APPROVAL REQUIRED

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

Patient :	**Patient, Test**			**Acc #:**	AL-BLD-28270
Patient #:		Birth:	03/01/1950		
Doctor:	COVID Direct Specimen	Age:	70 years	Collection Date:	06/11/2020 00:00
		Gender:	Male	Received in Lab:	06/11/2020 00:00

BLOOD/SEROLOGY TESTING

Test Name	Result
RESPIRATORY	
SARS-CoV-2 IgG RAPID CASSETTE	Positive
SARS-CoV-2 IgM RAPID CASSETTE	Positive

Comments:

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) Test Information:

The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is an EUA-approved lateral flow immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human venous whole blood, plasma from anticoagulated blood (Li+ heparin, K2-EDTA and sodium citrate), or serum. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. At this time, it is unknown for how long antibodies persist following infection and if the presence of antibodies confers protective immunity. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) should not be used to diagnose acute SARS-CoV-2 infection. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C 263a, to perform moderate or high complexity tests.

Results are for the detection of SARS CoV-2 antibodies. IgM and IgG antibodies to SARS-CoV-2 are generally detectable in blood several days after initial infection, although the duration of time antibodies are present post-infection is not well characterized. Individuals may have detectable virus present for several weeks following seroconversion. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

The sensitivity of COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) early after infection in unknown. Negative results do not preclude acute SARS-CoV-2 infection. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary. False positive results for COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) may occur due to cross-reactivity from pre-existing antibodies or other possible causes. Due to the risk of false positive results, confirmation of positive results should be considered using second, different IgG or IgM assay. The COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) is only for use under the Food and Drug Administration's Emergency Use Authorization.

COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) Test Performance Information:

The clinical performance of the COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) was evaluated by testing a total of 191 plasma (K2-EDTA) clinical samples - 90 positive samples and 101 negative samples from individual patients exhibiting pneumonia, respiratory symptoms and fever etc. Testing was performed at two sites in China from January to mid-March 2020. COVID-19 IgG/IgM Rapid Test Cassette (Whole Blood/Serum/Plasma) results for IgM and IgG detection were compared to the results of RT-PCR assays for SARS-CoV-2 from oropharyngeal swabs (Site #1) and sputum (Site #2).

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COVID-19 IgG/IgM Rapid Test Cassette Summary Statistics

Measure	Estimate	Confidence Interval
IgM Sensitivity	100% (30/30)	(88.7%; 100%)
IgG Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
(IgM+ or IgG+; Total) Sensitivity (PPA)	100% (30/30)	(88.7%; 100%)
(IgM-/IgG-; Total) Specificity (NPA)	97.5% (78/80)	(91.3%; 99.3%)
Cross-reactivity with HIV+	0% (0/10) - not detected	

Venipuncture Serum Draw 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-I 033 EDI™ Novel Coronavirus COVJD-19 IgM. The ELISA kits utlizied 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 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.

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:

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	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%.

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:** _____