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:	07/25/1977		
Doctor:	Test Doctor	Age:	42 years	Collection Date:	
		Gender:	Not specified	Received in Lab:	

BLOOD/SEROLOGY TEST (including COVID-19): see COMMENTS

Test Name	Result
RESPIRATORY	
SARS-CoV-2 Serology IgG	Positive
SARS-CoV-2 Serology IgM	Positive

Comments:

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

Test information:

Presence of IgG and IgM antibodies in venipuncture serum draws are determined by COVID-19 ELISA Diagnostics kits developed by Epitope Diagnostics, Inc: KT-1032 EDI™ Novel Coronavirus COVID-19 IgG ELISA Kit and KT-1033 EDI™ Novel Coronavirus COVID-19 IgM.

The ELISA kits utilizied for this test are designed, developed, and produced for the qualitative measurement of the human anti-COVID-19 IgG or IgM antibody in serum and utilizes the microplate based enzyme immunoassay technique. Assay controls and 1:100 or 1:10 diluted human serum samples are added to the microtiter wells of a microplate that was coated with COVID-19 recombinant full length nucleocapsid protein. After the first incubation period, the unbound protein matrix is removed with a subsequent washing step. A horseradish peroxidase (HRP) labeled polyclonal goat anti-human IgG tracer antibody is added to each well. After an incubation period, an immunocomplex of "COVID-19 recombinant antigen – human anti-COVID-19 IgG antibody - HRP labeled anti human IgG tracer antibody" is formed if there is specific coronavirus IgG antibody present in the tested specimen. The unbound tracer antibody is removed by the subsequent washing step. HRP tracer antibody bound to the well is then incubated with a substrate solution in a timed reaction and then measured in a spectrophotometric microplate reader. The enzymatic activity of the tracer antibody bound to the anti-COVID-19 IgG on the wall of the microtiter well is proportional to the amount of the anti-COVID-19 IgG antibody level in the tested specimen.

Intended Use:
This test is to be used as an aid for the detection of novel COVID-19. Patients with suspected clustering cases require diagnosis or differential diagnosis of novel coronavirus infection. This test is for in vitro diagnostic use only by laboratory professional use or healthcare professionals. This kit is being distributed under Section D of Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency and is only provided for use by clinical laboratories or to healthcare workers for clinical testing, and not for at home testing. The kits are registered under product code QKO, submission number is D376537. The establishment registration number is 2032839. Epitope Diagnostics, Inc. confirms that the materials are compliant with the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) guideline issued on May 4, 2020. The products are still eligible for distribution as in vitro diagnostics to laboratories certified to perform high complexity testing, and at the point-of care when covered by the laboratory's CLIA certificate for high-complexity testing. The test kit method and performance criteria were submitted to the Federal Drug Administration (FDA) under two routes: Emergency Use Authorization (EUA) and NOTIFY per Section IV.D of the Policy for Diagnostic Tests for Coronavirus Disease-2019.

Results:

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.

Test Performance Information:

IgG: Serum samples from two cohorts of patients were tested using the IgG ELISA kit at the Jiaxing City Center for Disease Control and Prevention and Zhejiang University Hospital. The combined cohort consisted of normal healthy patients with samples collected prior to the COVID-19 outbreak [December 3, 2019] (n = 54) and RT-PCR confirmed positive patients after the second week of the onset of the disease (n = 30). The results are as follows:

	Test Positive	**Test Negative**
Test Positive	30	0
Test Negative	0	54

For IgG the diagnostic sensitivity is 100%, the diagnostic specificity is 100%, the negative predictive value is 100%, the positive predictive value is 100%.

IgM: Serum samples from two cohorts of patients were tested using the IgM ELISA kit at the Jiaxing City Center for Disease Control and Prevention and Zhejiang University Hospital. The combined cohort consisted of normal healthy patients with samples collected prior to the COVID-19 outbreak [December 3, 2019] (n = 54) and RT-PCR confirmed positive patients after the second week of the onset of the disease (n = 20). The results are as follows:

	Test Positive	**Test Negative**
Test Positive	9	0
Test Negative	10	54
Test Borderline	1	0

For IgM the diagnostic sensitivity is 45%, the diagnostic specificity is 100%, the negative predictive value is 83.1%, the positive predictive value is 100%.

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Test Limitations:

1. This test is only for qualitative detection. Test results should not be the sole basis for clinical diagnosis and treatment. The confirmation of infection with novel coronavirus (COVID-19) must be combined with the patient's clinical signs in conjunction to other tests.

2. In the first week of the onset or after four weeks of the infection novel coronavirus (COVID-19) patients may be negative for IgM In addition, patients with low immunity or other diseases that affect immune function, failure of important systemic organs, and use of drugs that suppress immune function can also lead to negative results of new coronavirus IgM.

3. Bacterial or fungal contamination of serum specimens or reagents, or cross-contamination between reagents may cause erroneous results.

4. Water deionized with polyester resins may inactive the horseradish peroxidase enzyme.

5. This test has not been reviewed by the FDA.

6. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus.

7. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

8. Results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection or to inform infection status.

9. Positive results may be due to past or present infection with non-SARS-CoV-2 coronavirus strains, such as coronavirus HKU1, NL63, OC43, or 229E.

Reviewed By: _____ **Date:** _____