SARS-CoV-2 IgG/IgM Rapid Test
Package Insert

REF L031-11711	English

A rapid test for the qualitative detection of IgM and IgG antibodies to the SARS-CoV-2 virus in serum, plasma, or venous whole blood.

For prescription use only. For in vitro diagnostic use only. For Emergency Use Authorization only.

INTENDED USE

The ACON SARS-CoV-2 IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay intended for the qualitative detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 in human serum, plasma (K2-EDTA, sodium heparin and sodium citrate) and venous whole blood (K2-EDTA, sodium heparin and sodium citrate). The ACON SARS-CoV-2 IgG/IgM Rapid Test is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection. The ACON SARS-CoV-2 IgG/IgM Rapid Test should not be used to diagnose acute SARS-CoV-2 infection. At this time, it is unknown how long antibodies persist following infection and if the presence of antibodies confers protective immunity. 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 IgM and IgG 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 should report all results to the appropriate public health authorities.

The sensitivity of the ACON SARS-CoV-2 IgG/IgM Rapid Test 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 ACON SARS-CoV-2 IgG/IgM Rapid Test 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 IgG or IgM assay.

The ACON SARS-CoV-2 IgG/IgM Rapid Test is only for use under the Food and Drug Administration's Emergency Use Authorization.

SUMMARY

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Severe Acute Respiratory Syndrome (SARS-CoV). The novel coronaviruses belong to the β genus. COVID-19 is an acute respiratory infectious disease. People are generally susceptible. Currently, the patients infected by the novel coronavirus are the main source of infection; asymptomatic infected people can also be an infectious source. Based on the current epidemiological investigation, the incubation period is 1 to 14 days, mostly 3 to 7 days. The main manifestations include fever, fatigue and dry cough. Nasal congestion, runny nose, sore throat, myalgia and diarrhea are found in a few cases.

Standard recommendations to prevent infection spread include regular hand washing, covering mouth and nose when coughing and sneezing, and socially distancing as recommended by your local jurisdictions..

PRINCIPLE

The ACON SARS-CoV-2 IgG/IgM Rapid Test is a qualitative membrane-based immunoassay for the detection of IgG and IgM antibodies to SARS-CoV-2 in human serum, plasma or whole blood collected using K2-EDTA, sodium heparin or sodium citrate anticoagulants. The membrane is pre-coated with anti-human IgM antibody on the IgM Test Line region (M) and anti-human IgG antibody on the IgG Test Line region (G). During testing, SARS-CoV-2 antibodies, if present in the specimen, will react with the SARS-CoV-2 antigen-coated particles, which have been pre-coated on the test strip. The mixture then migrates upward on the membrane by capillary action, reacting with anti-human IgM antibody on the IgM Test Line region (M) and/or with anti-human IgG antibody on the IgG Test Line region (G), forming a colored line in IgM line region (M) and/or IgG line region (G). To serve as a procedure control, a colored line should appear in the control line region indicating that proper volume of specimen has been added and membrane wicking has occurred. The presence of the control line together with the absence of the colored lines in IgM line region (M) and IgG line region (G) indicates that the specimen does not have any SARS-CoV-2 antibodies.

REAGENTS

The test cassette contains SARS-CoV-2 recombination antigens coated particles and rabbit IgG coated particles; anti-human IgM, anti-human IgG and anti-rabbit IgG are coated on the membrane.

PRECAUTIONS

- For Emergency Use Authorization only
- For Prescription Use only
- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- Do not use the test if the pouch is damaged.
- Handle all specimens as if they contain infectious agents. Observe established precautions against biological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- The used test should be discarded according to local regulations.
- Humidity and temperature can adversely affect results.
- This package insert must be read completely before performing the test. Failure to follow directions in insert may yield inaccurate test results.
- Caution: Federal Law restricts this device to sale by or on the order of a licensed practitioner.
- This test has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by laboratories certified under CLIA that meet requirements to perform high-complexity tests.
- This test has been authorized only for the presence of IgG and IgM antibodies against SARS-CoV-2, not for any other viruses or pathogens.
- The emergency use of 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 declarations is terminated or authorization is revoked sooner.

STORAGE AND STABILITY

- The kit can be stored refrigerated (2-8°C) for up to 9 months from manufacturing date.
- The test is stable until the expiration date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- DO NOT FREEZE.
- Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- The ACON SARS-CoV-2 IgG/IgM Rapid Test can be performed using serum, or plasma or whole blood specimen collected using K2-EDTA, sodium heparin or sodium citrate anticoagulants.
- Testing should be performed immediately after specimen collection. Store specimens right after collection, if not tested immediately. Serum and plasma specimens may be stored at 2-8°C for up to 3 days. For long-term storage, specimens should be kept below -20°C. Whole blood collected by venipuncture should be stored at 2-8°C if not tested immediately. The specimens must be tested within 2 days of collection. Do not freeze whole blood specimens.
- Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed more than once.
- If specimens are to be shipped, they should be packed in compliance with local regulations covering the transportation of etiologic agents.
- Anticoagulants sodium heparin, K2-EDTA and sodium citrate do not affect the test result.

MATERIALS

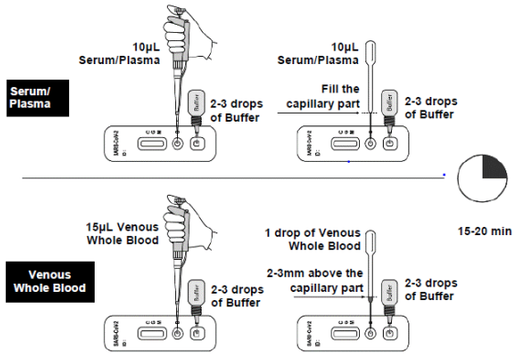
Materials Provided

- Test Cassettes (25/kit)
- Droppers (25/kit)
- Buffer (2 bottles/ 2.5mL each)
- Package insert (1)

Materials Required But Not Provided

- Pipette and disposable tips
- ACON External Positive and Negative Controls (Catalog # L021-1011)
- Timer
- Centrifuge to isolate plasma and serum

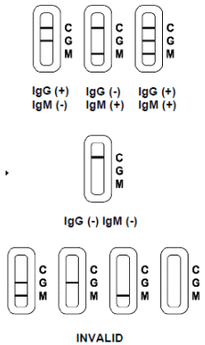
DIRECTIONS FOR USE



Allow the test, specimen and buffer to equilibrate to room temperature (15-30°C) prior to testing.

1. Remove the test from the foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed within one hour.
2. Place the test on a flat and clean surface. Transfer the specimen by a Pipette or a Dropper:
   - To use a **Pipette** for Serum, Plasma (sodium heparin, K2-EDTA and sodium citrate) or venous whole blood (sodium heparin, K2-EDTA and sodium citrate): Transfer 10 μL of Serum, Plasma, or 15 μL of venous Whole blood specimen into the Sample Well (S), then add 2~3 drops of buffer into the Buffer Well (B) and start the timer. Avoid air bubbles in the Sample and Buffer well. See illustration below.
   - To use a **Dropper** for Serum or Plasma (sodium heparin, K2-EDTA and sodium citrate): Hold the dropper vertically and fill the capillary part of the dropper (not to exceed the capillary part) with Serum or Plasma (approximately 10 μL), then carefully dispense the specimen into the Sample Well (S), immediately add 2~3 drops of buffer into the Buffer Well (B), and start the timer. Avoid air bubbles in the Sample and Buffer well. See illustration below.
   - To use a **Dropper** for venous whole blood (sodium heparin, K2-EDTA and sodium citrate):: Hold the dropper vertically, draw the specimen about 2-3mm above the capillary part and then transfer 1 full drop (approximately 15 μL) of specimen into the Sample Well (S). Immediately add 2~3 drops of buffer into the Buffer Well (B) and start the timer. Avoid air bubbles in the Sample and Buffer well. See illustration below.
3. Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS



Results	**Interpretation of results** (Please refer to the illustration above)
IgM (-) IgG (-)	**Only one colored control line appears in the control region. The result is negative for SARS-CoV-2 virus specific IgM and IgG antibodies.**
IgM (+) IgG (-)	**Colored control line appears in the control region and one colored line appears in the IgM line region (M). The result is positive for IgM antibodies and negative for IgG antibodies to SARS-CoV-2.**
IgM (+) IgG (+)	**Colored control line appears in the control region, one colored line appears in the IgG line region (G), and one colored line appears in the IgM line region (M). The color intensities of the lines do not have to match. The result is positive for IgG and IgM antibodies to SARS-CoV-2.**
IgM (-) IgG (+)	**Colored control line appears in the control region and one colored line appears in the IgG line region (G). The result is positive for IgG antibodies and negative for IgM antibodies to SARS-CoV-2.**
INVALID	**Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat testing with a new test cassette. If the problem persists, do not use the test kit and contact ACON Laboratories Inc.**

QUALITY CONTROL

Internal procedural controls are included in the test. The control line is coated with anti-rabbit IgG antibody on membrane which will bind to the pre-coated gold-conjugated rabbit IgG when an adequate volume of test specimen is applied into the sample well and adequate buffer volume is applies to the corresponding well on the test cassette. In the control region of the membrane, a colored line appears regardless of the presence of SARS-CoV-2 IgG or IgM antibodies in the specimen. This confirms sufficient specimen and buffer volume, and correct procedural technique. Absence of this line indicates an invalid result.

Positive and negative control standards are not supplied with this kit, however they should be purchased separately: ACON SARS-CoV-2 IgG/IgM Rapid Test Control Solution (Catalog # L021-1011). Please contact ACON Laboratories, Inc. for purchasing information. The positive and negative controls should be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance. Follow the test procedure provided here and in the control solution package insert. It is recommended that both controls be processed under the following circumstances:

- A new operator uses the test kits for the first time.
- A new shipment of test kits is received.
- Device storage falls out of the 2-30°C range.
- To verify a higher or lower than expected frequency of positive or negative results.
- To investigate the cause of repeated invalid results.
- A new test environment is used.

LIMITATIONS

1. This test is only to be used in CLIA certified laboratories that meet requirements to perform moderate or high complexity testing and not in point-of-care or at-home testing settings.
2. The test should be used for the detection of SARS-CoV-2 antibodies in serum, or plasma, or whole blood specimens collected with anticoagulants K2-EDTA, sodium heparin and sodium citrate. Other specimens have not been evaluated and should not be used with this assay. Do not use with fingerstick (capillary) whole blood samples.
3. The test is limited to the qualitative detection of IgM and IgG antibodies against the SARS-CoV-2 virus. The intensity of the test line does not necessarily correlate to SARS-CoV-2 antibody titer in the specimen.
4. It is unknown at this time if the presence of antibodies to SARS-CoV-2 confers immunity to re-infection
5. This test should only be used for testing samples collected 8 days after symptom onset. The performance of this test in samples collected less than 8 days after symptom onset has not been established
6. Results from antibody testing should not be used to diagnose or exclude acute SARS-CoV-2 infection or to inform infection status. An assay that directly detects the virus should be used to evaluate symptomatic patients for acute COVID-19.
7. A positive result may not indicate previous SARS-CoV-2 infection. Consider other information, including clinical history, physical findings, local disease prevalence, and other diagnostic procedures in assessing the need for a second but different serology test to confirm an immune response.
8. 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, OR if appropriate: Pedigreed specimens with direct evidence of antibodies to non-SARS-CoV-2 coronavirus (common cold) strains such as HKU1, NL63, OC43, or 229E have not been evaluated with this assay.
9. A negative result for an individual subject indicates absence of detectable anti-SARS-CoV-2 antibodies. Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. The sensitivity of this assay early after infection is unknown.
10. A negative result can occur if the quantity of the anti-SARS-CoV-2 antibodies present in the specimen is below the detection limits of the assay, or the antibodies that are detected are not present during the stage of disease in which a sample is collected.
11. Results from immunosuppressed patients should be interpreted with caution.
12. Reading test results earlier than 15 minutes or later than 20 minutes after the addition of Buffer may yield erroneous results.
13. This test should not be used for screening of donated blood.

CONDITIONS OF AUTHORIZATION FOR THE LABORATORY

The ACON SARS-CoV-2 IgG/IgM Rapid Test Letter of Authorization, along with the authorized Fact Sheet for Healthcare Providers, the authorized Fact Sheet for Recipients, 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.

Authorized laboratories using the ACON SARS-CoV-2 IgG/IgM Rapid Test ("your product" in the conditions below), must adhere to the Conditions of Authorization indicated in the Letter of Authorization as 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 will use your product as outlined in the authorized labeling. Deviations from the authorized procedures, including the 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 to you (support@aconlabs.com) any suspected occurrence of false positive or false negative 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 immunochromatographic 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. ACON Laboratories, 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."

PERFORMANCE CHARACTERISTICS

Clinical Performance

Study 1

The ACON SARS-CoV-2 IgG/IgM Rapid Test has been tested with serum collected in the U.S. during the pandemic. All patients were confirmed positive or negative with an EUA authorized RT-PCR test. A total of 127 unique serum samples were collected. Seventy-three samples were collected from RT-PCR negative individuals, and 54 from RT-PCR positive individuals. The results are summarized in the tables below:

SARS-CoV-2 IgM results from RT-PCR confirmed positive subjects

		ACON SARS-CoV-2IgG/IgM Rapid Test IgM Results		
Days from Symptom Onset	Number of Subjects Tested	IgM Positive results	IgM PPA	95% CI
0-7 days	3	3	100% (3/3)	29.2-100%
8-14 days	4	3	75% (3/4)	19.4-99.4%
≥15 days	47	38	80.9% (38/47)	66.7-90.9%
Total	54			

SARS-CoV-2 IgG results from RT-PCR confirmed positive subjects

		ACON SARS-CoV-2 IgG/IgM Rapid test IgG Results		
Days from Symptom Onset	Number of Subjects Tested	IgG Positive results	IgG PPA	95% CI
0-7 days	3	3	100% (3/3)	29.2-100%
8-14 days	4	4	100% (4/4)	39.8-100%
≥15 days	47	47	100% (47/47)	92.5-100%
Total Subjects	54			

SARS-CoV-2 IgG/IgM combined results from RT-PCR positive confirmed subjects

		ACON SARS-CoV-2 IgG/IgM Rapid test IgG/IgM combined Results		
Days from Symptom Onset	Number of Subjects Tested	IgG/IgM Combined Antibody Positive results	IgG/IgM Combined Antibody PPA	95% CI
0-7 days	3	3	100% (3/3)	29.2-100%
8-14 days	4	4	100% (4/4)	39.8-100%
≥15 days	47	47	100% (47/47)	92.5-100%
Total Subjects	54			

Overall NPA of IgG/IgM results with RT-PCR confirmed negative samples

	ACON SARS-CoV-2 IgG/IgM Rapid test Results	
Number of Subjects Tested	Overall (IgG+IgM) Negative Results	Overall NPA (95% CI)
73	70	95.89% (70/73) (95% CI: 88.5 – 99.1)

Study 2

The ACON SARS-CoV-2 Rapid Test was also tested with plasma samples collected in the U.S. before SARS-CoV-2 pandemic. A total of 368 unique plasma samples were collected from 4 sites in the U.S. before November 2019. Sodium heparin (167 samples) and sodium citrate (201 samples) were used as anticoagulants. NPA calculations were very similar in all matrices evaluated. The overall NPA performance of the test is summarized in the table below:

Overall negative percent agreement (NPA) from plasma samples collected in the US prior to COVID-19 pandemic.

	ACON SARS-CoV-2 IgG/IgM Rapid test Results (all samples combined)	
Number of Subjects Tested	Overall (IgG+IgM) Negative Results	Overall NPA (95% CI)
368	364	364/368 (98.9%); (95% CI: 97.2-99.7%)

Study 3

The ACON SARS-CoV-2 IgG/IgM Rapid Test was tested with 112 unique serum samples collected from RT-PCR positive individuals in China during the pandemic. The results are summarized in the tables below:

SARS-CoV-2 IgM results from RT-PCR confirmed positive subjects

		ACON SARS-CoV-2IgG/IgM Rapid Test IgM Results		
Days from Symptom Onset	Number of Subjects Tested	IgM Positive results	IgM PPA	95% CI
0-7 days	0	N/A	N/A	N/A
8-14 days	36	36	36/36 (100%)	90.3 - 100%
⩾15 days	76	61	61/76 (80.3%)	69.5 -88.5%
Total	112			

SARS-CoV-2 IgG results from RT-PCR confirmed positive subjects

		ACON SARS-CoV-2 IgG/IgM Rapid test IgG Results		
Days from Symptom Onset	Number of Subjects Tested	IgG Positive results	IgG PPA	95% CI
0-7 days	0	N/A	N/A	N/A
8-14 days	36	35	35/36 (97.2%)	85.5 -99.9%
≥15 days	76	75	75/76 (98.7%)	92.9 - 100%
Total Subjects	112			

SARS-CoV-2 IgG/IgM combined results from RT-PCR positive confirmed subjects

		ACON SARS-CoV-2 IgG/IgM Rapid test IgG/IgM combined Results		
Days from Symptom Onset	Number of Subjects Tested	IgG/IgM Combined Antibody Positive results	IgG/IgM Combined Antibody PPA	95% CI
0-7 days	0	N/A	N/A	N/A
8-14 days	36	36	36/36 (100%)	90.3 -100%
≥15 days	76	75	75/76 (98.7%)	92.9 – 100%
Total Subjects	112			

Study 4

The ACON SARS-CoV-2 Rapid Test was also tested with 686 unique serum (300 samples) and plasma samples (191 K2-EDTA, 155 sodium heparin, and 40 sodium citrate) collected in China before November 2019. The overall NPA performance of the test is summarized in the table below:

Overall negative percent agreement (NPA) from plasma samples collected in the China prior to COVID-19 pandemic.

	ACON SARS-CoV-2 IgG/IgM Rapid test Results (all samples combined)	
Number of Subjects Tested	Overall (IgG+IgM) Negative Results	Overall NPA (95% CI)
686	674	674/686 (98.3%); (97 - 99.1%)

Study 5: Seroconversion Study

A longitudinal study was conducted to evaluate the performance of the test in samples collected over time and detect seroconversion. In this study multiple serum samples were collected over time from 10 RT-PCR positive individuals, and the first bleed result from each subject was analyzed in each of the time bins post symptom onset as summarized in the tables below.

SARS-CoV-2 IgM longitudinal study results

		ACON SARS-CoV-2IgG/IgM Rapid Test IgM Results	
Days from Symptom Onset	Number of Subjects Tested	IgM Positive results	IgM PPA
0-7 days	10	6	60%
8-14 days	10	10	100%
≥15 days	10	10	100%

SARS-CoV-2 IgG longitudinal study results

		ACON SARS-CoV-2IgG/IgM Rapid Test IgG Results	
Days from Symptom Onset	Number of Subjects Tested	IgG Positive results	IgG PPA
0-7 days	10	4	40%
8-14 days	10	9	90%
≥15 days	10	10	100%

Independent Clinical Agreement Validation.

The SARS-CoV-2 IgG/IgM Rapid Test from ACON was tested on November 02, 2020 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). The test was validated against a panel of previously frozen samples consisting of 30 SARS-CoV-2 antibody-positive serum samples and 80 antibody-negative serum and plasma samples. Each of the 30 antibody-positive samples were confirmed with a nucleic acid amplification test (NAAT) and both IgM and IgG antibodies were confirmed to be present in all 30 samples. The presence of antibodies in the samples was confirmed by several orthogonal methods prior to testing with the ACON SARS-CoV-2 IgG/IgM Rapid Test. The presence of IgM and IgG antibodies specifically was confirmed by one or more comparator methods. Antibody-positive samples were selected at different antibody titers.

All antibody-negative samples were collected prior to 2020 and include: i) Seventy (70) samples selected without regard to clinical status, “Negatives” and ii) Ten (10) samples selected from banked serum from HIV+ patients, “HIV+”. A summary of the results of this study are shown in the tables below.

ACON SARS-CoV-2 IgG/IgM Rapid Test		**Comparator Method**			***Total***
		Positive (IgM+,IgG+)	**Negative (IgM/IgG)-**	**Negative, HIV+**	
Positive	**IgM +/ IgG+**	29	0	0	29
	IgM+, IgG-	0	1	0	1
	IgM-, IgG+	1	2	0	3
Negative	**IgM- / IgG-**	0	67	10	77
Total (n=110)		30	70	10	110

Measure	**Estimate**	**Confidence Interval**
IgM Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
IgM Specificity	98.8% (79/80)	(93.3%; 99.8%)
IgG Sensitivity	100% (30/30)	(88.7%; 100%)
IgG Specificity	97.5% (78/80)	(91.3%; 99.3%)
Combined Sensitivity	100% (30/30)	(88.7%; 100%)
Combined Specificity	96.2% (77/80)	(89.5%; 98.7%)
Combined PPV for prevalence =5.0%	58.4%	(30.9%; 80.4%)
Combined NPV for prevalence =5.0%	100%	(99.3%; 100%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

Potential Cross Reactivity

The ACON SARS-CoV-2 Rapid Test was evaluated for potential cross-reactivity testing 5 samples containing antibodies to the following underlying conditions: HIV, Hepatitis B virus, Hepatitis C virus, *Treponema pallidum*, EB virus, *Mycoplasma pneumoniae*, Varicella-zoster virus, Influenza A/B, Rhinovirus, *Haemophilus influenza*, other coronaviruses (229E, NL63, OC43, HKU1), *Chlamydia pneumonia, Legionella pneumophila*, Adenovirus, Measles virus, Cytomegalovirus, Herpes simplex virus-1/2 or Respiratory syncytial virus, Rheumatoid factor positive and ANA positive samples. No false positive results were observed.

Potential Interference

Potential interference with the ACON SARS-CoV-2 Rapid Test was evaluated by assessing the potentially interfering substances listed in the table below in SARS-CoV-2 antibody negative and IgG and IgM low positive specimens. No false results were observed with the ACON SARS-CoV-2 IgG/IgM Rapid Test at the concentrations of the potential interference substances shown in the table below.

Endogenous Interfering Substances	**Concentration**
Creatinine hydrochoride	5mg/dL
Urea	257mg/dL
Hemoglobin	9g/L
Glucose	1000mg/dL
Glynbenclomide	1mg/dL
Dopamine	0.09mg/dL
Albumin Human	6mg/dL
Bilirubin	37.5mg/dL (342μmol/L)
Uric acid	25mg/dL
Biotin	1200ng/mL
Triglyceride	1329mg/dL (15mmol/L)
Rheumatoid factor	80IU/mL
Antinuclear antibody (ANA)	Titer 1:240
Anti-mitochondrial antibody (AMA)	80U/mL
Exogenous Interfering Substances	**Concentration**
Ibuprofen	50mg/dL
Sulfamethoxazole	40mg/dL
Benzafibrate	10mg/dL
Acetylsalicylic acid	65mg/dL
Sodium Pyroracemic	2.7mg/dL
Lactate dehydrogenase	2000mg/dL
Methydopa	250U/L
Indomethacin	1.5mg/dL
Nicotinic acid	3.6mg/dL
Dextran	0.1mg/dL
Quindine hydrochloride mono hydrate	6g/dL
Probenecid	1.2mg/dL
Acetaminophen	60mg/dL
Ascorbic acid	20mg/dL
Glycerinum	30mg/dL
Oxalic acid	6.4mg/dL
Furosemide	1mg/dL
Mouse IgG	1000μg/mL

Within Laboratory Precision Study

Total 90 replicates were tested by three operators in five days using negative specimen, SARS-CoV-2 IgM positive specimen, and SARS-CoV-2 IgG positive specimen. The specimens were correctly identified >99% of the time.

BIBLIOGRAPHY

[1] P. Zhou et al. A pneumonia outbreak associated with a new coronavirus of probable bat origin, Nature, 579, 270-273.

Manufacturing site:
ACON Biotech (Hangzhou) Co., Ltd.
No.210 Zhenzhong Road, West Lake
District, Hangzhou, P.R.China, 310030

ACON **Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego, CA 92121, USA
www.aconlabs.com
Phone: 1-858-838-9502

Number: 1151216401
Effective date: 2020-12-15

SARS-CoV-2 IgG/IgM Rapid Test
Control Solution Package Insert

REF	L021-1011	English

For validating SARS-CoV-2 IgG/IgM Rapid Test.
For in vitro diagnostic use only.

INTENDED USE

The SARS-CoV-2 IgG/IgM Control Solutions are quality control reagents for use with the ACON SARS-CoV-2 IgG/IgM Rapid Test. It is intended to ensure the test performance and verify the user's ability to properly perform the test and interpret the results.

SUMMARY

The SARS-CoV-2 IgG/IgM Control Solution contains two vials - one positive control solution vial and one negative control solution vial. They are specifically formulated and manufactured to ensure performance of the test, and are used to verify the user's ability to properly perform the test and interpret the results. The SARS-CoV-2 IgG/IgM Positive Control Solution is recombinant Ab, spiked to human negative serum and will produce IgG and IgM Positive test results. The SARS-CoV-2 IgG/IgM Negative Control Solution contains human serum and will produce a Negative test result. Both positive and negative controls tested negative for antibodies against HIV, HCV, syphilis and HBsAg.

Use of Control Reagents manufactured by another source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance for ACON SARS-CoV-2 IgG/IgM Rapid Test.

WARNINGS AND PRECAUTIONS

- For Emergency Use Authorization only
- For *in vitro* diagnostic use only.
- This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by laboratories certified under CLIA, that meet requirements to perform moderate or high complexity tests.
- The emergency use of this product 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 Federal Food Drug and Cosmetic Act, 21 U.S.C. § 360bbb3(b)(1), unless the declaration is terminated or authorization is revoked sooner.
- Do not use after the expiration date.
- Mix well and let the control solution reach room temperature (15-30°C) prior to testing.
- The SARS-CoV-2 IgG/IgM Control Solution contains human and/or potentially infectious components. No known test method can offer complete assurance of the biosafety of the derivatives. Therefore, all human-sourced materials should be considered potentially infectious. It is recommended that these reagents should be handled using established good laboratory working practices.
- Handle the Control Solution and materials as if they are capable of transmitting infectious agents.
- Do not eat, drink or smoke in the area where specimens and the Control Solution are handled. Avoid any contact with bare hands, eyes or mouth during collecting and testing specimen.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection while handling the Control Solution and specimens. Wash hands thoroughly when finished.
- Handle and dispose all specimens and materials used to perform the test as if they contained infectious agents. Observe established precautions against biological hazards throughout all the procedures and follow the standard procedures for proper disposal of specimens.
- Observe Good Laboratory Practices when handling potentially infectious material. Discard all contaminated materials, specimens and reagents of human origin after proper decontamination and by following local, state and federal regulations.
- This product is not intended for use as a standard.
- The SARS-CoV-2 IgG/IgM Control Solution is only intended to be used with the ACON SARS-CoV-2 IgG/IgM Rapid Test.
- Use of Control Solution manufactured by another source may not produce the required results, and therefore, will not meet the requirements for an adequate quality assurance for ACON SARS-CoV-2 IgG/IgM Rapid Test.

STORAGE AND STABILITY

- Store the control solution at 2-8°C.
- Do not use the control solution until it is warmed to room temperature.
- Use the control solution before the expiration date showed on the control vials.
- The control solution can be used for two months after the vials are opened and stored at 2-8°C.
- Recap and store the control vials in their original container at 2-8°C after use.

MATERIALS PROVIDED

- SARS-CoV-2 IgG/IgM Positive Control Solution (1 vial/0.1mL)
- SARS-CoV-2 IgG/IgM Negative Control Solution (1 vial/0.1mL)
- Package Insert

MATERIALS REQUIRED BUT NOT PROVIDED

- SARS-CoV-2 IgG/IgM Rapid Test/Cassette
- Timer
- Buffer

DIRECTIONS FOR USE

Allow all test materials (e.g. test strip/cassette, control solution, etc.) to reach room temperature (15-30°C) prior to testing. Refer to the SARS-CoV-2 IgG/IgM Rapid Test Package Insert for detailed instructions. It is recommended that both controls be processed under the following circumstances:

- A new operator uses the test kits for the first time.
- A new shipment of test kits is received.
- Device storage falls out of the 2-30°C range.
- To verify a higher or lower than expected frequency of positive or negative results.
- To investigate the cause of repeated invalid results.
- A new test environment is used.

1. Open the control solution vial by unscrewing the cap. Mix well before testing. Hold the dropper provided in the test kit vertically and fill the capillary part of the dropper (not to exceed the capillary part) with the control (approximately 10 µL), then carefully dispense it into the Sample Well (S), immediately add 2~3 drops of buffer into the Buffer Well (B), and start the timer. Avoid air bubbles in the Sample and Buffer well.
2. Wait for the colored line(s) to appear. The result should be read at 15 minutes. Do not interpret the result after 20 minutes.

INTERPRETATION OF RESULTS

NEGATIVE: Only colored control line appears in the control region (C).
POSITIVE:* Colored control line appears in the control region (C) and colored test line(s) appears in the test line region (G) and (M).

***NOTE:** The color intensity of the IgM and IgG test line(s) may vary depending on the concentration of the SARS-CoV-2 IgM antibodies and SARS-CoV-2 IgG antibodies present in the specimen.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect operation are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test cassette. If the problem persists, do not use the test kit immediately and contact ACON Laboratories Inc.

EXPECTED RESULTS

- The SARS-CoV-2 IgG/IgM Rapid Test Control Solution will produce examples of the color response to be expected for positive and negative specimens when tested with the ACON SARS-CoV-2 IgG/IgM Rapid Test.
- The SARS-CoV-2 IgG/IgM Positive Control Solution will produce both IgG and IgM Positive test results on ACON SARS-CoV-2 IgG/IgM Rapid Test
- The SARS-CoV-2 IgG/IgM Negative Control Solution will produce both IgG and IgM Negative test result on ACON SARS-CoV-2 IgG/IgM Rapid Test.
- The failure to obtain Negative results for both IgG and IgM with the Negative Control or Positive results for both IgG and IgM with the Positive Control indicates that the test is not performed properly or that the test reagents were not functioning properly.
- If an inappropriate result is obtained for either the Negative or Positive Control, retest the control sample using a new test unit. If the problem persists, please contact ACON Laboratories Inc.

LIMITATION

1. The SARS-CoV-2 IgG/IgM Rapid Test Control Solution contains qualitative reagents, which are not to be used as quantitative calibrators. The controls should not be diluted and may be incompatible for use with other assays.
2. The SARS-CoV-2 IgG/IgM Rapid Test Control Solution must be used at room temperature 15-30°C. Performance of the assay at other temperatures may yield invalid results.

Index of Symbols

	Manufacturer		Temperature limit
LOT	Batch code	REF	Catalogue number
	Use-by date	CONTROL +	Positive Control Solution
IVD	*In vitro* diagnostic medical device	CONTROL -	Negative Control Solution

***ACON* Laboratories, Inc.**
5850 Oberlin Drive, #340
San Diego, CA 92121, USA
www.aconlabs.com Phone: 1-858-838-9502

Number:
Effective day: 2020-12-15