What is ASSURANCE AB™?

The ASSURANCE AB™ COVID-19 IgM/IgG Rapid Antibody Test is a rapid test for the qualitative detection of IgM and IgG antibodies associated with the SARS-CoV-2 virus. ASSURANCE AB™ is a single-use, self-contained test that provides results in 15 minutes, helping authorities, employers and healthcare workers make informed decisions to contain the spread of COVID-19.

Who is ASSURANCE AB™ for?

ASSURANCE AB™ is intended for individuals suspected of COVID-19 infection by a healthcare provider or who were exposed to an individual infected with COVID-19.

ASSURANCE AB™ is for use by laboratories and healthcare workers at the point-of-care.

What is antibody testing?

Antibody assays have the ability to detect past infections and indicate probable immunity.

ASSURANCE AB™ detects the presence of antibodies IgM and IgG, developed in response to the SARS-CoV-2 virus.

▶ IgM antibodies: develop EARLY after SARS-CoV-2 virus exposure
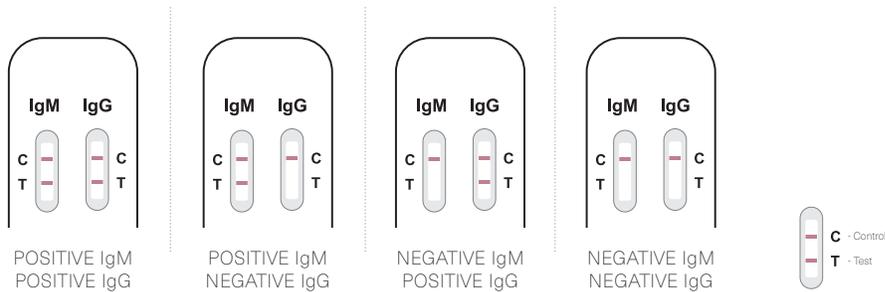▶ IgG antibodies: develop LATER after SARS-CoV-2 virus exposure; indicates longer-term immunity

ASSURANCE AB™ highlights

▶ Results in 15 minutes
▶ NO laboratory equipment required, easy-to-use
▶ Reduces risk of spreading the virus to healthcare workers administering tests or technicians processing tests
▶ Provides actionable information to all patients to help determine if a COVID-19 viral PCR test is needed
▶ Provides insightful information for when, after consultation with a healthcare provider, it is safe for individuals to go back to work and resume normal activities of daily life
▶ Testing accuracy is high due to antibodies being more uniformly available in blood samples than virus in nasopharyngeal swabs

ASSURANCE AB™ test administration

ASSURANCE AB™ requires a small sample of the patient's blood, usually collected via fingerstick. Blood and diluent are dispensed onto the self-contained testing cassette. Once applied, results appear on the testing device within 15 minutes. Results indicate the presence of antibodies, developed in response to the SARS-CoV-2 virus associated with the COVID-19 pandemic. Testing cassettes are embedded with a control sample.

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Understanding ASSURANCE **AB**™ results

POSITIVE IgM
POSITIVE IgG

POSITIVE IgM
NEGATIVE IgG

NEGATIVE IgM
POSITIVE IgG

NEGATIVE IgM
NEGATIVE IgG

C - Control
T - Test

If either or both of the control lines do not develop, the assay is invalid

What does a positive test result mean?
A positive test result indicates that the patient has been exposed to the SARS-CoV-2 virus and has developed antibodies associated with immunity. A patient with a positive test result may or may not be contagious. Laboratory test results should always be considered in the context of clinical observations and epidemiological data in making a final diagnosis and patient management decisions. Please refer to Instructions For Use.

What does a negative test result mean?
A negative test result indicates that the patient has not developed detectable antibodies associated with the SARS-CoV-2 virus and most likely does not have immunity to the virus. A person with a negative test result may or may not be contagious. Please refer to Instructions For Use.

About Predictive Laboratories, Inc.

Predictive Laboratories' molecular and genetic diagnostics focus on hard-to-diagnose and hard-to-detect diseases. Leveraging its vast genetic and genomic library, Predictive offers earlier detection of a variety of diseases through genetic assessments to guide personalized precision medicine.

Equipped with a state-of-the-art CAP and CLIA accredited laboratory, Predictive operations perform next-generation sequencing experiments, including whole exome sequencing, gene and genetic marker panels, and low-pass whole genome analysis of embryos for aneuploidies. Predictive arms physicians with the most robust diagnostic tools to provide personalized precision treatment for their patients. For more information, visit www.predictivelabs.com.

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