Integra Pharma Solutions, LLC

COVID-19 Rapid Antibody Test Kit

FDA: Emergency Use Authorization (EUA)

The United States FDA has made this test available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA is supported by the Secretary of Health and Human Services (HHS) declaration notice that circumstances exist to justify the emergency use of in-vitro diagnostics (IVDs) for the **detection** of novel SARS-CoV-2, which causes COVID-19. An IVD made available under an EUA has not undergone the same type of review as an FDA-approved or cleared IVD. FDA may issue an EUA when certain criteria are met, which includes that there are no adequate, approved, available alternatives, and based on the totality of scientific evidence available, it is reasonable to believe that this IVD may be effective in the **detection** of the virus that causes COVID-19.

The EUA for this test is in effect for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless terminated or revoked (after which the test may no longer be used).

All Products Carried by IPS and their Respective Manufacturers have submitted Applications to FDA for Approval Under EUA Pathway for Approved Medical Device

Integra Pharma Solutions, LLC, a wholly owned subsidiary of Trxade Group, Inc. carries only COVID-19 Rapid Antibody Test Kits that have submitted notice to FDA about external validation of results. All product manufacturers have submitted an application for consideration to the FDA for review and approval as an authorized EUA IVD.

Symptoms of COVID-19

Many patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness (e.g., cough, difficulty breathing). However, limited information is currently available to characterize the full spectrum of clinical illness associated with COVID-19. Based on what is known about the virus that causes COVID-19, signs and symptoms may appear any time from 2 to 14 days after exposure to the virus. Based on preliminary data, the median incubation period is approximately 5 days.

Place in Therapy

Currently, the test kit provides a qualitative overview of novel SARS-CoV-2 antibodies (IgM and IgG) that may be present in suspected patients. The test enables health systems and providers with the ability to appropriately allocate resources by triaging patients and healthcare workers into various subgroups that may be discharged, quarantined, require further testing and or consideration for initiating treatment. Of course, this remains at the discretion of the provider if not confirmed with molecular based testing.

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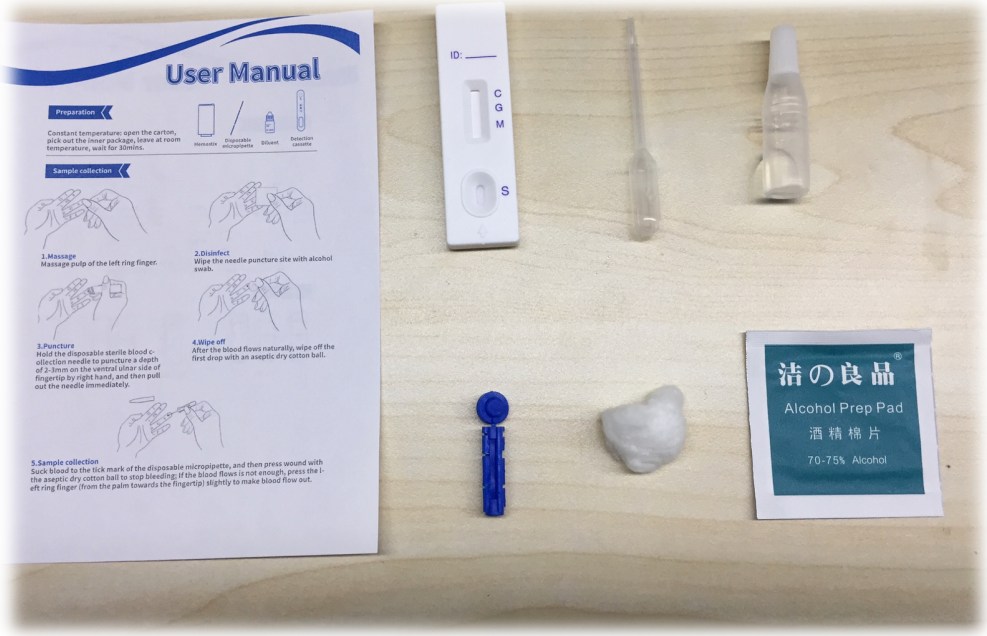
Features Regarding The COVID-19 Rapid Antibody Test:

- Rapid immunochromatography test (results in 15 min)
- Qualitative detection of antibodies (IgM and IgG) found to match those of COVID-19
- Whole blood, serum and or plasma may be used as specimen
- Not meant solely for diagnostic purposes or use at home
- Administered at the point-of-care under supervision of a qualified healthcare professional
- Negative test results do not rule out infection and follow up testing with molecular diagnosis should be considered in patients with signs and symptoms or recent exposure to the virus

Items Included within Test Kit:

- 20 test cassettes per box with each test package containing
  - Dried reagents with stabilizers
  - Gold-labeled novel coronavirus recombinant antigen
  - Mouse anti-human IgG monoclonal antibody
  - Mouse anti-human IgM monoclonal antibody
- 20 alcohol swabs and cotton balls
- 20 hemostixs (similar to lancet device)
- 20 disposable micropipettes
- 20 sample diluents individually packaged to perform 20 tests
- Package insert and FDA disclaimers



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Items Needed but Not Included with the Test:

- Personal protective equipment (PPE)
    - Mask
    - Gloves

Product Overview

The COVID-19 IgM/IgG Antibody Rapid Test is a lateral flow immunochromatographic assay intended for the qualitative detection of IgM and IgG antibodies to SARS-CoV-2 in whole blood, serum and plasma from patients with signs and symptoms of infection who are suspected of COVID-19.

The test card contains gold-labeled recombinant novel coronavirus antigen and quality control antibody gold marker with two detection lines labeled G (IgG) and M (IgM) and one control region line labeled C fixed on a nitrocellulose membrane. G is fixed with mouse anti-human IgG monoclonal antibody while M is fixed with mouse anti-human IgM monoclonal antibody for detecting novel coronavirus antibodies. The quality control antibody is fixed on the C line.

When an appropriate amount of test sample is added to the sample well of the test cassette, the sample will move forward along the test card via capillary action. If the sample contains IgM of IgG antibodies, the specific antibody will bind to the gold labeled novel coronavirus antigen. The antibody/antigen complex will be captured by the respective anti-human antibody immobilized on the nitrocellulose membrane, thus forming a red line for respective antibody and indicating a positive result of antibody within the host.

If neither antibody is present, no red lines will appear in the G and M designated sections of the test cassette. The control region (C) line should always present a red line, this ensures the integrity of the test as it indicates the sample has transported properly through the membrane. If the control region (C) line does not appear regardless of negative or positive test results, the test is considered invalid and a new test cassette should be used to retest the sample.

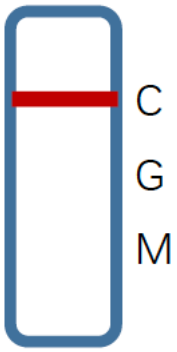
How to Administer the Test:

1. Ensure that the clinician performing the test adheres to all personal protective equipment (PPE) requirements to prevent exposure of virus
2. Do not open pouch until ready to use and verify kit expiration. Opened kits should be performed within one hour of opening or if humidity is > 60%, the test should be performed immediately. Prepare necessary materials used for collection of sample and testing such as opening pouch for sample and preparing lancet device
3. Obtain a specimen using standard laboratory protocols
    a. 2 full drops (20 microliters) for whole blood
    b. 1 full drop (10 microliters) for serum or plasma
4. Wash hands and dry thoroughly
5. Using alcohol swab to disinfect finger that will be pricked for sample collection. Ensure finger has dried before pricking to reduce pain.

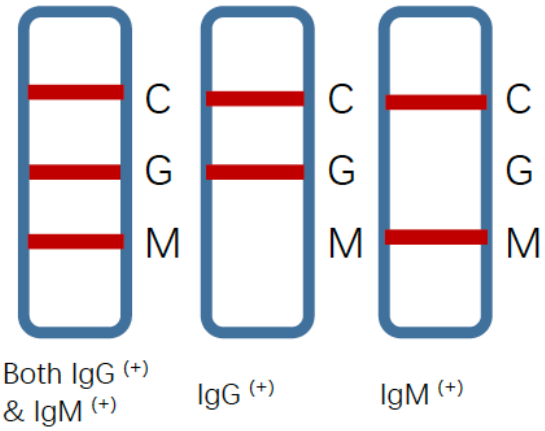
6. Position lancet device to the side of finger (less painful) and press down on injector to prick
7. Massage towards the fingertip to obtain sufficient amount of blood
8. Place 2 drops of whole blood or 1 drop of serum or plasma into the sample well of test cassette and apply dry swab to finger for blood to clot
9. Remove cap of the sample buffer solution and dispense 2-3 drops into sample well of test cassette
10. Allow test to run for 15 minutes
11. Read and interpret the by viewing testing window and appropriate line markings on test cassette
12. Test results that have run over 20 minutes and or do not display a line at the control region (C) marking are considered invalid

Interpretation of Results: A total of three detection lines are possible: [C, G (IgG), M (IgM)]

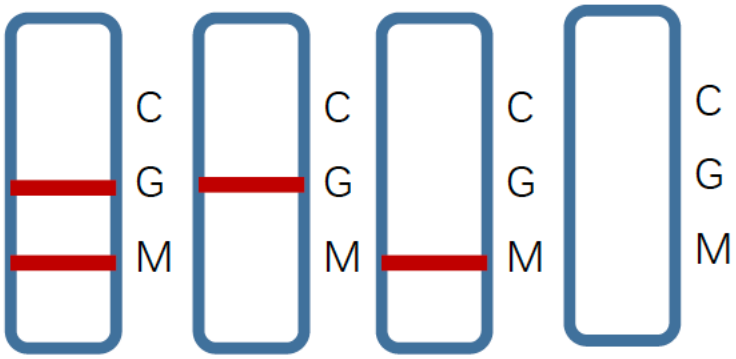
Negative Test Results:



Positive Test Results:



Invalid Test Results:



Clinical Evaluation:

To determine performance characteristics such as class sensitivity and specificity, a trial was conducted in which 370 samples were obtained. This trial is unique when compared to other trials, as it was a multi-center trial conducted across several hospitals in China. Additionally, the test had a remarkable class specificity of 100%. All samples were tested using high-complexity molecular-based laboratory testing with Real-Time Reverse Transcription Polymerase Chain Reaction (RT-RT-PCR) tests as this test method has been evaluated and approved for both qualitative and quantitative diagnostics.

From the 370 samples tested, 188 samples were positive while 182 samples were negative for SARS-CoV-2. The COVID-19 IgM/IgG Antibody Rapid Test was then performed on each patient to determine clinical performance.

Of the 188 positive samples confirmed via rt-RT-PCR, the COVID-19 IgM/IgG Antibody Rapid Test returned the following:

- IgM or IgG: 170 positive cases and 18 negative cases
- Class Sensitivity: **90.43%**

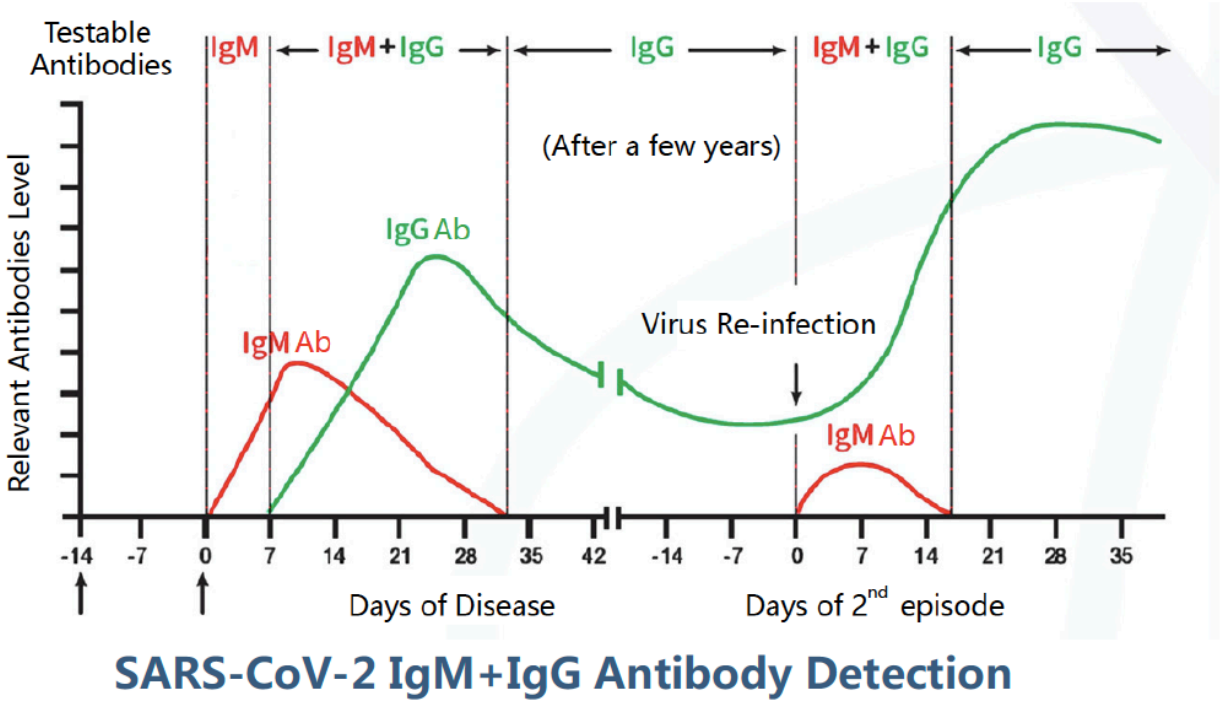
Of the 182 negative samples confirmed via rt-RT-PCR, the COVID-19 IgM/IgG Antibody Rapid Test returned the following:

- IgM or IgG: 182 negative cases and 0 positive cases
- Class Specificity: **100%**

Overall coincidence rate of **95.14%**

Clinical Interpretation:

- IgM: Antibodies appear on day 1-7 of an acute infection. Positive IgM test is indicative of an early stage of infection
- IgG: Antibodies appear mid to late stage of infection as B lymphocytes enter lymph node and transform into plasma cells, thus producing large amounts of IgG. Positive IgG test is indicative of late stage of infection
- Positive IgG and IgM is moderate or middle stage of infection



SARS-CoV-2 IgM+IgG Antibody Detection

Table 1: Sensitivity and Specificity Data from Testing Location 1

ZJU4H	Positive Test Result	Negative Test Result	Total
Sample Quantity	13	3	16
Test Positive	11	0	11
Test Negative	2	3	5
Sensitivity	84.62%		
Specificity		100%	
Overall Coincidence			87.50%

Table 2: Sensitivity and Specificity Data from Testing Location 2

Shenzhen Hospital	Positive Test Result	Negative Test Result	Total
Sample Quantity	58	24	82
Test Positive	56	0	56
Test Negative	2	24	26
Sensitivity	96.55%		
Specificity		100%	
Overall Coincidence			97.56%

Table 3: Sensitivity and Specificity Data from Testing Location 3

Wuhan Asia GH	Positive Test Result	Negative Test Result	Total
Sample Quantity	12	18	30
Test Positive	10	0	10
Test Negative	2	18	20
Sensitivity	83.33%		
Specificity		100%	
Overall Coincidence			93.33%

Table 4: Sensitivity and Specificity Data from Testing Location 4

NO 302 Hospital	Positive Test Result	Negative Test Result	Total
Sample Quantity	45	37	82
Test Positive	37	0	37
Test Negative	8	37	45
Sensitivity	82.22%		
Specificity		100%	
Overall Coincidence			90.24%

Table 5: Sensitivity and Specificity Data from Testing Location 5

Medical University	Positive Test Result	Negative Test Result	Total
Sample Quantity	60	100	160
Test Positive	56	0	56
Test Negative	4	100	104
Sensitivity	93.33%		
Specificity		100%	
Overall Coincidence			97.50%

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Table 6: Aggregate Sensitivity and Specificity Data

Aggregate Data	Positive Test Result	Negative Test Result	Total
Sample Quantity	188	182	370
Test Positive	170	0	170
Test Negative	18	182	200
Sensitivity	90.43%		
Specificity		100%	
Overall Coincidence			95.14%

Pricing and Availability:

- Please contact us for more information regarding pricing
- Our manufacturing partner has the ability to produce 750,000 units per month

Call to Order:

1-866-468-6535 or visit www.RxIntegra.com