BECKMAN COULTER
ACCESS
Immunoassay Systems

Instructions For Use

ACCESS SARS-CoV-2 IgM
SARS-CoV-2 IgM

REF C58957

For Use Under the Emergency Use Authorization (EUA) Only

For *In Vitro* Diagnostic Use

Rx Only

FOR USE ON ACCESS FAMILY OF IMMUNOASSAY SYSTEMS

Samples should be collected from individuals within 8 days to 30 days post symptom onset. Samples should not be tested less than 8 days post symptom onset. Negative samples collected for 8 days post symptom onset should be reflexed to direct detection of the virus. Negative samples collected 8 days or more post symptom onset should be reflexed to a test that detects and reports SARS-CoV-2 IgG .

ANNUAL REVIEW

Reviewed by	Date	Reviewed by	Date

PRINCIPLE

CAUTION

For U.S.A. only, Federal law restricts this device to sale and distribution by or on the order of a physician, or to a clinical laboratory; and use is restricted to by or on the order of a physician.

INTENDED USE

The Access SARS-CoV-2 IgM is a paramagnetic particle, chemiluminescent immunoassay intended for the qualitative detection of IgM antibodies to SARS-CoV-2 in human serum, serum separator tubes and plasma (lithium heparin, dipotassium EDTA, tripotassium EDTA, sodium citrate). The Access SARS-CoV-2 IgM 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 Access SARS-CoV-2 IgM 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, that meet requirements to perform moderate or high complexity tests.

Results are for the detection of SARS-CoV-2 antibodies. IgM 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 results to the appropriate public health authorities.

The sensitivity of the Access SARS-CoV-2 IgM assay early after infection is 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 the Access SARS-CoV-2 IgM assay 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 a second different assay.

Samples should only be tested from individuals that are 8 days to 30 days post symptom onset. SARS-CoV-2 antibody negative samples collected 8 days or more post symptom onset should be reflexed to a test that detects and reports SARS-CoV-2 IgG.

The Access SARS-CoV-2 IgM assay is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY AND EXPLANATION

Coronavirus disease-2019 (COVID-19) is caused by a novel coronavirus known as severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) which has spread worldwide in 2020 causing a global pandemic. COVID-19 is characterized by fatigue, fever, cough, shortness of breath and other respiratory symptoms.[1] The virus uses the transmembrane receptor angiotensin-converting enzyme 2 (ACE-2) to infect epithelial cells in the airways and lungs.[2] Some individuals infected with SARS-CoV-2 have no, or mild symptoms while others develop severe respiratory distress requiring mechanical ventilation.[3] Infected individuals develop an immune response to the virus in the form of anti-SARS-CoV-2 IgM and IgG antibodies over the course of days to weeks.[4] Testing for the presence of IgM/IgG antibodies to SARS-CoV-2 can help to inform clinical management of patients with recent or prior COVID-19.

Serology testing is essential for COVID-19 surveillance. Testing for antibodies to the SARS-CoV-2 virus assists with an understanding of how the disease has spread in a particular population.

METHODOLOGY

The Access SARS-CoV-2 IgM assay is a two-step immunocapture immunoassay. A prediluted patient sample is added to a reaction vessel along with paramagnetic particles coated with a mouse monoclonal anti-human IgM antibody. Human IgM present in the patient specimen is captured by the anti-human IgM antibody on the paramagnetic particles. After incubation, materials bound to the solid phase are held in a magnetic field while unbound materials are washed away. Conjugate diluent and recombinant SARS-CoV-2 protein alkaline phosphatase conjugate are added to the vessel. The recombinant SARS-CoV-2 protein contains the receptor binding domain (RBD) of the viral S1 protein.[5] The conjugate will bind to any anti-SARS-CoV-2 IgM that was captured by the paramagnetic particle solid phase in the first step. Following a second incubation and wash step, a chemiluminescent substrate is added to the vessel and light generated by the reaction of substrate and alkaline phosphatase is measured with a luminometer. By comparison of the light intensity with the cut-off value determined during calibration on the instrument, the presence or absence of anti-SARS-CoV-2 IgM is determined.

SPECIMEN

SPECIMEN STORAGE AND STABILITY

Stability				
Specimen	**Type**	**20°C to 25°C (hours)**	**2°C to 8°C (hours)**	**-20°C or colder (days)**
Serum	Serum separator tube	8	48	30
Plasma	Heparin EDTA Citrate	8	48	30

Thaw samples only once.

SPECIMEN COLLECTION AND PREPARATION

Blood Specimen

1. The role of preanalytical factors in laboratory testing has been described in a variety of published literature.[6,7] To minimize the effect of preanalytical factors observe the following recommendations for handling and processing blood samples:[6]
   A. Collect all blood samples observing routine precautions for venipuncture.
      a. Follow blood collection tube manufacturer's recommendations for centrifugation.
      b. Ensure residual fibrin and cellular matter has been removed prior to analysis.
   B. Allow serum samples to clot completely before centrifugation in a vertical position, with the collection tube closure directed upwards.
      a. Follow the tube manufacturer's recommendations for the length of serum/cells contact time before centrifuging samples. The clotting may be slower at cooler temperatures, or if the patient is on anticoagulant therapy.
2. Each laboratory should determine the acceptability of its own blood collection tubes and separation products that are in use. There may be variations in these products between manufacturers and between manufacturing lots.
3. Alternate collection types may be appropriate if the laboratory has established its own performance characteristics as defined by applicable law.
4. Avoid assaying lipemic or hemolyzed samples.

REAGENTS

CONTENTS

Access SARS-CoV-2 IgM Reagent Pack

Ref. No. C58957, 200 determinations, 2 packs, 100 tests/pack

Well	Ingredients
R1a:	Paramagnetic particles coated with mouse anti-human IgM antibody in TRIS buffer with surfactant, protein (bovine), < 0.1% sodium azide and 0.1% ProClin* 300.
R1b:	MES buffer, surfactant, protein (bovine), < 0.1% sodium azide and 0.1% ProClin 300.
R1c:	MES buffer with recombinant SARS-CoV-2 protein alkaline phosphatase conjugate, surfactant, protein (bovine) < 0.1% sodium azide and 0.1% ProClin 300.

*ProClin™ is a trademark of The Dow Chemical Company ("Dow") or an affiliated company of Dow.

WARNING AND PRECAUTIONS

- For Emergency Use Authorization (EUA) only
- **For *in vitro* diagnostic use.**
- This test has not been FDA cleared or approved; this test has been authorized by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
- This test has been authorized only for the presence of IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.
- Samples and blood-derived products may be routinely processed with minimum risk using the procedure described. However, handle these products as potentially infectious according to universal precautions and good clinical laboratory practices,[8] regardless of their origin, treatment, or prior certification. Use an appropriate disinfectant for decontamination. Store and dispose of these materials and their containers in accordance with local regulations and guidelines.
- For hazards presented by the product refer to the following sections: REACTIVE INGREDIENTS and GHS HAZARD CLASSIFICATION.

REACTIVE INGREDIENTS

⚠ CAUTION

Sodium azide preservative may form explosive compounds in metal drain lines. See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

GHS HAZARD CLASSIFICATION

SARS-CoV-2 IgM Particles (Compartment R1a) — WARNING

H317	May cause an allergic skin reaction.
H412	Harmful to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before use.
	reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SARS-CoV-2 IgM Conjugate Diluent (Compartment R1b)	WARNING	
		
	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%
SARS-CoV-2 IgM Conjugate (Compartment R1c)	WARNING	
		
	H317	May cause an allergic skin reaction.
	H412	Harmful to aquatic life with long lasting effects.
	P273	Avoid release to the environment.
	P280	Wear protective gloves, protective clothing and eye/face protection.
	P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
	P362+P364	Take off contaminated clothing and wash it before use.
		reaction mass of: 5-chloro-2-methyl-4-isothiazolin -3-one [EC# 247-500-7] and 2-methyl-4-isothiazolin-3-one [EC# 220-239-6](3:1) < 0.05%

SDS | Safety Data Sheet is available at beckmancoulter.com/techdocs

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT

1. Access SARS-CoV-2 IgM Calibrator
   Provided as one negative and one positive for SARS-CoV-2 IgM
   Ref. No. C58958
2. QC (Quality Control) materials: Access SARS-CoV-2 IgM QC
   Ref. No. C58959
3. Access Substrate

Ref. No. 81906

4. Access Wash Buffer II, Ref. No. A16792
   UniCel DxI Wash Buffer II, Ref. No. A16793

REAGENT PREPARATION

Provided ready to use.

REAGENT STORAGE AND STABILITY

Stability	
Unopened at 2°C to 10°C	Up to stated Expiration Date
After opening at 2°C to 10°C	28 days

- Store upright.
- Refrigerate at 2°C to 10°C for a minimum of two hours before use on the instrument.
- Signs of possible deterioration are a broken elastomeric layer on the pack or quality control values out of range.
- If the reagent pack is damaged (e.g., a broken elastomer), discard the pack.
- Discard reagents if any discoloration is observed.
- Do not use reagents after the expiration date indicated on the box label.

CALIBRATION

CALIBRATION INFORMATION

An active calibration point is required for all tests. For the Access SARS-CoV-2 IgM assay, a calibration is required every 28 days. See calibrator Instructions for Use (IFU) for additional calibration information. Refer to the appropriate system manuals and/or Help system for information on calibration method, configuring calibrators, calibrator test request entry, and reviewing calibration data.

QUALITY CONTROL

Please refer to Quality Control Instructions for Use.

Quality control materials simulate the characteristics of samples and are essential for monitoring the system performance of immunochemical assays. Include quality control materials in each 24-hour time period, or as required by individual laboratory procedures, because samples may be processed at any time in a “random access” format rather than a “batch” format.

Include Access SARS-CoV-2 IgM QC or other commercially available quality control materials that cover at least two levels of analyte.

More frequent use of quality controls or the use of additional controls is left to the discretion of the operator, based upon good laboratory practices or laboratory accreditation requirements and applicable laws. Follow manufacturer’s instructions for reconstituting and storing controls. Each laboratory should establish mean values and acceptable ranges to assure proper performance. Quality control results that do not fall within acceptable ranges may indicate invalid test results. Examine all test results that were generated since obtaining the last acceptable quality control test point for this analyte. Refer to the appropriate system manuals and/or Help system for information about reviewing quality control results.

TESTING PROCEDURE(S)

PROCEDURE

1. Refer to the appropriate system manuals and/or Help system for a specific description of installation, start-up, principles of operation, system performance characteristics, operating instructions, calibration procedures, operational limitations and precautions, hazards, maintenance, and troubleshooting.

   A. The system default unit of measure for sample results is S/CO.

2. Mix the contents of a new (unpunctured) reagent pack by gently inverting the pack several times before loading it on the instrument. Do not invert an open (punctured) pack.

3. Use ten (10) µL of sample for each determination, in addition to the sample container and system dead volumes, when requesting the SARS-CoV-2 IgM assay.

4. Refer to the appropriate system manuals and/or Help system for information on managing samples, configuring tests, requesting tests, and reviewing test results.

LIMITATIONS

1. Do not dilute samples as this could lead to incorrect results.

2. For assays that employ antibodies, the possibility exists for interference by heterophile antibodies in the test sample. Patients who are regularly exposed to animals, or are subjected to medical treatments that utilize immunoglobulins or immunoglobulin fragments, may produce human anti-animal antibodies, e.g. HAMA, that interfere with immunoassays. These interfering antibodies may cause erroneous results.

3. Other potential interferences could be present in the sample and may cause erroneous results in immunoassays. Some examples that are documented in literature include rheumatoid factor, endogenous alkaline phosphatase, fibrin, and proteins capable of binding to alkaline phosphatase.[9] Carefully evaluate results if the sample is suspected of having these types of interferences.

4. The Access SARS-CoV-2 IgM assay results should be interpreted in light of the total clinical presentation of the patient, including: symptoms, clinical history, data from additional tests, and other appropriate information.

5. Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection or to inform infection status.

6. It is unknown at this time if the presence of antibodies to SARS-CoV-2 confers immunity to reinfection.

7. This assay is intended for qualitative detection only. Test value itself cannot be used to determine the quantity of SARS-CoV-2 IgM antibodies.

8. The magnitude of the measured result above the threshold is not indicative of the total amount of antibody present in the sample.

9. The individual immune response following SARS-CoV-2 infection varies considerably and might give different results with assays from different manufacturers. Results of assays from different manufacturers should not be used interchangeably.

10. Negative results do not preclude acute SARS-CoV-2 infection. IgM antibodies may not be detected in the first few days of infection; the sensitivity of the Access SARS-CoV-2 IgM assay early after infection is unknown. If acute infection is suspected, direct testing for SARS-CoV-2 is necessary.

11. SARS-CoV-2 IgM antibodies may be below detectable levels in patients who have been exhibiting symptoms for less than 8 days.

12. A negative result can occur if the quantity of antibodies for the SARS-CoV-2 virus present in the specimen is below the detection limit of the assay, or if the virus has undergone minor amino acid mutation(s) in the epitope recognized by the antibody used in the test.

13. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history and local disease prevalence, in assessing the need for an alternative serology test to confirm an immune

response. 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.

14. False positive test results for IgM antibodies can occur due to cross-reactivity with pre-existing antibodies or from other possible causes.

15. This test is not to be used for screening donated blood.

Conditions of Authorization for the Laboratory

The Access SARS-CoV-2 IgM assay along with the authorized Fact Sheet for Healthcare Providers, the Authorized Fact Sheet for Patients, and authorized labeling are available on the FDA website: https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas or at http://www.beckmancoulter.com. Authorized laboratories using the Access SARS-CoV-2 IgM ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization are listed below:

1. Authorized laboratories* using your product will include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media.
2. Authorized laboratories using your product will use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the authorized instruments, authorized clinical specimen types, authorized control materials, authorized other ancillary reagents and authorized materials required to use your product are not permitted.
3. Authorized laboratories that receive your product will notify the relevant public health authorities of their intent to run your product prior to initiating testing.
4. Authorized laboratories using your product will have a process in place for reporting test results to healthcare providers and relevant public health authorities, as appropriate.
5. Authorized laboratories will collect information on the performance of your product and report to DMD/OHT7-OIR/OPEQ/CDRH (via email: CDRH-EUA-Reporting@fda.hhs.gov) and Beckman Coulter, Inc. (www.beckmancoulter.com) any suspected occurrence of false reactive or false non-reactive results and significant deviations from the established performance characteristics of your product of which they become aware.
6. All laboratory personnel using your product must be appropriately trained in automated immunoassay techniques and use appropriate laboratory and personal protective equipment when handling this kit, and use your product in accordance with the authorized labeling. All laboratory personnel using the assay must also be trained in and be familiar with the interpretation of results of the product.
7. Beckman Coulter, Inc., authorized distributors, and authorized laboratories using your product will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

   *The letter of authorization refers to, "Laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform moderate or high complexity tests" as "authorized laboratories."

RESULTS INTERPRETATION

Test results are determined automatically by the system software. Detection of analyte in the sample is determined from the measured light production by means of the stored calibration data. Results are reported as reactive or non-reactive.

Refer to the appropriate system manuals and/or Help system for complete instructions for a qualitative assay and reviewing sample results.

Result	Interpretation	Reporting Instructions
< 1.00 S/CO SARS-CoV-2 IgM	Non-Reactive	Report result as non-reactive for SARS-CoV-2 IgM antibodies
≥ 1.00 S/CO SARS-CoV-2 IgM	Reactive	Report result as reactive for SARS-CoV-2 IgM antibodies

PERFORMANCE CHARACTERISTICS

PERFORMANCE CHARACTERISTICS

POSITIVE AGREEMENT

The positive percent agreement (PPA) of the Access SARS-CoV-2 IgM assay was evaluated in 173 individual serum and plasma samples from symptomatic subjects diagnosed with SARS-CoV-2 by PCR methods from France and the United States. The results are presented in the following table, classified by days between symptom onset and the blood sample draw. The 95% confidence interval was determined by the Wilson Score method.

Days post symptom onset	Total Samples	Number Non-Reactive	Number Reactive	PPA (95% CI)
0 - 7	22	10	12	54.5% (34.7 - 73.1%)
8 - 14	36	3	33	91.7% (78.2 - 97.1%)
15 - 30	115	2	113	98.3% (93.9 - 99.5%)

The positive percent agreement of the Access SARS-CoV-2 IgM assay for all serum and plasma samples tested was 91.3% (158/173; 95% CI 86.2 - 94.7%).

NEGATIVE AGREEMENT

The negative percent agreement (NPA) of the Access SARS-CoV-2 IgM assay was evaluated in a study of 1,400 samples collected prior to December 2019* in France and the United States. This total includes 1,000 samples from blood donors in France and 200 samples each from routine clinical laboratory diagnostic samples in France and the United States. Based on this evaluation, the overall negative percent agreement of the Access SARS-CoV-2 IgM assay is 99.9% (1,398/1,400), with a 95% confidence interval of 99.5 - 100.0% determined by the Wilson Score method.

Population	Total Samples	Number Non-Reactive	Number Reactive	NPA (95% CI)
Blood Donors (France)	1,000	999	1	99.9% (99.4 - 100.0%)
Diagnostic Samples (France)	200	199	1	99.5% (97.2 - 99.9%)
Diagnostic Samples (United States)	200	200	0	100.0% (98.1 - 100.0%)
Total	1,400	1,398	2	99.9% (99.5 - 100.0%)

*It has been shown that over 90% of the adult population have antibodies to all four common circulating coronaviruses.[10,11]

LONGITUDINAL STUDY

The serological status was evaluated in a panel of 51 serum and plasma specimens collected from 14 individuals from the date of symptom onset. Of the 14 individual patients, 12 showed positive results in all blood draws for the Access SARS-CoV-2 IgM, and 2 patients showed a change in SARS-CoV-2 IgM status. The results for 3 patients are listed in the following table along with corresponding results from the Access SARS-CoV-2 IgG test.

Patient	Draw	Days post symptom onset	IgM Result (S/CO)	IgM Interpretation	IgG Result (S/CO)	IgG Interpretation
A	1	4	1.73	Reactive	0.15	Non-reactive
	2	8	17.33	Reactive	17.04	Reactive
	3	10	17.89	Reactive	40.76	Reactive
	4	12	17.09	Reactive	50.54	Reactive
	5	14	17.74	Reactive	55.93	Reactive
	6	17	18.17	Reactive	52.59	Reactive
B	1	20	0.36	Non-reactive	0.32	Non-reactive
	2	23	13.05	Reactive	53.38	Reactive
	3	26	13.53	Reactive	60.84	Reactive
C	1	13	3.67	Reactive	49.36	Reactive
	2	19	3.06	Reactive	42.86	Reactive
	3	22	1.88	Reactive	38.43	Reactive
	4	27	1.62	Reactive	34.77	Reactive
	5	33	0.83	Non-reactive	25.31	Reactive
	6	40	0.73	Non-reactive	19.83	Reactive

INTERFERING SUBSTANCES

High concentrations of endogenous serum components were assessed for interference in the Access SARS-CoV-2 IgM assay. The test protocol was based on CLSI EP07, Interference Testing in Clinical Chemistry, 3rd Edition.[12] Human serum was spiked with a patient sample containing SARS-CoV-2 IgM antibodies to achieve a positive reactivity in the Access SARS-CoV-2 IgM assay. None of the substances tested demonstrated significant interference in the Access SARS-CoV-2 IgM assay as defined by a shift is concentration greater than 20% using the test concentrations indicated in the table below.

Substance	Interferent Concentration Tested
Bilirubin (conjugated)	43 mg/dL
Bilirubin (unconjugated)	43 mg/dL
Hemoglobin	300 mg/dL
Triglycerides (intralipid)	1,771 mg/dL

CROSS REACTIVITY

Cross-reactivity of the Access SARS-CoV-2 IgM assay was evaluated by testing serum and plasma samples for each of the potentially cross-reacting conditions listed in the following table. The following table shows the cross-reactivity results.

Category	Number of Samples	Number of Reactive Samples	Number of Non-Reactive Samples
Anti-Influenza A	5	0	5
Anti-Influenza B	5	0	5
Anti-Hepatitis C Virus (HCV)	16	1	15
Anti-Hepatitis B Virus (HBV)	17	0	17
Anti-HIV	10	0	10
Anti-Nuclear Antibodies (ANA)	10	0	10
Anti-Adenovirus Positive IgG	2	0	2
Cytomegalovirus (CMV) IgM	9	0	9
Rheumatoid Factor (RF) Total	14	0	14
Rheumatoid Factor (RF) IgM	15	1	14

ADDITIONAL INFORMATION

REVISION HISTORY

Revision A

New release.

Revision B

Reagent and Quality Control use update.

Revision C

Intended Use update.

SYMBOLS KEY

Glossary of Symbols is available at beckmancoulter.com/techdocs (document number C02724).

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