Alcala LABS

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ACCESSION STICKER HERE

SARS-COVID-19 *RAPID CASSETTE* TEST REQUISITION FORM

PATIENT INFORMATION

Last Name _____ First Name _____ MI _____

Gender: ☐ M ☐ F ☐ M/F ☐ F/M Date of Birth ____/____/_____

Patient Address _____

City, State, ZIP code _____ **Contact Information (E-mail & Phone)**

Occupation/Exposure setting: _____

Pregnancy Status: ☐ Yes ☐ No ☐ N/A

Race: ☐ Amer Ind/Alaskan ☐ White ☐ Black/Afr Amer
☐ Asian ☐ Native Hawaiian/Pacific Islander ☐ Other

PROVIDER INFORMATION

Facility/Group _____ Referring Physician _____

NPI Provider Nr: _____

Physician Address _____

City, State, ZIP code _____

Diagnostic Codes (ICD-10 codes see Page 2) _____

Clinical Information (date of onset/exposure, travel history, previous lab results – attach additional info.) _____

Ethnicity: ☐ Hispanic/Latino ☐ Non-Hispanic/Non-Latino ☐ Other

Billing information: ☐ Self-Pay (see Page 2) ☐ Commercial Insurance (attach copy) ☐ Medicare (attach copy)

COVID-19 RAPID CASSETTE ANTIBODY test (check all that apply):

☐ IgG ☐ IgM

SAMPLE HANDLING

Time Collected: _____ AM/PM Date Collected: _____

Collected by: _____

The following ***MUST*** be completed (check all that apply):
☐ Clinical Information provided.
☐ **COVID-19 IgG & IgM RAPID CASSETTE must be read and image captured within 10 minutes of application of Blood Specimen**.

INFORMED CONSENT

I consent to the collection of specimens for the purpose of DNA testing, and certify that the tests ordered have been explained to me by an authorized health care provider. I understand that only tests ordered by a qualified provider will be performed. This sample may be stored indefinitely and used for internal test validation after personal identifiers have been removed. I also authorize lab to bill my insurance provider and to receive payment of benefits for the tests ordered by my physician. I further authorize lab and the ordering physician to release to my insurance provider any medical information necessary to process this claim. I acknowledge that lab may be an out-of-network facility with my insurance provider.

Signature of Patient or Legal Guardian:
If Guardian, Print Name:
Date:

PROVIDER INFORMATION

I attest that the requested testing is medically necessary and appropriate based on the patient's diagnosis and treatment plan. I have personally completed the diagnosis codes above to indicate the accurate diagnosis for this patient.

Authorized Provider Signature:

Date:

BILLING INFORMATION

☐ Insurance Bill ☐ Account Bill ☐ Patient Bill ☐ Pre-Pay (Payment Information must be completed)

Ordering Physicians should refer to applicable National and Local Coverage Determinations for further information concerning reimbursement policy. Tests submitted for Medicare and Medicaid reimbursement must meet program requirements (ICD10-codes required) or the claim may be denied.

Bill Ordering Institution: Bill Insurance:

(Provide legible photocopy of front & back of insurance card)

Name of Insured: Relation to Patient: Insurance Company: Member

Social Security #: Member Group #: Insurance Address: Member Policy #:

Insurance Phone:

PAYMENT INFORMATION (PRE-PAY)

Check Card Used for Payment: ☐ VISA ☐ MasterCard ☐ American Express ☐ Discover

Card Number: Card Security Code:

Signature: Exp. Date:

Test information:

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 Performance - 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	

ICD10 Codes: SARS-CoV-2:

U07.1	COVID-19
Z20.828	Contact with and (suspected) exposure to other viral communicable diseases