

Implementation Training



cobas® Liat | Implementation | Agenda

Cobas Liat system components

Logging in and setting up Admin, Supervisor and Users

Adding/Validating a new assay lot

Running a patient test

Reviewing Results

Cleaning and Disinfecting

Additional Tasks (Advanced tools key)

Roche Support



cobas[®] Liat system components



Liat System arrives in a box by itself with support documentation, Advanced Tools Key, Cleaning Tool, Bar code log in cards and PIN and stylus



Assay kits contain 20 individually foil packed assay tubes (and pipette) and a barcode card



Control Kits contain 3 positive controls and 6 amies (3 of which are run as a negative control and 3 mixed to reconstitute the position control) and pipettes and a barcode card



***Swabs and UTM/Liquid Amies are NOT included in your kits or sold by Roche.** Please review the package insert for the assay and order accordingly.

For successful training you will need:



The Liat system and everything that came in the box



2 Assays from a lot you have not yet validated and the package insert from that assay kit. Additional assays if you will be going patient test too.



1 control kit and the barcode card from that kit



If running patient test, the corresponding transport media/swab

Logging in and setting up Admin, Supervisor and Users



Logging in and setting up Admin, Supervisor and Users

Materials Needed: Barcode cards and PIN cards from your initial shipment

- When you log in for the first time, you must either type in ADMIN (or scan the ADMIN barcode) and use the PIN on the PIN card (23646) to log in
- There are several settings we recommend you review and/or change under SETTINGS:
 - Time/Date (make sure they are correct)
 - Operator Lock Out time (Factory default-10 min)
 - Assay Tube insertion Time
- Once you have customized your settings, you can start to add users
- The difference between the user types—is their ability to perform certain tasks within the Liat

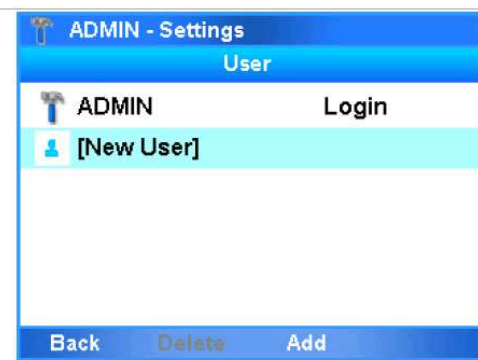
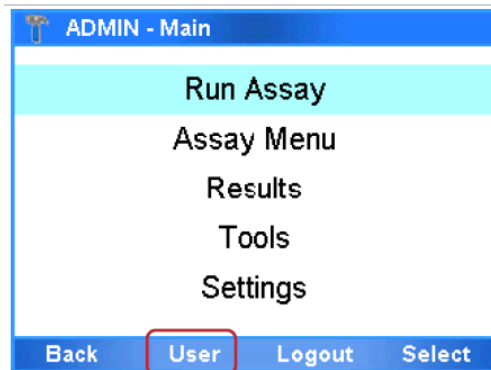


Logging in and setting up Admin, Supervisor and Users

Icon	Security level	Permitted actions
	User	Run authorized assays and view assay tube lots.
	Supervisor	As user, plus: review results, manage users (with security level Supervisor or User), set up the analyzer (except network settings), manage assay tube lots, install assays.
	Administrator	As Supervisor, plus: network configuration settings, manage all users, update assays and software, register assays and software.

Logging in and setting up Admin, Supervisor and Users

- To set up a new user:
 - Log in as an ADMIN, and select SETTINGS from the main menu. Select USER and then scroll to NEW user. Then select ADD.
 - Either type in, or SCAN that user ID. Note—the log in IS case sensitive.



- Code 39
- Code 93
- Code 128
- Code 128-A
- Code 128-B
- Codabar
- GS1 Databar-14



Logging in and setting up Admin, Supervisor and Users

- Then you will need to select a PIN # for that user. It must be numeric only.
- Then you may select a department for that user (optional) and a security level. Users may be set up as ADMIN, SUPERVISOR or USER.
- Then you may select which assays that user is trained/allowed to run if you want to limit their access.
- When you have finished, press ADD in the bottom right corner to add that user.

ADMIN: Enter PIN				
.	ABC	DEF	Enter	
1	2	3		
GHI	JKL	MNO	Symb	CLR
4	5	6		
PQRS	TUV	WXYZ	0	Caps
7	8	9		
Back Cancel OK				

ADMIN - Settings	
User Info	
User Name:	LABUSER
PIN:	***
Department:	
Contact:	
Security Level:	USER
Allowed Assay:	
Back Delete Change OK	

ADMIN - Settings: New User	
User Info	
User Name:	LABUSER
PIN:	1234
Department:	
Contact:	
Security Level:	USER
Allow Assay:	FABA
Back Scan Enter Add	



Adding and validating a new assay lot



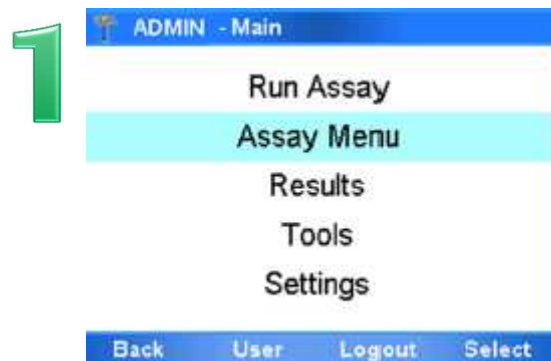
Adding and validating a new assay lot

Materials Needed: 2 Assay Tubes, 1 positive control, 2 negative controls, barcodes cards from assay and controls

- In order to use a new assay lot, you will need to run controls to “validate” the lot
- You will be prompted to run **both** a positive and negative control
- Log in as an Admin or Supervisor
- You have the ability to SHARE lot validation between Liats (we will cover this later)



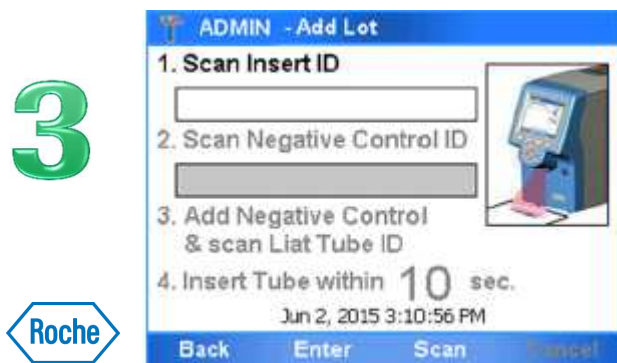
Adding and validating a new assay lot



On the **Main** menu, select the **Assay Menu** option and choose the **Select** button.



Select the **[New Lot]** option and choose the **Select** button.



Obtain the package insert from the new lot. Choose the **Scan** button and scan the package insert barcode on the first page of the package insert of the lot you want to add.



Adding and validating a new assay lot

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ADMIN - Add Lot: FABA

1. Scan Insert ID
FABA - Liat Influenza Assay
2. Scan Negative Control ID
[Barcode Field]
3. Add Negative Control & scan Liat Tube ID
4. Insert Tube within 10 sec.

Oct 26, 2015 11:37:53 AM

Back Enter Scan Cancel

Choose the **Scan** button and place the barcode of the negative control under the barcode reader.



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Hold the Dilution Amies tube by the tube cap and shake down the liquid using a quick, sharp, downward wrist motion (as if shaking down a mercury thermometer), to pool the liquid at the bottom of the tube.



Adding and validating a new assay lot

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Obtain the transfer pipette from the **cobas**[®] Liat Tube pouch (actual size shown below). Firmly squeeze the bulb of the pipette until the bulb is fully flat.

While holding the pipette bulb fully flat, insert the pipette tip into the sample below the liquid surface.

Slowly release the bulb while keeping the pipette tip below the liquid surface, drawing up the sample. After releasing the bulb completely, withdraw the pipette from the sample.

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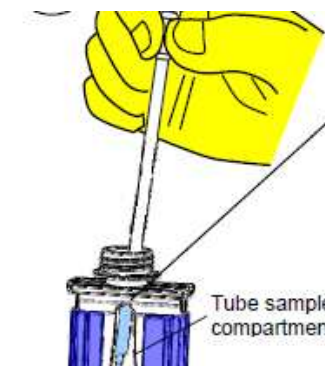
Unscrew the cap from the **cobas**[®] Liat Tube.

While watching through the viewing window in the sleeve, carefully insert the pipette into the **cobas**[®] Liat Tube. Place the pipette tip near the bottom of the sample compartment.

Slowly squeeze the bulb to empty the contents of the pipette into the **cobas**[®] Liat Tube. Do not release the pipette bulb.

Note: Do not puncture the **cobas**[®] Liat Tube or the seal at the bottom of the sample compartment. If either of these is damaged, discard both the **cobas**[®] Liat Tube and the transfer pipette, and restart the testing procedure with new assay components.

While still holding the pipette bulb, withdraw the pipette from the tube. Screw the cap back on the **cobas**[®] Liat Tube. Dispose of the transfer pipette.



Adding and validating a new assay lot

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Place the prepared assay tube under the barcode reader

9



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Wait for a message to inform you that the negative control result has been accepted. Choose the **OK** button to confirm the message.

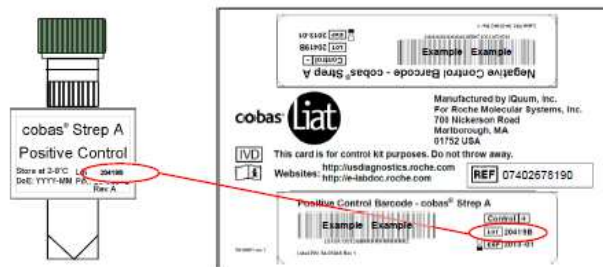
- ❶ If the QC was not completed successfully, repeat the measurement of the negative control.

When asked to do so, remove the assay tube from the analyzer and dispose of it in accordance with the disposal policy of your institution.

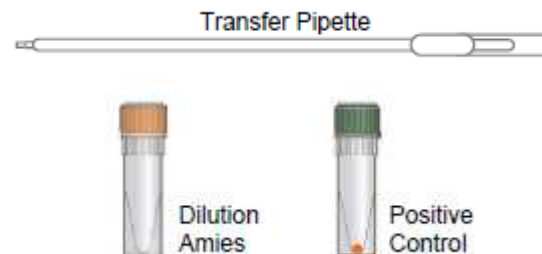
Adding and validating a new assay lot

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Choose the **Scan** button and place the barcode of the



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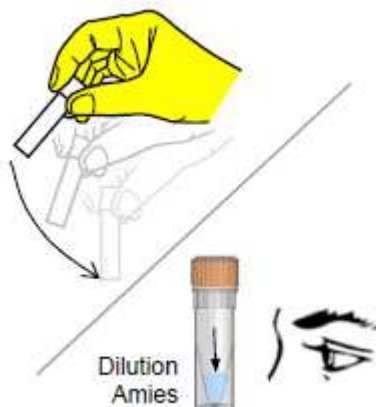


a. Obtain:

- < 1 transfer pipette
- < 1 Positive Control tube (pellet comprising dried positive control material at bottom of tube)
- < 1 Dilution Amies tube (unit dose of Amies medium)

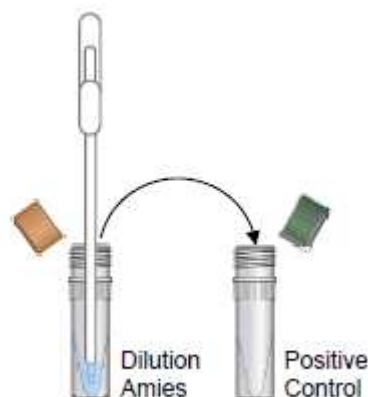
Adding and validating a new assay lot

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Hold the Dilution Amies tube by the tube cap and shake down the liquid using a quick, sharp, downward wrist motion (as if shaking down a mercury thermometer), to pool the liquid at the bottom of the tube.

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Transfer the Amies liquid from the Dilution Amies tube to the Positive Control tube:

- i. Squeeze the pipette bulb until the bulb is fully flat and insert the pipette tip into the liquid in the Dilution Amies tube.
- ii. Slowly release the bulb while keeping the pipette tip below the liquid surface. A small volume of liquid will remain in the tube after the bulb is fully released.
- iii. Insert pipette into the Positive Control tube until the tip is at the bottom of the tube.
- iv. Slowly squeeze the bulb to empty the contents of pipette. Avoid creating bubbles.
- v. While still squeezing the pipette bulb, withdraw the pipette from the tube.
- vi. Cap the Positive Control tube. Hold the Positive Control tube by the cap and shake down the liquid in the tube using a quick, sharp, downward wrist motion.

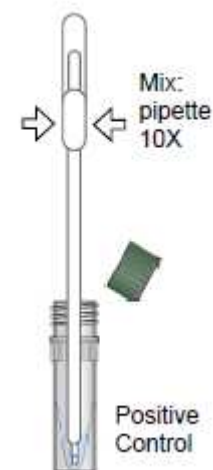
Adding and validating a new assay lot

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Let the Positive Control tube sit for 5 minutes to begin dissolving the dried positive control material.

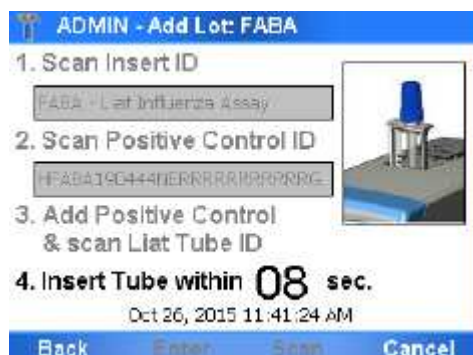
16



After the Positive Control tube from step 2 has sat for 5 minutes, use the transfer pipette from the **cobas**® Liat® Strep A Tube pouch to slowly pipette the sample up and down 10 times to dissolve and mix the positive control. Avoid generating bubbles.

Adding and validating a new assay lot

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Follow the instructions in the assay tube package insert on how to add the positive control sample to an assay tube from this lot.

Choose the **Scan** button.

Place the prepared assay tube under the barcode reader.

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Within the time limit for inserting assay tubes, insert the prepared assay tube in the analyzer.

→ Processing starts automatically.

Wait for a message to inform you that the positive control result has been accepted. Choose the **OK** button to confirm the message.

❶ If the QC was not completed successfully, repeat the measurement of the positive control. Check the Instructions for Use of the control for further information.



Adding and validating a new assay lot

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ADMIN - Add Lot: FAB A (Busy)
R00085 ID:HFABA190444NERR...

File moved
Wait for DONE status to remove tube

Status: **DONE** Estimated Time Remaining: **00:00**

Back Abort ViewData Report

When asked to do so, remove the assay tube from the analyzer and dispose of it in accordance with the disposal policy of your institution.

Wait until the information in the title bar stops flashing, then choose the **Back** button.

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ADMIN - Assay Menu

Assay	Lot#	Validated	Expiration	Days left
FABA	50126A	2015-03-09	2020-05-31	

[New Lot]
[New Assay]

Main Print Delete Select

Check the entry for the new assay tube lot.

Running a Patient Test



Running a Patient Test

Materials Needed: Assay Tube, Patient Sample in Media

- Familiarize yourself with the sample type for your assay
 - Strep A: Throat swab in liquid amies
 - Flu A/B and Flu AB+RSV: Nasopharyngeal swab in UTM
- Note: Roche does NOT sell collection or transport kits. You will need to purchase this from your distributor under your standard processes
- Once you obtain the patient sample, it should be placed within the UTM and the test performed immediately.



Collection kits direct from Vendor

To use with the cobas® Influenza A/B & Influenza A/B & RSV

Supplier	Product name	P/N	Units	Includes
BD	Universal Viral Transport 3 mL Collection Kit with Flexible <u>Minitip</u> Flocked Swab	220531	50	- UTM media vial - Swab
BD	Universal Viral Transport vial, 3mL	220220	50	- UTM/UVT media vial
BD	Flexible <u>Minitip</u> Flocked Swab	220252	100	- Swab
Copan	Copan UTM Tube and Flocked Swab	305C	6 x 50	- UTM media vial - Swab
Copan	Copan UTM – Bulk Tubes (no swabs)	330C	6 x 50	- UTM media vial
Copan	Flexible Nasopharyngeal flocked swab, Nylon tip	503cs01	10 x 50	- Swab

To use with the cobas® Strep A

Supplier	Product name	P/N	Units	Includes
BD	BD <u>ESwab</u> Collection Kit Regular Flocked Swab	220245	50	- Liquid <u>Amies</u> vial - Swab
Copan	COPAN <u>ESWAB™</u>	480C	10 x 50	- Liquid <u>Amies</u> vial - Swab

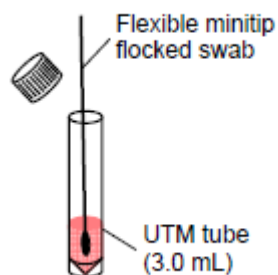


Running a Patient Test- Sample Storage

- **Strep A:** specimen not tested immediately may be refrigerated (2-8°C, preferred) or stored at room temperature (20-25°C) for up to 48 hours.
 - Specimens should be transported at 2-8°C. Ensure that all applicable regulations for the transport
- **Flu A/B:** Specimen should be tested immediately after collection. Specimens not tested immediately
- may be refrigerated (2-8°C) for up to 72 hours.
 - Specimens should be transported at 2-8°C or kept on wet ice while in transit. For long duration transport or storage, specimens should be frozen at -70°C or colder and transported on dry ice.
- Storage at -20°C is less satisfactory than storage at 4°C or -70°C. Ensure that all applicable regulations for the transport of etiologic agents are met

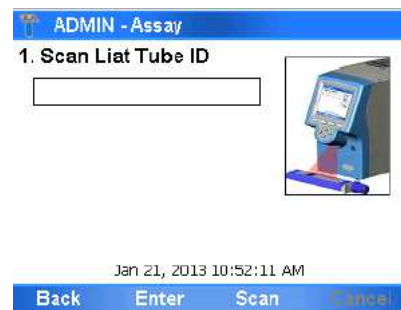
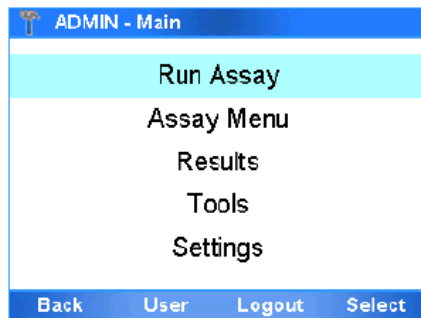
Running a Patient Test- Running the Test

Remove the swab and immediately insert the swab into the transport media tube. Place the swab head at least ½ inch below the surface of the media, and swirl the swab in the media. Break the swab shaft and leave the swab in the tube. Attach the cap securely.



Running a Patient Test- Running the Test

- Log in to the system
- Select RUN ASSAY on the main menu
- Tear open the foil package on the assay tube. Remove the tube and the pipette
- Select SCAN and scan the assay tube by sliding the tube flat on the table surface towards the system
- The system will then prompt you to enter a patient ID, or scan the sample/patient ID barcode



Running a Patient Test- Running the Test

- Use the transfer pipette to load ~200 µL of the sample into the **cobas**® Liat Influenza A/B Tube. You do not need to measure the sample volume; the **cobas**® Liat will adjust the sample volume if more sample was loaded, or output an error if not enough sample was loaded.
- Unscrew the sample tube cap. Lift the cap and any attached swab to allow a pipette to be inserted into the sample tube. Avoid lifting the swab completely out of the sample tube.
- Firmly squeeze the bulb of the pipette until the bulb is fully flat.
- While holding the pipette bulb fully flat, insert the pipette tip into the sample just below the liquid surface. Slowly release the bulb while keeping the pipette tip below the liquid surface. This will draw up ~200 µL of sample into the pipette. After releasing the bulb completely, withdraw the pipette from the sample.



Running a Patient Test- Running the Test

- Unscrew the cap from the **cobas®** Liat Influenza A/B Tube.
- While watching through the viewing window in the sleeve, carefully insert the pipette into the **cobas®** Liat Influenza A/B Tube. Place the pipette tip near the bottom of the sample compartment.
- Slowly squeeze the bulb to empty the contents of the pipette into the **cobas®** Liat Influenza A/B Tube. Avoid creating bubbles in the sample. Do not release the pipette bulb.
- Note: Do not puncture the **cobas®** Liat Tube or the seal at the bottom. If you do puncture the seal at the bottom of the sample compartment, discard both the **cobas®** Liat Influenza A/B Tube



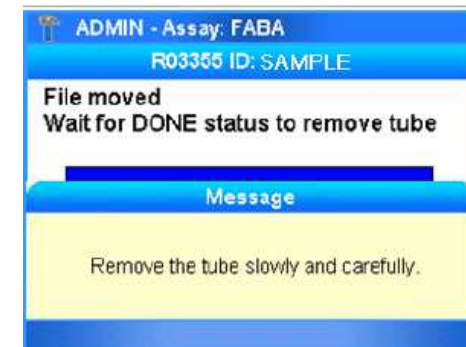
Running a Patient Test- Running the Test

- Select **Scan** and re-scan the **cobas**® Liat Influenza A/B Tube barcode. The tube entry door on top of the Analyzer will open automatically.
- Remove the **cobas**® Liat Influenza A/B Tube sleeve.
- Immediately insert the **cobas**® Liat Influenza A/B Tube, teeth to the left, into the **cobas**® Liat until the tube clicks into place.
- If the tube is not inserted by the time the door closes, re-scan the **cobas**® Liat Influenza A/B Tube barcode and insert the **cobas**® Liat Influenza A/B Tube again. Once the **cobas**® Liat Influenza A/B Tube is properly inserted, the **cobas**® Liat will close the door automatically and begin the test.



Running a Patient Test- Running the Test

- The screen will display a countdown.
- Once the test is complete, the tube entry door will open. You may remove the tube slowly and carefully and dispose of according to your institution's policies.



Running a Patient Test- Reviewing and approving result

ADMIN - Assay: FABA
R03355 ID: SAMPLE

File moved
Cycle 50 of 50

Status: **DONE** Estimated Time Remaining: **00:00**

Main Abort ViewData Report

On the assay status screen, choose the **Report** button.

ADMIN - Assay: FABA
Report

Assay: Liat Influenza Assay (FABA)
Use: For In vitro Diagnostic Use
Time/Date: 14:09:55, 2015-11-25
Sample ID: **SAMPLE**

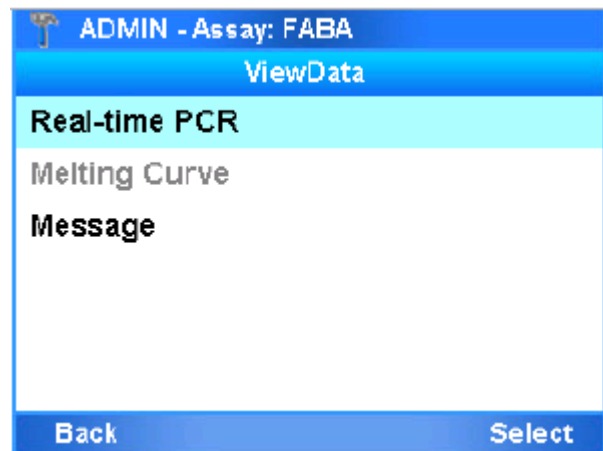
Report Results:
Influenza A Not Detected
Influenza B Not Detected

Details:

Back Print EndRun Approval

In the **Report** screen, if the result information does not fit into one screen, use the  and  navigation buttons to display the rest of the information.

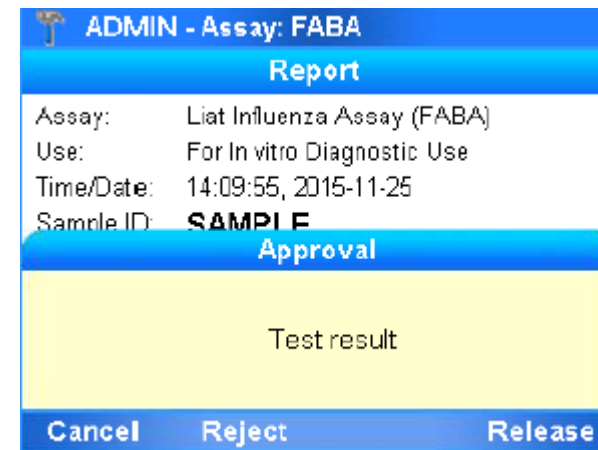
Running a Patient Test- Reviewing and approving result



To display the growth curve, choose the **ViewData** button in the assay status screen, and then choose the **Real-time PCR** option.

- ❶ From the graph screen, you can print the graph.

Choose the **Approval** button.



On the **Approval** message, choose the **Release** button to accept the result or the **Reject** button to reject it.

- ➔ On the report, your user name is added to the **Approved By** line.



Reviewing Results



Reviewing Results

On the **Main** menu, select the **Results** option and choose the **Select** button.

→ A screen is displayed for selecting specific results.

Select the filter:

Use the ▲ and ▼ buttons to select a specific filter.

- **All files**
- **Patient/Sample ID**
- **Assay**
- **User**
- **Calib**
- **Unreleased**
- **Needs Approval**
- **Delete Results**

- ❶ With filter options ending with a colon, you need to enter a value, for example an ID or name.
Choose the **Properties** button to display the total number of result reports, the space used so far (**Flat File**), and the remaining space available.

ADMIN - Results				
All File				
1	ABC 2	DEF 3	Enter	
GHI 4	JKL 5	MNO 6	Symb	CLR
PQRS 7	TUV 8	WXYZ 9	0	Caps
Back		Properties		Next

Choose the **Next** button.

Reviewing Results

ADMIN - Results				
All dates				
1	ABC 2	DEF 3	Enter	
GHI 4	JKL 5	MNO 6	Symb	CLR
PQRS 7	TUV 8	WXYZ 9	0	Caps
Back	Properties	OK		

On the next filter screen, define the time period for which the results should be included.

- ❶ Use the ▲ and ▼ buttons to select a specific period.

All dates

Today

Last 2 days

This week

Last month

MMDDYY-MMDDYY (you need to enter the two dates)

Choose the **OK** button.

Reviewing Results

ADMIN - Results			
Date	Sample ID	Assay	Result
2014-09-11	SAMPLE1	FABA	+ 
2014-09-11	SAMPLE2	FABA	- 
2014-09-11	SAMPLE3	FABA	@
2014-08-12	SAMPLE4	FABA	-  
2014-08-12	SAMPLE5	FABA	+  
2014-08-12	SAMPLE6	FABA	+ 
2014-08-12	SAMPLE7	FABA	- 
2014-08-14	SAMPLE8	FABA	?
Back Main File View			

On the **Results** screen, select the desired result entry.

- +** Positive
- Negative
- ?** Indeterminate
- !** Invalid
- @** Aborted
-  Approved
-  Rejected
-  Send
-  Received from host

Double-touch a column header to sort the table according to this criterion.

Choose the **View** button.

Cleaning



Cleaning

Keeping the analyzer clean prevents contamination and ensures trouble-free operation.

- ☐ Soft lint-free cloth
- ☐ 70% isopropanol or 5-10% bleach solution

► To clean the touch screen

- 1 Wipe the touch screen gently with a soft lint-free cloth.

To clean the front buttons and the exterior of the analyzer

Moisten a lint-free cloth with either 70% isopropanol or 5-10% bleach solution.

Gently wipe the surfaces as required.

If you used bleach solution, wipe the affected areas twice with a fresh lint-free cloth moistened with 70% isopropanol to remove all bleach residues.

Cleaning Tool

Using powder-free gloves, remove the Cleaning Wand from the bag.

Remove one Cleaning Tool Foam Pad from the bag.

Insert the Foam Pad over the open end of the hook on the Cleaning Wand as shown below.



Pull the Foam Pad down until it rests flat.



Cleaning Tool

Prior to cleaning, power off the cobas® Liat by holding the power button for several seconds.

Power on the cobas® Liat and allow the cobas® Liat to initialize. If no error messages are displayed during initialization or if only error messages with "Use cleaning tool" are displayed, proceed to step 3. If any other error messages are displayed, contact Roche Support before continuing with this procedure.

After the log in screen is displayed, power off the cobas® Liat.

Remove alcohol swab from the pouch. Dampen the Foam Pad by folding the alcohol swab over the foam pad and squeezing to transfer the alcohol to the foam pad. Discard swab when done. A similar 70% Isopropyl Alcohol swab may be substituted.

Insert the Cleaning Tool to the first printed line on the Wand and rub up and down between the two lines labeled "Optics."



Slowly retract the Cleaning Tool, rubbing up and down as it is withdrawn from the cobas® Liat.

If visible contamination is present on the pad after cleaning, replace it and repeat until no visible contamination is present.

Dispose of used Foam Pads as bio-hazardous waste.

Clean the wand with a 10% bleach solution between uses and between cobas® Liat instruments.

Additional Tasks



Additional Tasks –Advanced Tools Key

There are several functions you can perform with the Advanced Tools Key. This key looks like a black usb stick and was included in your cobas Liat kit.

- Have someone with ADMIN rights log into the system
- Once you are on the MAIN MENU
- Insert the Advanced Tools Key into the back of the Liat
- Enter the admin PIN # again
- Select your function



Additional Tasks-Advanced Tool Key

Backup Results

*Back up results from one or more **cobas**[®] Liat[®] Analyzers to the ATK*

Performing this function appends the results on the Analyzer and the ATK; no results are overwritten.

Use this function to copy results from **cobas**[®] Liat[®] Analyzers.

- Select "Backup" to copy results from the Analyzer to the ATK.

Backup Restore

*Back up assay scripts, results, validated assay lots, and system settings from a first Analyzer to the ATK, and/or restore validated assay lots, and system settings from the ATK to a second Analyzer.**

Restoring overwrites the data on the second Analyzer. Use this function to "clone" an Analyzer to a loaner Analyzer. Users must be recreated on the second Analyzer.

- Select "Backup" on the first Analyzer (e.g., an Analyzer to be returned for service) to copy data to the ATK.
- Select "Restore" on the second Analyzer (e.g., loaner Analyzer) to overwrite data from the ATK to that Analyzer.
- After completing and verifying the Restore, insert the ATK, and select "Clean Advanced Tools USB Key" to erase all data on the ATK to prevent inadvertently overwriting the data on another Analyzer.



Additional Tasks-Advanced Tool Key

Sync Lots:

Sync assay lots between an Analyzer and the ATK.

Performing this function appends the assay lots on the Analyzer and the ATK; no data is overwritten. Lots installed on an Analyzer using this function does not require validation via the Add Lot process.

- Select "Yes" to merge assay lots stored on the ATK with the Analyzer.

Update Lots:

Back up assay lots from one Analyzer to the ATK, and/or restore assay lots from the ATK to another Analyzer.

Restoring overwrites the assay lots on the Analyzer. Lots installed on an Analyzer using this function do not require validation via the Add Lot process.

- Select "Backup" to backup assay lots from the Analyzer to the ATK.
- Select "Update" to overwrite assay lot data from the USB key to the Analyzer.

Diagnostic Backup:

Back up recent assay results and diagnostics files for technical support purposes.

- Select "Yes" to copy recent assay results from the Analyzer onto the ATK.



Additional Tasks-Advanced Tool Key

All Results Backup:

Back up all assay results and diagnostic files.

- Select "Yes" to copy all assay results from the Analyzer onto the ATK.

Clean Advanced Tools Key:

Erase all data stored on the ATK.

Sending the Data to Roche Support

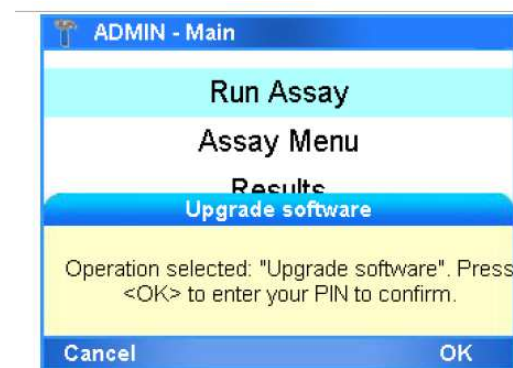
In order to provide Roche Support with data, please do the following:

1. Perform a **Diagnostic Backup** (or another function as requested).
2. Insert the **cobas® Liat®** Advanced Tools Key into a computer running Windows XP or later.
3. Open the USB drive root folder.
4. Execute Start.exe. The program will compress the data into a single file with the extension ".7z".
5. Your local Roche representative will provide further instructions for sending the data to Roche.



Additional Tasks (usb updates)

- From time to time, Roche will release software updates and/or new assay scripts as we launch new assays for the system. Upgrading your Liat is simple:
- Have someone with ADMIN rights log into the system
- Insert the usb into the back of the Liat
- Enter PIN # again
- Follow the on-screen directions
- You may be asked to register the software, follow the directions



Roche Support



Roche Support

If you have any questions about the Liat system, operational questions, complaints, concerns please call:

1-800-800-5973



References:

Cobas Liat Users Manual, version 6.0

Package Insert: Strep A assay, Strep A controls

Package Insert: Influenza A/B, Influenza A/B controls

Cleaning Tool Instruction Guide

Advanced Tools Key Instruction Guide

