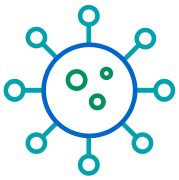
cobas® SARS-CoV-2 & Influenza A/B assay

Reduce the risk of a misdiagnosis with an accurate test you can trust



Symptoms of COVID-19 and influenza may look the same. It can be difficult for clinicians to identify based on signs & symptoms alone and if left undiagnosed, may result in health complications or community spread.

With nearly 900,000 deaths[1] from COVID-19 reported so far and half a million deaths on average from influenza every year, effective tools are needed to deliver rapid results to manage patient care early and effectively in emergency care settings.

The **cobas**® SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the **cobas**® Liat® System is a multiplex real-time polymerase chain reaction (PCR) test that detects and differentiates SARS-CoV-2, influenza A and influenza B in 20 minutes from a single nasal sample and in just one test.

Relying on the rapid and accurate **cobas**® SARS-CoV-2 & Influenza A/B performance, healthcare providers on the front line now have the urgent answers they need to rule-in or rule-out these three infections.

cobas® SARS-CoV-2 & Influenza A/B:

- **One sample, one test,** 20 minutes, know if it's COVID-19 or Flu
- **Take the workload out of testing** with simple intuitive user handling
- **Minimize cross-contamination** and risk of exposure during testing with the closed-system design

cobas® SARS-CoV-2 & Influenza A/B performance[§]

Target	Positive Agreement	Negative Agreement	LoD
SARS-CoV-2*	100%	100%	1.2 x 10^{-2} $TCID_{50}$/mL
Influenza A**	98.4%	96.5%	2 x 10^{-3}– 2 x 10^{-2} $TCID_{50}$/mL
Influenza B**	97.9%	99.4%	2 x 10^{-3}–4 x 10^{-3} $TCID_{50}$/mL

[§]**cobas**® SARS-CoV-2 & Influenza A/B Nucleic acid test for use on the **cobas**® Liat® System, Package Insert V01, Pleasanton, CA; Roche Molecular Systems, Inc., 2020.

*Compared to an FDA-cleared EUA, **cobas**® SARS-CoV-2 Test on **cobas**® 6800/8800 Systems; EUA data;

**Compared to an FDA-cleared laboratory based multiplexed real-time reverse transcriptase PCR (RT-PCR) test; combined PPA and NPA from retrospective and prospective samples for influenza A and influenza B, respectively; CLIA data.

Rapid accurate answers to manage the unknown

cobas® SARS-CoV-2 & Influenza A/B assay specifications

Instrument	**cobas**® Liat® Analyser
Targets	SARS-CoV-2 Influenza A Influenza B
Sample type	Nasopharyngeal swab, nasal swab
Collection media	Viral transport media
Sample extraction	Fully automated and integrated
Technology	Real-time PCR
Control	Integrated sample processing control, positive and negative controls
Time to result	~20 minutes
Reagents	Ready-to-use, pre-packed tube format
Kit Storage	2-8°C
Registration	Emergency Use Authorization (EUA); CE-IVD

Sample

Add your patient sample to the **cobas**® Liat® assay tube with provided transfer pipette.

Scan

Scan assay tube using built-in barcode reader.

Start

Insert assay tube into the **cobas**® Liat® Analyser.

cobas® SARS-CoV-2 & Influenza A/B ordering information

Product	Configuration	Material number
cobas® SARS-CoV-2 & Influenza A/B Assay	20 tests per unit	09 211 101 190
cobas® SARS-CoV-2 & Influenza A/B Control Kit	3 sets per unit	09 211 128 190
cobas® Liat® Analyser	1 instrument	07 341 920 190

References

1 *https://www.hopkinsmedicine.org/health/conditions-and-diseases/coronavirus/coronavirus-disease-2019-vs-the-flu. Accessed 09Sep2020*

2 ***cobas**® SARS-CoV-2 & Influenza A/B Nucleic acid test, Package Insert V01, Pleasanton, CA, Roche Molecular Systems, Inc. 2020*

In the United States:

- This test has not been FDA cleared or approved;
- This test has been authorized by FDA under an EUA for use by authorized laboratories;
- This test has been authorized only for the simultaneous qualitative detection and differentiation of nucleic acid from SARS-CoV-2, influenza A virus and influenza B virus; not for any other viruses or pathogens; and
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb- 3(b)(1), unless the authorization is terminated or revoked sooner

The **cobas**® Liat® System is available in select markets.

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