FACT SHEET FOR HEALTHCARE PROVIDERS
SML GENETREE Co., Ltd.
Ezplex SARS-CoV-2 G Kit

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Ezplex SARS-CoV-2 G Kit.

The Ezplex SARS-CoV-2 G Kit is authorized for use with certain respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: SML GENETREE Co., Ltd. - Ezplex SARS-CoV-2 G Kit.

What are the symptoms of COVID-19?
Many patients with COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, dyspnea), although some individuals experience only mild symptoms or no symptoms at all. The current information available to characterize the spectrum of clinical illness associated with COVID-19 suggests that, when present, symptoms include cough, shortness of breath or dyspnea, fever, chills, myalgias, headache, sore throat, new loss of taste or smell, nausea or vomiting or diarrhea. Signs and symptoms may appear any time from 2 to 14 days after exposure to the virus, and the median time to symptom onset is approximately 5 days. For further information on the symptoms of COVID-19 please see the link provided in “Where can I go for updates and more information?” section.

Public health officials have identified cases of COVID-19 infection throughout the world, including the United States. Please check the CDC COVID-19 webpage (see link provided in “Where can I go for updates and more information?” section at the end of this document) or your local jurisdictions website for the most up to date information.

What do I need to know about COVID-19 testing?
Current information on COVID-19 for healthcare providers is available at CDC’s webpage, Information for Healthcare Professionals (see links provided in “Where can I go for updates and more information?” section).

This test is to be performed only using certain respiratory specimens collected from individuals suspected of COVID-19 by their healthcare provider.

- The Ezplex SARS-CoV-2 G Kit can be used to test nasopharyngeal swabs, oropharyngeal swabs, and sputum specimens.
- The Ezplex SARS-CoV-2 G Kit should be ordered for the detection of COVID-19 in individuals suspected of COVID-19 by their healthcare provider.
- The Ezplex SARS-CoV-2 G Kit can also be used to test up to five individual nasopharyngeal or oropharyngeal swabs where each specimen is collected by a healthcare provider using individual vials containing transport media.
- The Ezplex SARS-CoV-2 G Kit is authorized for use in laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions. Current guidance is available at the CDC’s website (see links provided in “Where can I go for updates and more information?” section).

When collecting and handling specimens from individuals suspected of being infected with COVID-19, appropriate personal protective equipment should be used as outlined in the CDC Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19). For additional information, refer to CDC Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons Under Investigation (PUIs) for Coronavirus Disease 2019 (COVID-19) (see links provided in “Where can I go for updates and more information?” section).

What does it mean if the specimen tests positive for the virus that causes COVID-19?
A positive test result for COVID-19 indicates that RNA from SARS-CoV-2 was detected, and therefore the patient is infected with the virus and presumed to be...
contagious. Laboratory test results should always be
considered in the context of clinical observations and
epidemiological data (such as local prevalence rates and
current outbreak/epicenter locations) in making a final
diagnosis and patient management decisions. Patient
management should be made by a healthcare provider
and follow current CDC guidelines.

The Ezplex SARS-CoV-2 G Kit has been designed to
minimize the likelihood of false positive test results.
However, it is still possible that this test can give a false
positive result, even when used in locations where the
prevalence is below 5%. In the event of a false positive
result, risks to patients could include the following: a
recommendation for isolation of the patient, monitoring
of household or other close contacts for symptoms,
patient isolation that might limit contact with family or
friends and may increase contact with other potentially
COVID-19 patients, limits in the ability to work, delayed
diagnosis and treatment for the true infection causing the
symptoms, unnecessary prescription of a treatment or
therapy, or other unintended adverse effects.

All laboratories using this test must follow the standard
testing and reporting guidelines according to their
appropriate public health authorities.

What does it mean if the specimen tests negative for
the virus that causes COVID-19?
A negative test result for this test means that SARS-
CoV-2 RNA was not present in the specimen above the
limit of detection. However, a negative result does not
rule out COVID-19 and should not be used as the sole
basis for treatment or patient management decisions. It
is possible to test a person too early or too late during
COVID-19 infection to make an accurate diagnosis via
Ezplex SARS-CoV-2 G Kit.

Specimens with low viral loads may not be detected in
sample pools due to the decreased sensitivity of pooled
testing. Your interpretation of negative results should
take into account clinical and epidemiological risk
factors.

When diagnostic testing is negative, the possibility of a
false negative result should be considered in the context
of a patient’s recent exposures and the presence of
clinical signs and symptoms consistent with COVID-19.
The possibility of a false negative result should
especially be considered if the patient’s recent
exposures or clinical presentation indicate that COVID-
19 is likely, and diagnostic tests for other causes of
illness (e.g., other respiratory illness) are negative.

If COVID-19 is still suspected based on exposure history
together with other clinical findings, re-testing using a
new sample with a sensitive method or without pooling
should be considered by healthcare providers in
consultation with public health authorities. Additional
testing may be helpful to ensure testing was not
conducted too early.

Risks to a patient of a false negative test 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.

The performance of this test was established based on
the evaluation of a limited number of clinical specimens.
The clinical performance has not been established in all
circulating variants but is anticipated to be reflective of
the prevalent variants in circulation at the time and
location of the clinical evaluation. Performance at the
time of testing may vary depending on the variants
circulating, including newly emerging strains of
SARSCoV-2 and their prevalence, which change over
time.

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

An IVD made available under an EUA has not
undergone the same type of review as an FDA-approved
or cleared IVD. FDA may issue an EUA when certain
criteria are met, which includes that there are no

Report Adverse events, including problems with test performance or results, to MedWatch by submitting the online FDA Form 3500
(https://www.accessdata.fda.gov/scripts/medwatch/index.cfm?action=reporting.home) or by calling 1-800-FDA-1088
adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in diagnosing COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

What are the approved available alternatives?
Any tests that have received full marketing status (e.g., cleared, approved), as opposed to an EUA, by FDA can be found by searching the medical device databases here: https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/medical-device-databases. A cleared or approved test should be used instead of a test made available under an EUA, when appropriate and available. FDA has issued EUAs for other tests that can be found at: https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization.

Where can I go for updates and more information?

**CDC webpages:**
- General: https://www.cdc.gov/COVID19

**FDA webpages:**
- General: www.fda.gov/novelcoronavirus

**SML GENETREE Co., Ltd.:**
6F, Hanmaeum Bldg.,
225 Baumoero, Seocho-gu
Seoul, Republic of Korea
Seungmok Lee
+82-2-2057-7900
smlee@genetree.co.kr

Technical Support:
Tel: +82-2-2057-7900