Fact Sheet for Healthcare Providers: CovWipe-19 SARS-CoV-2 Oral Rapid Test

This fact sheet has been provided to inform you on the potential risks and benefits of the CovWipe-19 Oral, a rapid test for the qualitative detection of SARS-CoV-2 IgG and IgM antibodies in human oral fluid. The CovWipe-19 was developed by Oranoxis for emergency use to identify or confirm SARS-CoV-2 infection.

If you are an individual whose specimen was or will be tested with CovWipe-19, please refer to the Fact Sheet for Recipients.

What are the symptoms of SARS-CoV-2 (COVID-19)?

According the World Health Organization (WHO) and the Centers for Disease Control and Prevention (CDC), the most common symptoms for COVID-19 are fever, dry cough, and fatigue. Others symptoms such as loss of taste or smell, sore throat, and difficulty breathing were reported. Once infected it may take 2-14 days before an individual demonstrates symptoms.

Due to the relative newness of COVID-19 and the limited data and information regarding the disease, the full spectrum of illness associated with COVID-19 is still unknown. Please check the CDC webpage for the most up-to-date information regarding COVID-19.

What do I need to know about COVID-19 testing?

The most –up-to-date information regarding COVID-19 for healthcare providers can be found on the DCD's webpage, *Information for Healthcare Professionals* (see links in "More Information" section).

The CovWipe-19 can be used to test human oral fluid. The test measures human IgM and IgG that are generated by the immune system in response to the virus. The Oranoxis' patented sample enrichment mechanism enables the CovWipe-19 to detect trace concentrations of IgM and IgG in oral fluid.

Positive results can be indicative of active infection with SARS-CoV-2, but does not rule out co-infection with other diseases. The agent detected may not be the definite cause of disease. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. All results must be combined with clinical observations, patient history, and epidemiological information.

All specimens should be collected with appropriate infection control precautions and personal protective equipment (PPE).

For the current guidance on COVID-19 infection control precautions please visit the CDC website and search for the "Where Can I go for updates and more information."

Appropriate PPE should be worn whenever collecting or handling specimens from individuals suspected of having COVID-19 as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019*. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019* (see links in "More Information" section).

What do the test results mean?

For information on how to interpret test results please see the CovWipe-19 IFU.

A positive test result on the CovWipe-19 indicates that the antibodies to COVID-19 were detected, and the individual is possibly infected and can transmit COVID-19 to other individuals.

When IgM antibodies are present it can indicate that a subject has had a recent or prior infection with COVID-19. When IgG antibodies are present it can indicate a past infection, but it does not exclude recently infected individuals who are still contagious, especially if IgM antibodies are detected at the same time. It is still unknown how long IgM or IgG antibodies to COVID-19 will remain present in the body after infection or if they confer immunity to the infection. Positive results for IgM or IgG does not mean that a subject's existing symptoms are a result of COVID-19 infection.

A negative test results with the CovWipe-19 means that the COVID-19 specific antibodies were not present in the sample provided by the donor. The donor may have been infected recently and antibodies to COVID-19 are yet to be detectable.

The CovWipe-19 has been optimized to minimize the rates of false positives and false negatives. Other confirmation methods should always be used to reduce risk . Laboratory test results should always be considered with clinical observations and epidemiological data in mind.

Report Adverse Events, such as problems with test performance or results, to Oranoxis at info@oranoxis.com and to MedWatch by submitting Form 3500 to the FDA. ((https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088.

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Risks to an individual of a false negative result include: delayed or lack of supportive treatment, lack of monitoring of infected individuals and their household or other close contacts for symptoms resulting in increased risk of spread of COVID-19 within the community, or other unintended adverse events.

What is an EUA?

The United States FDA has made this oral test available under an emergency access mechanism called the Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of in vitro diagnostics (IVDs) for detection and/or diagnosis of the virus that causes COVID-19.

Any device or test kit made available under an EUA has not undergone the same type of review as an FDA approved or FDA cleared IVD. An EUA may be issued when criteria are met when no other approved alternatives exist. Based on existing scientific evidence, it is reasonable to believe that this IVD may be effective in the detection of COVID-19.

More Information and Resources

CDC webpages:
General: https://www.cdc.gov/COVID19
Healthcare Professionals: https://www.cdc.gov/coronavirus/2019-nCoV/guidance-hcp.html
Information for Laboratories: https://www.cdc.gov/coronavirus/2019- nCoV/guidance-laboratories.html
Laboratory Biosafety: https://www.cdc.gov/coronavirus/2019- nCoV/lab-biosafety-guidelines.html
Isolation Precautions in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/controlrecommendations.html
Specimen Collection: https://www.cdc.gov/coronavirus/2019- nCoV/guidelines-clinical-specimens.html
Infection Control: https://www.cdc.gov/coronavirus/2019- ncov/infection-control/index.html

FDA webpages:
General: www.fda.gov/novelcoronavirus
EUAs: https://www.fda.gov/medicaldevices/emergency-situations-medical-devices/emergencyuse-authorizations

Manufacturer Information

Oranoxis Inc., located in San Diego, CA, is specialized in the development, manufacture, and marketing of rapid immunoassay diagnostic products for rapid testing biochemical samples in oral fluid/saliva.

The CovWipe-19 Oral is designed, laboratory tested, and manufactured by the following:

Oranoxis Inc.
7438 Trade St.
San Diego, CA 92121

Contact Information:
(Email) info@oranoxis.com
(Website) www.oranoxis.com

Report Adverse Events, such as problems with test performance or results, to Oranoxis at info@oranoxis.com and to MedWatch by submitting Form 3500 to the FDA. ((https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088.