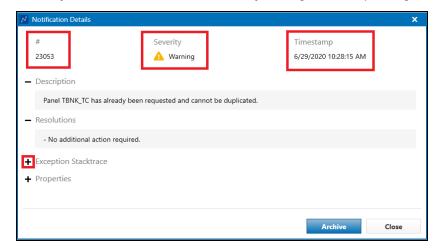


Current Notifications: Notifications which are not viewed in detail are shown as "Current".

Acknowledged Notifications: When a notification is viewed its status changes to "*Acknowledged*".

Click the **Archive** button in the "Notification Details" dialog box to remove the entries from current view. If needed, entries can be retrieved by search **Filter** option.

The notification detail window contains the Notification Number, Severity and Timestamp. To view a detailed description of the notification, click the + button. Similarly, Resolutions can also be viewed by clicking the corresponding + button.



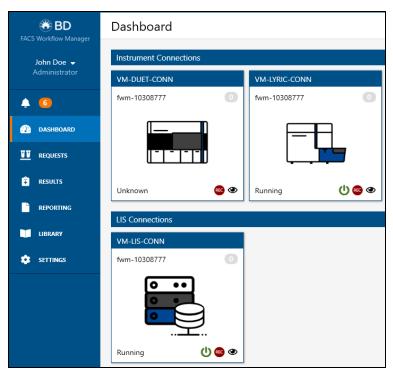
The filtering options at the top of the notification workspace enables the user to select filtering criteria: Error number, date/time of occurrence, Component and Status.



Once the filtering criteria has been defined, click the **Filter** button. Clicking **Reset** will remove all filtering criteria.

Dashboard workspace

To access the dashboard, click the **DASHBOARD** button on the user menu. The Dashboard provides information related to the type and the status of the instrument(s) and LIS(s) connection(s).



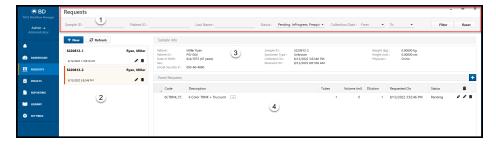
The following table gives an overview of the functions that are available on the Dashboard for each instrument.

Dashboard panel	SI. No.	Function
1 FACSLyric-1	1	Connection Name
FWM-4 2 3	2	Hostname of the computer on which the connection is running
8 Running 6 7 8	3	Number of queued messages are displayed in the message counter. When LIS does not respond to the FWM messages they get queued and are subsequently transmitted to the LIS when it responds again. Click the message counter to clear the queue if needed.
	4	Instrument type icon
	5	Status: Running, Stopped, Deploying, Starting, Unknown (if not deployed or deployment service is not available)
	6	Start button
	7	Record button to monitor traffic of the connection. Value can be defined between 24h - 72h. Align this value with Purge Diagnostic Data value in System - Settings.
	8	View the communication messages

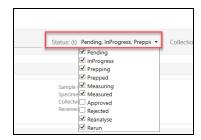
Requests workspace

Requests workspace provides Sample information along with Panel requests that are received from the LIS or created manually. Samples will be displayed in the Requests Workspace until all panel requests are either approved or rejected.

To access the Requests workspace click the **REQUESTS** button. The filtering options at the top of the workspace allows you to filter Requests in the workspace based on the following criteria: Sample ID, Patient ID, Last Name, Status and Collection Date (Section 1).



Select all the required options from the Status drop-down list.

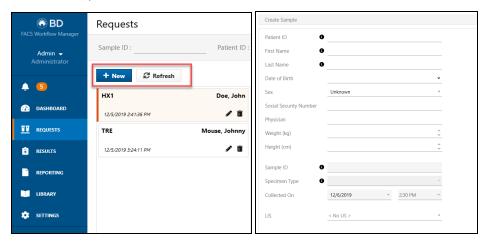


The Filter button on the workplace allows you to filter the requests based on the selected entry(ies). Similarly, the Reset button allows to reset all values to default.

Section 2 lists all available patient requests based on the selection criteria.



The + New button provides access to the Create Sample page where information related to a new sample can be entered. The Refresh button refreshes the list of all available samples.



The Sample Info (Section 3) displays all the patients/samples information related to the sample that is selected in the list of available samples: Patient name, Patient ID, Date of Birth, Sex, Social Security #, Sample ID, Specimen Type, Date and time of Collection, Date and Time of Receiving, Weight (kg), Height (cm), Physician name.



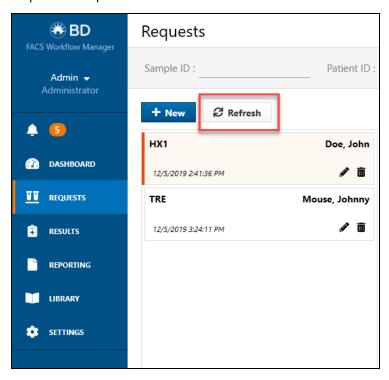
The Panel Requests (Section 4) lists the available panel(s) for the selected sample. The +L status icon next to a panel request indicates that the panel request was received from an LIS. To add more panels click the + button.



Managing requests

Panel requests from LIS

Panel Requests can be either received from LIS or manually created in the Requests Workspace. Click the **REQUESTS** button in the navigation menu to access the Requests workspace.



Panel Requests received automatically from the LIS are displayed as a list. When the LIS supports Host Query and has an enabled connection, FWM can retrieve Panel Request information from LIS based on the identified Sample ID of the connected instruments.

To ensure that all the latest information is displayed on the screen and to update the list of Samples, click the **Refresh** button.

Creating a manual request

Click + New button on the Request workspace to open the Create Sample page.
 Enter the following Sample details to create a new request: Patient ID, First Name,
 Last Name, Sample ID and Specimen Type.

Note: These fields are mandatory and must be populated to create a new request. All other basic details are filled in automatically if an existing Patient ID is used.

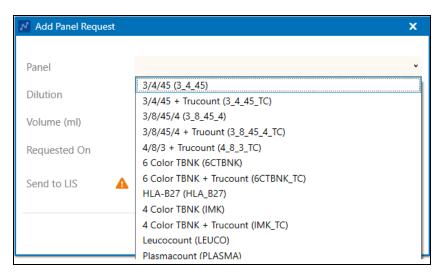
- Specimen types need to be created in advance in the Library workspace (page 60).
 The Default specimen type is Unknown (UNK).
- Click the Save button and the new Sample opens in the list of Samples.



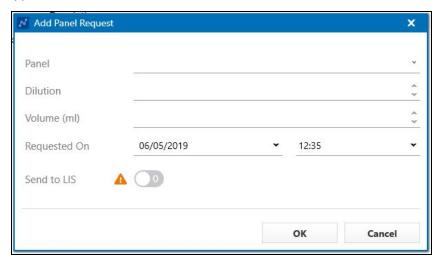
 Click the created Request ID to view the panel requests which are to be measured on the sample.



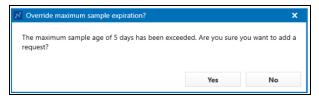
- To add panel requests, click the + button. The Add Panel Request window opens.
- Select the panel from the drop-down in the Add Panel Request window.



- If any specific dilution or volume is required, it can be added to the request.
- Enable the Send to LIS option to enable transmission of the results of this request
 to the LIS. If a default LIS is defined in the LIS field in the Create Sample page, the
 appropriate LIS will be assigned automatically and results will be send to LIS after
 approval.

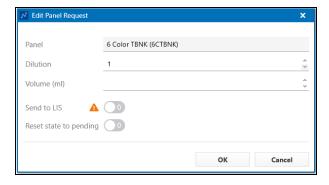


• If the maximum sample age has exceeded, a warning will be shown asking if the user wants to continue with the request. Select **Yes** to continue or **No** to stop.



Editing a panel request

- To edit a panel request, Click the Pencil button.
- Dilution and volume can be updated.
- Enable Reset state to Pending to force the state back to pending.



Deleting a panel request

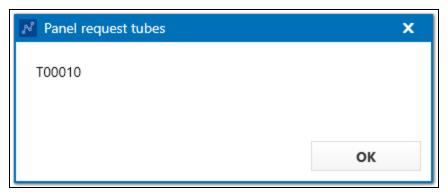
- To delete a panel request, click the Delete icon
- Confirm that you want to delete
- To delete all panel requests, click the Delete icon in the header of the column.



View Tube ID information

• To view secondary tube ID information received from LIS, click the Tube icon





Editing a patient and sample

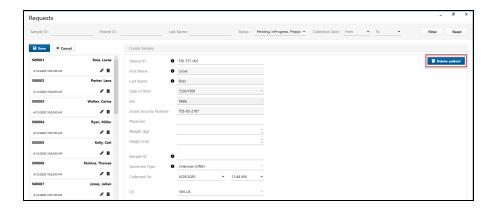
- To edit a patient and sample, Click the **Pencil** button.
- If the request came from LIS, some of the fields cannot be changed.



Deleting a patient

- Log in as administrator.
- To delete a patient, click the + New button.
- Enter the Patient ID and click the **Tab** key on your keyboard, then click the **Delete** patient button.
- A confirmation of deleting the Patient needs to be provided.

Note: All patient related samples for this patient are permanently removed.



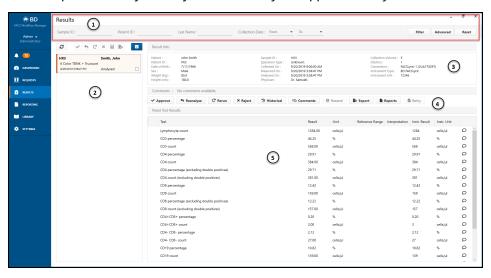
Results workspace

Once Assay results in the BD flow cytometer's software (BD FACSuite™ and/or BD FACSVia™) are approved, they will be transmitted to FWM. Depending on the settings for the review process, results are either sent automatically to LIS or they need to be reviewed and approved before transferring them to the LIS.

Alternatively, if the "Automatic Approval" feature is used, results are directly sent to the LIS, if no warnings or errors are reported. In case of warning or error messages, the results need to be reviewed and approved.

Depending on the availability of the optional "Data Management" feature, results and PDF reports are also transferred to FWM, where they are available for review. They are archived, thus remaining accessible for future or external analysis.

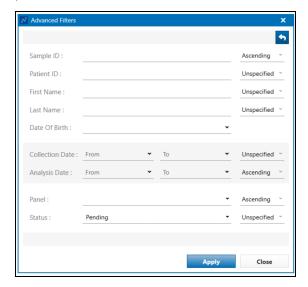
The Results workspace is accessed by clicking the **RESULTS** button. It contains a list of Results that are received from the instrument(s) and LIS(s). Results will display in the workspace and they will stay there until they are approved or rejected.



The top Section 1 (see the above graphic) contains functionalities to filter Results in the Results workspace, based upon: Sample ID, Patient ID, Last Name and Collection Date.



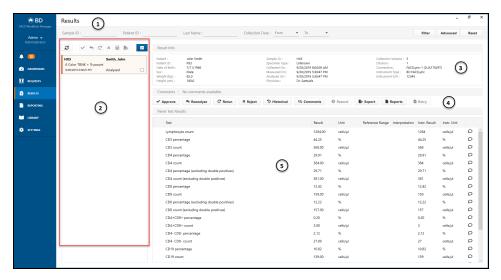
Click the **Advanced** button on the Results workspace for filtering the results. The Advanced Filters box also opens upon clicking the **Advanced** button, where the user can set the parameters of the advanced filtering. Click the **Apply** button to apply the parameters.

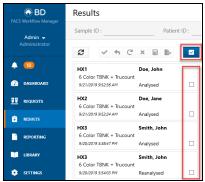


Click the Reset button to reset the result filtering parameters that are entered.



The Result Set List (Section 2) of the Results workspace, shown in the following graphic, lists the Sample results that are available for viewing and/or for taking any of the actions listed in panel 4 (Approve, Reanalyse, Rerun, Reject, Historical, Comments, Resend, Export, Reports, Retry). To review results, click the Result Set that needs to be reviewed.





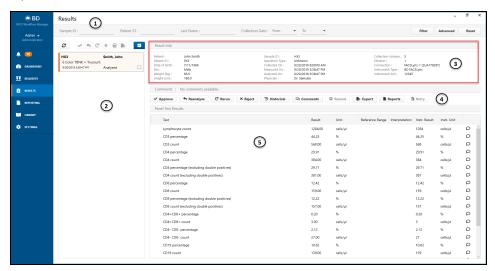
Actions that can be performed on multiple Result Sets are displayed at the top of the Result Set list:



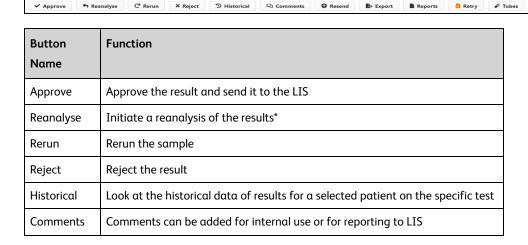
Number	Function
1	Refresh the Results List
2	Approve Selected Results
3	Reanalyse Selected Results
4	Rerun Selected Results
5	Reject Selected Results
6	Recalculate Multipanel Results
7	Retry: Use to retrieve documents from instrument of selected Results
8	Select all: The "Select all" button will only select the latest Result sets of each sample.

The Result Info (Section 3) displays information related to the selected Result Set.

Note: The Measured On and Analysed On date and time fields are for indication only. The exact information should be retrieved from the FACSuite™/FACSVia™ result reports or audit trails.



The action bar (Section 4) of the Results workspace contains the actions listed in the table below:

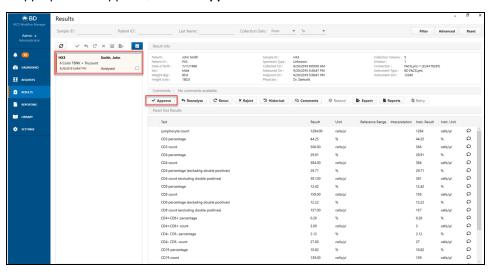


Button Name	Function
Resend	Resend approved results to the LIS
Export	The Export button allows you to export the results to a file by creating copies of PDF reports and instrument data files.*
Reports	View available reports generated by the flow cytometer and customizable Summary Report generated by FWM*
Retry	Retry import of reports/documents and data files from the instrument*
Tubes	View secondary Tube ID information received from LIS. Button will be hidden when no data is available.

^{*}With "Document Management" feature only.

Approving a Result

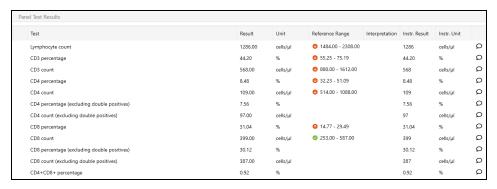
To approve a result, select a Result Set from the Result Set List, review the results and if appropriate to approve, click the **Approve** button on the action bar.



Result Sets can be either approved individually or in batch. To approve an individual Result Set, select it and then click the **Approve** button. To approve a batch of Result

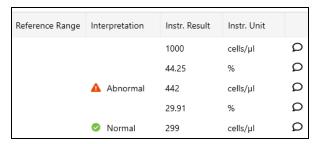
Sets, click the check boxes next to the Result Sets and click the button with the check mark above the Result Sets list.

The status of the evaluations of the reference ranges and interpretation rules will be indicated with icons in the Panel Test Results (Section 5).



The status of the reference range evaluations will be indicated as follows:

Icons	Description
Green checkmark	Within reference range
Orange down arrow	Below normal reference range
Orange up arrow	Above normal reference range
Red down arrow	Below analytical range
Red up arrow	Above analytical range



The status of the interpretations evaluation will be indicated as follows:

Icons	Description
Green checkmark	Normal interpretation
Red warning sign	Abnormal interpretation

Results will be automatically approved if the following criteria are fulfilled:

- The "Automatic Review" feature is licensed and enabled
- The panel is configured to allow "Automatic Approval"
- All Documents and Reports are available (if "Document Management" feature is enabled)
- No abnormal interpretations
- No failed reference ranges
- No result errors

Approved Result Sets will be sent to the LIS automatically, provided the LIS connection is established. Depending on the configuration and capabilities of the LIS, PDF reports of the approved results will also be uploaded to the LIS. Approved Result Sets, including related reanalysis Result Sets, will be no longer displayed in the default listing in the Results workspace. These Results Sets can be retrieved through the Advanced filter in the Results workspace.

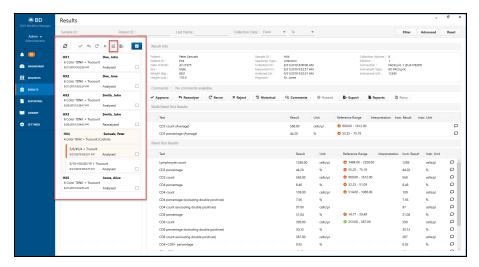


Multi Panel Results

A Multi Panel assigns multiple panels to a single request code and allows you to add additional Multi Panel tests. All Result Sets of a Multi Panel will be grouped together. Each Result Set of the underlying Panels in the Multi Panel can be reviewed individually by selecting it.

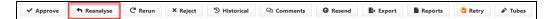
Results of Multi Panel tests can be calculated from numerical patient and sample details and the test results of the underlying panels. Multi Panel test results are shown in the "Multi Panel Test Results" section above the results of the selected Result Set. The Multi Panel test results will only be available once Panel test results from which they are calculated are available.

The calculated Multi Panel results are based on the latest Result Set of the underlying panels. If you want to recalculate the Multi Panel results from alternate Result Sets, select the required Result Sets and Click the Recalculate icon at the top of the Results Set List.



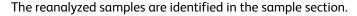
Reanalyse a result

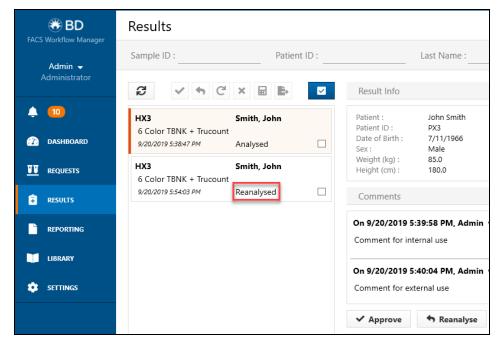
To reanalyse a result click the **Reanalyse** button. If the "Document Management" feature is available, the corresponding Entry Run Packages will be exported to the Reanalysis Export Location. See *Document Management settings*.



When the reanalysis is initiated, the Reanalyse button changes into **Cancel Reanalysis** button and the reanalysis can be canceled by clicking it.







Rerun a Panel Request

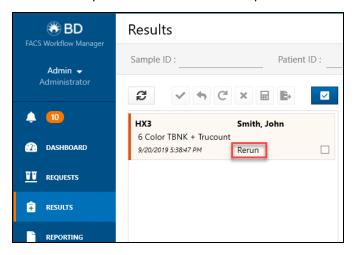
To rerun a panel, click the **Rerun** button. The existing panel results are stored and the sample can be rerun in the flow cytometer. Once the new results become available, these can be analyzed and compared with the previous run.



When the rerun is initiated the **Rerun** button changes into **Cancel Rerun** button and the rerun can be canceled by clicking it.



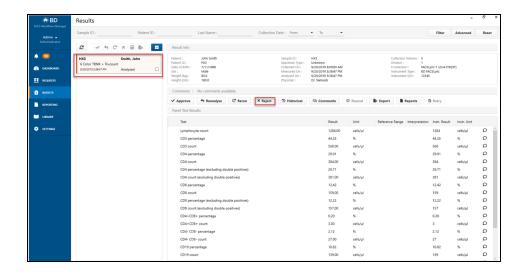
The rerun samples are identified in the sample section.



Reject a result

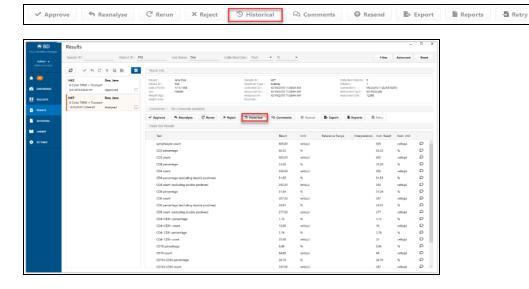
To reject a result, select the Result Set from the Result Set list and then click the **Reject** button.





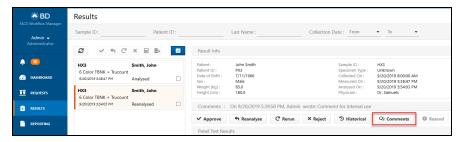
Viewing historical results

To compare previous results that may have been generated before for the same patient and panel request, click the **Historical** button.

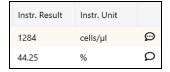


Commenting on a result

Results can be commented on at two levels. General comments can be made for the whole Result of a Sample by clicking the **Comments** button. Comments can also be marked *for internal use only* or to be reported back to LIS (default option). Comments will be shown as descriped in the image below.

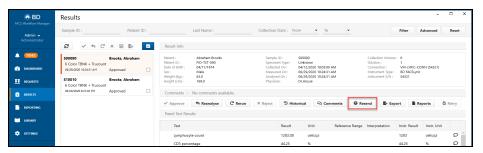


Comments can also be added at the test level by clicking the Speech bubble icon next to each test. Once a Comment is entered dots are shown in the Speech bubble icon indicating that a Comment is added.



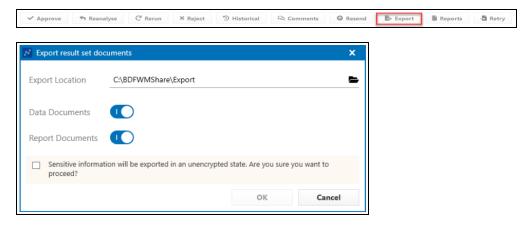
Resend result

If a result set needs to be resent to the LIS, e.g. in case the results are not received successfully by the LIS, click the **Resend** button. The currently viewed result set will be sent to LIS again.



Export results files

To export the result files, click the **Export** button. The "Export result set documents" dialog opens. The export location and the documents to be exported (Data documents and/or Report Documents) can be defined.

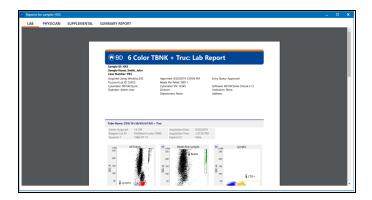


The user is prompted to confirm that it is **OK** to proceed with exporting sensitive information in an unencrypted state.

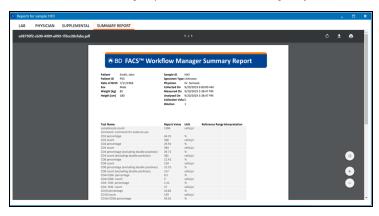
Viewing reports

To view the flow cytometer reports associated with the selected results click the **Reports** button.



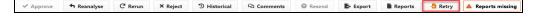


To access the summary report click the **Summary Report** button.

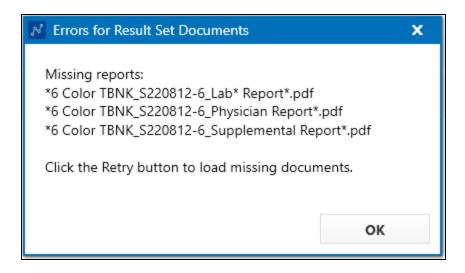


Retry collecting incomplete Result Set documents

If the systems fails to collect all documents for a Result Set, the color of the retry button will change to orange and will be enabled. Click the Retry Button to reattempt collection of the documents of the selected Result Set.

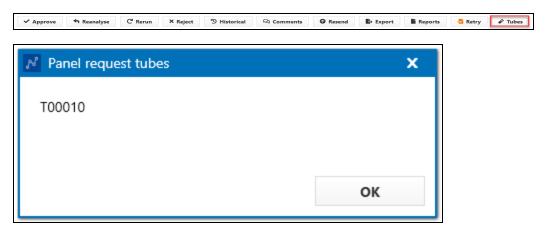


Click the Warning sign to view which files are missing.



Tubes

Click Tubes button to view secondary Tube ID information received from LIS. Button will be hidden when no data is available.



5

Workflow

This chaptersection covers the following topics:

- Workflow overview (page 50)
- Managing request (page 50)
- Creating worklist (page 51)
- Sample preparation (page 56)
- Acquisition and analysis of samples (page 58)
- Reviewing of results (page 58)

Workflow overview

This chapter provides an overview of the workflow process when BD FWM data is integrated with BD FACSVia[™] and/or BD FACSLyric[™] flow cytometers. FWM also supports data integration with BD FACSDuet[™] Sample Preparation System, when the preparation of samples acquired on BD FACSLyric[™] is done automatically.

Overview

The following table provides an overview of the steps within a workflow process when using FWM connected to BD FACSVia™ or BD FACSLyric™, with or without BD FACSDuet™.

Step	Action
Managing Requests	The user reviews panel requests prior to sample preparation. See the Requests workspace (page 24) section in the Chapter "Operating the System".
Worklist Creation	Worklist is either created manually or automatically on BD FACSDuet™ software. In both cases FWM will be queried for test information.
Sample Preparation	Sample preparation is either done manually by the user or by means of automation with BD FACSDuet™ Sample Preparation System.
Acquisition and Analysis	Samples are acquired and analyzed on BD FACSVia™ or in BD FACSLyric™. Refer to the BD FACSVia™ and/or BD FACSLyric™ System Instructions for Use.
Reviewing of Results	Results are reviewed on BD FACS™ Workflow Manager. See the Results workspace (page 33) section in the Chapter "Operating the System".

Managing request

See the Requests workspace (page 24) in the Chapter "Operating the System".

Creating worklist

FWM software

Launch the FWM software and sign in. Open the REQUESTS workspace by clicking the **REQUESTS** button on the navigation panel.

The FWM system automatically receives Requests from the LIS. Use the Refresh button to update the list. For instructions on adding and creating requests, see Requests workspace (page 24).

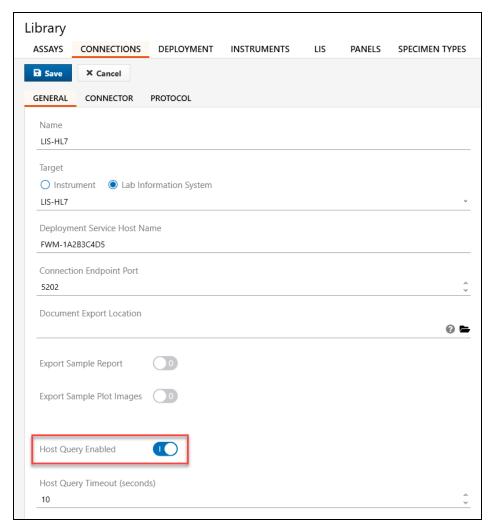


LIS Host Query

If the LIS system supports the Host Query functionality and this is enabled, requests that are in the LIS system can be retrieved and recalled by FWM. In this way the requests will be made available automatically on the Request Analysis list.

To enable the Host Query functionality:

- Click the LIBRARY button on the navigation panel, and then select the CONNECTIONS button.
- Enable the Host Query Enabled function by turning it ON.



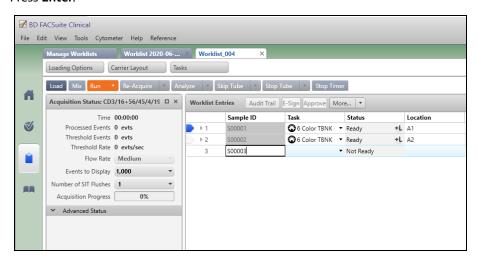
• To apply changes, undeploy and redeploy the connection.

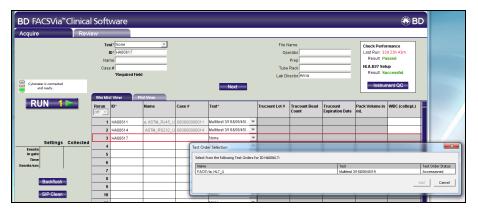


When the BD FACSDuet™ is connected with the FWM and it is used in combination with the BD FACSLyric™ flow cytometer for automatic sample preparation, BD FACSDuet™ automatically builds the worklist(s).

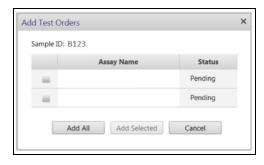
Manual creation of a worklist on BD FACSLyric™ and BD FACSVia™ Flow Cytometers

- Launch the BD FACSuite™ Clinical Application or BD FACSuite™ application or the BD FACSVia[™] software and log in.
- To create a worklist manually in BD FACSVia[™] or BD FACSuite[™] application, proceed with either scanning specimen barcodes or manually type the Sample ID in the corresponding field.
- Press Enter.



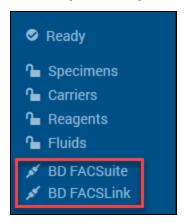


- The software automatically queries FWM for any panel request that is associated with each given Sample ID.
- Associated patient information from the LIS is added to the worklist entries: if no
 patient information is available, a warning will notify that no matching panel
 request is found.
- Proceed until the worklist is built.
- If multiple panel requests are ordered for a given patient, in the BD FACSuite™
 Clinical and BD FACSuite™ applications, a dialog opens to allow the selection of
 panel request that needs to be added in the specific worklist.
- Use the Add All or the Add Selected buttons or double-click the assay name.



Automatic creation of a worklist on BD FACSDuet™ Sample Preparation System

Turn on the BD FACSDuet^{\mathbb{M}} and check the status symbols at the bottom of the menu in the BD FACSDuet^{\mathbb{M}} software to confirm the connection is active with both the FWM and BD FACSLyric^{\mathbb{M}} Flow Cytometer.



- BD FACSDuet[™] builds the worklist in the BD FACSDuet[™] software by scanning the barcodes on the primary specimen tubes when these are loaded into the BD FACSDuet[™] instrument.
- The primary specimen tubes can be randomly placed in the primary tube racks. The Worklist will be built dynamically to reflect the order of the Primary Specimen tubes in the rack.
- Scanning the barcode of the Primary specimen tube of patient request in the LIS/FWM, triggers the FWM query for the associated test orders and the worklist is automatically created on the BD FACSDuet™ software.
- In the absence of associated test orders in the FWM, if the Host Query function is enabled, FWM will query the LIS.
- The information in the LIS will be used by the BD FACSDuet[™] software through FWM to populate the worklist. If the information is not in the LIS, the user can manually enter the test orders (if available) in the BD FACSDuet[™] software.

For more details on how to operate the BD FACSDuet^m software, refer to the BD FACSDuet^m Sample Preparation System Instructions for Use.

Sample preparation

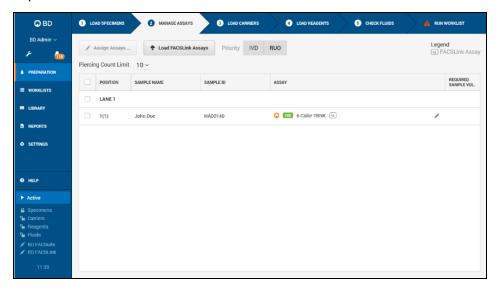
Overview

This chapter explains the procedure of sample preparation. Follow Lab's Standard Operating Procedure(s) (SOPs) if sample preparation is carried out manually.

If samples are prepared using BD FACSDuet^m refer to BD FACSDuet^m Sample Preparation System Instructions for Use.

Manage assays

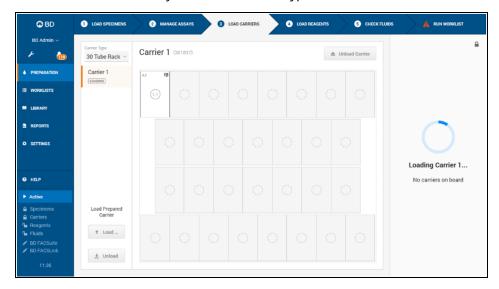
Once the specimens are loaded and the worklist is created, access the Manage Assays tab to review and/or assign additional panel requests if needed for any patient request.



Load secondary tube carrier

Based on the number of loaded specimens and the type of assays requested for any specimen, the BD FACSDuet™ software provides the following information:

- Number of worklist(s) to be created
- Number of secondary tubes to be loaded on a carrier
- Position of the secondary tubes based on the type of carrier.



Loading reagents

Reagents are loaded based on the test type entered in the worklist. The position of any given reagent within a Reagent Rack is verified by scanning rack and reagent barcodes. The reagent position is automatically associated with secondary tubes and primary specimens for which that reagent is required.

Publishing worklist to flow cytometer

When the samples are ready for acquisition on the BD FACSLyric[™] flow cytometer, the worklist is published to the FWM and transferred to the BD FACSLyric[™].

If the BD FACSDuet^m is physically integrated to BD FACSLyric^m, the worklist is transferred via FWM and the carrier with the secondary tubes is moved into the BD FACSLyric^m for starting the acquisition automatically.

If the BD FACSDuet^m is only Data integrated and not physically integrated, only the worklist is transferred to FWM while the carrier needs to be transferred manually to the BD FACSLyric^m.

In both cases, the scanning of the barcode of the carrier will recall the worklist from the FWM to the BD FACSuite $^{\text{TM}}$ application. Once the worklist and carrier are transferred the acquisition can start.

Acquisition and analysis of samples

Refer to the BD FACSVi $a^{\text{\tiny{M}}}$ Flow Cytometer and/or BD FACSLyric $^{\text{\tiny{M}}}$ System Instructions for Use.

Following analysis on either BD FACSuite™ applications or BD FACSVia™ software, the results can be automatically sent to FWM where they are reviewed and approved before being sent to LIS.

Reviewing of results

See the Results workspace (page 33) in the Chapter "Operating the System".

System configuration

This chapter section covers the following topics:

- Library workspace (page 60)
- Deployment (page 74)

Library workspace

Overview

The Library workspace provides users with the ability to review or modify library items. Click the **Library** button to access the Library workspace.



The Library workspace is comprised of the following functions:

- Assays (page 61)
- Connections (page 69)
- Deployment (page 74)
- Instruments (page 75)
- LIS (page 77)
- Panels (page 79)
- Specimen types (page 81)
- Tests (page 83)



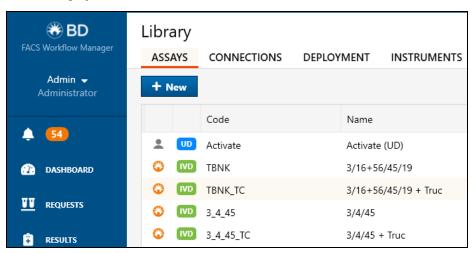
Assays

An assay describes about an analytical method on a connected instrument such as the Code of the assay, the Results that will be reported from it and the Files that may be collected from it. When the "Assays" tab is selected, a list of available assays are displayed.

Each assay is identified with a Code, a Name and the number of Secondary Tubes needed to perform the specific assay.

Green IVD symbol with BD logo denotes the BD IVD assays used in BD FACSLyric™ and BD FACSVia™ flow cytometers that are pre-loaded and pre-configured in the FWM, User Defined Assays (UD) are identified with a blue UD symbol and a Client icon.

Description of the Assays are mentioned under the Name category and the number of secondary tubes required to run that specific assay is indicated in the Secondary Tubes category.



Creating an Assay on Flow Cytometer/Transfer to FWM

User Defined Assays created in BD FACSuite™ application will be shared with FWM. Assign LIS code for a shared assay in BD FACSuite™ application and then click the **Send** button to transfer the code to FWM.

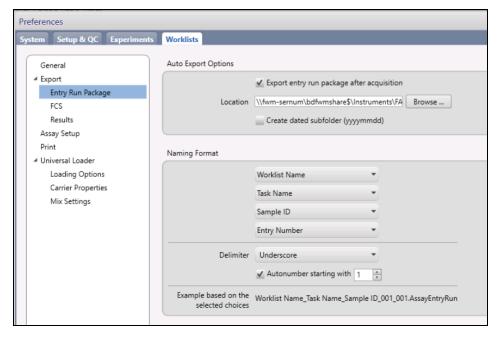
See BD FACSLyric™ System Instruction for the procedure to create an assay.

Assays shared by BD FACSuite™ application with FWM will show as UD in the FWM Assay Library. In FWM the name of the assay and panel needs to be updated. See Editing an Assay (page 68) for further instructions.

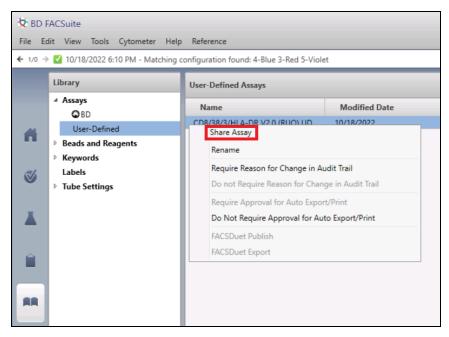
For BD FACSLyric™ users, the recommended pathway to create an assay is to start on the BD FACSuite™ application. Click the + New button in the Assays window in the Library workspace to create an assay. Further validation and entry on BD FACSuite™ application is required. Assays cannot be added and transferred from BD FACSVia™ Flow Cytometer to FWM.

Recommended steps to create a UD Assay in BD FACSuite™:

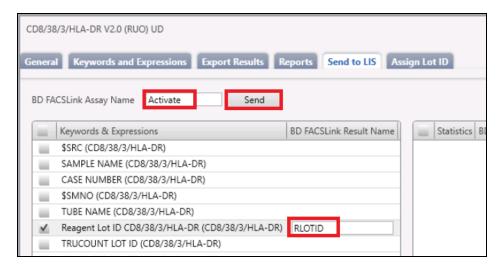
- Open the BD FACSuite™ application and log in.
- If the Document Management feature is enabled: Open Preferences, click the Worklists tab, expand the "Export" menu, and select Entry Run Package.
 - Enable "Export entry run package after acquisition".
 - Location should point to the shared folder of FACS Workflow Manager. Use the same location for the export locations of the reports of the UD Assay.
 - Disable "Create dated subfolder (yyyymmdd)"
 - Naming has to be the following format:
 - Worklist
 - Task Name
 - Sample ID
 - 4. Entry Number



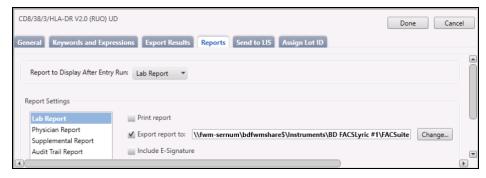
- Open Library, expand the Assays menu, and select User-Defined.
- Right-click the assay and select **Share Assay**.



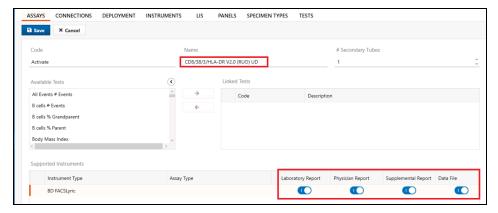
- Select Send to LIS tab and click Edit.
- Enable the test results to be transferred and enter the LIS test code.
- Set BD FACSLink Assay Name and click Send.
 Popup message is shown with the text that the assay name was sent successfully
- Click **Done** to save settings.
 Do not use the already existing IVD assay codes from FWM.



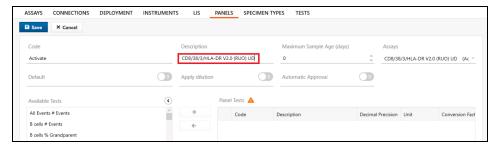
Select the Reports tab and configure the export location of the reports.
 Only the Laboratory Report, Physician Report, and Supplemental Report can be imported by FWM.



- Open FWM Client and log in. Select Library Assay in FWM and edit new UD Assay.
- Change Name of Assay and use the exact same Assay name as in BD FACSuite™
 application. A slight difference in the name can cause that the reports to not be
 imported in FACS™ Workflow Manager.
- If the Document Management feature is enabled: Enable the reports that need to be archived.



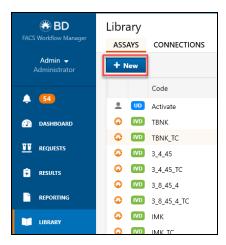
- Select Library Panels and edit new UD Panel in FWM.
- Change Description of Panel and use the exact same Assay name as in BD FACSuite™ application.



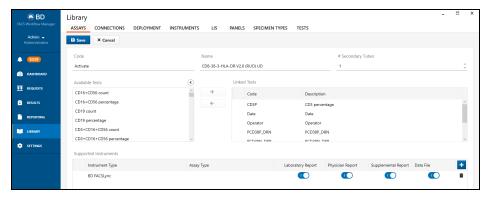
- Warning sign next to UD Panel is normal because no results have been sent yet.
- Send results from BD FACSuite[™] application to FWM.
- Select Library Tests in FWM and edit Test descriptions if necessary.
- Select Library Panels, edit UD Assay and change Test descriptions if necessary.
- Code mapping on Instrument and LIS can be configured if necessary.

Adding an assay

• Click the + New button in the Assays page in the Library workspace.



- Enter the assay Code (Instrument assay code), Assay Name, and the # Secondary Tubes required to run the assay.
- To add tests to the assay, select the desired test from the Available Tests and click the -> icon to add it.
- Tests can be removed from the assay by clicking the <- icon.
- Select the instrument type supporting the assay by clicking the + icon on the right side. Select the documents to import.
- Click the **Save** button to save the Assay.



Editing an Assay

Each User Defined Assay can be edited by clicking the Pencil icon. Once edited, press the **Save** button to save your changes. IVD Assays can't be edited.

Deleting an assay

Only the User Defined Assays (UD) can be deleted by clicking the Delete icon respectively. This option is not available for IVD assays. Linked panels need to be deleted first before an Assay can be deleted.

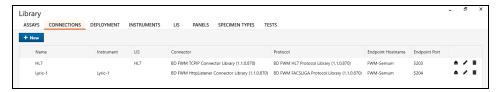


Connections

A Connection is an instrument and/or an LIS that is connected to FWM.

The following information is available for each connection:

- Name
- Instrument
- LIS
- Connector
- Protocol
- Endpoint Hostname
- Endpoint Port



Editing/Deleting a connection

Each connection can be edited and deleted by clicking the Pencil icon and the Delete icons, respectively. Once edited, press the **Save** button to save the edits.

Deploy/Undeploy Connection(s)

Each connection can be deployed and undeployed.

Redeploy Connection(s)

If a troubleshooting event occurs you might be instructed by phone support to redeploy a connection. To redeploy a connection, start by undeploying the selected connection by clicking the Eject button

Add Connection(s)

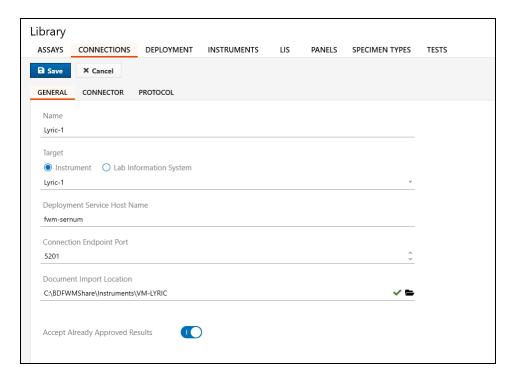
For deployment and undeployment see Deployment (page 74)

To add a new connection click the + **New** button.

Note: If a new connection needs to be added, call your BD Field Service Engineer. For phone support you may be required to redeploy a connection.

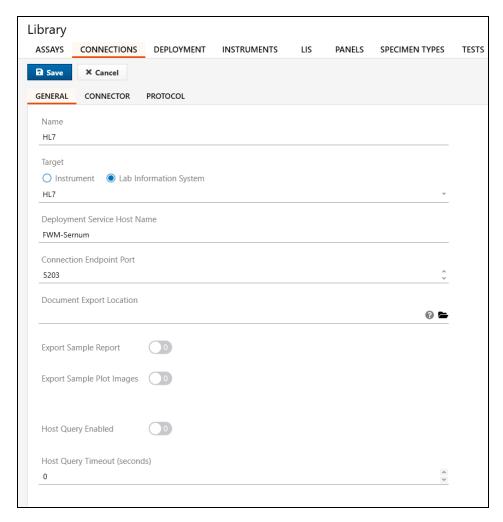
Under Connections - General Tab an Instrument or a Lab Information System (LIS) can be added. The following information needs to be filled in: Name of instrument or LIS that is a connection, instrument or LIS that is the Target of the connection, Deployment Service Host Name and Connection Endpoint Port. In case the target is Instrument, Document import location can be set and enabling the "Accept Already Approved Results" button can be used to send results of the same request multiple times to LIS regardless of the previous result status in FACS™ Workflow Manager.

When the Accept Already Approved Results button is disabled, the Reanalyse or rerun button needs to be used to send already approved results to the LIS in the FACS™ Workflow Manager.



In case the target is LIS, Document Export Location needs to be set when enabling Export Sample Report and/or Export Sample Plot Images. These settings are only available when Document Management is activated.

When using remote export location, configure the Document Share Credential first in **Settings - Security**. Use the question mark icon to test the credentials.



The Host Query option for an LIS connection can be enabled if the LIS can support it. To enable the Host Query function the Host Query Enabled switch must be turned on. To apply the settings, the connection needs to be undeployed and then deployed again.

The Connector tab contains information related to the Type of Connector and the Settings.

The Protocol tab contains information related to the Protocol settings to a specific Connector.

In all the screens, a Save and a Delete button are available to save or delete the entered connections information.

Deployment

The Deployment service manages all instruments and LIS connections, which by default is located and running on the FWM workstation.

For special custom scenarios like high number of connected connections or separate departments, it may be necessary to run one or more deployment services on additional computers, which needs to be connected to the FWM system.

A Deployment service installs, removes, starts, and stops the connection services of instruments or LIS. Deployments can be added, viewed (Eye icon), edited (Pencil icon), or deleted (Delete icon).



Adding a deployment

Note: If an additional deployment service must be added, call your BD Field Service Engineer.

- To add new deployment service, click the **+ New** button.
- The following information needs to be entered to add a new deployment service: Deployment name, Thumbprint, Hostname, and Port number.
- Click the **Save** button to save the information. The new deployment service will show in the list.



Instruments

List of instruments available for connection comes under Instruments category. Instrument information can be viewed, edited, and deleted using the respective icons.

Adding an instrument

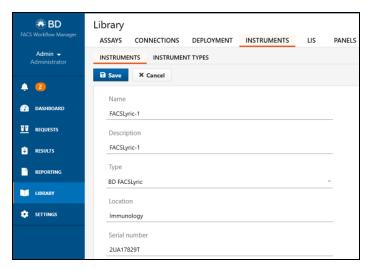
- To add new instrument click the + New button.
- The following information needs to be entered to add a new instrument:

Instrument Name, Description, Type, Location and Serial number.

- Link Instruments to a specific LIS via the location. If there is no location specified, the instrument will use the default LIS.
- Enter the serial number of the workstation for BD FACSLyric[™] or BD FACSVia[™]
 Flow Cytometers. Use the serial number of the instrument if you want to add a BD
 FACSDuet[™] Sample Preparation System.

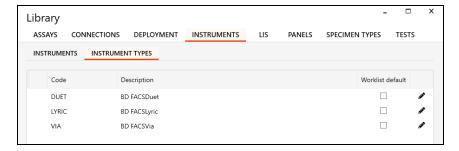
Note: Only compatible instruments can be added. These include BD FACSDuet[™], BD FACSLyric[™] and BD FACSVia[™].

- Click the Save button to save the information.
- Added instrument will show in the list.



The following information related to the Instruments are listed below:

- Instrument Code
- Description
- Worklist default

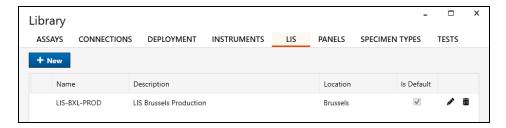


The Pencil icon allows you to view and edit the information for each entered line. When you click the + icon of a selected instrument it allows you to add Test Code Mapping, Panel Code Mapping and Specimen Type Code Mapping. And the Delete icon can be used to remove them. Redeploy connection after making changes in Code mapping.

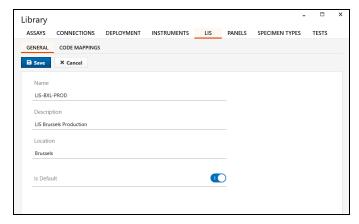


LIS

The LIS Tab provides an overview of the list of available LIS.



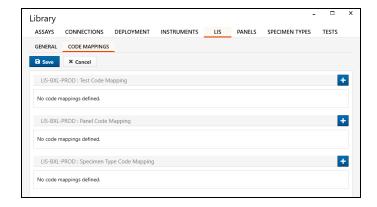
The +New button allows addition of new LIS. Name and Description need to be filled in, and the Location is not mandatory. Click **Is Default** to select default LIS.



The Location field can be used to indicate to which department the LIS is dedicated. If the Host Query functionality is used with the LIS, the location of the LIS and the Instruments from which Host Queries will be generated must match.

Click the **Save** button to save the entered information. If the action is successful a green pop-up message will show on the screen. For each LIS listed, there is a box that is checked if the LIS is the default one.

Also a Pencil icon (to edit the information) and a Delete icon (to delete the connection) are available.



The user has the option to add LIS code mappings: Test Code Mapping, Panel Code Mapping and Specimen Type Code Mapping by selecting the + button. Redeploy connection after making changes in Code mapping.

Panels

The Panels section displays information like: Panel code, Panel Description, Panel Type (Single or Multi), Maximum Sample Age, Default.



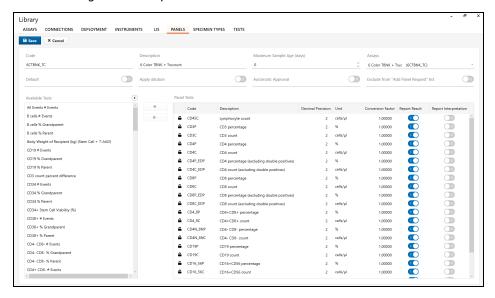
Two types of panels can be added:

- A single panel: Using the + New Panel button
- A multi panel: Using the + New Multi Panel button

To add a New panel in the Panel list, the corresponding Assay needs to be available in the Assay Library, if it is not available, it needs to be created. If all the available tests are not listed in the Panels screen, tests need to be created in the Library Test workspace.

Enter all required information. Enable the **Default** button if you want the panel to be auto selected when a panel request is created manually. If the "Automatic Approval"

feature is enabled, it will automatically review the results of the panel based on the reference ranges and interpretation rules in the tests.



Note: Automatic Approval is available only if the "Automatic Review" feature is active in the License (see Settings Workspace).

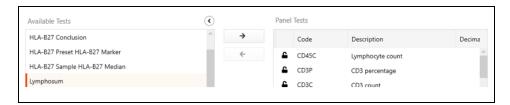
Enable button **Exclude from "Add Panel Request" list** to hide the panel in the list when adding panels to requests. Example: If IVD panels are not used, they can be excluded from the list and only show UD assays.

To save, click the Save button and the new panel is added in the list.

When clicking the **Save** button if information is missing, a message is displayed on the right-top side of the screen and the Warning icon opens on the side of the panel Code.

Panel test

Click the Pencil icon to edit the information and then save it again. To add and/or remove one or more Panel Tests, select the test(s) to be added and/or removed and use the right and left arrow to move them. Panel tests that have a Closed lock icon can not be removed because they have results linked to this test in the panel.

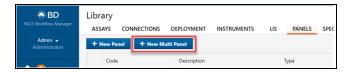


To expand the Panel Test window click the arrow on the top-right of the Available Tests window. This will be reduced to a line on the left side of the screen. Within the Panel Tests section, for any given test, the following information is available: Panel tests Code, Panel Tests Description, Decimal Precision, Unit, Conversion Factor, Report Result, Report Interpretation.

Note: Decimal precision has no rounding functionality.

Adding a multi panel

To add a Multi Panel click the + New Multi Panel button.



The Multi Panel option enables the user to assign multiple panels to a single request code. Enter the code of the Request and its Description. The panel code will be its name, if you set it as Default, when manually creating a panel Request in the request workspace, this Panel will be shown first in the drop-down list. Enter if Automatic Approval is requested.

Note: This is only available if Automatic Review is activated in the license.

Available panels can be added by selecting the panel and clicking the -> button. They can be removed by clicking the <- button.

Once the panel has been created, it can be saved by clicking the **Save** button.

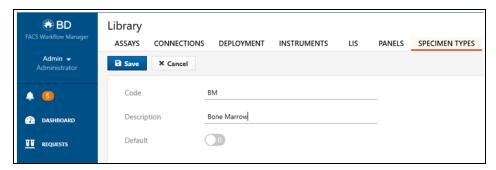
Specimen types

The Specimen Types workspace lists the Specimen Types that are available and entered already.

For each Specimen Type the Code, Description, and Default options are available. Each specimen type can be viewed (Eye icon), edited (Pencil icon) and deleted (Delete icon). If a specimen type is used as default, the Default box is selected.



To add a New Specimen Type, the + New button is available. Specimen Type Code and Description are requested. If the specimen type is to be made as Default, the Default icon can be selected.





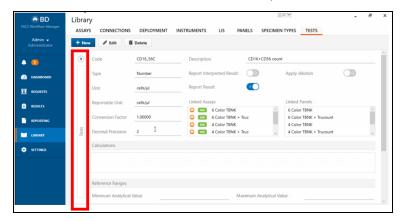
There can be only one Specimen type selected as Default. If the default specimen type is changed, a Warning message displays on the top-right side of the screen to warn about the change.



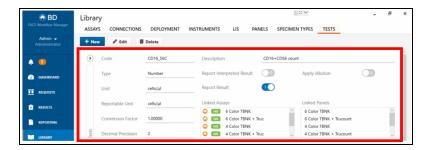
Tests

The Tests workspace comprises of different sections:

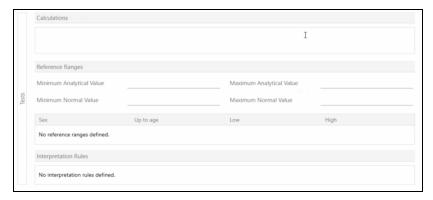
On the left side of the workspace there is the list of the available Tests entered in the Library. This section can be minimized by clicking the arrow on the top-right side of the section, to allow expansion of the rest of the workplace. When minimized, the Tests bar will show on the left side of the workplace.



The section on the top of the Tests workspace shows all the fields that are populated automatically upon selection of one of the tests on the left side: Code, Description, Type, Unit and Reportable Unit, Conversion Factor, Decimal Precision, Report Interpreted Result, Report Result, Apply Dilution (if any) and Linked Assays (assays in which the selected test is present).



In the following section, Calculation values, Reference Ranges and Interpretation Rules can be added and displayed.



Adding a test

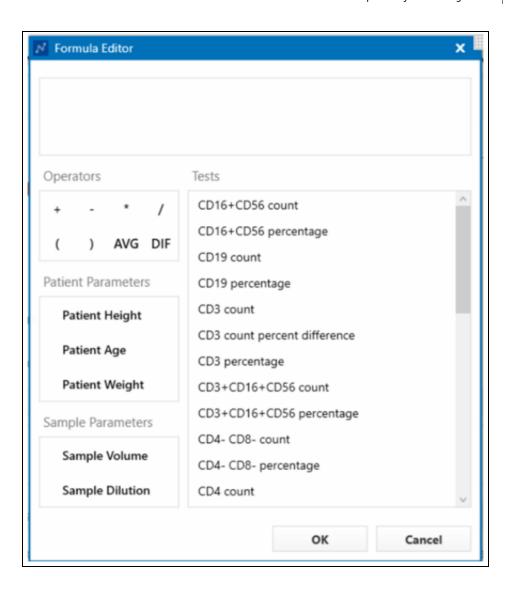
- Click the + New button.
- Enter Code, Description, Type, Unit and Reportable Unit, Conversion factor and Decimal Precision.

Note: Decimal precision has no rounding functionality.

- Enable Report Interpreted Result, Report Result (if applicable), and Apply Dilution.
- To add a calculation, click the Calculator icon.



• In the top empty field of the Formula Editor, define the rules using the Operators, Patient Parameters, Sample Parameters and Tests elements available.

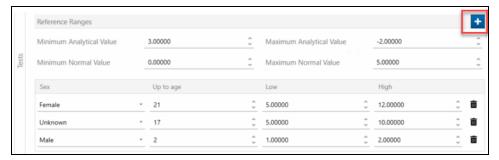


To add Reference Ranges:

- Minimum Analytical Value = the lowest value that the system can measure
- Maximum Analytical Value = the highest value that the system can measure
- Minimum Normal Value = the minimum value which is in normal range
- Maximum Normal Value = the maximum value which is in normal range

Click the up and down arrows for each value.

Use the + button to add one or more fields in the second part of the table: Sex, Up to age, Low and High.



Click the Delete icon to remove fields.

Adding Interpretation Rules

Adding interpretation rules requires validation by the user. To Enter Interpretation Rules, click the + button.



- Select one of the operators: <, >, >=, <=, =, <>, Between.
- Enter a value in the second field. For the "between" operator, you will need to enter 2 values.
- Enter the interpretation text in the last field.
- Normal checkbox can be enabled to indicate that the interpretation is not abnormal.

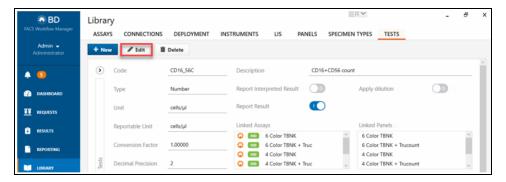
 If the "automatic review" feature is used, results with abnormal interpretations will not be approved.

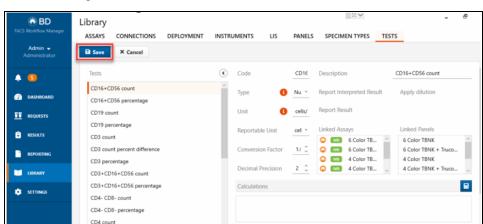


The order in which the interpretation rules are listed is important. The first interpretation rule in the list which is valid will be used. It is possible to change the order by using drag and drop.

Edit a test

To Edit a test, click the **Edit** button.





Once the changes are made, click the Save button.

Deleting a test

To delete a test, select the test to be deleted and click the **Delete** button. Editing and deleting tests is possible if no results linked to the test are in the database.

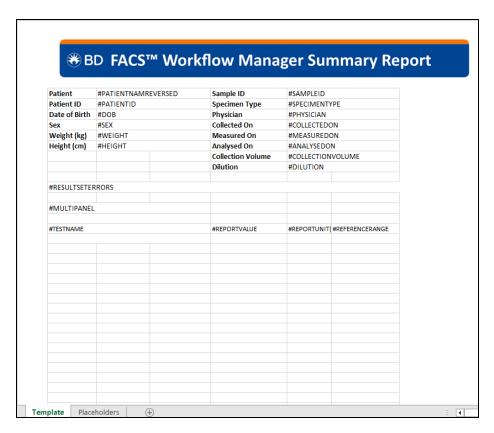
Summary report template

Edit template

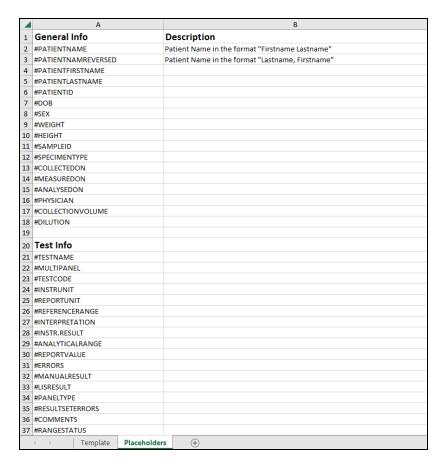
The result summary report template is an Excel (.xlsx) file which is located at: C:\ProgramData\BD\FACS Workflow

 $\label{lem:manager} Manager \ Templates \ Result Summary Report Template. xlsx \ . \ It has two sheets: "Template" and "Placeholders".$

The "Template" sheet shows the layout, labels, and placeholders.



The "Placeholders" sheet contains all placeholders that can be used in the "Template" sheet.



Follow these steps to edit the template:

- 1. Copy the template file to a computer and open it using the Microsoft Excel application.
- 2. Save the file and overwrite the original file.

Labels and placeholders can be translated and changed. Layout, header, colors, and logo can be changed to suit customer needs.

Example of a translated placeholder:

```
#REPORTUNIT { Unit }
```

Unit will be the value shown as column name in the report.

System administration

This chaptersection covers the following topics:

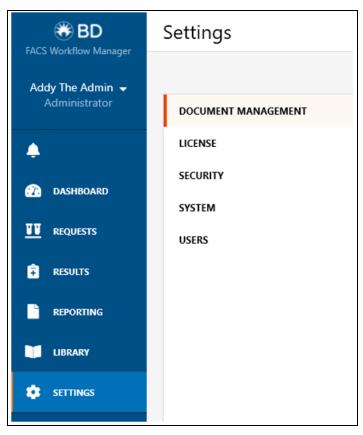
- System settings (page 92)
- Reporting (page 102)
- Backup (page 106)

System settings

Overview

This chapter provides brief description of FWM System Settings. The Administrator can review and modify the System Settings. The Settings are grouped under different tabs: Document Management, License, Security, System, and Users.

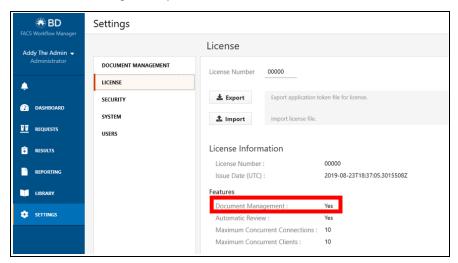
The Settings workspace can be accessed by clicking the **Settings** button in the navigation menu.



Document Management

The Document Management settings are visible only if the feature is licensed and activated.

To view the Document Management settings, click the **Document Management** button in the Settings workspace under the License Tab.

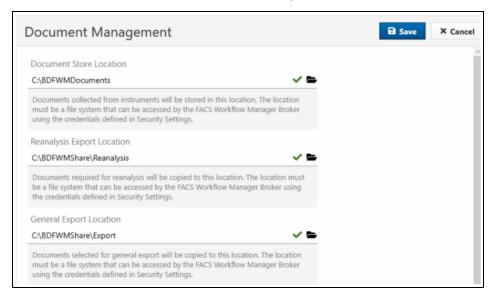


Editing Document Management

Click the **Edit** button to edit the Document Management settings. It enables the user to define the locations for storing three different document categories:

- Document Store Location: Folder path where documents are stored by the system. The default path is a local folder path on the FWM workstation. A folder path to a network share can also be configured. In this case, a user credential with the required permissions to the network share must be maintained in the "Security" settings. A backup of this network share needs to be established independently from the backup of FWM.
- Reanalysis Export Location: Folder path where the system exports acquisition
 data files if a result is marked for reanalysis. The default is a local folder path on
 the FWM workstation that is shared and available for access from other computers
 on the network.

• **General Export Location:** Folder path where the system exports documents upon user request. The default is a local folder path on the FWM workstation that is shared and available for access from other computers on the network.

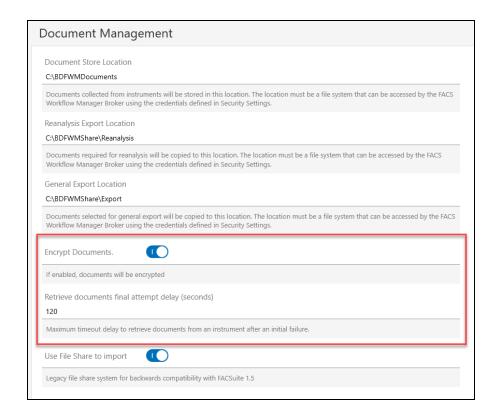


Encrypt Documents: The Toggle button defines whether documents that are stored in the Document Store Location will be encrypted. Document encryption is enabled as a default and should not be disabled unless required for troubleshooting.

Retrieve documents final attempt delay (seconds): Defines the amount of time in seconds that the system attempts to retrieve documents from the instrument for each result set. If the time is exceeded (based on the entered delay), the system will no longer attempt to retrieve the documents for the result set.

A user can use the Retry button on a result set in the Results workspace to prompt the system to retrieve the documents again in case they could not be retrieved before.

Use File Share to import: The Toggle button defines if the system needs to check the file share to import the reports. This needs to be enabled when using BD FACSuite™ application v1.5.

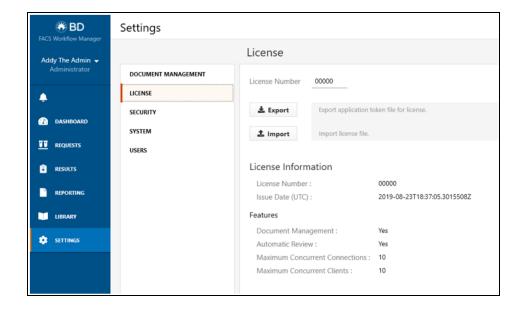


License

Click the **License** button in the Settings workspace to view the FWM license or to activate a license.

License activation

Enter the License Number provided in the license certificate and then click the **Export** button. To receive the license activation key, save the export application token file for the license and send it to the email address indicated in the license certificate. Once the Export button is clicked, the license number will be locked.



Import license

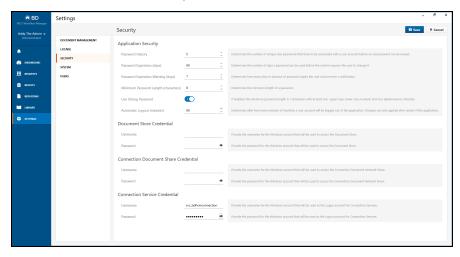
Import the file by clicking the Import button once the activation key is received. A green dialog on the upper right corner of the workspace informs the user that the activation was successful.

The details of the license are shown:

- In the License Information, the License Number and Issue Date (UTC) are indicated.
- The Features list Document Management, Automatic Review, Maximum
 Concurrent Connections and Maximum Concurrent Clients. If Document
 Management and Automatic Review Features are activated, Yes is indicated. To
 activate these features and/or add connections and clients (Default is 0 for both),
 contact your BD representative.

Security

Click the **SECURITY** button to view the Security settings. To edit the Security settings, click the **Edit** button. Use the up and down arrows to edit each field.



Application Security settings can be modified:

- Password History: Determines the number of unique new passwords that have to be associated with a user account before an old password can be reused.
- Password Expiration (days): Determines the number of days a password can be
 used before it expires and the system requires the user to change it.
- Password Expiration Warning (days): Determines how many days in advance of password expiration the user must receive a notification.
- Minimum Password Length (characters): Determines the minimum length of a password.
- Use Strong Password: If enabled (optional) determines that to be a strong
 password, it has to have a minimum length of 7 characters with at least one
 uppercase, numeric, and non-alphanumeric character. The minimum length of the
 strong password can be increased with the Minimum Password Length (characters)
 setting.
- Automatic Logout (minutes): Determines after how many minutes of inactivity a
 user account will be logged out of the application. Changes are only applied after
 restart of the application.

Document store credential

The Username and Password of the Document Store Credential need to be added. This Username and Password would be the same as the Windows account which is used to access the Document Store where documents are stored. The Eye icon allows you to display the entered password. These credentials will be configured by BD Service personnel as needed during installation of the system.

Connection Document Share Credential

The Username and Password of the Connection Document Share Credential need to be added. This Username and Password would be the same as the Windows account which will be used to access the Connection Document Network Share (the files on the connected instrument workstation). The Eye icon allows you to display the entered password. These credentials will be configured by BD Service personnel as needed during installation of the system.

Connection Service Credential

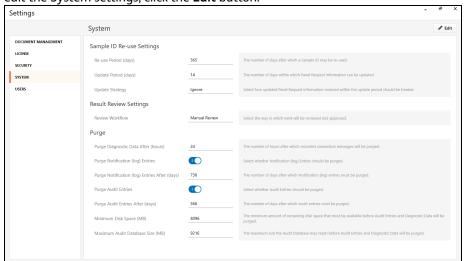
The Username and Password of the Connection Service Credential need to be added. This Username and Password would be the same as the Windows account which will be used as the Logon account for the Connection Services. The Eye icon allows you to display the entered password. This credential will be configured by BD Service personnel during installation of the system.

Save Security Settings

To Save the Security Settings (new or edited) click the Save button.

System

To view the System settings, click the **SYSTEM** button in the Settings workspace. To edit the System settings, click the **Edit** button.



Sample ID Re-Use Settings

- Re-use Period (days): Determines the number of days after which a Sample ID may be re-used.
- Update Period (days): Determines the number of days within which Panel request information may be updated.
- Update Strategy: Select how updated Panel Request Information received within the update period should be treated.

Result Review Settings

- Review Workflow: Determines how result approval will be managed. The following options are available from a drop-down menu:
 - No Review: All results are automatically approved upon receipt from an instrument.
 - Manual Review: All results must be manually approved by a user.

 Automatic Review: Results without error, abnormal interpretations or failed reference ranges are automatically approved. Results showing errors, abnormal interpretations or failed reference ranges must be approved by a user.

Purge

- Purge Diagnostic Data After (hours): Determines the number of hours after which
 recorded messages from connections will be purged. This value has to be aligned
 when using the network traffic recording of a connection in the dashboard.
- Purge Notification (log) Entries: Selection can be made whether Notifications should be purged.
- Purge Notification (log) Entries After (days): Determines the number of days after which Notifications must be purged.
- Purge Audit Entries: Selection can be made whether Audit Entries should be purged.
- Purge Audit Entries After (days): Determines the number of days after which Audit entries must be purged.
- Minimum Disk Space (MB): Determines the minimum amount of remaining disk space that must be available before Audit Entries and Diagnostic Data will be purged.
- Maximum Audit Database Size (MB): Determines the maximum size the Audit Database may reach before Audit Entries and Diagnostic Data will be purged.

Save System Settings

To Save the System Settings (new or edited) click the Save button.

Users

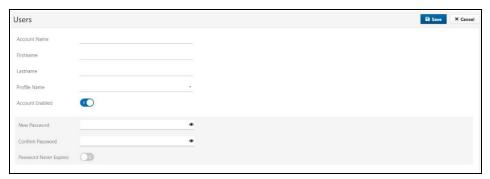
To view the list of application users, click the **Users** button in the Settings workspace.

Note: Users cannot be deleted, they can only be disabled.

Add user

- To add a new user click the New button.
- Enter the following information: Account name, First Name, Last Name, Profile Name and Password.

- The password needs to be confirmed and retyped (Confirm Password). For both
 Password and Confirm Password there is the possibility to make it visible by clicking
 on the Eye icon.
- Password Expiration and Account can be enabled. By default the password expiration is enabled and it will expire.



When all details are entered, click the Save button.

Profile name

The Profile name is chosen from a drop-down menu. The following table provides details on these Profiles:

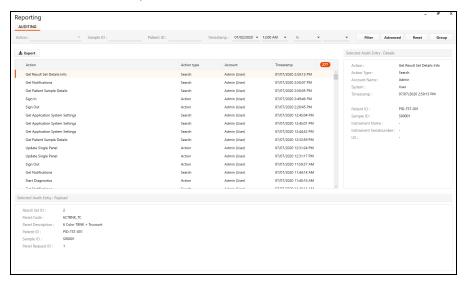
Profile name	Functions
Administrator	Users with this profile can perform all actions.
Operator	Users with this profile can view and manage the status of connections, review and manage requests and review results.
Reviewer	Users with this profile have the same access as Operators but can additionally approve and reject results.
Service	This profile is reserved for the BD Service account and cannot be assigned to any other account. With a BD Service account, patient details cannot be seen and actions in the requests and results module cannot be performed. BD Service account has no access to reporting workspace.
Super User	Users with this profile have the same access as Reviewer but additionally have access to manage the Library.

To save the Users Settings (new or edited) click the Save button.

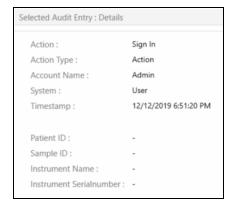
Reporting

This chapter provides users the ability to review the Audit log for processed panel requests. The audit log also contains information on changes to the system configuration. The Reporting workspace can be accessed by clicking the **REPORTING** tab on the navigation menu.

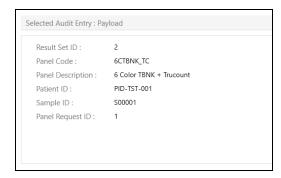
Note: The Measured On and Analysed On date and time fields are for indication only and presented in UTC time format. The exact information should be retrieved from the FACSuite™ result reports or audit trails.



The Audit entry for the selected action is visible in the right side of the Reporting screen.



Payload of the selected Audit Entry is visible at the bottom of the Reporting screen.



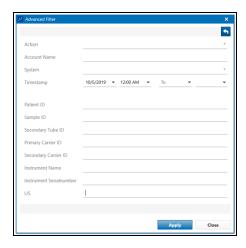
Reporting Filtering

Select the Action from a drop-down menu, Enter Sample ID, Patient ID and Timestamp. Once the parameters are entered, click the **Filter** button.

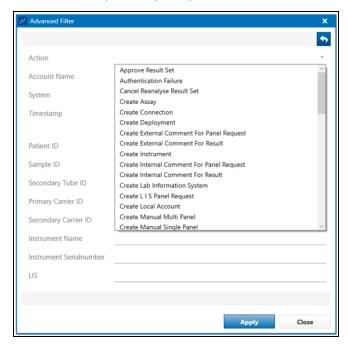


Advanced filtering

Click the **Advanced** button. Fill the parameters and save them by clicking **Apply** button.

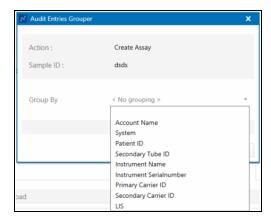


Use the drop-down menu to select appropriate action. The connection menu enables to filter per system connection specific actions (actions performed by the system without any manual action done in the FWM Client application) like creation of result sets, instrument panel request queries.



Group filtering

Group filtering enables grouping the audit entries by Account Name, System, Patient ID, Secondary Tube ID, Instrument Name, Instrument Serial number, Primary Carrier ID, Secondary Carrier ID and LIS.

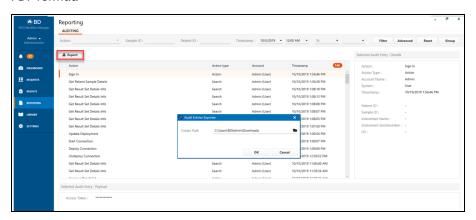


To apply the filter criteria, click the **OK** button.

To clear all filter options, click the **Reset** button.

Exporting audit entry

The Audit log can be exported by clicking the **Export** button. The file is exported in a PDF format.



Backup

This topic gives a brief description on how to set up Manual Backups, Restore, Schedule Backups and how to configure them.

Manual Backup

The backup is automatically performed on a daily basis. To perform a manual database backup follow the below steps:

- Log in to the FWM workstation with the BD Admin or any user Admin account.
- Click the Start button and type Task and select Task Scheduler.
- Right-click the FWM Full Backup task and then from the context menu, select Run now.

Restore backup

To restore backup, follow the steps below:

- Close all FACS Workflow Manager Client applications.
- Go to Windows Services by typing Services in the Windows search bar.
- Stop the following Services: BD FACS™ Workflow Manager Broker Service, BD FACS™ Workflow Manager Deployment Service.
- Right-click the Database Backup Restore icon on the desktop and Run as

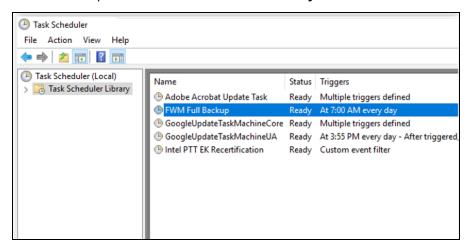


- Choose the backup to restore from the list by entering the number in the command prompt.
- Confirm that existing files are overwritten.
- Restart the services: BD FACS™ Workflow Manager Broker Service, BD FACS™ Workflow Manager Deployment Service.

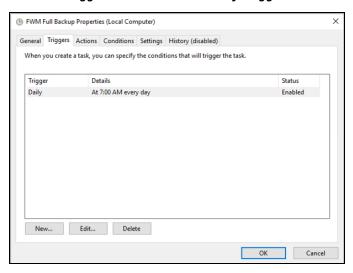
Schedule backup

To change the backup interval, perform the following steps as administrator:

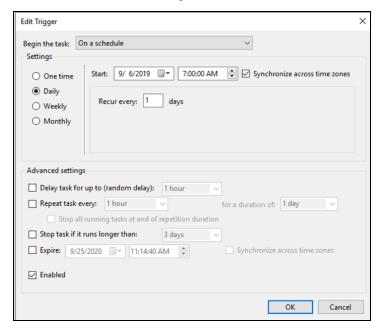
 Open the Windows Task Scheduler -> Go to Windows Search -> Type Task Scheduler and open it -> Select Task Scheduler Library.



- Right-click the FWM Full Backup -> and select Properties.
- Select the Triggers tab -> Select the Daily Trigger and click Edit.



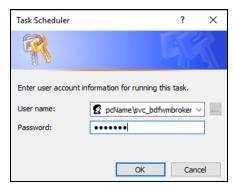
- In the Edit Trigger window setup, select the trigger as desired.
- Click **OK** to exit and save changes.



 In the security window that opens, prefix the username with the pc host name followed by a backslash.

For example: pcName\svc-bdfwmbroker.

• Enter the password that was set during installation.



Click OK to exit and close Task Scheduler.

Configure Backup Retention

To change the number of historical backups to keep, perform the following steps:

- Run notepad as Administrator.
- Open file
 - C:\ProgramData\BD\FACSWorkflowManager\Scripts\backup.xml
 (change filter to "All files *.*")
- Change the MaximumHistory setting to the number of historical backups desired (replace the number 10 with the desired number [see following graphic]. Do not remove any other character in the text).

```
<?xml version="1.0" encoding="utf-8"?>
<FacsBackup>
        <Backups>
                <!--Define each backup job-->
                <Backup>
                         <!--Backup name may not be longer than 25 characters-->
                         <Name>FWM Full Backup</Name>
                         <DatabaseInfo>
                                 <!--Hostname of the Database Server-->
                                 <ServerName>FWM-SERNUM</ServerName>
                                  <!--Instance name of the database server, default for FWM is FACSWM-->
                                 <InstanceName>FACSWM</InstanceName>
                                  <!--List the names of the databases to backup-->
                                  <Databases>
                                          <Database>
                                                  <Name>BDFACSWorkflowManager</Name>
                                          </Database>
                                                  <Name>BDFACSWorkflowManagerAudit</Name>
                                          </Database>
                                 </Databases>
                         </DatabaseInfo>
                         <!--The Fully Qualified path to the backup destination. If network location, use UNC Path-->
                         <Destination>C:\Backup</Destination>
                         <!--The Temporary path where files will be collected and archive is created before it is moved to Destination Path-->
<Temp>C:\Backup</Temp>
                         <!--List the Fully Qualified path for each folder or individual file to backup-->
                         <FileAndFolderSource>
    <FileFolder>C:\BDFWMDocuments/FileFolder>
                                 <FileFolder>C:\BDFWMShare\Reanalysis</FileFolder>
                         </FileAndFolderSource>
                       <!--Backup retention history.-->

<MaximumHistory>10

                c/Rackups
        </Backups>
/FacsBackup>
                                                                                                Ln 1, Col 1
                                                                                                                  100% Windows (CRLF)
                                                                                                                                         UTF-8
```

- To save the file click File and click Save.
- Close the file.

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