Quick Reference Instructions
cobas® liat CT/NG/MG nucleic acid test

cobas® liat CT/NG/MG assay kit components

- ☐ 20 assay tubes
- ☐ 2 **cobas® liat** transfer pipette packs (12 pipettes/pack)
- ☐ 1 package insert barcode card

REF 09449604190

cobas® liat CT, NG and MG control kit components

- ☐ 3 sets of controls
- ☐ 1 negative/positive control barcode card

Note: *Negative and positive control barcodes for **cobas® liat** CT/NG/MG are in Section 1 of the control barcode card.*

REF 09449639190

cobas® PCR Media Uni Swab Sample Kit

- ☐ 100 Uni Swab Sample Packets

cobas® PCR Urine Sample Kit

- ☐ 100 Urine Sample Packets

IVD
Rx only

CLIA-COMPLEXITY: WAIVED

A Certificate of Waiver is required to perform this test in a CLIA Waived setting. To obtain CLIA waiver information and a Certificate of Waiver, please contact your state health department. Additional CLIA waiver information is available at the Centers for Medicare and Medicaid website at www.cms.hhs.gov/CLIA. Failure to follow the instructions or modification to the test system instructions will result in the test no longer meeting the requirements for waived classification.

Transporting and storing specimen

For specimen transport and shipping, follow the standards and regulations as detailed in the Instructions for Use.

If immediate testing is not possible, store urine samples in **cobas®** PCR Media up to 3 hours at room temperature (15-30 °C) or up to 48 hours at 2-8 °C.

If immediate testing is not possible, store vaginal swab samples in **cobas®** PCR Media up to 24 hours at room temperature (15-30 °C) or up to 72 hours at 2-8 °C.

Run specimen transferred into a **cobas® liat** CT/NG/MG assay tube as soon as possible or store it up to 4 hours at room temperature (15-30 °C).

Collecting specimen and performing cobas® liat CT/NG/MG test

Read the Instructions For Use and the User Guide for complete test procedure and information before proceeding with test.

This test is only for male urine or vaginal swab specimens.

Obtain the following materials:

For collecting specimen

For collecting urine specimen

☐ 1 Urine Sample Packet

or

For collecting vaginal swab specimen

☐ 1 Uni Swab Sample Packet

For performing cobas® liat CT/NG/MG test

☐ 1 **cobas® liat** CT/NG/MG assay tube

☐ 1 **cobas®** PCR Media tube with specimen

☐ 1 transfer pipette

Note: *Do not use a damaged, dropped, or previously used assay tube.*

1A Collecting urine specimen

Collect urine specimen according to the **cobas®** PCR Urine Sample Kit Instructions for Use.

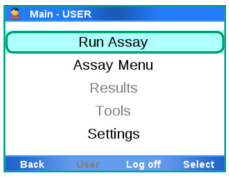
or

1B Collecting vaginal swab specimen

Collect vaginal swab specimen according to the **cobas®** PCR Media Uni Swab Sample Kit Instructions for Use.

2 Running a cobas® liat test

Start up the analyzer and log on. From the **Main** menu, choose **Run Assay** and choose the **Select** button. Then **Scan** the assay tube barcode.



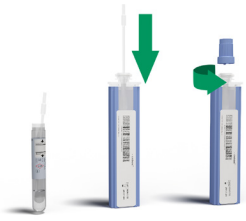
3 Scan the sample ID barcode, or choose Enter to enter the ID manually.

Note: *Depending on analyzer configuration, if required to confirm the received patient information, choose the* **Confirm** *button.*

4 Firmly squeeze the bulb of the transfer pipette, lower it into the sample liquid, and release the bulb to draw up the sample.

Slowly transfer the sample into the assay tube by squeezing the bulb, and then recap the assay tube. Do not invert the assay tube and shake.

Note: *Do not puncture the assay tube or the seal at the bottom of the sample compartment. If either of these is damaged, discard the assay tube and the transfer pipette. Restart the testing procedure with new assay components.*



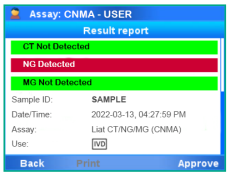
5 Choose Scan and rescan the assay tube barcode.

6 Turn the assay tube. Remove the assay tube sleeve and then insert the assay tube into the analyzer tube entry door. Processing begins automatically.

7 When the assay run is complete, remove and discard the assay tube.

8 Choose the Report button to view the result report.

To return to the **Main** menu, choose **Back** and then choose the **Main** button.



Note: *For result interpretation, refer to Table 1.*

Lot validation procedure

For each new lot of assay tubes, controls must be run. Use the lot validation procedure to validate assay tube lots on the **cobas® liat** analyzer.

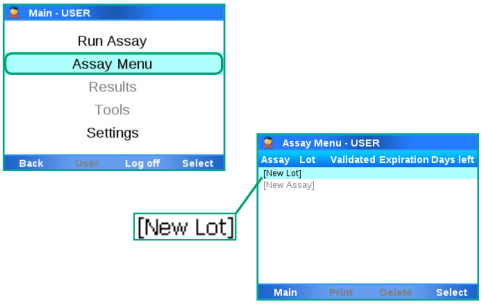
Obtain the following materials:

- ☐ 2 **cobas® liat** CT/NG/MG assay tubes
- ☐ 1 set of controls
- ☐ 1 package insert barcode card
- ☐ Negative/positive control barcode on negative/positive control barcode card
- ☐ 2 transfer pipettes

Note: *Additional control runs should be performed in accordance with local, state, federal and/ or accrediting organization requirements.*

1 Initiating a lot validation procedure

Start up the analyzer and log on. From the **Main** menu, choose **Assay Menu**. From the **Assay Menu**, choose **[New Lot]**.



2 Choose **Scan** and scan the package insert barcode from the package insert barcode card.

Note: *You may be prompted to confirm that you have read the Package Insert, i.e. Instructions For Use.*

3 Negative control run

Check that the lot number on the negative/ positive control barcode card matches the control tube lot number.

Choose **Scan** and scan the negative control barcode in **Section 1** of the negative/positive control barcode card.

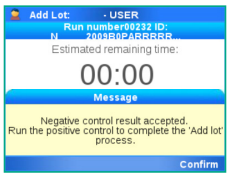
4 **Firmly squeeze the bulb of the transfer pipette, lower it into the liquid, and release the bulb to draw up the control.** Slowly transfer the control into the assay tube by squeezing the bulb, and then recap the assay tube. Do not invert the assay tube and shake.

Note: *Do not puncture the assay tube or the seal at the bottom of the sample compartment. If either of these is damaged, discard the assay tube and the transfer pipette. Restart the testing procedure with new assay components.*

5 Choose **Scan** and scan the assay tube barcode.

6 Turn the assay tube. Remove the assay tube sleeve and then insert the assay tube into the analyzer tube entry door. Processing begins automatically.

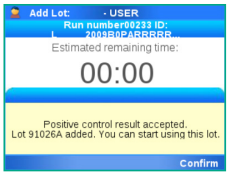
7 Once the negative control result is accepted, choose **Confirm**. Then remove and discard the assay tube.



8 Choose **Back** and repeat steps 3–6 for the positive control using the positive control barcode in **Section 1** of the negative/positive control barcode card.

When the positive control result is accepted you can begin using the lot. Choose **Confirm** and navigate **Back** to the **Main** menu.

Note: *If the result is rejected, repeat the control run. If repeated control run is still rejected, contact your local Roche representative.*



Note: *For result interpretation, refer to Table 2.*

Result interpretation

Table 1. Interpretation of **cobas® liat** CT/NG/MG results when running a sample.

cobas® liat analyzer display	**Result interpretation**
CT Not Detected	Valid negative test for CT (no CT detected).
CT Detected	Valid positive test for CT (CT present).
CT Invalid	Presence or absence of CT could not be determined. Repeat assay with same sample.
NG Not Detected	Valid negative test for NG (no NG detected).
NG Detected	Valid positive test for NG (NG present).
NG Invalid	Presence or absence of NG could not be determined. Repeat assay with same sample.
MG Not Detected	Valid negative test for MG (no MG detected).
MG Detected	Valid positive test for MG (MG present).
MG Invalid	Presence or absence of MG could not be determined. Repeat assay with same sample.
Assay Invalid	Presence or absence of MG, NG, and CT could not be determined. Repeat assay with same sample.
Assay Aborted by System	Run failed or aborted by system. Repeat assay with same sample.
Assay aborted by script: Script aborted	Run failed or aborted by script. Repeat assay with same sample.
Assay Aborted by User	Run aborted by user.

Table 2. Interpretation of **cobas® liat** CT/NG/MG results when running lot validation procedure or additional control runs.

cobas® liat analyzer display	**Result interpretation**
Negative Control Valid	Control is negative for the presence of CT, NG, and MG.
Negative Control Invalid. Repeat Run	Result is invalid. The Negative Control should be re-tested to obtain valid result. Repeat run.*
Positive Control Valid	Control is positive for the presence of CT, NG, and MG.
Positive Control Invalid. Repeat Run	Result is invalid. The Positive Control should be re-tested to obtain valid result. Repeat run.*

Note: **If the repeated run is still invalid, contact your local Roche representative (Roche Response Center toll-free: 1-**800-800-5973**).*

Software version 3.4 or higher

Roche support

If you have any questions or problems, contact your local Roche representative:
https://www.roche.com/about/business/roche_worldwide.htm

Trademarks and patents

https://diagnostics.roche.com/us/en/about-us/patents

Rx only

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Roche Response Center toll-free: 1-800-800-5973)

IVD

Roche

Warnings and precautions

Handle samples, used assay tubes, and transfer pipettes according to laboratory best practices.

Clean instruments and surrounding surfaces according to instructions provided in the cleaning section of the **cobas® liat** system User Guide.

Follow your institution's safety procedures for working with chemicals and handling biological samples.

Dispose of materials in accordance with state, federal, or local requirements.

Operating environment

Operating temperature is between 15 °C and 32 °C (59-90 °F), and relative humidity is between 15% and 80%. Operating altitude is up to 2000 meters (6500 ft) above sea level.

eLabDoc

Electronic user documentation, including Instructions for Use and User Guide, can be downloaded using the eLabDoc e-service on navify Portal:
www.navifyportal.roche.com

Document revision information		
Doc Rev. 1.0	01/2025	First publication.