Solaris Diagnostics

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Phone: (844)550-0308 Fax: (859)305-6105
Laboratory Director: Preetpal Sidhu, Ph.D.
CLIA # 18D2142802

Laboratory Use Only

PATIENT INFORMATION (PLEASE PRINT)

Last Name	First Name	MI
Address	DOB	Sex ☐M ☐F
City ZIP	Social Security #	
Cell Phone	Home Phone	

CLINIC INFORMATION

Provider Signature: _____

INSURANCE BILLING INFORMATION

☐ Medicare ☐Medicaid ☐ Other	☐ Self ☐ Spouse ☐ Child	
Subscriber Last Name	First Name	MI
Beneficiary/Member #	Group #	
Claims Address	City Street ZIP	

COLLECTION INFORMATION

Date:	Time ☐ AM ☐ PM
Collect By:	☐ Signed ABN Obtained

DIAGNOSIS CODE INFORMATION

1) 2) 3) 4) 5) 6)

Physicians and other Providers are required to only order medically necessary tests supported by an ICD-10 diagnosis from the patient's medical record or explain and have patient sign an ABN.

PATIENT SIGNATURE

Patient Signature: _____

I authorize Solaris Diagnostics to analyze the specimen provided by me and report the results of such analysis to the ordering Physician in conformance with his/her order.

Performed w/ E-Swab or Cervical Brush

Women's Health

☐ **Women's Health Complete**

☐ **Bacterial Vaginosis**
- ☐ Mobiluncus curtisii & mulieris
- ☐ Megasphaera type 1&2
- ☐ Ureaplasma urealyticum
- ☐ Prevotella bivia
- ☐ Gardnerella vaginalis
- ☐ BVAB2
- ☐ Atopobium vaginae
- ☐ Mycoplasma hominis
- ☐ L.crispatus/gasseri/iners/jensenii

☐ **Aerobic Vaginitis**
- ☐ Staphylococcus aureus w/MRSA
- ☐ Streptococcus agalactiae (GBS)
- ☐ Escherichia coli
- ☐ Enterococcus faecalis

☐ **Candidiasis Panel**
(albicans, tropicalis, glabrata, krusei, lusitaniae, parapsilosis)

☐ **STI Panel**
- ☐ Trichomonas Vaginalis
- ☐ Chlamydia trachomatis
- ☐ Neisseria gonorrhoeae
- ☐ Mycoplasma genitalium
- ☐ Mycoplasma hominis
- ☐ Ureaplasma urealyticum

☐ **Genital Ulcer Panel**
- ☐ Herpes simplex 1 & 2
- ☐ Haemophilus ducreyi
- ☐ Treponema pallidum

Performed w/ Urine C&S Tube

Urine

☐ **UA Reflex C&S**

☐ **Culture and Sensitivity**

☐ **Culture Supplement (PCR)**
- ☐ Mycoplasma hominis
- ☐ Ureaplasma urealyticum
- ☐ Candida spp.

PCR (ABR & Sensitivity)

☐ **UA Reflex to UTI ID Complete**

☐ **UTI ID Panel Complete**

☐ **Uncomplicated UTI**
- ☐ Enterococcus faecalis
- ☐ Escherichia coli
- ☐ Klebsiella pneumoniae
- ☐ Proteus mirabilis
- ☐ Staph. Saprophyticus

☐ **UTI Additional Pathogens**
- ☐ Candida Species
- ☐ Enterobacter cloacae
- ☐ Klebsiella oxytoca
- ☐ Morganella morganii
- ☐ Mycoplasma hominis
- ☐ Providencia stuartii
- ☐ Pseudomonas aeruginosa
- ☐ Serratia marcescens
- ☐ Staphylococcus aureus
- ☐ Streptococcus agalactiae
- ☐ Ureaplasma urealyticum

☐ **Urine STI Panel**
- ☐ Mycoplasma hominis
- ☐ Ureaplasma urealyticum
- ☐ Mycoplasma genitalium

☐ **Leukorrhea Panel**
- ☐ Trichomonas Vaginalis
- ☐ Neisseria gonorrhoeae
- ☐ Chlamydia trachomatis

Performed w/ E-Swab

Respiratory (ABR)

☐ **In Office Flu Test Performed**

☐ **Viral Targets**

☐ **Influenza Panel**
- ☐ Influenza (A, H1-2009, H3)
- ☐ Influenza B
- ☐ Influenza C
- ☐ Parainfluenza (1, 2, 3, 4)

☐ **Common Cold Panel**
- ☐ Adenovirus
- ☐ Human Bocavirus
- ☐ Human Coronavirus (HKU1/NL63/229E/OC93)
- ☐ Human Enterovirus
- ☐ Human Rhinovirus
- ☐ Human Parechovirus

☐ **Respiratory Syncytial Virus A/B**

☐ **Human Metapneumovirus A/B**

☐ **SARS (Severe Acute Resp Syndrome)**

☐ **MERS (Middle East Resp Syndrome)**

☐ **Bacterial Targets**

☐ **Pneumonia Panel**
- ☐ Mycoplasma pneumoniae
- ☐ Chlamydia pneumoniae
- ☐ Streptococcus pneumoniae
- ☐ Klebsiella pneumoniae
- ☐ Haemophilus influenzae/Type B
- ☐ Legionella pneumophila/longbeachae

☐ **Moraxella catarrhalis**

☐ **Coxiella burnetii**

☐ **Whooping Cough**
- ☐ Bordetella pertussis
- ☐ Bordetella parapertusis
- ☐ Bordetella holmesii

☐ **Pneumocystis Jirovecii (Fungal)**

MRSA

☐ **MRSA** (S.aureus, mecA)

Strep Differentiation

- ☐ Group A Strep
- ☐ Group B Strep
- ☐ Group C&G Strep

COVID-19

☐ SARS-COV-2

Performed w/ E-Swab

Ear Panel

☐ **Ear Infection Panel**
- ☐ Acinetobacter baumannii
- ☐ Candida albicans
- ☐ Chlamydophila pneumo.
- ☐ E. Coli
- ☐ Enterobacter aerogenes
- ☐ Enterobacter cloacae
- ☐ Haemophilus influenzae
- ☐ Haemophilus influ. (B)
- ☐ Klebsiella pneumoniae
- ☐ Moraxella catarrhalis
- ☐ Mycoplasma pneumo.
- ☐ Proteus mirabilis
- ☐ Pseudo. aeruginosa
- ☐ Staph. aureus/MRSA
- ☐ Strep. dysgalactiae (Group C,G)
- ☐ Strep. pneumoniae
- ☐ Strep. pyogenes (Group A)

Performed w/ E-Swab

Eye Panel (ABR & Sens.)

☐ **Eye Infection Panel**

☐ **Viral Infection**
- ☐ Adeno Virus
- ☐ HHV-1
- ☐ VZV
- ☐ Rubeola Virus (Measles)

☐ **Bacterial Infection**
- ☐ H. Influenza
- ☐ Strep. Pneumonia
- ☐ Staph. Aureus
- ☐ Moraxella catarrhalis
- ☐ Chlamydia trachomatis
- ☐ Neisseria gonorrhoeae
- ☐ E.Coli

Performed w/ Fecal Swab

Gastrointestinal

☐ Gastrointestinal Complete

☐ **Bacterial Gastroenteritis**
- ☐ Campylobacter spp.
- ☐ Clostridium difficile
- ☐ Enteroaggregative E. coli
- ☐ Enteroinvasive E. coli
- ☐ Enteropathogenic E. coli
- ☐ Enterotoxigenic E. coli
- ☐ Plesiomonas Shigelloides
- ☐ Salmonella spp.
- ☐ Shigella spp.
- ☐ Vibrio Cholerae
- ☐ Yersinia enterocolitica

☐ **Stool Parasites**
- ☐ Cryptosporidium spp.
- ☐ Dientamoeba fragilis
- ☐ Entamoeba histolytica
- ☐ Giardia lamblia

☐ **Viral Gastroenteritis**
- ☐ Norovirus G1, G2
- ☐ Adenovirus
- ☐ Astrovirus
- ☐ Rotavirus
- ☐ Sapovirus

Helicobacter pylori

☐ Helicobacter pylori

Clostridium difficile

☐ Clostridium difficile

Fecal Occult (Stool Sample Req'd)

☐ Occult Blood, Fecal

Performed w/ E-Swab

Wound

☐ **Wound ID (ABR & Sensitivity)**
- ☐ Acinetobacter baumannii
- ☐ Bacteroides spp.
- ☐ Citrobacter freundii
- ☐ Enterobacter aerogenes
- ☐ Enterobacter cloacae
- ☐ Enterococcus faecalis
- ☐ Enterococcus faecium
- ☐ Escherichia coli
- ☐ Klebsiella Oxytoca
- ☐ Klebsiella Pneumoniae
- ☐ Morganella morganii
- ☐ Proteus mirabilis
- ☐ Proteus vulgaris
- ☐ Pseudomonas aeruginosa
- ☐ Staphylococcus aureus
- ☐ Streptococcus pyogenes
- ☐ Clostridium novyi
- ☐ Clostridium septicum
- ☐ Clostridium perfringens
- ☐ Kingella kingae

Performed w/ E-Swab

HHV(s)

☐ **HHV(s) complete**
- ☐ HHV 1 (Herpes Simplex 1)
- ☐ HHV 2 (Herpes Simplex 2)
- ☐ HHV 3 (VZV)

Performed w/ nail clipping

Nail Fungus

☐ **Nail Fungal complete**
- ☐ Acremonium strictum
- ☐ Alternaria
- ☐ Aspergillus niger
- ☐ Aspergillus terreus
- ☐ Epider. floccosum
- ☐ Fusarium solani
- ☐ Microsporum audouinii
- ☐ Microsporum canis
- ☐ Trichophyton interdigitale
- ☐ Trichophyton rubrum
- ☐ Neofusi. mangiferae
- ☐ Candida Spp

Additional Testing

Continued Patient Authorization Information:

I also authorize my Physician and his/her staff to disclose any protected health information ("PHI") needed to determine my benefits for laboratory analysis services to Lab for the purposes of obtaining payment for providing laboratory services to Patient. The Lab and receiving health information under this authorization will not receive direct or indirect remuneration in exchange for disclosing the health information. I understand that my treatment, payment, enrollment, or eligibility for benefits will not be conditioned on whether I sign this form. I understand that I have the right to refuse to sign this authorization. I understand that, as set forth in the notice of privacy practices, I have the right to revoke this authorization, in writing, at any time except to the extent that the Physician/Lab which is to make the disclosure has already taken action in reliance on it. I understand that PHI used or disclosed pursuant to this authorization may be re-disclosed by the recipient and its confidentiality may no longer be protected by federal or state law. If not previously revoked, this consent will terminate upon that date which is one year after Patient's last encounter for which Physician ordered laboratory analysis from Lab for Patient. A disclosure may not be made on the basis of a consent which:

(1) has expired;

(2) on its face substantially fails to conform to any of the requirements set forth in 42 C.F.R. § 2.31(a);

(3) is known to have been revoked; or

(4) is known, or through a reasonable effort could be known, by the person holding the records to be materially false.

Additionally, I authorize payments from insurance companies, or other third-party payers to be made to Lab for the laboratory services it has provided. I understand that I am responsible for the payment of any deductibles or co-insurance charges, if applicable. I understand that Lab may be an out-of-network provider with my insurer or third-party payer. If my insurance company, or other third-party payer makes payment directly to me, I will endorse said check and forward it to Lab within 30 calendar days of its receipt. I understand that failure to do so may result in my account being forwarded to collections and reported to a credit bureau. If I am a self-pay patient, I accept full financial responsibility for any payment due Lab for its laboratory services provided on my behalf.

This information has been disclosed to you from records protected by Federal confidentiality rules (42 C.F.R. Part 2). The Federal rules prohibit you from making any further disclosure of this information unless further disclosure is expressly permitted by the written consent of the person to whom it pertains or as otherwise permitted by 42 C.F.R. Part 2. A general authorization for the release of medical or other information is NOT sufficient for this purpose.

I, the undersigned acknowledge that this specimen was provided voluntarily for analysis and I authorize Solaris Diagnostics to administer results on my behalf and to bill my health insurance provider for services provided to me. I hereby allow the release of any personal or medical information as needed to process this claim and I acknowledge and understand payment(s) for services may be made on my behalf by my health insurance provider to Solaris Diagnostics. I may be responsible for co-pays and deductibles not covered by my health insurance provider.

SARS-CoV-2 Collection Guide

Solaris Diagnostics

Accepted Specimen Types

- Nasopharyngeal (NP) Swabs and Oropharyngeal (OP) Swabs
- Sputum

Use only synthetic tip, and plastic (or aluminum) shaft swabs

How to Collect Nasopharyngeal Samples

- Insert swab through the nares parallel to the palate.
- Do this until there is resistance, or the distance is equivalent to that from the ear to the nostril of the patient indicating contact with the nasopharynx.
- Gently, rub and roll the swab. Leave the swab in place for several seconds to absorb secretions before removing.
- Place swabs immediately into a sterile vial containing viral transport media.
- Label the vial with the patients' information.
- Refrigerate sample until it is ready to ship.

How to Collect Oropharyngeal Samples

- Insert the swab into the posterior pharynx and tonsillar areas.
- Rub swab over both tonsillar pillars and posterior oropharynx. Avoid touching the tongue, teeth, and gums.
- Place swabs immediately into a sterile vial containing viral transport media.
- Label the vial with the patients' information.
- Refrigerate sample until it is ready to ship.

NP and OP specimens may be kept in separate vials or combined at collection into a single vial.

How to Collect Sputum Samples

- Educate the patient about the difference between sputum and oral secretions.
- Have the patient rinse the mouth with water
- Have the patient expectorate deep-cough sputum directly into a sterile screw-cap collection cup or sterile dry container.
- Label the sample with the patients' information.
- Refrigerate sample until it is ready to ship.

Shipping Instructions

- Place sample in an insulated mailer with cold packs.
- Multiple samples can be shipped in one mailer but must be individually packaged.
- Use one supplied pre-paid label per mailer and seal it.
- Call your designated Solaris sales representative or call Solaris Diagnostics directly at (844)550-0308 to request a pick-up.
- If you are on our local pick-up route, add an ice pack in the courier box along with the specimens.

Sample may be rejected for following reasons:

- The specimen was not stored at the appropriate temperature.
- The specimen was not shipped with ice packs in an insulated mailer.
- The patient information is not complete.
- Inappropriate sample collection.
- Insufficient specimen volume.

Educational References from the Center for Disease Control and Prevention

- CDC Information for Healthcare Professionals - https://www.cdc.gov/coronavirus/2019-nCov/hcp/index.html
- CDC nCov-19 Homepage - https://www.cdc.gov/coronavirus/2019-nCov/about/index.html
- CDC Fact Sheet - https://www.cdc.gov/coronavirus/2019-nCov/downloads/2019-nCov-factsheet.pdf

FACT SHEET FOR PATIENTS

Solaris SARS-CoV-2 RT-PCR Test **March 15, 2020**

2019 Novel Coronavirus (2019-nCoV)

You are being given this Fact Sheet because your sample(s) were tested for the 2019 novel coronavirus (2019-nCoV) using the Solaris SARS-CoV-2 RT-PCR Test. Testing was done because you meet CDC criteria for 2019-nCoV testing.

This Fact Sheet contains information to help you understand the risks and benefits of using this test for the diagnosis of 2019-nCoV infection. After reading this Fact Sheet, if you have questions or would like to discuss the information provided, please talk to your healthcare provider.

- **For the most up to date information on 2019-nCoV please visit the CDC 2019 Novel Coronavirus webpage:**
- **https://www.cdc.gov/nCoV**

What is 2019-nCoV Infection?
2019-nCoV infection is caused by the 2019-nCoV. The 2019-nCoV infection can cause mild to severe respiratory illness in humans and was recently idenitifed in Wuhan, China. Limited information is available to characterize the spectrum of clinical illness associated with 2019-nCoV. 2019-nCoV likely spreads to others when a person shows signs or symptoms of being sick (e.g., fever, coughing, sneezing, difficulty breathing, etc.).

What is the Solaris SARS-CoV-2 RT-PCR Test?
The test is designed to detect 2019-nCoV in respiratory specimens, for example nasal or oral swabs.

Why was my sample tested?
Your sample(s) were tested because your healthcare provider believes you may have been exposed to 2019-nCoV based on your signs and symptoms (e.g., fever, cough, difficulty breathing), and because:

- You live in or have recently traveled to a place where transmission of 2019-nCoV is known to occur, and/or
- Because you have been in close contact with an individual suspected of or confirmed to have 2019-nCoV infection.

The sample(s) collected from you were tested to help find out whether you may be infected with 2019-nCoV.

What are the known and potential risks and benefits of the test?
Potential risks include:

- Possible discomfort or other complications that can happen during sample collection.
- Risk that the test result is incorrect (see below for more information).

Potential benefits include:

- The results, along with other information, can help your healthcare provider make informed recommendations about your care.
- The results of this test may help limit the spread of 2019-nCoV to your family and others in your community.

What does it mean if I have a positive 2019-nCoV test result?
If you have a positive test result, it is very likely that you are infected with 2019-nCoV. Therefore, it is also likely that you may be placed in isolation to avoid spreading the virus to others. There is a very small chance that this test can give a positive result that is wrong (a false

Where can I go for updates and more information? The most up-to-date information on 2019-nCoV is available at the CDC General webpage: **https://www.cdc.gov/nCoV**. In addition, please also contact your healthcare provider with any questions/concerns.

positive result). However, your healthcare provider will work with you to determine how best to care for you based on the test results along with other factors of your medical history, such as symptoms, possible exposures, and geographic location of places you have recently traveled.

What does it mean if I have a negative test result?
A negative test result means that 2019-nCoV was not found in your sample. For 2019-nCoV, a negative test result for a sample collected while a person has symptoms usually means that 2019-nCoV did not cause your recent illness.

It is possible for this test to give a negative result that is incorrect (false negative) in some people with 2019-nCoV infection, meaning you could possibly still have an infection with 2019-nCoV even though the test is negative. Therefore, while a negative test most likely means you do not have 2019-nCoV infection, your healthcare provider will consider the test result together with all other aspects of your medical history (such as symptoms, possible exposures, and geographical location of places you have recently traveled) in deciding how to care for you.

It is important that you work with your healthcare provider to help you understand the next steps you should take.

Is this test FDA-approved or cleared?
No. This test is not yet approved or cleared by the United States (U.S.) FDA. When there are no FDA-approved or cleared tests available, and other criteria are met, FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's (HHS's) declaration that circumstances exist to justify the use of in vitro diagnostics under EUA for the detection and/or diagnosis of 2019-nCoV. This EUA will remain in effect (meaning this test can be used) for the duration of the 2019-nCoV emergency, unless it is terminated or revoked by FDA (after which the test may no longer be used).

Where can I go for updates and more information? The most up-to-date information on 2019-nCoV is available at the CDC General webpage: **https://www.cdc.gov/nCoV**. In addition, please also contact your healthcare provider with any questions/concerns.

FACT SHEET FOR HEALTHCARE PROVIDERS

Solaris SARS-CoV-2 RT-PCR Test **March 15, 2020**

2019 Novel Coronavirus (2019-nCoV)

This Fact Sheet informs you of the significant known and potential risks and benefits of the emergency use of the Solaris SARS-CoV-2 RT-PCR .

Testing is to be conducted on specimens from people who meet CDC criteria for 2019-nCoV testing, available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section). The Solaris SARS-CoV-2 RT-PCR should be ordered only to presumptively detect 2019-nCoV infection. If outside the U.S., testing should follow appropriate public health authority consultation and/or guidance for the diagnosis and reporting of 2019-nCoV infection. All information and guidance, including for 2019-nCoV laboratory testing, may change as more data is gathered on this virus. Please check the CDC's 2019 Novel Coronavirus, webpage (see links provided in "Where can I go for updates and more information" section) regularly for the most current information.

All patients whose specimens are tested with this assay will receive the Fact Sheet for Patients: Solaris SARS-CoV-2 RT-PCR Test

What are the symptoms of 2019-nCoV?
Most patients with confirmed 2019-nCoV infection have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with 2019-nCoV infection. Based on what is known about MERS-CoV and SARS-CoV, signs and symptoms may appear any time from 2 to 14 days after exposure to 2019-nCoV virus. The median incubation period is unknown at this time.

Public health officials have identified cases of 2019-nCoV infection in the United States, which may pose risks for public health. To date most reported cases of 2019-nCoV infection outside of China have been directly or indirectly linked through residence in or travel to Wuhan City, China. There also are reports of human to human transmission through close contact with an individual confirmed to be ill with 2019-nCoV in countries outside China. Please check the CDC webpage for the most up to date information.

This test is to be performed only using respiratory specimens collected from individuals who meet CDC criteria for 2019-nCoV testing.

What do I need to know about 2019-nCoV testing?
Current information on 2019-nCoV infection for healthcare providers, including case definitions and infection control, is available at CDC's webpage, *Information for Healthcare Professionals* (see links provided in "Where can I go for updates and more information" section).

- The Solaris SARS-CoV-2 RT-PCR Test can be used to test upper and lower respiratory specimens (such as nasopharyngeal or oropharyngeal swabs, bronchoalveolar lavage, sputum, lower respiratory tract aspirate, nasopharyngeal wash/aspirate or nasal aspirate).
- The Solaris SARS-CoV-2 RT-PCR Test should be ordered for the presumptive detection of 2019-nCoV in individuals who meet CDC criteria for 2019-nCoV testing.
- The Test is authorized for use in qualified laboratories designated by CDC and in the U.S., certified under CLIA to perform high complexity tests.

Specimens should be collected with appropriate infection control precautions following CDC *Guideline for Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings (2007).*

Use appropriate personal protective equipment when collecting and handling specimens from individuals suspected of being infected with 2019-nCoV as outlined in the CDC *Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with*

2019 Novel Coronavirus (2019-nCoV). These specimens are only shipped for analysis to laboratories designated by CDC as qualified for analysis. For additional information, refer to CDC *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV) (*see links provided in "Where can I go for updates and more information" section).

What does it mean if the specimen tests positive for 2019-nCoV?
A positive test result for 2019-nCoV indicates that RNA from 2019-nCoV was detected, and the patient is presumptively infected with 2019-nCoV and presumed to 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. Patient management should follow current CDC guidelines.

The Solaris SARS-CoV-2 RT-PCR Test has been designed to minimize the likelihood of false positive test results. However, 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 2019-nCoV infected patients, limits in the ability to work, the 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 confirmatory testing and reporting guidelines according to their appropriate public health authorities.

What does it mean if the specimen tests negative for 2019-nCoV?
A negative test result for this test means that 2019-nCoV RNA was not present in the specimen above the limit of detection. However, a negative result does not rule out 2019-nCoV infection and should not be used as the sole basis for treatment or patient management decisions. A negative result does not exclude the possibility of 2019-nCoV infection.

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 2019-nCoV infection. The possibility of a false negative result should especially be considered if the patient's recent exposures or clinical presentation indicate that 2019-nCoV infection is likely, and diagnostic tests for other causes of illness (e.g., other respiratory illness) are negative. If 2019-nCoV infection is still suspected based on exposure history together with other clinical findings, re-testing should be considered in consultation with public health authorities.

Risks to a patient of a false negative 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 2019-nCoV within the community, or other unintended adverse events.

What is an EUA?
The United States (U.S.) 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 use of in vitro diagnostics (IVDs) under EUA for the detection and/or diagnosis of 2019-nCoV.

An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. However, based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the detection of 2019-nCoV.

The EUA for this test is in effect for the duration of the 2019-nCoV emergency, unless terminated or revoked (after which the test may no longer be used). An FDA approved or cleared IVD should be used instead of an IVD under EUA, when applicable and available.

Where can I go for updates and more information?

CDC webpages:

General: https://www.cdc.gov/nCoV
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/infectioncontrol/guidelines/isolation/index.html#a4
Specimen Collection: https://www.cdc.gov/coronavirus/2019-nCoV/guidelines-clinical-specimens.html

FDA webpages:

General: www.fda.gov/novelcoronavirus
EUAs:(includes links to patient fact sheet and manufacturer's instructions) https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations

Solaris Diagnostics

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