

Quick Reference Instructions

cobas® liat Bordetella panel nucleic acid test

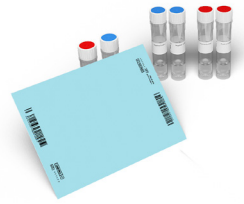
cobas® liat Bordetella panel assay kit components



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

REF 09857664190

cobas® liat Bordetella panel control kit components



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

REF 09857672190

Specimen Collection Kit

Note: Materials required but not provided. Refer to the Instructions for Use for a list of acceptable swabs and transport media.



- 1 specimen collection media tube
- 1 nasopharyngeal swab

Transporting and storing specimen


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

If needed, store specimens at 15–30 °C for up to 4 hours after collection, or at 2–8 °C for up to 72 hours.

If testing cannot be performed within 72 hours, specimens may be frozen at -70 °C or colder.

Run specimen transferred into a **cobas® liat** Bordetella panel 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 Bordetella panel 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 nasopharyngeal swab specimens.

Obtain the following materials:

For collecting specimen

- 1 collection media tube with a nasopharyngeal swab

Note: Refer to applicable collection media instructions for preparation.

For performing cobas® liat Bordetella panel test

- 1 **cobas® liat** Bordetella panel assay tube
- 1 specimen in collection media
- 1 transfer pipette

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

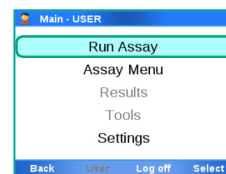
1 Collecting specimen

Collect specimen using a sterile swab according to applicable manufacturer instructions and/or standard collection technique.



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.

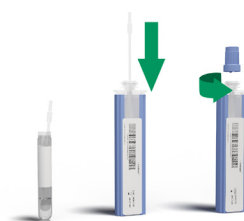
Note: Depending on analyzer configuration, if required to confirm the received patient information, choose the **Confirm** button.



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 or shake.

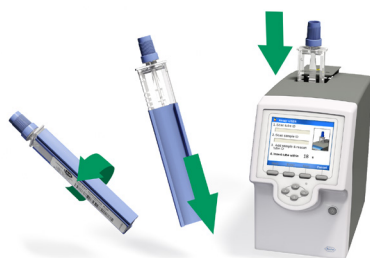
Note: Do not puncture the assay tube or the seal at the bottom of the sample compartment. If either of these is damaged, discard the assay tube and the transfer pipette. Restart the testing procedure with new assay components.



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.

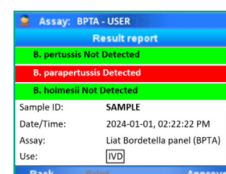


7 When the assay run is complete, remove and discard the assay tube.



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** Bordetella panel 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.

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 on the negative/positive control barcode card.

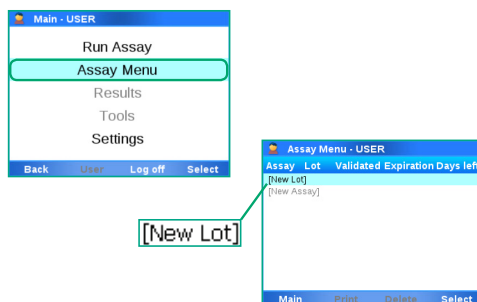


6 Turn the assay tube. Remove the assay tube sleeve and then insert the assay tube into the analyzer tube entry door. Processing begins automatically.



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]**.



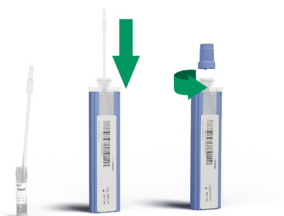
2 Choose **Scan** and scan the package insert barcode from the package insert barcode card.

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



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 or shake.

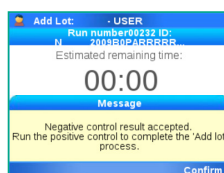
Note: Do not puncture the assay tube or the seal at the bottom of the sample compartment. If either of these is damaged, discard the assay tube and the transfer pipette. Restart the testing procedure with new assay components.



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



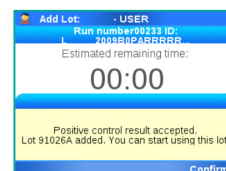
7 Once the negative control result is accepted, choose **Confirm**. Then remove and discard the assay tube.



8 Choose **Back** and repeat steps 3–6 for the positive control using the positive control barcode on 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** Bordetella panel results when running a sample.

| cobas® liat analyzer display | Result interpretation |
|------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| B. pertussis Not Detected | Valid negative test for <i>B. pertussis</i> (no <i>B. pertussis</i> detected). |
| B. pertussis Detected | Valid positive test for <i>B. pertussis</i> (<i>B. pertussis</i> present). |
| B. pertussis Invalid | Presence or absence of <i>B. pertussis</i> could not be determined. Repeat assay with same sample. |
| B. parapertussis Not Detected | Valid negative test for <i>B. parapertussis</i> (no <i>B. parapertussis</i> detected). |
| B. parapertussis Detected | Valid positive test for <i>B. parapertussis</i> (<i>B. parapertussis</i> present). |
| B. parapertussis Invalid | Presence or absence of <i>B. parapertussis</i> could not be determined. Repeat assay with same sample. |
| B. holmesii Not Detected | Valid negative test for <i>B. holmesii</i> (no <i>B. holmesii</i> detected). |
| B. holmesii Detected | Valid positive test for <i>B. holmesii</i> (<i>B. holmesii</i> present). |
| B. holmesii Invalid | Presence or absence of <i>B. holmesii</i> could not be determined. Repeat assay with same sample. |
| Assay Invalid | Presence or absence of <i>B. pertussis</i> , <i>B. parapertussis</i> , <i>B. holmesii</i> 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** Bordetella panel 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 <i>B. pertussis</i> , <i>B. parapertussis</i> , <i>B. holmesii</i> . |
| 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 <i>B. pertussis</i> , <i>B. parapertussis</i> , <i>B. holmesii</i> . |
| 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 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>



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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 country, state, 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

08/2025

Initial release.