Alcala Testing and Analysis Services
3703 Camino del Rio South #100-A,
San Diego, CA, 92108
Phone: (619) 450-5870 **Fax:** (619) 450-6023
Medical Director: David J. Smith, MD
CLIA# 05D2027247

APPROVAL REQUIRED

Patient :	**UT-06, CAP**			**Acc #:**	AL-RPP-27256
Patient #:		Birth:	07/25/2018		
Doctor:	Test Doctor	Age:	2 years	Collection Date:	
		Gender:	Not specified	Received in Lab:	

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

Test Name	Result
RESPIRATORY	
Adenovirus	Positive
Chlamydophila pneumoniae	Negative
Coronavirus 229E	Negative
Coronavirus HKU1	Negative
Coronavirus NL63	Negative
Coronavirus OC43	Negative
Human Bocavirus	Negative
Human Metapneumovirus	Negative
Influenza A	Negative
Influenza A H3	Negative
Influenza A/H1	Negative
Influenza B	Negative
Mycoplasma pneumoniae	Negative
Parainfluenza virus 1	Positive
Parainfluenza virus 2	Negative
Parainfluenza virus 3	Negative
Parainfluenza virus 4	Negative
Respiratory Syncytial Virus A	Negative
Respiratory Syncytial Virus B	Negative
Rhinovirus/Enterovirus	Negative
SARS-CoV-2	Positive

Comments:

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

Test information:

The NxTAG® CoV Extended Panel - for use on the Luminex® MAGPIX® Instrument - is an RT-PCR 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. **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):

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- **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 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-

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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.

Test Performance Information:

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.*

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.*

Reviewed By: _____ **Date:** _____