

Sample Template for: Comprehensive Policies and Procedures Manual

For use with the **cobas[®] Liat[®] System**

Disclaimer

The content of this document is intended only as a guide to assist you in developing a comprehensive policies and procedures manual. This is an optional auxiliary tool. It reflects the current reagent package inserts and instrument operator's manual for the product at the time of publication. Additional **cobas[®] Liat[®] System** usage information, which resides in bulletins, updated manuals/package inserts or any other valid labeling source, may not be present.

Roche Diagnostics makes no representation or warranty that by utilizing the information contained in these procedures, a facility will be in compliance with all applicable laws or regulations. Compliance with applicable laws or regulations remains solely the responsibility of the individual facility.

Updates, review, and approval of procedures for all laboratory tests, as well as supplementing them with any other information necessary to perform a valid test, is the responsibility of the facility's program director or his/her designee. It is his/her responsibility to revise the procedure used in the facility when procedure changes are announced by Roche Diagnostics, or when there is a change in laws, regulations or their interpretations. Roche Diagnostics hereby disclaims all liability for any facility's compliance with any laws or regulations.

If you have any questions regarding the content of this document, please contact your local representative or call the Roche Support Network Customer Support Center **cobas[®] Liat[®]** hotline at 1-800-800-5973.

Introduction

Roche Diagnostics is pleased to offer this tool to assist you in developing your policies and procedures manual for the use of the **cobas[®] Liat[®] System** in your facility. This guide contains sample policies and procedures for use with the **cobas[®] Liat[®] System** and is intended only as a guide. It is important that you edit and make updates as may be required by your internal policies and changes in policies or related laws or regulations or their interpretation. This is a working document that is in general compliance with CLIA Title 42; Chapter IV, Subchapter K, Part 493; cfr.493-1251 requirements for policies and procedures manuals*.

All text in this template is editable to reflect information specific to your facility and preferences. You will find blank spaces ___ and *<gray italicized text>* throughout this document. These are provided to alert you to areas that you will commonly want to customize and to provide examples of text for you to consider. You will need to delete or adjust the font of the *<gray italicized text>* after you have customized your entries.

* http://www.ecfr.gov/cgi-bin/text-idx?SID=1248e3189da5e5f936e55315402bc38b&node=pt42.5.493&rgn=div5#se42.5.493_11251
(accessed on 9/10/2015)

cobas[®] Liat[®] System

Policies and Procedures Manual Approval

Policy: It is the responsibility of the *<enter the department and title of the staff position(s)>* to compose and maintain the **cobas[®] Liat[®] System Policies and Procedures Manual**. It must be approved, signed and dated by *<Enter the title of the Director the program in your facility>* when it is placed in use and then reviewed and approved annually throughout the use of the test system. If a new Director assumes this responsibility, the procedures must be re-approved, signed and dated by the new Director. Changes to this manual, or discontinuation of the test system must be approved, signed and dated by the Director including the date of change or discontinuation. A copy of the manual with change history is maintained throughout the use of the test system and for at least *<enter the number of years you wish to retain this manual>* years after it has been discontinued.

Initial approval date: _____ Date test discontinued: _____

Signature: _____

Signature: _____

Printed Name: _____

Printed Name: _____

Date	Reviewed/Revised	By Whom (Signature)	Title

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Principle of the Method

The **cobas**[®] Liat[®] System (the **cobas**[®] Liat[®] Analyzer and disposable **cobas**[®] Liat[®] Assay Tubes) is for *in vitro* diagnostic use. The system is designed to identify and/or measure the presence of genetic material in a biological sample. The system automates all nucleic acid test (NAT) processes, including reagent preparation, target enrichment, inhibitor removal, nucleic acid extraction, amplification, real-time detection, and result interpretation in a rapid manner.

cobas[®] Liat[®] Strep A Assay

The **cobas**[®] Liat[®] Strep A assay utilizes nucleic acid purification and polymerase chain reaction (PCR) technology to detect *Streptococcus pyogenes* by targeting a segment of the *Streptococcus pyogenes* genome. The **cobas**[®] Liat[®] Strep A assay is an automated *in vitro* diagnostic test for the qualitative detection of Strep A DNA in throat swab specimens in Liquid Amies transport media from patients with signs and symptoms of pharyngitis. The sample-to-result time is ~15 minutes.

The assay is performed on the **cobas**[®] Liat[®] Analyzer. The **cobas**[®] Liat[®] Analyzer automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples using real-time PCR. The assay targets a well-conserved region of the Strep A genome. An Internal Process Control (IPC) is also included. The IPC is present to control for adequate processing of the target bacteria through all steps of the assay process and to monitor the presence of inhibitors in the sample preparation and PCR.

The system consists of an instrument with integrated software for running tests and analyzing the results. The system requires the use of a single-use disposable **cobas**[®] Liat[®] Strep A Tube that contains the nucleic acid purification and PCR reagents, and hosts the sample preparation and PCR processes.

cobas[®] Liat[®] Influenza A/B Assay

The **cobas**[®] Liat[®] Influenza A/B Assay is a rapid, automated *in vitro* diagnostic test for qualitative detection and differentiation of Influenza type A and type B viral RNA. The assay is performed on the **cobas**[®] Liat[®] Analyzer. The **cobas**[®] Liat[®] Analyzer automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples using real-time RT-PCR assays.

The system consists of an instrument and preloaded software for running tests and viewing the results. The system requires the use of a single-use disposable **cobas**[®] Liat[®] Influenza A/B Tube that holds the sample purification and RT-PCR reagents and hosts the sample preparation and RT-PCR processes.

The **cobas**[®] Liat[®] Influenza A/B Assay includes reagents for the detection and differentiation of Influenza A and B viral RNA in nasopharyngeal swab (NPS) specimens in universal transport media (UTM) from patients suspected of having Influenza. The assay targets a well-conserved region of the matrix gene of Influenza A viral RNA (Inf A target) and non-structural protein (NS) gene of Influenza B (Inf B target). An Internal Process Control (IPC) is also included. The IPC is present to control for adequate processing of the target viruses through all steps of the assay process and to monitor the presence of inhibitors in the Real-Time Polymerase Chain Reaction (RT-PCR) reactions.

cobas[®] Liat[®] Influenza A/B & RSV Assay

The **cobas**[®] Liat[®] Influenza A/B & RSV Assay is an automated *in vitro* diagnostic test for the qualitative detection of Influenza A, Influenza B, and Respiratory Syncytial Virus (RSV) RNA in nasopharyngeal (NP) swab specimens. The sample-to-result time is ~20 minutes.

The assay is performed on the **cobas**[®] Liat[®] Analyzer. The **cobas**[®] Liat[®] Analyzer automates and integrates sample purification, nucleic acid amplification, and detection of the target sequence in biological samples using real-time PCR assays. The assay targets well-conserved regions of Influenza A, Influenza B, and RSV RNA. An Internal Process Control (IPC) is also included. The IPC is present to control for adequate processing of the target virus through all steps of the assay process and to monitor the presence of inhibitors in the PCR.

The system consists of an instrument and preloaded software for running tests and viewing the results. The system requires the use of a single-use disposable **cobas**[®] Liat[®] Influenza A/B & RSV Tube that holds the nucleic acid purification and PCR reagents, and hosts the sample preparation and RT-PCR processes. Other than adding the sample to the **cobas**[®] Liat[®] Influenza A/B & RSV Tube, no reagent preparation or additional steps are required. Because each **cobas**[®] Liat[®] Influenza A/B & RSV Tube is self-contained, cross-contamination between samples is minimized.

Intended Use Policy

cobas[®] Liat[®] Strep A Assay:

The **cobas[®] Liat[®] Strep A** nucleic acid test for use on the **cobas[®] Liat[®] System (cobas[®] Liat[®] Strep A)** is a qualitative *in vitro* diagnostic test for the detection of *Streptococcus pyogenes* (Group A β -hemolytic *Streptococcus*, Strep A) in throat swab specimens from patients with signs and symptoms of pharyngitis. Additional follow-up testing by culture is required if the **cobas[®] Liat[®] Strep A** assay result is negative and clinical symptoms persist, or in the event of an outbreak of acute rheumatic fever (ARF). Results from the **cobas[®] Liat[®] Strep A** assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician. *<add any other extent of use statements specific to your facility>*.

cobas[®] Liat[®] Influenza A/B Assay:

The **cobas[®] Liat[®] Influenza A/B** nucleic acid test for use on the **cobas[®] Liat[®] System (cobas[®] Liat[®] Influenza A/B)** is an automated multiplex real-time RT-PCR assay for the rapid *in vitro* qualitative detection and discrimination of Influenza A virus and Influenza B virus RNA in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The test is intended for use as an aid in the differential diagnosis of Influenza A and Influenza B in humans and is not intended to detect Influenza C. Negative results do not preclude Influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions. Positive results do not rule-out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Results from the **cobas[®] Liat[®] Influenza A/B Assay** should be interpreted in conjunction with other laboratory and clinical data available to the clinician. *<add any other extent of use statements specific to your facility>*.

cobas[®] Liat[®] Influenza A/B & RSV Assay:

The **cobas[®] Liat[®] Influenza A/B & RSV** nucleic acid test for use on the **cobas[®] Liat[®] System (cobas[®] Liat[®] Influenza A/B & RSV)** is an automated multiplex real-time RT-PCR assay for the rapid *in vitro* qualitative detection and discrimination of Influenza A virus, Influenza B virus and respiratory syncytial virus (RSV) RNA in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. The test is intended for use as an aid in the differential diagnosis of Influenza A, Influenza B, and RSV in humans and is not intended to detect Influenza C. Negative results do not preclude Influenza virus or RSV infection and should not be used as the sole basis for treatment or other patient management decisions. Conversely, positive results do not rule out bacterial infection or co-infection with other viruses. Results from the **cobas[®] Liat[®] Influenza A/B & RSV Assay** should be interpreted in conjunction with other laboratory and clinical data available to the clinician. *<add any other extent of use statements specific to your facility>*.

Limitations of the Methods

cobas[®] Liat[®] Strep A Assay

The following are limitations of the Strep A assay method:

- The performance of the **cobas[®] Liat[®] Strep A** assay was evaluated using the procedures provided in the package insert only. Modifications to these procedures may alter the performance of the test.
- Negative results do not preclude Strep A infection and should not be used as the sole basis for treatment or other patient management decisions. Results from the **cobas[®] Liat[®] Strep A** assay should be interpreted in conjunction with other laboratory and clinical data available to the clinician.
- Additional follow-up testing by culture is required if the **cobas[®] Liat[®] Strep A** assay result is negative and clinical symptoms persist, or in the event of an outbreak of acute rheumatic fever (ARF).
- Analyte targets (bacterial nucleic acid) may persist *in vivo*, independent of pathogen viability.
- Detection of analyte target does not imply that the corresponding pathogen is infectious, or is the causative agent for clinical symptoms.
- False negative results may occur if a specimen is improperly collected, transported or handled; or if inadequate numbers of organisms are present in the specimen.
- This test has not been evaluated for patients without signs and symptoms of Strep A infection.
- This test is a qualitative test and does not provide the quantitative value of detected organism present.
- Cross-reactivity with organisms other than those tested can lead to erroneous results.
- This test cannot rule out diseases caused by other bacterial or viral pathogens besides Group A Strep.
- Good laboratory practices and changing gloves between handling patient specimens are recommended to avoid contamination of specimens or reagents.

cobas[®] Liat[®] Influenza A/B and/or cobas[®] Liat[®] Influenza A/B RSV Assay

The following are limitations of the **cobas[®] Liat[®] Influenza A/B & RSV** assay method:

- The performance of the **cobas[®] Liat[®] Influenza A/B & RSV Assay** was evaluated using the procedures provided in the package insert only. Modifications to these procedures may alter the performance of the test.
- Negative results do not preclude Influenza A, Influenza B, or RSV infection and should not be used as the sole basis for treatment or other patient management decisions. Results from the **cobas[®] Liat[®] Influenza A/B & RSV Assay** should be interpreted in conjunction with other laboratory and clinical data available to the clinician.
- Analyte targets (viral nucleic acid) may persist *in vivo*, independent of virus viability. Detection of analyte target(s) does not imply that the corresponding virus(es) are infectious, or are the causative agents for clinical symptoms.
- This test has been evaluated for use with human specimen material only.
- False negative results may occur if a specimen is improperly collected, transported or handled. False negative results may occur if inadequate numbers of organisms are present in the specimen.
- If the virus mutates in the target regions, Influenza viruses A or B or RSV may not be detected or may be detected less predictably.
- This test has not been evaluated for patients without signs and symptoms of Influenza and RSV infection.
- This test is a qualitative test and does not provide the quantitative value of detected organism present.
- Cross-reactivity with respiratory tract organisms other than those tested can lead to erroneous results.
- This assay has not been evaluated for patients receiving intranasal administered Influenza vaccine.
- This assay has not been evaluated for immunocompromised individuals.
- This test cannot rule out diseases caused by other bacterial or viral pathogens.

General Policies

<Consider the list below and insert/delete/edit/add general policies according to your practices>

Policies

The following is a list of general policies to consider when using the **cobas**[®] Liat[®] System:

- **cobas**[®] Liat[®] System testing is conducted according to manufacturer recommended procedures. Deviation from manufacturer recommended procedures is not permitted. Each box of reagents is checked for package insert revisions and changes to this manual are made accordingly. Outdated versions of package inserts are kept for reference.
- **cobas**[®] Liat[®] System reagents are not used past their expiration date.
- Only a currently certified operator may perform testing on the **cobas**[®] Liat[®] System. Operators must successfully complete the in-servicing program described in the Operator Certification section of this manual.
- **Infection control and operator and patient safety:** The related policies and procedures below are followed for purposes of infection control and patient and operator safety when conducting tests with the **cobas**[®] Liat[®] System:

<list your facility's policies and procedures related to safety and infection control (e.g., Hand washing; handling infectious pathogens, disposal of sharps and biohazardous materials, use of personal protective equipment, etc)>

- **Patient identification policy:** The following policy and procedure is followed for purposes of patient identification for **cobas**[®] Liat[®] System testing:
 - *<Enter your facility's policy and procedure for patient identification.>*
- **Sample labeling policy:** The following policy and procedure is followed for purposes of labeling samples for **cobas**[®] Liat[®] testing:
 - *<Enter your facility's policy and procedure related to sample labeling.>*
- Administrative level access (ADMIN) is granted to limited staff. Staff with ADMIN access can back up and restore assay results, change system settings, transfer information between analyzers, work in connectivity/network features, upload assay lots across multiple **cobas**[®] Liat[®] Analyzers and manage user records. See the **cobas**[®] Liat[®] User's Manual, the **cobas**[®] Liat[®] Advanced Tools Key instructions and the **cobas**[®] Liat[®] host interface manuals for detailed information and instructions.
- Results backup is performed *<enter your facility's policy and frequency for backing up results>* using the **cobas**[®] Liat[®] Advanced Tools Key. Backed up results are stored for a period of *<enter your facility's policy for duration of retention of results.>*
- If the **cobas**[®] Liat[®] System becomes inoperable, the alternate system of testing is:

- Strep A *<insert your alternate testing method for Strep A>*
- Influenza A/B *<insert your alternate testing method for Influenza A/B>*
- RSV *<insert your alternate testing method for RSV >*

Quality Assurance

Policy: The following practices are undertaken in order to ensure and monitor on-going proper performance of the **cobas**[®] Liat[®] System and reduce errors throughout its usage for patient testing:

<List all Quality Assurance initiatives you would like to include below. Consider the examples below and insert/delete/edit/add items according to your practices or preferences.>

1. Preliminary new method validation studies. *<enter your policies and procedures for validating new qualitative systems.> (Method validation may be optional depending upon your interpretation of regulatory guidelines and sense of good laboratory practice. Delete this item if you are not required to conduct method validation studies.)*
2. Internal Process Control (IPC) is included in every **cobas**[®] Liat[®] Strep A and **cobas**[®] Liat[®] Influenza A/B and **cobas**[®] Liat[®] Influenza A/B & RSV assay tube. It verifies the adequate processing of the biological sample. The IPC passes if sample purification and target amplification meet validated acceptance criteria.
3. External positive and negative control testing is conducted each time a new reagent lot is added to the system. The **cobas**[®] Liat[®] system requires the validation of new tube lots as part of its “Add Lot” procedure and will not allow testing with a new tube lot without successful completion of positive and negative external control testing.
4. Ongoing external positive and negative control testing is conducted *<insert your facility’s policy for ongoing frequency of external positive and negative QC testing>*
5. Proficiency Testing is performed using the *<insert the name of your proficiency survey and the frequency of events> (Proficiency testing may be optional depending upon your interpretation of regulatory guidelines and sense of good laboratory practice. Delete this item if you are not required to participate in a proficiency program.)*
6. Performance of new and replacement analyzers is confirmed by *<insert your new and replacement meter validation practices.>*
7. Testing may only be conducted by fully trained and currently certified operators. See the Operator Certification section of this manual.

Quality Control Testing (Strep A, Influenza A/B, and/or Influenza A/B & RSV)

General Quality Control Policies

Policy: Successful quality control testing is essential to ensuring reliable patient results. Internal Processing Control (IPC) is integrated into each assay run. External controls provide additional quality control to demonstrate positive or negative assay results using the **cobas**[®] Liat[®] System and **cobas**[®] Liat[®] Strep A or **cobas**[®] Liat[®] Influenza A/B or **cobas**[®] Liat[®] Influenza A/B & RSV assay tube.

Internal and external quality control testing are conducted according to the following schedule:

Type of QC Testing	Frequency	Notes
Internal Processing Control (IPC)	With each control or patient test	IPC is integrated into each cobas [®] Liat [®] Strep A, cobas [®] Liat [®] Influenza A/B, and cobas [®] Liat [®] Influenza A/B & RSV Tube.
External positive and negative controls	<p>Validation of every new cobas[®] Liat[®] Strep A or cobas[®] Liat[®] Influenza A/B or cobas[®] Liat[®] Influenza A/B & RSV Tube lot that is added to the system.</p> <p><i><enter your facility's policy for regularly scheduled external QC testing></i></p> <p><i><enter your facility's policy for conducting external QC testing under special circumstances (e.g., troubleshooting unexpected results, validation of new analyzers, remedial operator training, etc.)></i></p>	The cobas [®] Liat [®] System requires the validation of new tube lots as part of its "Add Lot" function and will not allow testing with a new tube lot without successful completion of positive and negative external control testing.

Internal Process Control

Internal Process Control (IPC) is included in every assay tube. It verifies the adequate processing of the biological sample. The IPC passes if sample purification and target amplification meet validated acceptance criteria. This process occurs automatically with each test and requires no operator processing. Like the Strep A or Influenza A/B or Influenza A/B & RSV assay target, the IPC target is also evaluated in every assay run. In the case that the assay target is not detected, the IPC target must be detected for the result to be called "Not Detected"; if the IPC is also not detected or if the IPC PCR curve is abnormal, the result is called "Assay Invalid. Repeat Assay." In some cases, high

concentration of the assay target may inhibit the amplification of IPC; as such, IPC is not taken into consideration when the assay target is detected.

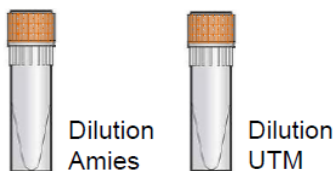
External Quality Control Testing Procedure

Gather the following items:

1. **cobas**[®] Liat[®] assay Quality Control Kit
2. Lot-specific Negative Control Barcode Card from the QC kit
3. Lot-specific Positive Control Barcode Card from the QC kit
4. Two **cobas**[®] Liat[®] assay tubes with sleeves on from the test kit you are using (leave the sleeve on the tube until you are ready to insert the tube into the analyzer tube slot)
5. 200 µL pipettes from the QC kit and the **cobas**[®] Liat[®] assay tube pouch
6. Two sample dilution medium tubes from the QC kit (Liquid Amies tubes for Strep A or UTM tubes for Influenza A/B or Influenza A/B & RSV)
7. One positive control tube containing a pellet of dried chemically-inactivated Strep A, Influenza A/B or Influenza A/B & RSV at the bottom of the tube
8. Operational **cobas**[®] Liat[®] Analyzer

Prepare a negative control sample.

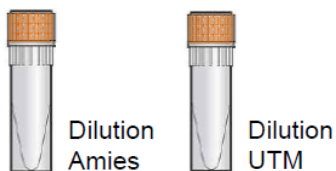
1. Take a dilution medium tube (liquid Amies for Strep A or UTM for Influenza A/B or Influenza A/B & RSV) from the QC kit. The dilution tube serves as the negative control sample.



2. Hold the dilution tube by the tube cap and shake down the liquid using a quick, sharp, downward wrist motion (as if shaking down a mercury thermometer). Visually check that all of the liquid is at the bottom of the tube. If not, repeat the shakedown procedure.

Prepare a positive control sample

1. Take a dilution tube (Liquid Amies for Strep A or UTM for Influenza A/B or Influenza A/B & RSV) from the QC kit.



1. Hold the dilution 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. Visually check that all of the liquid is at the bottom of the tube. If not, repeat the shakedown procedure.
2. Take a Positive Control tube from the QC kit:

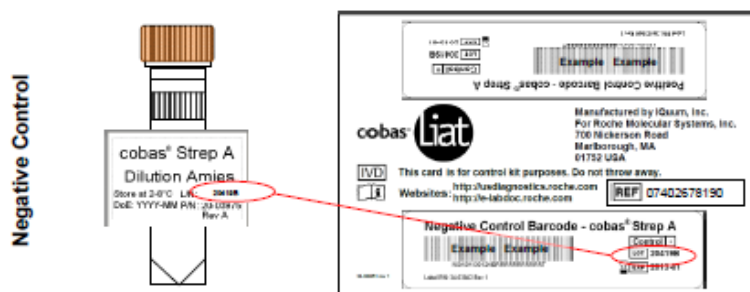


3. Using a transfer pipette, gently transfer all the liquid from the dilution tube into the bottom of the Positive Control Tube. Avoid creating bubbles in the sample.
4. Recap the Positive Control Tube.
5. Holding the tube by the cap, shake down the liquid in the tube using a quick, sharp, downward wrist motion.
6. Allow the Positive Control Tube to sit for 5 minutes as the dried material within the tube dissolves.
7. Using a transfer pipette from the **cobas**® Liat® assay tube pouch, slowly pipette the sample up and down 10 times to dissolve and mix the positive control sample.

Test External Control Samples

1. Select **Run Assay** from the Main Menu.
2. Select **Scan** and scan the **cobas**® Liat® assay tube barcode on the tube sleeve by placing the tube on the table and sliding the tube towards the analyzer until the red scan light is over the entire barcode.
3. Select **Scan** again and scan the appropriate negative or positive control barcode on the control kit barcode card (match the lot number of the sample tube label to the lot number of the control barcode label on the Control Kit Barcode Card).

Example:



4. Obtain a transfer pipette from the **cobas**® Liat® assay tube pouch or QC kit. Firmly squeeze the bulb of the pipette until it is fully flat.
5. While holding the pipette bulb fully flat, insert the pipette tip into the sample below the liquid surface.
6. 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.
7. Unscrew the cap from the **cobas**® Liat® assay tube.
8. While watching through the viewing window in the sleeve, carefully insert the pipette into the tube placing the pipette tip near the bottom of the sample compartment.
9. Slowly squeeze the bulb to empty the contents of the pipette into the sample compartment of the tube. Do not release the pipette bulb. **Note:** Do not puncture the tube or the seal at the bottom of the sample compartment. If either of these is damaged, discard both the tube and the transfer pipette and restart the testing with new assay components.

10. While still holding the pipette bulb flat, withdraw the pipette from the tube. Screw the cap back on the tube.
11. Scan the tube sleeve barcode again. The tube entry door on top of the analyzer will automatically open.
12. Remove the **cobas**[®] Liat[®] assay tube sleeve and immediately insert the tube into the tube entry slot until it clicks into place. The tube only fits in one way. If the tube is not inserted by the time the door closes, re-scan the **cobas**[®] Liat[®] assay tube barcode and insert the **cobas**[®] Liat[®] assay tube again. Once the tube is inserted the door will close automatically and the assay will begin.
13. When the test is complete, the **cobas**[®] Liat[®] Analyzer screen displays the message "Please remove the tube slowly."
14. Lift the tube out of the **cobas**[®] Liat[®] Analyzer and discard following all applicable biohazard safety precautions.
15. Touch or click **Report** after completion of the assay.
 - Negative Control Results:** The Report Result must be Strep A (or Influenza A and B) not detected for the negative control to pass.
 - Positive Control Results:** The Report Result must be Strep A or Influenza A and B detected for the positive control to pass.
16. Select **Back**.

Troubleshooting Error Messages or Unexpected Results

1. The **cobas**[®] Liat[®] Analyzer monitors its operation and logs abnormal events. Based on the severity, the **cobas**[®] Liat[®] Analyzer tries to recover or fix errors while running. If the error is unrecoverable, the **cobas**[®] Liat[®] Analyzer stops. If repeating the test as suggested in the results table above does not yield a clear positive or negative result. Call the Roche Support Network Customer Support Center **cobas**[®] Liat[®] hotline at 1-800-800-5973.
2. **Event Logs:** Certain error messages are recorded in the Event Log file. To view the log, select **Tools**, then **Event Logs**. Large Event Logs might take some time to load. Viewing the Event Log requires Supervisor or higher security level. If needed, select **Print** to print the Event Log. See the **cobas** Liat User's Manual for a full list of error messages and their meanings.
3. **Real Time Error Messages:** See the **cobas**[®] Liat[®] System User's Manual for a table that lists the real-time messages and suggested troubleshooting. Certain error messages are accompanied by a unique alphanumeric error code displayed after the error messages. Please provide this code when contacting Roche Support Network Customer Support Center **cobas**[®] Liat[®] hotline at 1-800-800-5973.
4. **Warning!** Only a Roche-qualified service representative can service the system or perform preventative maintenance. Never attempt to repair or adjust the system yourself. Disassembly could result in electrical hazards. Contact the Roche Support Network Customer Support Center **cobas**[®] Liat[®] hotline at 1-800-800-5973 if the **cobas**[®] Liat[®] System fails to operate properly.

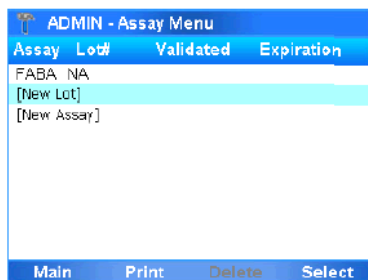
Add Lot Procedure (Strep A, Influenza A/B and/or Influenza A/B & RSV)

It is necessary to validate new lots of **cobas**[®] Liat[®] assay tubes by running a positive and negative control test before they can be used for routine testing. This process is a part of the Add Lot function (See **cobas**[®] Liat[®] System User's Manual for additional detail). The **cobas**[®] Liat[®] Analyzer will prompt you to add the lot if you try to run an assay from a new lot that has not been validated.

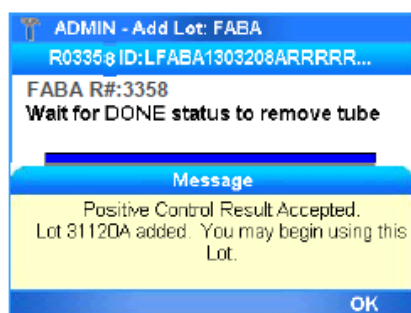
1. Select **Assay Menu** on the main menu of the **cobas**[®] Liat[®] Analyzer:



2. Select **New Lot** from the Assay Menu:

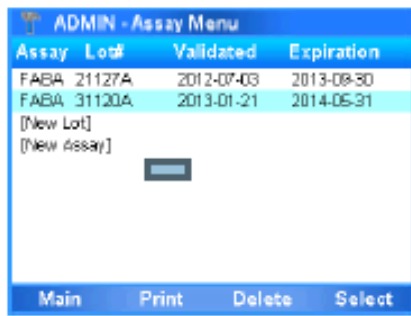


3. Obtain the package insert from the new lot. Select **Scan** and scan the package insert barcode on the first page of the package insert of the lot being added. If the **cobas**[®] Liat[®] Analyzer recognizes the new package insert barcode, it prompts "2. Scan Negative Control ID."
4. Follow the above External Control Testing procedures to run the negative control.
5. After the negative control result is accepted, select **Back**. The **cobas**[®] Liat[®] Analyzer will prompt "2. Scan Positive Control ID."
6. Follow the above External Control Testing procedures to run the positive control.
7. The new lot is successfully added into the **cobas**[®] Liat[®] Analyzer when both negative and positive control results are accepted.



8. After the positive control is accepted, select **Back** to return to the Main Menu.

9. From the Main Menu, select **Assay Menu** and verify that the new lot is listed.



Assay	Lot#	Validated	Expiration
FABA	21127A	2012-07-03	2013-08-30
FABA	31120A	2013-01-21	2014-05-31
[New Lot]			
[New Assay]			

[New Lot]
[New Assay]

Main Print Delete Select

Patient Testing (Strep A, Influenza A/B and/or Influenza A/B & RSV)

Patient Sample Collection

Policy: Proper sample collection and testing technique are essential to the **cobas**[®] Liat[®] Strep A testing process. All staff members who perform testing on the **cobas**[®] Liat[®] System must be fully trained and currently certified to collect samples and conduct patient testing according to the procedures outlined below. Patient testing is not conducted if regularly scheduled Quality Control testing has failed.

Sample Collection (Strep A)

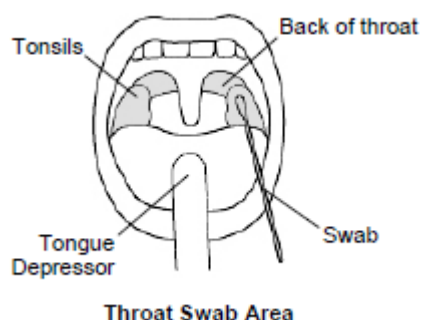
Acceptable Sample Type: Throat swab

Acceptable Sample Collection Materials:

- Liquid Amies collection and transport system containing a sterile swab and a tube filled with 1 mL of Amies liquid transport medium.
- Do *not* use cotton or calcium alginate swabs or swabs with wood shafts.
- See package insert for list of approved sample collection kits.

Throat Sample Collection Procedure

1. Gather the following items you need to collect a throat swab:
 - a. Gloves and other personal protective equipment per established procedures.
 - b. Liquid Amies Medium (1 mL)
 - c. Sterile collection swab
2. Identify the patient according to the established protocols.
3. Explain the purpose and steps of the procedure to the patient.
4. Place patient in a seated position facing the light.
5. Wash hands, don gloves and remove swab from protective packaging.
6. Instruct patient to open mouth as wide as possible. If needed, use a tongue depressor to press the tongue downward to the floor of the mouth so that the throat can be seen.



7. Rub swab up and down on the back of the throat, the tonsil area and against any white patches in the tonsillar area
8. Remove swab from the mouth.
Note: Do not touch tongue, cheek, teeth or gums with the swab.
9. Immediately insert swab into Amies media –swirl the swab against the inside wall of the tube three times.
10. Break swab shaft off and discard appropriately, leaving swab end placed in media. Attach media cap securely.
11. Label the specimen according to established policies.
12. Remove and discard gloves and wash hands according to established policies and procedures.

Handling/Storage of Throat Samples:

The following are guidelines for storage and handling of throat samples:

- Ideally, specimens should be tested immediately after collection.
- Specimens can be refrigerated (2-8° C) or stored at room temperature (20-25° C) for up to 48 hours.
- Specimens can be transported (2-8° C).
- All applicable transport regulations should be met with regard to transportation of etiologic agents.

Sample Collection (Influenza A/B or Influenza A/B & RSV)

Acceptable Sample Type: Nasopharyngeal swab sample

Acceptable Sample Collection Materials:

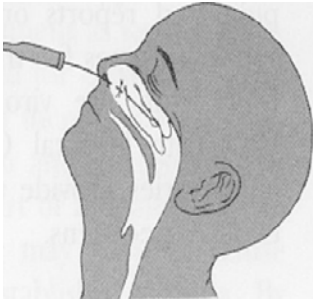
- Universal Transport Media- UTM (3 mL) BD Cat#220531 or Copan #305C
- Sterile flexible mini-tip flocced swab with a synthetic tip (e.g., Dacron, nylon, or rayon) and an aluminum or plastic shaft.
- *Do not* use cotton or calcium alginate swabs, or swabs with wood shafts.
- See package insert for list of approved sample collection kits.

Nasopharyngeal Sample Collection Procedure

Important: Wear a mask and eye protection when performing this procedure.

1. Gather the following items that you need to collect your nasopharyngeal sample:
 - a. Gloves
 - b. Tube containing 3 mL Universal Transport Media (3 mL)
 - c. Appropriate sterile swab
 - d. Nasal tissues

2. Identify the patient according to the established protocols.
3. Explain the purpose and steps of the procedure to the patient.
4. Wash hands and don gloves.
5. Ask the patient to blow his/her nose into a tissue.
6. Place the patient in a seated position with head against a fixed object (e.g., a wall) to prevent patient from pulling away during the sample collection procedure.
7. Tilt the patient's head back at 70 degree angle.
8. Open the sterile swab, insert it into one nostril and aim straight back (not upwards). Continue along the floor of the nasal passage for several centimeters until reaching the nasopharynx region (resistance will be met). Do not force the swab. If an obstruction is met, before reaching the nasopharynx, remove the swab and try the other nostril.



Note: The distance from the nose to the ear gives an estimate of the distance the swab should be inserted.

9. Gently rotate the swab for 5-10 seconds to loosen epithelial cells.
10. Remove the swab and immediately insert the swab into the transport media tube, placing the swab head at least ½ inch below the surface of the media.
11. Break the swab shaft and leave the swab in the tube. Attach the cap securely.
12. Label the specimen according to established policies.
13. Remove and discard gloves and wash hands according to established policies and procedures.

Handling/Storage of Nasopharyngeal Samples

The following are guidelines for storage and handling of nasopharyngeal samples:

- Ideally, specimens should be tested immediately after collection.
- Specimens not tested immediately can be refrigerated (2-8° C) for up to 72 hours.
- Transported samples (in appropriate media) should be kept at 2-8° C or on wet ice while in transport.
- For longer duration transport/storage, specimens can be frozen at -70 °C or colder and transported on dry ice. A storage condition at -20° C is less satisfactory than 4°C or -70° C.
- All applicable transport regulations should be met with regard to transportation of etiologic agents.

Rejection Criteria for Throat and Nasopharyngeal Samples

The following are rejection criteria for nasopharyngeal samples:

- Improper transport media
- Leaky transport tube
- Improper storage of sample
- Incorrect swab used for collection of sample
- Mislabeled sample
- Improper collection of sample
- <enter any of your facility's additional sample rejection criteria.>

Patient Test Procedure (Strep A, Influenza A/B and/or Influenza A/B & RSV)

1. Gather the following items:

- a. **cobas**[®] Liat[®] Strep A or Influenza A/B or Influenza A/B & RSV assay tube (from a lot that has been validated and entered into the system)
- b. **cobas**[®] Liat[®] Transfer pipette (in **cobas**[®] Liat[®] reagent box with tubes)
- c. Appropriately collected patient sample
- d. Biohazard container
- e. Operational **cobas**[®] Liat[®] Analyzer

2. Scan the barcode:

- a. Tear open the foil packaging of the **cobas**[®] Liat[®] Tube and remove the tube and the transfer pipette.
Note: Do not use a damaged **cobas**[®] Liat[®] assay tube. Do not open individual tube packaging until you are ready to perform testing. Each single-use **cobas**[®] Liat[®] assay tube is used to process one test. Do not attempt to reuse a spent **cobas**[®] Liat[®] assay tube.
- b. Select **Run Assay** on the Main Menu.
- c. Select **Scan** and scan the **cobas**[®] Liat[®] assay tube barcode on the tube sleeve by placing the tube on the table and sliding the tube towards the analyzer until the red scan light is over the entire barcode.
- d. Select **Scan** again and scan the Patient or Sample barcode, or select **Enter** and type in a Sample or Patient ID. The screen will then prompt you to add the sample to the assay tube and rescan the tube.

3. Add the sample to the assay tube:

- a. Unscrew the cap from the **cobas**[®] Liat[®] assay tube. Do not discard the cap.
- b. Hold the swab sample tube on its ends with the thumb and forefinger; vigorously shake the tube for 5 seconds to evenly disperse the patient specimen in the liquid medium.
- c. Unscrew the sample tube cap. Hold the tube between the thumb and ring finger, and hold the cap between the index finger and middle finger. Lift the cap and any

attached swab to allow a pipette to be inserted into the tube. Avoid lifting the swab completely out of the tube.

- d. Firmly squeeze the bulb of the pipette until the bulb is fully flat.
- e. While holding the pipette bulb fully flat, insert the pipette tip into the sample just below the liquid surface.
- f. Slowly release the bulb while keeping the pipette tip below the liquid surface. You will see the liquid sample rising into the pipette. After releasing the bulb completely, withdraw the pipette from the sample. This will deliver ~200 µL of sample into the tube.

Note: You do not need to measure the sample volume; the **cobas**[®] Liat[®] Analyzer will adjust the sample volume if more sample was loaded, or output an error if not enough sample was loaded.

- g. Insert the pipette into the **cobas**[®] Liat[®] assay tube.
- h. Place the pipette tip near the bottom of the sample compartment. Do not puncture the tube or the seal at the bottom.
- i. Slowly squeeze the bulb to empty the contents of the pipette into the **cobas**[®] Liat[®] assay tube.
Note: Avoid creating bubbles in the sample. Do not release the pipette bulb.
- j. While still squeezing the pipette bulb, withdraw the pipette from the tube. Screw the cap back on the tube.

4. Insert the **cobas**[®] Liat[®] assay tube into the analyzer and run test.

- a. Select **Scan** and re-scan the **cobas**[®] Liat[®] assay tube barcode. The tube entry door on top of the analyzer will open automatically.
- b. Remove the **cobas**[®] Liat[®] assay tube sleeve.
- c. Immediately insert the **cobas**[®] Liat[®] assay tube into the analyzer until the tube clicks into place. The **cobas**[®] Liat[®] assay tube only fits in one way. If the tube is not inserted by the time the door closes, re-scan the **cobas**[®] Liat[®] assay tube barcode and insert the **cobas**[®] Liat[®] assay tube again. Once the **cobas**[®] Liat[®] assay tube is properly inserted, the **cobas**[®] Liat[®] Analyzer will close the door automatically and begin the test.
- d. During the test, the analyzer screen displays the running status and estimated time remaining. Once the test is complete, the analyzer displays the message, *"Please remove the tube slowly..."* and opens the tube entry door automatically.
- e. Gently lift the **cobas**[®] Liat[®] assay tube out of the analyzer and discard the tube according to established procedure for disposing of biohazardous materials.

5. View the result.

- a. Select **Report** to see the Result Report.
- b. Select **Print** to print the report (if applicable).
- c. Select **Back**, and then **Main** to return to the main menu for the next test.

6. Interpret the results.

The **cobas**[®] Liat[®] System reports results as "Detected", "Not Detected", "Indeterminate", "Assay Invalid" or an error message. See table below for guidance on how to interpret and follow up on various results:

cobas[®] Liat[®] Strep A Assay Results:

Report Results	Interpretation
----------------	----------------

Strep A Not Detected	Negative test for Strep A (no Strep A DNA detected)
Strep A Detected	Positive test for Strep A (Strep A DNA present)
Strep A Indeterminate. Repeat Assay.	Presence or absence of Strep A cannot be determined. Repeat assay with same sample or, if possible, new sample.
Assay Invalid. Repeat Assay	Presence or absence of Strep A cannot be determined. Repeat assay with same sample or, if possible, new sample.
[Error] Assay Aborted	Presence or absence of Strep A cannot be determined. Repeat assay with same sample or, if possible, new sample.

cobas® Liat® Influenza A/B Results

Report Result		Interpretation
Influenza A	Influenza A Not Detected	Negative test for Influenza A (no Influenza A RNA detected)
	Influenza A Detected	Positive test for Influenza A (Influenza A RNA present)
	Influenza A Indeterminate. Repeat Assay.	Presence or absence of Influenza A cannot be determined. Repeat assay with same sample or, if possible, new sample.
Influenza B	Influenza B Not Detected	Negative test for Influenza B (no Influenza B RNA detected)
	Influenza B Detected	Positive test for Influenza B (Influenza B RNA present)
	Influenza B Indeterminate. Repeat Assay.	Presence or absence of Influenza B cannot be determined. Repeat assay with same sample or, if possible, new sample.
Assay Invalid. Repeat Assay.		Presence or absence of Influenza A, and Influenza B cannot be determined. Repeat assay with same sample or, if possible, new sample.
[Error]. Assay Aborted		Presence or absence of target viruses cannot be determined. Repeat assay.

cobas® Liat® Influenza A/B & RSV Results

Report Result		Interpretation
Influenza A	Influenza A Not Detected	Negative test for Influenza A (no Influenza A RNA detected)
	Influenza A Detected	Positive test for Influenza A (Influenza A RNA present)
	Influenza A	Presence or absence of Influenza A

	Indeterminate. Repeat Assay.	cannot be determined. Repeat assay with same sample or, if possible, new sample.
Influenza B	Influenza B Not Detected	Negative test for Influenza B (no Influenza B RNA detected)
	Influenza B Detected	Positive test for Influenza B (Influenza B RNA present)
	Influenza B Indeterminate. Repeat Assay.	Presence or absence of Influenza B cannot be determined. Repeat assay with same sample or, if possible, new sample.
RSV	RSV Not Detected	Negative test for RSV (no RSV RNA detected)
	RSV Detected	Positive test for RSV (RSV RNA present)
	RSV Indeterminate. Repeat Assay.	Presence or absence of RSV cannot be determined. Repeat assay with same sample or, if possible, new sample.
Assay Invalid. Repeat Assay.		Presence or absence of Influenza A, Influenza B, and RSV cannot be determined. Repeat assay with same sample or, if possible, new sample.
[Error]. Assay Aborted		Presence or absence of target viruses cannot be determined. Repeat assay.

7. **Report the results:** Results are reported by means of *<insert your facility's policy for reporting results (e.g. – electronic, hard copy)>*.
8. **Record the results:** Patient results are recorded by means of *<insert your facility's policy for recording results (e.g. – electronic record, hard copy)>*.
9. **Discard** the used **cobas[®] Liat[®]** assay tube, pipette and specimen tubes according to established safety guidelines for disposal of biohazardous material.

Procedure Notes

- a. The typical time from the test being ordered to the time that the results are given to the provider is *<insert your designated turnaround time for this test.>*
- b. Internal Process Control (IPC) is included in every assay tube. It verifies the adequate processing of the biological sample. The IPC passes if sample purification and target amplification meet validated acceptance criteria.
- c. Do not substitute Amies or UTM sample dilution media with other reagents.
- d. Do not open the cap of the **cobas[®] Liat[®]** assay tube during or after the run on the **cobas[®] Liat[®]** Analyzer.
- e. Operating the analyzer outside the temperature range of 4°C to 42°C (39 to 108°F) will cause an error message to be displayed on the analyzer screen.
- f. Store the **cobas[®] Liat[®]** assay tubes at 2-8°C.

Troubleshooting Error Messages or Unexpected Results

The **cobas**[®] Liat[®] Analyzer monitors its operation and logs abnormal events. Based on the severity, the **cobas**[®] Liat[®] Analyzer tries to recover or fix errors while running. If the error is unrecoverable, the **cobas**[®] Liat[®] Analyzer stops. If repeating the test as suggested in the results table above does not yield a clear positive or negative result. Call the Roche Support Network Customer Support Center **cobas**[®] Liat[®] hotline at 1-800-800-5973.

Event Logs: Certain error messages are recorded in the Event Log file. To view the log, select **Tools**, then **Event Logs**. Large Event Logs might take some time to load. Viewing the Event Log requires Supervisor or higher security level. If needed, select **Print** to print the Event Log. See the **cobas**[®] Liat[®] System User's Manual for a full list of error messages and their meanings.

Real Time Error Messages: See the **cobas**[®] Liat[®] System User's Manual for a table lists the real-time messages and suggested troubleshooting. Certain error messages are accompanied by a unique alphanumeric error code displayed after the error messages. Please provide this code when contacting Roche Support Network Customer Support Center **cobas**[®] Liat[®] hotline at 1-800-800-5973.

Warning! Only a Roche-qualified service representative can service the system or perform preventative maintenance. Never attempt to repair or adjust the system yourself. Disassembly could result in electrical hazards. Contact the Roche Support Network Customer Support Center **cobas**[®] Liat[®] hotline at 1-800-800-5973 if the **cobas**[®] Liat[®] System fails to operate properly.

Software/Connectivity

Connectivity

The **cobas**[®] Liat[®] System provides connectivity for transferring patient results to a laboratory information system (LIS), a hospital information system (HIS), or Point-of-Care (PoC) Management System. Transfer occurs via an Observation Reporting Interface (also called Electronic Data Interchange (EDI) or ORI), which is based on HL7 [3] for devices or POCT data managers that are permanently connected to the network. This interface is intended for the exchange for patient result and order information. The **cobas**[®] Liat[®] System can transfer patient results to a host, but does not provide any remote management functionality. Refer to the **cobas**[®] Liat[®] System User's Manual and **cobas**[®] Liat[®] System host interface manuals for additional information.

Advanced Tools USB Key – The following functions can be performed using the Advanced Tools Key. An ADMIN level account is required to use the Advanced Tools Key. See the **cobas**[®] Liat[®] Advanced Key Instructions for Use which come with the key for detailed instructions.

Backup Results - Back up results from one or more **cobas**[®] Liat[®] analyzers to the ATK. Performing this function appends the results on the **cobas**[®] Liat[®] 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 **cobas**[®] Liat[®] Analyzer to the ATK.

Backup Restore - Back up assay scripts, results, validated assay lots, and system settings from a first **cobas**[®] Liat[®] Analyzer to the ATK, and/or restore validated assay lots, and system settings from the ATK to a second **cobas**[®] Liat[®] Analyzer. Restoring overwrites the data on the second **cobas**[®] Liat[®] Analyzer. Use this function to “clone” an analyzer to a loaner analyzer. Users will be recreated on the second **cobas**[®] Liat[®] Analyzer.

- Select “Backup” on the first **cobas**[®] Liat[®] Analyzer (e.g., an analyzer to be returned for service) to copy data to the ATK.
- Select “Restore” on the second **cobas**[®] Liat[®] 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 **cobas**[®] Liat[®] Analyzer.

Sync Lots - Sync assay lots between a **cobas**[®] Liat[®] Analyzer and the ATK. Performing this function appends the assay lots on the **cobas**[®] Liat[®] Analyzer and the ATK; no data is overwritten. Lots installed on a **cobas**[®] Liat[®] 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 **cobas**[®] Liat[®] Analyzer.

Update Lots - Back up assay lots from one **cobas**[®] Liat[®] Analyzer to the ATK, and/or restore assay lots from the ATK to another **cobas**[®] Liat[®] Analyzer. Restoring overwrites the assay lots on the **cobas**[®] Liat[®] Analyzer. Lots installed on a **cobas**[®] Liat[®] Analyzer using this function do not require validation via the Add Lot process.

- Select “Backup” to backup assay lots from the **cobas**[®] Liat[®] Analyzer to the ATK.
- Select “Update” to overwrite assay lot data from the USB key to the **cobas**[®] Liat[®] Analyzer.

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

- Select “Yes” to copy recent assay results from the **cobas**[®] Liat[®] Analyzer onto the ATK.

All Results Backup - Back up all assay results and diagnostic files.

- Select “Yes” to copy all assay results from the **cobas**[®] Liat[®] Analyzer onto the ATK.

Clean Advanced Tools Key - Erase all data stored on the ATK.

System Maintenance and Calibration

Cleaning the Analyzer

Policy: The **cobas**[®] Liat[®] Analyzer is cleaned according to manufacturer's instructions below. The analyzer should be cleaned according to the following schedule: <insert your facility's schedule for cleaning bench equipment>

- Keep the touch screen clean from excessive fingerprints and moisture by gently wiping it with a soft, lint free cloth.
- The exterior of the **cobas**[®] Liat[®] Analyzer and front buttons can also be cleaned using a soft lint free cloth moistened with either 70% isopropanol or 5-10% bleach solution. If bleach is used, it must be wiped twice using 70% isopropanol to remove all bleach residues.
- Periodically check the rear vent and bottom of the **cobas**[®] Liat[®] Analyzer for excessive dust or debris.
- When prompted by the message "Use cleaning tool" on the **cobas**[®] Liat[®] Analyzer screen, use the provided cleaning tool following the instructions included with the Cleaning tool kit.

Analyzer Self-Check

The **cobas**[®] Liat[®] Analyzer performs self-diagnostics during power-on startup (initialization) and utilizes an advanced error diagnostics system to monitor the **cobas**[®] Liat[®] Analyzer's performance during an assay. An operator is not required to perform any maintenance, other than touch screen calibration. Under normal operation, the **cobas**[®] Liat[®] Analyzer alerts the operator in the event that a malfunction or error is detected.

Analyzer Auto Calibration

Each **cobas**[®] Liat[®] Analyzer is calibrated to factory standards prior to shipping. The **cobas**[®] Liat[®] Analyzer requires no adjustment or calibration from the operator. The **cobas**[®] Liat[®] Analyzer periodically performs automatic recalibration. During auto calibration, "(AutoCal)" is displayed on the title bar. If the user selects Run Assay at this time, a message appears stating, "AutoCal started. This could take up to a minute." Select **OK** to close this message window. Wait until (AutoCal) is no longer in title bar.

Warning! Only a Roche-qualified service representative can service the system or perform preventative maintenance. Never attempt to repair or adjust the system yourself. Disassembly could result in electrical hazards. Contact the Roche Support Network Customer Support Center **cobas**[®] Liat[®] hotline at 1-800-800-5973 if the **cobas**[®] Liat[®] System fails to operate properly.

Touch Screen Calibration

Policy: When a user touches one item on the screen but activates another item, the touch screen may need to be recalibrated. Supervisor or higher security level user is required for this calibration.

To calibrate the touch screen

1. From the Main menu, select **Tools**, and then **Calibration**.
2. Select **Touch Screen** to start the calibration process.
3. Follow the instructions on the screen.
4. After calibration is complete, touch the screen to confirm the new settings or wait 30 seconds to discard the change.

Product Ordering and Replacement Information

Contact your local Roche Representative to purchase the **cobas**[®] Liat[®] Analyzer, **cobas**[®] Liat[®] assays, Assay Quality Control kits and other accessories. See the **cobas**[®] Liat[®] System User's Manual for product and accessory order numbers.

Contact your local Roche Representative to purchase the **cobas**[®] Liat[®] Analyzer, **cobas**[®] Liat[®] assays, Assay Quality Control kits and other accessories. See the **cobas**[®] Liat[®] System User's Manual for product and accessory order numbers.

Roche Support

If you have any questions or problems, please contact the Roche Support Network Customer Support Center **cobas**[®] Liat[®] hotline at 1-800-800-5973 with the system information collected as required below.

- cobas**[®] Liat[®] Analyzer serial number
- Assay name
- Run number (available in Result Report)
- Error message and code (if displayed)
- Maintenance contract number (as applicable)
- System diagnostic information, using the Diagnostic Backup function of the Advanced Tools USB Key (see Advanced Tools Key instruction for use).

Analyzer

The **cobas**[®] Liat[®] Analyzer must be disposed of in accordance to relevant local regulations and in coordination with your local authorities, as appropriate.

Note: The **cobas**[®] Liat[®] Analyzer may potentially be infectious. It should therefore be decontaminated before disposal.

Product Specifications

Operating Conditions and Technical Data

Category	Specification
Temperature range	+15°C to +32°C recommended
Relative humidity	15% to 80% (non-condensing)
Maximum altitude	2,000 m (6,500 ft) above sea level
Internal storage	Approximately 20,000 test results with date and time can be stored on the cobas Liat (depending on result file size)
User interface	Built-in touch screen & keypad
Barcode reader	Class 2 Laser Product
Connectivity port	Ethernet, RJ-45, TCP/IP 2 Universal Serial Bus (USB) maximum load of 250 mA
Main connection	Power supply adapter: Input 100-240 V AC / 50-60Hz Output: 15V DC / 8.6A
Power consumption	130W on AC Mains Power
Safety class	II
Dimensions	24.1 cm x 11.4 cm x 19.0 cm (9.5"L x 4.5"W x 7.5"H)
Weight	3.76 kg (8.3 lbs)
Declaration of conformity	The instrument meets the requirements laid down in Council Directive 89/336/EEC relating to "Electromagnetic compatibility" and Council Directive 73/23/EEC relating to "Low Voltage Equipment." The following standards were applied: IEC/EN 61326 (EMC), IEC/EN 61010-1 (Safety) and IEC/EN 60825-1:2007 (Laser Safety).

Storage and Transport Conditions

Category	Specification
Temperature range	-12°C to +50°C
Storage relative humidity	5% to 90% (non-condensing)

Operator Competency Program

*< Operator training is considered an important part of good laboratory practice (CDC Document **Good Laboratory Practices for Waived Testing Sites**; 11/11/2005). CLIA requires that personnel qualifications and training be documented but does not specify the elements of operator training for waived testing. Other regulating agencies may have more specific requirements. The program outlined below is an example of a comprehensive plan which includes common training practices. Edit, delete or add elements to reflect your facility's operator competency assurance practices.>*

Policy: Operators must be fully trained and currently certified in order to be authorized to perform patient testing. Operators undergo initial competency training and undergo annual recertification training thereafter according to the program outlined below. Additionally, any operator may be retrained if his/her competency is questioned for any reason in the course of routine testing.

All initial operator certification and recertification training is conducted by a qualified trainer. *<insert the staff position(s) of qualified trainers here; e.g., a manufacturer's representative or designee, designated individuals trained by a manufacturer's representative or designee.>*

Operator training records are maintained by means of *<enter your facility's policy and practice for maintaining operator training records.>*

Competency Training Program

1. Completion of initial training and recertification including all elements in the **cobas**[®] Liat[®] training checklist.
2. Successful completion of *<enter % correct required in your facility>* on the Operator Competency Test.
3. *<Enter any of your facility's additional operator competency assurance policies.>*

cobas[®] Liat[®] Operator Evaluation Checklist

cobas[®] Liat[®] Operator: _____ Evaluation Date: _____

Certified Trainer: _____

Check all completed items in the checkbox. Circle N/A where applicable if a task is outside the operator's scope of service.

cobas[®] Liat[®] System Basics

- Knows system parts and where they are located
- Understands basic system methodology
- Understands intended use
- Understands system limitations
- Understands elements of the Quality Assurance program
- Reviews Quality Control policy and records
- N/A (Operator only collects samples and does not conduct testing)

cobas[®] Liat[®] Strep A Patient Testing

Collecting Throat Swab Sample

- Gathers all needed materials
- Identifies patient properly
- Prepares patient properly
- Follows all safety and infection control policies correctly
- Collects throat swab sample correctly
- Labels and handles sample properly
- N/A (Operator does not collect samples)

Performing Strep A Test

- Gathers all needed materials
- Properly scans tube barcode
- Properly enters patient sample ID
- Adds patient sample to **cobas** Liat Strep A tube properly
- Completes test process properly
- N/A (Operator does not conduct Strep A tests)

Viewing and Interpreting Results

- Selects **Report** to see the Result Report and prints result (if applicable)
- Interprets results according to the testing procedure
- Reports results properly
- Records results properly
- Discards used **cobas** Liat Strep A tube, pipette, and specimen tubes properly
- N/A (Operator does not view, interpret or record results.)

cobas[®] Liat[®] Influenza A/B and/or cobas[®] Liat[®] Influenza A/B & RSV Patient Testing

Nasopharyngeal Sample Collection

- Gathers all needed materials
- Identifies patient properly
- Prepares patient properly
- Follows all safety and infection control policies correctly
- Collects throat swab sample correctly
- Labels and handles sample properly
- N/A (Operator does not collect samples)

Performing cobas[®] Liat[®] Influenza A/B and/or cobas[®] Liat[®] Influenza A/B & RSV Test

- Gathers all needed materials
- Properly scans tube barcode
- Properly enters patient sample ID
- Adds patient sample to **cobas** Liat Strep A tube properly
- Completes test process properly
- N/A (Operator does not perform Influenza A/B tests)

Viewing and Interpreting Results

- Selects **Report** to see the Result Report and prints result (if applicable)
- Interprets results according to the testing procedure
- Reports results properly
- Records results properly
- Discards test supplies properly
- N/A (Operator does not view, interpret, report or record results)

cobas[®] Liat[®] Quality Control Testing

- Understands the principle of Internal Process Controls (IPC)
- Understands the policy and frequency of external QC testing
- N/A (Operator is not authorized to conduct or monitor QC testing)

Preparing Negative and Positive External Control Samples

- Gathers all needed materials
- Prepares Strep A negative and positive control samples properly
- Prepares Influenza A/B negative and positive control samples properly
- Follows all safety and infection control policies correctly

Performing cobas[®] Liat[®] External QC Tests

- Gathers all needed materials
- Properly scans tube barcode

- Properly scans control sample barcodes
- Adds control sample to **cobas**[®] Liat[®] Strep A tube properly
- Completes control test process properly

Viewing and Interpreting Results

- Selects **Report** to see the external QC Result Report and prints result (if applicable)
- Interprets results according to the testing procedure
- Records QC results properly
- Discards used test materials properly

Problem Solving

- Refers to the **cobas**[®] Liat[®] System User's Manual for suggested troubleshooting actions when error messages arise
- Reviews external QC results as appropriate
- Contacts the appropriate person/department when questions arise concerning testing or reporting results
- Knows when to call the Roche Support Network Customer Support Center **cobas**[®] Liat[®] hotline (1-800-800-5973)
- N/A (Operator does not conduct **cobas**[®] Liat[®] System testing and/or is not authorized to undertake any troubleshooting)

Maintenance

- Understands Internal Process Control (IPC)
- Cleans **cobas**[®] Liat[®] Analyzer properly
- Knows how to view the event log
- Successfully adds new **cobas**[®] Liat[®] assay tube lots
- Successfully calibrates **cobas**[®] Liat[®] touchscreen
- Uses cleaning tool properly to clean tube slot optics when appropriate
- N/A (Operator is not authorized to perform any maintenance functions.)

cobas[®] Liat[®] Operator Certification Test

<Edit, delete or add questions to reflect your preferences>

cobas[®] Liat[®] Operator: _____ Evaluation Date: _____

cobas[®] Liat[®] Strep A Assay

1. When should a negative Strep A test be followed up by a culture? (circle all that are true)
 - a. If the result is negative and clinical symptoms persist
 - b. If the result is negative and symptoms resolve
 - c. In the event of an outbreak of Influenza.
 - d. In the event of an outbreak of acute rheumatic fever (ARF)
2. What kind of transport medium is required for the **cobas[®] Liat[®] Strep A** assay?

3. From what part of the body should the sample be collected?

4. Match the following **cobas[®] Liat[®] Strep A** results with their correct interpretation and suggested follow-up action:

1. Strep A Not Detected	a. Presence or absence of Strep A cannot be determined. Repeat assay with same sample or, if possible, new sample.
2. Strep A Detected	b. Positive test for Strep A (Strep A DNA present)
3. Strep A Indeterminate. Repeat Assay.	c. Negative test for Strep A (no Strep A DNA detected)
4. Assay Invalid. Repeat Assay	
5. [Error] Assay Aborted	
5. Samples not tested immediately can be stored at 2 – 8° C or 20 – 25° C for up to 48 hours. T or F (Circle one)

cobas[®] Liat[®] Influenza A/B Assay

6. A **cobas[®] Liat[®]** test that is positive for both Influenza A and Influenza B indicates that Influenza C is present. T or F (Circle one)
7. What kind of transport medium is required for the **cobas[®] Liat[®]** Influenza A/B assay?

8. From what part of the body should the sample be collected?

9. Draw line to match the following **cobas[®] Liat[®]** Influenza A/B test results with their correct interpretation and suggested follow-up actions:
 1. Influenza A Not Detected a. Presence or absence of Influenza A cannot be determined. Repeat assay with same sample or, if possible, new sample.
 2. Influenza A Indeterminate. Repeat Assay. b. Presence or absence of target viruses cannot be determined. Repeat assay
 3. Influenza B Detected c. Presence or absence of Influenza A, and Influenza B cannot be determined. Repeat assay with same sample or, if possible, new sample
 4. Assay Invalid. Repeat Assay d. Positive test for Influenza B (Influenza B RNA present)
 5. [Error] Assay Aborted e. Negative test for Influenza A (no Influenza A RNA detected)
10. Samples not tested immediately can be stored at 2 – 8° C for up to 72 hours and should be transported on wet ice. T or F (Circle one)

cobas[®] Liat[®] System

11. What is the basic methodology of the **cobas[®] Liat[®] System**?
- Enzymatic
 - Detection of biologic genetic material (nucleic acid) by Polymerase Chain Reaction (PCR) technology
 - Distillation of attenuated antigens
 - Antigen colony count
12. How many times will you need to scan the assay tube sleeve in order to run a test?
- _____
13. In what ways can the patient ID be entered into the analyzer?
- _____
14. Any pipette can be used with the **cobas[®] Liat[®] Analyzer**. T or F (Circle one)
15. The assay tube entry door can be opened manually at any time. T or F (Circle one)
16. Describe the two types of control testing performed on the **cobas[®] Liat[®] System**:
- _____
- _____
17. How frequently is external control testing performed?
- _____
18. Where do you find the barcodes for scanning QC lots when performing External QC tests?
19. What agents can be used for cleaning the **cobas[®] Liat[®] Analyzer**? Circle all that may be used:
- 70% Isopropyl alcohol
 - 5-10% Ethanol
 - 5-10% antimicrobial dish soap solution
 - 5-10% bleach followed by wiping with 70% isopropyl alcohol to remove bleach residue
20. What should you do if you see the message "Use cleaning tool" on the **cobas[®] Liat[®] Analyzer** screen?
- Clean the screen with an alcohol wipe
 - Clean the tube slot with an alcohol wipe
 - Clean the tube slot with the cleaning tool following the instructions in the cleaning tool kit.
 - Clean the buttons on the front of the analyzer with an alcohol wipe

Answer Key

1. a and d
2. Liquid Amies Medium
3. Throat
4. 1. c; 2. b; 3. a; 4. a; 5. a
5. T
6. F
7. Universal Transport Medium (UTM)
8. Nasopharynx
9. 1. e; 2. a; 3. d; 4. c; 5. b
10. T
11. b
12. Twice
13. Scan or Manual Entry
14. F
15. F
16. Internal and external liquid
17. *<enter your facility's policy for frequency of external QC testing.>*
18. Barcode cards are found in each QC kit.
19. a and d
20. c

<Enter name of facility>

cobas[®] Liat[®] Operator Certification Record

Operator Name:		Operator ID:	
Qualified Trainer? (Yes/No):			
Date of initial training:		Qualified Trainer:	
Date of annual recertification:		Qualified Trainer:	
Date of annual recertification:		Qualified Trainer:	
Date of annual recertification:		Qualified Trainer:	
Date of annual recertification:		Qualified Trainer:	
Date of annual recertification:		Qualified Trainer:	
Performance Notes (Special achievements, adverse incidents, remedial training, etc.)			
Date decommissioned:		Qualified Trainer:	

Forms

cobas[®] Liat[®] Strep A Patient Test Log

cobas[®] Liat[®] Influenza A/B Test Log

cobas[®] Liat[®] Influenza A/B & RSV Test Log

cobas[®] Liat[®] Strep A External QC Log

cobas[®] Liat[®] Influenza A External QC Log

cobas[®] Liat[®] Adverse Event Log

cobas[®] Liat[®] Maintenance Log

cobas[®] Liat[®] Reagent Log

<Enter name of facility>

cobas[®] Liat[®] System Strep A Patient Test Log

Date/Time Specimen Collected/Tested	Patient Name	Patient ID#	Test Tube Lot Number	Test Results	Operator

<Enter name of facility>

cobas[®] Liat[®] Influenza A/B Patient Test Log

Date/Time Specimen Collected/Tested	Patient Name	Patient ID#	Test Tube Lot Number	Influenza A Test Result	Influenza B Test Result	Operator

<Enter name of facility>

cobas[®] Liat[®] Influenza A/B & RSV Patient Test Log

Date/Time Specimen Collected/Tested	Patient Name	Patient ID#	Test Tube Lot Number	Influenza A Test Result	Influenza B Test Result	Operator

<Enter name of facility>

cobas[®] Liat[®] System Strep A External QC Test Log

Date/Time	Control Sample (Positive/Negative?)	Control Lot# # Expiration	Test Tube Lot Number and Expiration	Test Results	Operator

<Enter name of facility>

cobas[®] Liat[®] System External QC Test Log

Date/Time	Control Sample (Positive/Negative?)	Control Lot# # Expiration	Test Tube Lot Number and Expiration	Influenza A Test Results	Influenza B Test Results	Operator

<Enter name of facility>

cobas[®] Liat[®] Adverse Event Record

Date/Time _____	Test (Strep A/Influenza A/B)? _____	Analyzer Serial # _____	Test Tube Lot # & Expiration _____
Description of Event:	Initials _____		
Resolution of Event:	Date of resolution: _____ Supervisor/Manager _____		

<Enter name of facility>

cobas[®] Liat[®] Maintenance Log

cobas[®] Liat[®] analyzer serial number:

Date/Time	Type of Maintenance	Comments	Operator

<Enter name of facility>

cobas[®] Liat[®] System Strep A Reagent Log

Strep A Tube Lot / Expiration Date	Expiration Date	Date Received	Date Validated	Notes	Operator

<Enter name of facility>

cobas[®] Liat[®] System Influenza A/B Reagent Log

Strep A Tube Lot / Expiration Date	Expiration Date	Date Received	Date Validated	Notes	Operator

<Enter name of facility>

cobas[®] Liat[®] System Influenza A/B & RSV Reagent Log

Strep A Tube Lot / Expiration Date	Expiration Date	Date Received	Date Validated	Notes	Operator

Roche Diagnostics has made all reasonable efforts to ensure that all the information contained in this manual is correct at the time of printing. However, Roche Diagnostics reserves the right to make any changes necessary without notice as part of ongoing product development.

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