CovWipe-19 Oral

SARS-CoV-19 IgM/IgG Antibody Rapid Test

Intended Use

The Oranoxis SARS-CoV-2 test (CovWipe-19 Oral) is a rapid test for qualitative detection IgG and IgM antibodies to COVID-19 in human oral fluid/saliva.

The lateral flow immunoassay device is designed for mass population SARS-CoV-2 antibody testing and can be applied regularly to monitor at -risk populations, acting as a primary form of testing of infection or a secondary form of PCR SARS-CoV-2 test confirmation.

This assay provides only a preliminary analytical test result. A more specific alternate testing method must be used while considering the patient's clinical characteristics in order to obtain a confirmed analytical result.

For In Vitro Diagnostic Use Only.

Test Principles

Coronaviruses are enveloped RNA viruses that can infect and distribute amongst humans, mammals and birds. Coronaviruses, such as SARS-CoV-2, can cause respiratory, enteric, hepatic, and neurologic diseases. Common symptoms of human SARS-CoV-2 infection include respiratory symptoms, fever, cough, shortness of breath and dyspnea. In more severe cases, infection can lead to pneumonia, severe acute respiratory syndrome, kidney failure, and even death. COVID-19 can be excreted through respiratory secretions, transmitted through oral fluid, sneeze, contact, and transmitted through air droplets.

CovWipe-19 consists of independent IgG and IgM components. The sample of human blood or oral fluid is added to the sample port of the test kit.

Materials

Each package contains:

1. CovWipe-19 device
2. Buffer Cap
3. Dessicant

Materials recommended but not provided:

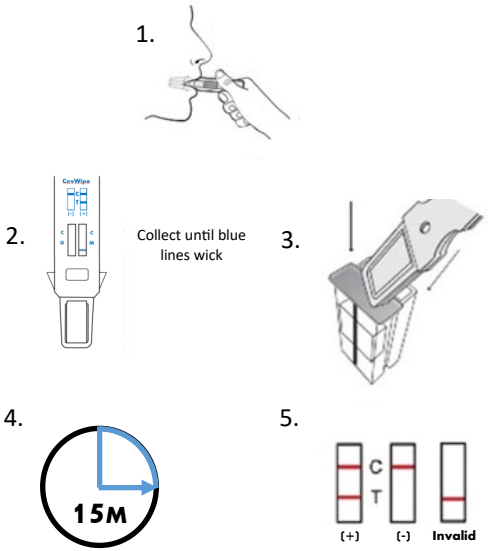
- Timer
- Gloves
- Face Mask (while testing others)

Directions for Use

Allow the CovWipe device to come to room temperature [15-30ºC (59-86ºF)] prior to testing. For saliva testing, donor must not place anything in the mouth including food, drink, gum, or tobacco products for at least 15 minutes prior to collection.

Check the expiration date on the foil pouch. Do not use if the package is damaged, punctured, or expired. The test device should remain in its original sealed pouch until use. Do not freeze.

Oral Fluid Testing



1. Remove the test device from the sealed foil pouch.
2. Collect and add sample as follows:
   Insert collection pad into mouth. Actively swab against gums, inner cheek, and under tongue for specimen collection. When sufficient saliva has been collected to run the blue lines at the bottom of the display windows will disappear/wick up. The saliva specimen should only touch the absorbent area. Do not swipe the test device at any point above the visible outer collection pad.
3. Once the blue indicator line is wet/wicking use the corner of the device tip to puncture the middle of the cover of the sealed cavity (see Step 3 illustration below) and push the collection pad of the test device all the way in. Place the test device on a flat surface and set a timer for 15 minutes.
4. Read the test results at 15 minutes.

Interpretation of Results

NEGATIVE*: Only the line in the Control region (C) appears. Test region (IgM/IgG) will not appear to indicate a negative result.

POSITIVE: A colored line in the Control region (C) and a colored line in the Test region (G/M) indicates a positive result. Positive results should also be reported in accordance with local, state, and federal regulations.

*NOTE: Both windows must show a test line in the Control region (C) for results to be valid.

INVALID: Control region line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test. If the problem persists, discontinue using the lot and contact your supplier.

Test Limitations

- Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered.
- Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.
- CovWipe-19 is for research and professional use only and not for medical diagnostic purposes.
- CovWipe-19 is intended for testing human oral fluid.
- "Dry Mouth" or "Dry Mouth Syndrome," certain medications, or certain diseases may affect results.
- When placing the collection pad in mouth for saliva collection, the donor must not chew any part of the tip.
- Do not use after the expiration date indicated on the package.
- Do not use the test if the foil pouch is punctured or damaged.
- Do not reuse tests.
- Handle all specimens as if they contain infectious agents. Follow established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens.
- Used testing materials should be discarded in accordance with local regulations.

Quality Control

Each lot is tested before release. Oranoxis is a FDA Registered Medical Device Manufacturing Facility with ISO 13485:2016 certifications. For batch release records, registration numbers, certification numbers, CE information, etc. please email info@oranoxis.com.

Manufactured by Oranoxis Inc.
7438 Trade Street, San Diego, CA 92121 USA

For more info, please visit:
www.Oranoxis.com
1-800-559-2490

Revision 1.3