CELLEX™

CELLEX qSARS-CoV-2 IgG/IgM RAPID TEST

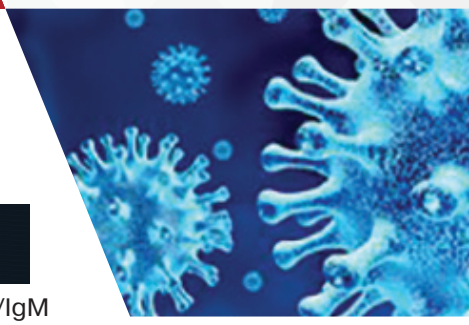
SPARTAN™ MEDICAL

Our COVID-19 Antibody Rapid Test has received FDA Emergency Authorization (EUA) and was developed by Cellex, a U.S. biotechnology company.

SEROLOGY TESTING IS IDENTIFIED AS A TOOL FOR WIDESPREAD AND EFFECTIVE TESTING FOR COVID-19 EXPOSURE AND AN IMMUNE RESPONSE.

The Duke-Margolis Center for Health Policy provided recommendations for a U.S. Federal response to the coronavirus pandemic which states, "reliable, serologic evidence of immunity at the individual level will also have important implications for the conditions under which individuals return to work, and their ability to work in settings at high risk for coronavirus transmission, particularly certain health care settings.[1] " The CDC has also developed guidance on a COVID-19 Serology Surveillance Strategy through rapid, large-scale antibody testing for communities.[2]

1. A National COVID-19 Surveillance System: Achieving Containment
2. https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html



RELIABLE & ACCURATE

Combined IgG/IgM Antibodies

Sensitivity	**93.8%**
Specificity	**96.0%**

Cellex qSARS-CoV-2 IgG/IgM Rapid Test was more accurate at ruling out cases, showing a 99.7% negative predictive value at 5% prevalence.

- ✔ **Combined Serology Test**
  IgG and IgM Antibodies
- ✔ **Rapid Test**
  Results in 15 minutes
- ✔ **Self-contained**
  No lab equipment needed
- ✔ **Simple**
  Swabs not required
  Simple whole blood test
- ✔ **Portable**
  Cassette testing in any location

QUALITY CONTROL

The Cellex qSARS-CoV-2 IgG/IgM Rapid Test offers quality control throughout manufacturing, and also at the point of care.

Cellex maintains a GMP manufacturing, which is ISO 13485 certified and in compliance with U.S. FDA's QSR (Quality System Regulation).

As an extra assurance of quality at the point of care, Cellex provides two layers of quality control:

1. Internal Control: Each test contains a built-in control feature, the C Line. The C Line develops after addition of the specimen and sample diluent. If the C Line does not develop, the test is invalid.
2. Positive and Negative Control Set: Available separately, this set can be used to ensure the proper performance of the assay to validate the tests.

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THREE SIMPLE STEPS

✔ **Results in 15-20 Minutes**

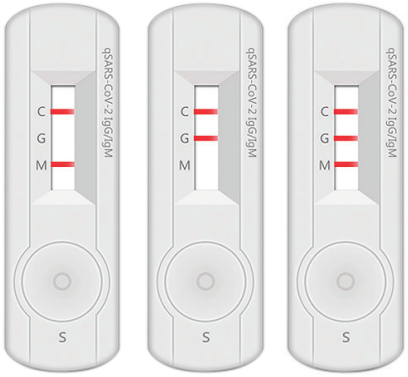
1) Add a whole 10ul drop

2) Add 2 drops of sample diluent

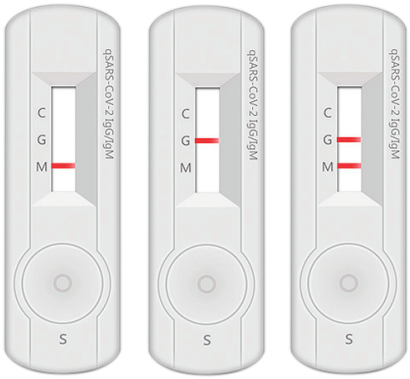
3) Read results in 15-20 minutes

✔ **Interpretation of Results**

Negative



Positive



Invalid

The Cellex qSARS-CoV-2 IgG/IgM Rapid Test was developed by Cellex Incorporated and available to the Federal Government through a partnership between HealthDatix, Inc. and Spartan Medical Inc. a CVE certified, Service-Disabled Veteran-Owned Small Business (SDVOSB).

CAT. NO.	DESCRIPTION
5515C025	Cellex qSARS-CoV-2 IgG/IgM Rapid Test (Whole Blood/Serum/Plasma)
5515	Cellex qSARS-CoV-2 Positive/Negative Control Set (positive and negative controls for quality control testing at microbiology labs)

LEARN MORE:

Contact Spartan Medical Inc.

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Service Disabled Veteran Owned Small Business
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