cobas® Liat® System FAQ Document

General Questions

Q: How long can an assay tube sit at room temperature?

A: An assay tube should be removed from the refrigerator when a sample is ready to be run on the instrument. We recommend running the test immediately once the sample is added. However, it can sit at room temperature for up to 4 hours once the sample has been added.

Q: What is the shelf life of the assays and the controls?

A: All reagents are in self-contained assay tubes and are stable until the date of expiration listed on the assay tube package.

- Do not use kits or reagents beyond their expiration dates.
- Do not open individual tube packaging until you are ready to perform testing.
- Store the cobas Influenza A/B, Influenza A/B & RSV, and Strep A assay tubes at 2-8ºC.

Positive Control tubes and Dilution UTM tubes contained in factory-sealed pouches are stable until expiration date indicated on the pouches. After opening a pouch, controls are stable for 30 days at 2-8°C or until the expiration date, whichever comes first. Write the date opened on the pouch where indicated. Close the zip lock seal on the pouch after each use.

Q: Can I accidentally use an expired tube?

A: No. The expiration date is embedded into the barcode and will prevent a user from accidentally using an expired tube.

Q: Why do you have to scan the assay tube twice?

A: Used as a safety mechanism to make sure the tube you scanned to begin the process is the same one you are putting into the Liat analyzer.

Q: Can you start/stop a test?

A: No. If you chose to abort a test, you cannot restart it. You would have to use a new assay tube to resume testing.

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Q: What is the maximum time allowed for inserting the assay tube after scanning its barcode?

A: 1 – 20 seconds after scanning the barcode. You can modify this time in system setting on your **cobas** Liat system.

Q: Does the system have to go through the 3 a.m. reboot? (About auto monitoring cobas Liat user manual – SW 3.2)

A: There is an automatic daily restart programmed for 3 AM local time (once your settings have been updated), which helps to maintain the health of your analyzer.

The analyzer has a built-in auto monitoring system to ensure that it is functioning optimally at all times. During monitoring, you may see informational messages displayed.

Choose the **No** button to start the restart process. Choose the **Yes** button to affect a 60-second delay. After 60 seconds, another notification appears and allows for a final opportunity to delay for an additional 60 seconds before automatically restarting the analyzer. Follow the on-screen instructions, and the analyzer restarts.

Do **NOT** turn off your **cobas** Liat analyzer during reboot.

Q: Can I share lots between instruments?

A: Yes, lots can be synced between an analyzer and the ATK. On the first analyzer, choose **Update Lots > Backup** to back up assay lots from the first analyzer to the ATK. On the second analyzer, choose **Sync Lots > Yes** to merge assay lots stored on the ATK with the second analyzer.

Sample Transport and Storage

Q: What are the storage requirements of the assay tubes?

A: Store the **cobas** Influenza A/B, Influenza A/B & RSV, and Strep A tubes at tube at 2-8° C.

Do not open packaging until ready to perform test

Do not use kits or reagents beyond their expiration dates

Q: What are the storage requirements for frozen samples?

A: ***Strep A*** - Specimens should be tested immediately after collection. Specimens 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 of biological agents are met. Strep samples are **NOT** to be frozen.

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Influenza A/B & Influenza A/B & RSV - 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. Ensure frozen samples are completely thawed before testing.

Product Questions: cobas Liat Analyzer

Q: What is the required maintenance and/or cleaning of the instrument?

A: Keep the touch screen clean from excessive fingerprints and moisture by gently wiping it with a soft, lint-free cloth.

The exterior of the 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 analyzer for excessive dust or debris.

Only when prompted by the message “Use cleaning tool” on the screen, use the provided cleaning tool following the instructions included with the cleaning tool kit.

Q: What does an “Invalid Assay” result mean when running a sample? (for more information review the “Interpretation of Results” section in the cobas Influenza A/B, Influenza A/B & RSV, or Strep package insert)

A: An invalid result means that the presence or absence of Influenza A/B, Influenza A/B & RSV, and Strep A cannot be determined. Repeat the same assay with the sample or, if possible, a new sample.

If you switched to molecular testing from a traditional rapid test, you now have the possibility of getting an “invalid” result – a key advantage of your new system.

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The **cobas** Liat PCR System has extremely high sensitivity, which reduces false negative results. If the analyzer can't confirm the absence of a pathogen, it provides an "invalid" result, unlike traditional rapid tests.

Q: How many results will the cobas Liat analyzer hold?

A: Approximately 20,000 test results with date and time

Q: Do you have to be logged in to run a test?

A: Yes, User accounts control access to the analyzer and determine which functions the user can perform on the analyzer, including the assays the user can perform. The system logs each user action that triggers a system change in an audit trail entry together with user information and time stamp (in UTC). Examples of access roles include:

- *User* – Run authorized assays and view assay tube lots. Change own password and badge barcode
- *Supervisor* – As user, plus: review results, manage users (with access role 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.

Q: Can an operator scan their badge as their barcode?

A: Yes, if the analyzer is configured for a badge barcode authentication mode, the user can scan the badge barcode.

Q: If an operator is logged in and walks away, can someone else stop their test and start their own?

A: If you try to log on as a new user before the assay run finishes, the system indicates that it is busy.

Q: What are the placement requirements when installing a cobas Liat analyzer?

A: Place the analyzer on a level, vibration free, and non-reflective surface, away from direct sunlight. Allow at least 10 cm (4 inches) of space at the rear of the analyzer for airflow. Ensure that the vents are not blocked. Allow at least 6 cm (2.5 inches) of space in front of the analyzer for easy barcode scanning. Position the analyzer near a grounded main outlet to avoid creating a trip hazard with the power cable.

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Universal Transport Media (UTM)

Q: Do you have to use the UTM/Amies as indicated in the package insert, or can you use another brand?

A: To ensure test accuracy, use only brands indicated in the package insert as they have been validated for use with the **cobas** Liat system.

Technical Support

Q: How do I reach technical support?

A: Roche provides 24 hour-a-day, 365 day-a-year telephone assistance.

Contact Support and/or Service Representatives	
Technical Support	1-800-800-5973
Email	indianapolis_usa.liatsupport@roche.com
Website	liatsupport.roche.com

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