REVISED

3703 Camino del Rio South #100-A,
San Diego, CA 92108-4031, US
619-450-5870 - Phone
619-450-6023 - Fax
CLIA# 05D2027247 - Director: David J. Smith, MD

Patient :	**Patient, Test**			**Acc #:**	AL-RPP-249973
Patient #:		Birth:	03/01/1950		
Doctor:	COVID Direct Specimen	Age:	71 years	Collection Date:	05/21/2021 00:00
		Gender:	Male	Received in Lab:	05/24/2021 00:00

RESPIRATORY PATHOGEN TEST (including COVID-19): see COMMENTS

Test Name	Result
RESPIRATORY	
Influenza A	Negative
Influenza B	Negative
SARS-CoV-2	Negative

Comments:

This test was performed at Alcala Testing and Analysis Services (CLIA# 05D2027247).

IMPORTANT NOTE: if Test Name above = "SARS-CoV-2" or "SARS-CoV-2 PCR MAIL-IN" the test performed was an RT-PCR test (also known as a nucleic acid amplification technique or NAAT test). If Test Name above = "SARS-CoV-2 ANTIGEN" the test performed was an ANTIGEN test (see test information below).

Test information - RT-PCR TESTS

The NxTAG® CoV Extended Panel - for use on the Luminex® MAGPIX® Instrument - is an RT-PCR test (also known as a nucleic acid amplification technique or NAAT test) for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swab specimens from individuals suspected of COVID-19 by their healthcare provider. The following genes are detected by the NxTAG CoV Extended Panel Assay: ORF1ab (contains Rdrp gene), N and E gene.

CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel - the oligonucleotide primers and probes for detection of 2019-nCoV were selected from regions of the virus nucleocapsid (N) gene. The panel is designed for specific detection of the 2019-nCoV (two primer/probe sets). An additional primer/probe set to detect the human RNase P gene (RP) in control samples and clinical specimens is also included in the panel. RNA isolated and purified from upper and lower respiratory specimens is reverse transcribed to cDNA and subsequently amplified in the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS version 1.4 software.

FOSUN COVID-19 RT-PCR Detection kit - This EUA-approved method is a fluorescent probe-based Taqman RT-PCR assay system. The ORF1ab (Rdrp region included), N and E gene of SARS-CoV-2 will be detected qualitatively, including a separate internal reference. dUTP and UNG enzyme are used in the kit to prevent contamination of the amplified products. RNA isolated and purified from upper and lower respiratory specimens is reverse transcribed to cDNA and subsequently amplified in the Applied Biosystems 7500 Fast Dx Real-Time PCR Instrument with SDS version 1.4 software.

PHOENIXDX® COFLUENZA RT-PCR 4-PLEX IVD is a real-time RT-PCR-based diagnostic test for the in vitro qualitative detection of Influenza A, Influenza B and SARS-CoV-2 in respiratory specimens and sera. Positive results indicate the presence of Influenza A, Influenza B or SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information must be considered to determine the actual patient infection status.

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Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities. Please contact your Primary Care Provider (PCP) and implement steps to help prevent the spread of COVID-19 as recommended by the CDC (Center for Disease Control):

Stay home. Most people with COVID-19 have mild illness and can recover at home without medical care. Do not leave your home, except to get medical care. Do not visit public areas.

Take care of yourself. Get rest and stay hydrated. Take over-the-counter medicines, such as acetaminophen, to help you feel better.

Stay in touch with your doctor. Call before you get medical care. Be sure to get care if you have trouble breathing, or have any other emergency warning signs, or if you think it is an emergency.

Avoid public transportation, ride-sharing, or taxis.

When to Seek Emergency Medical Attention

Look for **emergency warning signs*** for COVID-19. If someone is showing any of these signs, **seek emergency medical care immediately:**

- Trouble breathing
- Persistent pain or pressure in the chest
- New confusion
- Inability to wake or stay awake
- Bluish lips or face

*This list is not all possible symptoms. Please call your medical provider for any other symptoms that are severe or concerning to you. **Call 911 or call ahead to your local emergency facility:** Notify the operator that you are seeking care for someone who has or may have COVID-19.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

The NxTAG CoV Extended Panel is for use in US laboratories certified under the Clinical Laboratory Improvement Amendments of 1988(CLIA), 42 U.S.C. §263a, to perform high complexity tests, or by similarly qualified non-US laboratories. The NxTAG CoV Extended Panel is only for use under the Food and Drug Administration's Emergency Use Authorization (EUA). This test has been authorized by the FDA under an EUA for use by authorized laboratories for the detection of nucleic acid from SARS-CoV-2.

NxTAG® Respiratory Pathogen Panel (For In Vitro Diagnostic Use), is a qualitative test intended for use on the

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Luminex® MAGPIX® instrument for the simultaneous detection and identification of nucleic acids from multiple respiratory viruses and bacteria extracted from nasopharyngeal swabs collected from individuals with clinical signs and symptoms of a respiratory tract infection. The organism types and subtypes detected by the test are Influenza A, Influenza A H1, Influenza A H3, Influenza B, Respiratory Syncytial Virus A, Respiratory Syncytial Virus B, Coronavirus 229E, Coronavirus OC43, Coronavirus NL63, Coronavirus HKU1, Human Metapneumovirus, Rhinovirus/Enterovirus, Adenovirus, Parainfluenza virus 1, Parainfluenza virus 2, Parainfluenza virus 3, Parainfluenza virus 4, Human Bocavirus, Chlamydophila pneumoniae, and Mycoplasma pneumoniae. The test is indicated as an aid in the detection and identification of viral and bacterial agents causing respiratory tract infections in symptomatic adult and pediatric patients, who are either hospitalized, admitted to emergency departments, or who are outpatients with suspected respiratory tract infection. The results of this test should not be used as the sole basis for diagnosis, treatment, or other patient management decisions. Negative results in the setting of a respiratory illness may be due to infection with pathogens not detected by this test or lower respiratory tract infection that is not detected by a nasopharyngeal swab specimen. Positive results do not rule out co-infection with other pathogens. The agent detected may not be the definite cause of disease. The use of additional laboratory testing (e.g. bacterial and viral culture, immunofluorescence, and radiography) and clinical presentation must be taken into consideration in order to obtain the final diagnosis of respiratory tract infection. Performance characteristics for influenza A were established using specimens obtained during the 2013/2014 and 2014/2015 influenza seasons when influenza A/H3 and A/H1 were the predominant influenza A viruses in circulation. When other influenza A viruses are emerging, performance characteristics may vary. If infection with a novel influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health departments for testing.

Clinical Performance Information - RT-PCR TESTS:

SARS-CoV-2 (COVID-19):

The NxTAG® CoV Extended Panel (NxTAG CoV) *is an EUA-approved (In Vitro Diagnostic Use Under Emergency Use Authorization) test authorized by the FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. incorporates multiplex Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) with the Luminex® proprietary universal tag sorting system on the Luminex platform to easily detect SARS-CoV-2s. Extracted total nucleic acid is added to pre-plated, Lyophilized Bead Reagents (LBRs) and mixed to resuspend the reaction reagents. The reaction is amplified via RT-PCR and the reaction product undergoes near simultaneous bead hybridization within the sealed reaction well. The hybridized, tagged beads are then sorted and read on the MAGPIX® instrument.* ***Sensitivity:*** *The Limit of Detection (LoD) study established the lowest SARS-CoV-2 viral concentration (Genomic Copy Equivalents or GCE = 5.00E+03 GCE/mL) that can be detected by the NxTAG® CoV Extended Panel Assay at least 95% of the time using viral genomic RNA. 100% at 3X LoD and 5X LoD.* ***Specificity:*** *100% PPV and NPV.*
The CDC protocol *EUA-approved IFU confirms* ***100% Sensitivity*** *at an LOD of 1000 to 3162 RNA copies/mL (or 1000 to 3162 NDU/mL = NAAT Detectable Units/mL). The viral load concentration in undiluted SeraCare positive specimens was confirmed to be 100% at 5.00E+03 GCE/mL and* ***100% Sensitivity*** *at an LOD of at least 5.00E+03 GCE/mL (or 5000 NDU/mL = NAAT Detectable Units/mL).*
The FOSUN COVID-19 RT-PCR detection panel *was confirmed at* ***100% Sensitivity*** *at 5.00E+03 GCE/mL and* ***100% Sensitivity*** *at an LOD of at least 5.00E+03 GCE/mL (or 5000 NDU/mL = NAAT Detectable Units/mL).*

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PHOENIXDX® COFLUENZA RT-PCR *4-PLEX IVD is confirmed with a clinical sensitivity and specificity of 100% for SARS-CoV-2 detection, 100% sensitivity and 96.63% specificity for Influenza A detection, and 100% sensitivity and 98.48% specificity for Influenza B detection.*

NxTAG® Respiratory Pathogen Panel (RPP) *for In Vitro Diagnostic Use (IVD), incorporates multiplex Reverse Transcriptase Polymerase Chain Reaction (RT-PCR) with the Luminex® proprietary universal tag sorting system on the Luminex platform to easily detect respiratory pathogen targets. Extracted total nucleic acid is added to pre-plated, Lyophilized Bead Reagents (LBRs), and mixed to resuspend the reaction reagents. The reaction is amplified via RT-PCR and the reaction product undergoes near simultaneous bead hybridization within the sealed reaction well. The hybridized, tagged beads are then sorted and read on the MAGPIX® instrument, and the signals are analyzed using the NxTAG Respiratory Pathogen Panel Assay File for SYNCT™ Software, providing a reliable, qualitative call for each of the 20 targets and internal controls within each reaction well.*

Test information - ANTIGEN TESTS:

CareStart™ COVID-19 Antigen Rapid Diagnostic Test for Detection of SARS-CoV-2: The CareStart™ COVID-19 Antigen test is a lateral flow immunochromatographic assay intended for the qualitative detection of the nucleocapsid protein antigen from SARS-CoV-2 in nasopharyngeal swab specimens directly collected, or collected in BD universal transport media, from individuals suspected of COVID-19 by their healthcare provider within five days of symptom onset. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet the requirements to perform moderate, high or waived complexity tests. This test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

Results are for the identification of the SARS-CoV-2 nucleocapsid protein antigen. The antigen is generally detectable in nasopharyngeal swab specimens during the acute phase of infection. Positive results indicate the presence of viral antigens, but the clinical correlation with patient history and other diagnostic information is necessary to determine infection status. Positive results do not rule out a bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease. Laboratories within the United States and its territories are required to report all results to the appropriate public health authorities.

Negative results are presumptive and confirmation with a molecular assay, if necessary, for patient management may be performed. Negative results do not rule out SARS-CoV-2 infection and should not be used as the sole basis for treatment or patient management decisions, including infection control decisions. Negative results should be considered in the context of a patient's recent exposures, history and the presence of clinical signs and symptoms consistent with COVID-19.

Clinical Performance Information - ANTIGEN TESTS:

To initially evaluate the clinical performance of the CareStart™ COVID-19 Antigen test, a total of 126 blinded frozen swab samples, including 106 retrospective clinical specimens and 20 contrived specimens, were tested in one (1) CLIA waived investigational site by five (5) minimally trained operators in the U.S during the 2020 COVID-19 season. A total of 126 frozen samples consisting of 43 positive nasopharyngeal (NP) swabs, 63 negative NP swab specimens, and 20 contrived near the cut-off samples (10 positives and 10 negatives). NP swab specimens collected from the patients with COVID-19

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like symptoms in the U.S during the 2020 COVID-19 season and stored in BD universal transport media tube were provided by multiple vendors in the U.S. All the NP swab specimens were confirmed as positive or negative and validated with Ct value by the FDA EUA RT-PCR as a comparator method prior to the study. In addition to the clinical population, a total of 20 contrived near the cut-off samples, 10 low positives near the Limit of Detection (LoD) (2x LoD), and 10 negatives (zero analytes) samples, were prepared using the inactivated SARS-CoV-2 strain spiked into the simulated nasal swab matrix, BD universal transport media. The heat-inactivated SARS-CoV-2 isolate USA-WA1/2020 was used to prepare the positive samples.

CareStart™ COVID-19 Antigen (retrospective samples) Performance against the Comparator Method:

		Comparator	
CareStart™ COVID-19	Positive	Negative	Total
Positive	38	0	38
Negative	5	63	68
Total	43	63	106

Positive Percent Agreement (PPA) - Sensitivity: 88.37% (95% CI: 75.52% – 94.93%)
Negative Percent Agreement (NPA) - Specificity: 100% (95% CI: 94.25% – 100%)

Reviewed By: _____ **Date:** **05/24/2021 15:39**