Pinnacle BioLabs
315 Deaderick Street
15th Floor #1550
Nashville, TN 37238

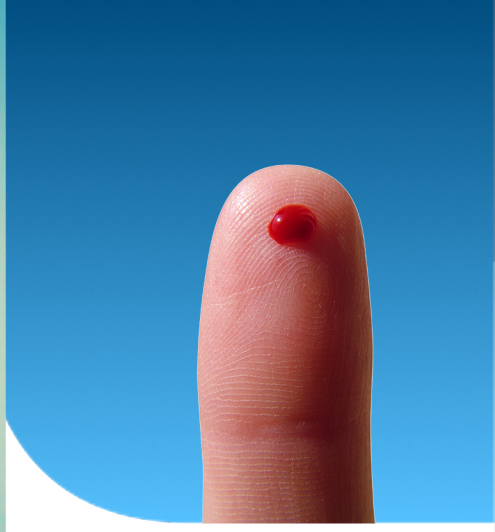
Product Specifications Master Sheet
for

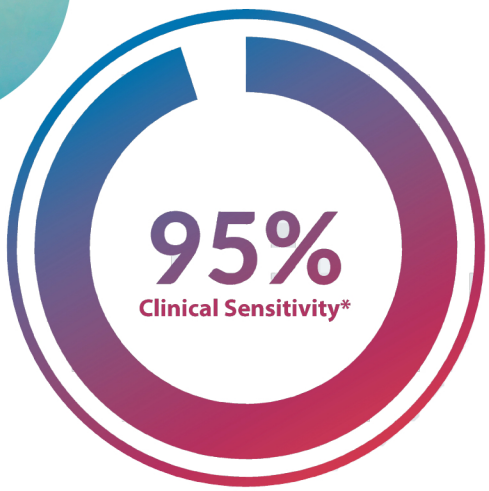
Sars-CoV-2 IgG/IgM Rapid Test

Pinnacle IVD Corporation
315 Deaderick Street
15h Floor
Nashville, TN 37238

1-800-609-6419
lab@pblabs.com

COVID NEO





*These statements have not been evaluated by the FDA.

Rapid antibody testing in 15 minutes from one drop of blood.

Providers can test for SARS-CoV-2 antibodies in a point of care setting and get results in 15 minutes, with just one drop of blood.

Results in 15 minutes from one drop of whole blood, serum, or plasma. For professional use only. This test has not been reviewed by the FDA. Negative results do not rule out SARS- CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals. 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. 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. Not for the screening of donated blood.

Pinnacle covID NEO IgG / IgM Antibody Test

This kit contains 25 complete test kits, 25 pipettes, one 5mL buffer, and one package insert with quick guide.

SKU: NEO25
UPC: 029741887695

PINNACLE BIOLABS

www.PBLabs.com

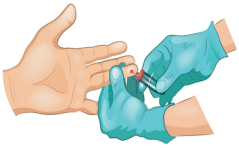
Results in 15 minutes from one drop of blood.

95% less expensive than laboratory COVID-19 testing.

10 uL of whole blood, serum, or plasma.

An effective mass-screening protocol.

COVID NEO



Collect sample

Add sample + buffer

Wait 15 minutes

Negative

Positive

Positive

COMPANY PROFILE

Pinnacle BioLabs is a privately held corporation started in 2011 as a point-of-care in vitro diagnostics manufacturer of colorectal cancer test kits, drug of abuse testing, and various other disease states via urinalysis. Pinnacle BioLabs is a US Food and Drug Administration certified manufacturer of in-vitro diagnostic test kits. US FDA registration number: 3010982075. Our National Provider Identification (NPI number) is 1497269120. Recognizing socio-economic changes, Pinnacle's OTC division received the first and only OTC clearance for a colon cancer detection test, the patented Second Generation FIT® test. Within three years of FDA clearance, Second Generation FIT® became the number one colon cancer test kit in both units sold and total revenue in North America.

PINNACLE BIOLABS

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15th Floor
Nashville, TN 372389

PHONE 1.800.609.6419

WEB www.PBlabs.com

EMAIL: COVID@PBLabs.com

Shelf life: Approximately two years.
For In Vitro Diagnostic Use Only.
This Product is shipped and sold under Emergency Use Authorization from the US FDA.

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1. Purpose for Submission

Emergency Use Authorization (EUA) is being requested by Pinnacle IVD Corporation located at 315 Deaderick Street, 15th Floor, #1550, Nashville, TN 37238, for the distribution and use of the cov-ID NEO IgG/IgM Rapid Test for the in vitro qualitative detection of IgG and IgM antibodies to the SARS-CoV-2 virus in the human whole blood specimens from patients with suspicion of or symptoms of infection with this virus. Additional testing and confirmation procedures should be performed in consultation with public health and/or other authorities to whom reporting is required. Positive results should also be reported in accordance with local, state, and federal regulations. Performance is unknown in asymptomatic patients.

2. Measurand

Specific IgG and IgM antibodies of the SARS-CoV-2.

3. Applicant

Official Name: Pinnacle IVD Corporation
Official Address: 315 Deaderick St #1550, Nashville, TN 37238
Official Website: www.PBLabs.com

4. Proprietary and Established Names

Proprietary Name - cov-ID NEO IgG/IgM Rapid Test

Established Name - Pinnacle cov-ID NEO IgG/IgM Rapid Test

5. Regulatory Information

5.1. Approval/Clearance Status

The Cov-ID NEO IgG/IgM Rapid Test is not cleared, CLIA waived, approved, or subject to an approved investigational device exemption. cov-ID NEO is manufactured, shipped and sold through an Emergency Use Authorization filing with the US Food and Drug Administration.

5.2. Product Code:

QKO sku: cov25

6. Proposed Intended Use

6.1. Intended Use

The cov-ID NEO IgG/IgM Rapid Test is a colloid-gold immunoassay test intended for a lateral flow immunoassay for the qualitative detection and differentiation of IgG and IgM of Novel Coronavirus (SARS-CoV-2) in human blood specimens.

The test identifies anti-Sar-Cov-2 IgG and IgM antibodies in human blood within days of being exposed to the infection. The IgG and IgM antibodies are generally detectable in human whole blood specimens early on during the infection and appearance of early symptoms of COVID-19. It is intended as a rapid screening test with provides results within minutes. Positive results are indicative of active infection. The test is indicated as a screening test. The positive test must be confirmed by other methods, and combined with clinical observations, patient history, and epidemiological information.

The cov-ID NEO IgG/IgM Rapid Test comes with instructions to be used rapidly with minimal training. The test uses process that is expected to be very familiar for medically trained professionals and consumers alike. The cov-ID Neo IgG/IgM Rapid Test is indicated only for use under the Food and Drug Administration’s Emergency Use Authorization at this time.

6.2. Special Conditions for Use Statements:

For prescription use only
For in vitro diagnostic use only

6.3. Special Instrument Requirements:

The cov-ID NEO IgG/IgM Rapid Test kit contains all the necessary components needed to conduct the test. The results can be visually read and interpreted, and do not require any additional equipment.

7. Device Description and Test Principle

7.1. Product Overview/Test Principle

The cov-ID NEO IgG/IgM Rapid Test is a colloid-gold immunoassay test intended for a lateral flow immunoassay for the qualitative detection of antibodies to Sars-Cov-2 virus in human whole blood specimens. The test is intended to be used on individuals with signs and symptoms of suspected COVID-19. It is a rapid screening test that provides results within minutes.

The cov-ID NEO IgG/IgM Rapid Test is a lateral flow chromatographic immunoassay. The test cassette consists of: 1) a burgundy colored conjugate pad containing recombinant SARS-CoV-2 antigen conjugated with colloid gold (SARS-CoV-2 conjugated) and quality control antibody gold conjugates, 2) a nitrocellulose membrane strip containing two test bands (IgG and IgM bands) and a control band (C band). The IgG band is pre-coated with monoclonal anti-human IgG for the detection of IgG anti-SARS-CoV-2, IgM band is pre-coated with reagents for the detection of IgM anti-SARS-CoV-2 and the C band is pre-coated with quality control antibody.

When an adequate volume of test specimen is dispensed into the sample well of the cassette, the specimen migrates by capillary action across the cassette.

SARS-CoV-2 IgM antibodies if present in the specimen will bind to the SARS-CoV-2conjugates. The immunocomplex is then captured on the membrane by the pre-coated anti-human IgM antibody, forming a burgundy colored IgM band, indicating SARS-CoV-2 IgM positive test result.

SARS-CoV-2 IgG antibodies if present in the specimen will bind to the SARS-CoV-2 conjugates. The immunocomplex is then captured by the pre-coated reagents on the membrane, forming a burgundy colored IgG band, indicating a SARS-CoV-2 IgG positive test result.

7.2. Description of Test Steps

The steps for using the cov-ID NEO IgG/IgM Rapid Test are described below:

Step 1: Storage and Stability

The kit should be stored at 2~30°C in cool and dry place, protected from light.

Step 2: Open the Test Kit and Prepare for the Test

After opening the aluminum foil pouch, the test card will become invalid due to moisture absorption. Therefore, it is important that the test is performed and resulted within one hour of opening the individually wrapped foil cassette. Do not use after expiration date indicated on the package. Do not use the test if its foil pouch is damaged. Do not reuse test.

Step 3: Disinfect

Wash the hand with soap and water; alcohol wipe can also be used to disinfect the hands before sample collection. Choose the non-dominant hand and face it palm side up and gently massage the finger to be pricked as shown in as shown in Figure 71.

Figure 71. Massage fingertip

Step 4: Puncture Skin

Remove the cap from the finger-stick device and use the disposable finger-stick device to stick the ring finger as shown in Figure 72.

Figure 72. Finger Stick Device

Step 5: Remove Excess Blood

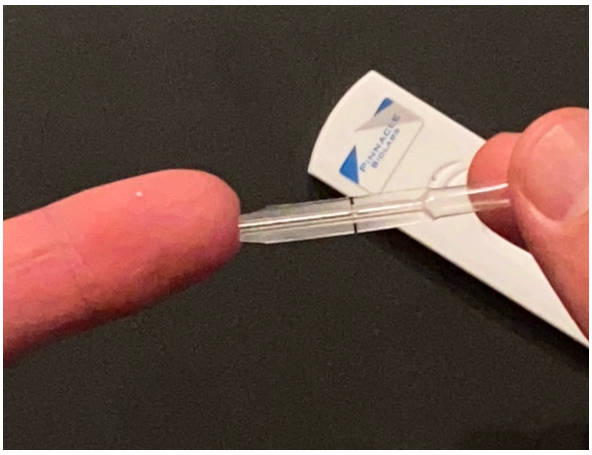
It is recommended to wipe off the first droplet of blood with the provided gauze pad shown in Figure 73.

Figure 73. First droplet of blood removal with gauze pad

Step 6: Pipette Blood

Fill the pipette dropper with the blood specimen as shown in Figure 74.

Figure 74. Pipetting of blood



Step 7: Add Blood Drops to the Test Strip

Holding the dropper vertically, dispense 1 drop (about 10 µL) of whole blood into the sample well, making sure that there are no air bubbles as shown in Figure 75.

Figure 75. Blood drops added to test strip

Step 8: Add Diluent

Add 2 drops (about 70-100 µL) of Sample Diluent immediately as shown in Figure 76.

Figure 76. Diluent added to test strip

Step 9: Read Results

Set up timer for 15 minutes. Read and record results at the 14-1minute mark. It is important not to read results after 15 minutes as described in Section 8.

7.3. Control Material(s) to be used with cov-ID NEO IgG/IgM Rapid Test

The quality control is embedded in the test strip. The test card contains a quality control band C, which is visible as a blue band when removed from the individually foil wrapped casette. Regardless of the presence or absence of a detection band, the blue band should turn red. The quality control band is a color band of the quality control antibody immune complex. If the quality control band C does not appear red after test performance, the test result is invalid, and the sample needs to be tested again with another test card.

8. Interpretation of Results

8.1. Examination and Interpretation of Patient Specimen Results:

The results for the "Cov-ID NEO IgG/IgM Rapid Test" can be read as follows:

Figure 81. IgM/IgG positive

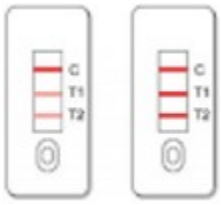


Figure 82. IgG positive/ IgM negative

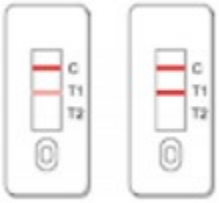


Figure 83. IgM positive, IgG Negative

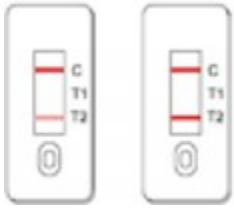
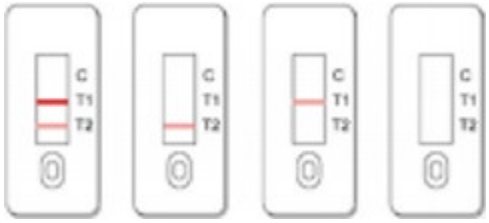


Figure 84. Negative

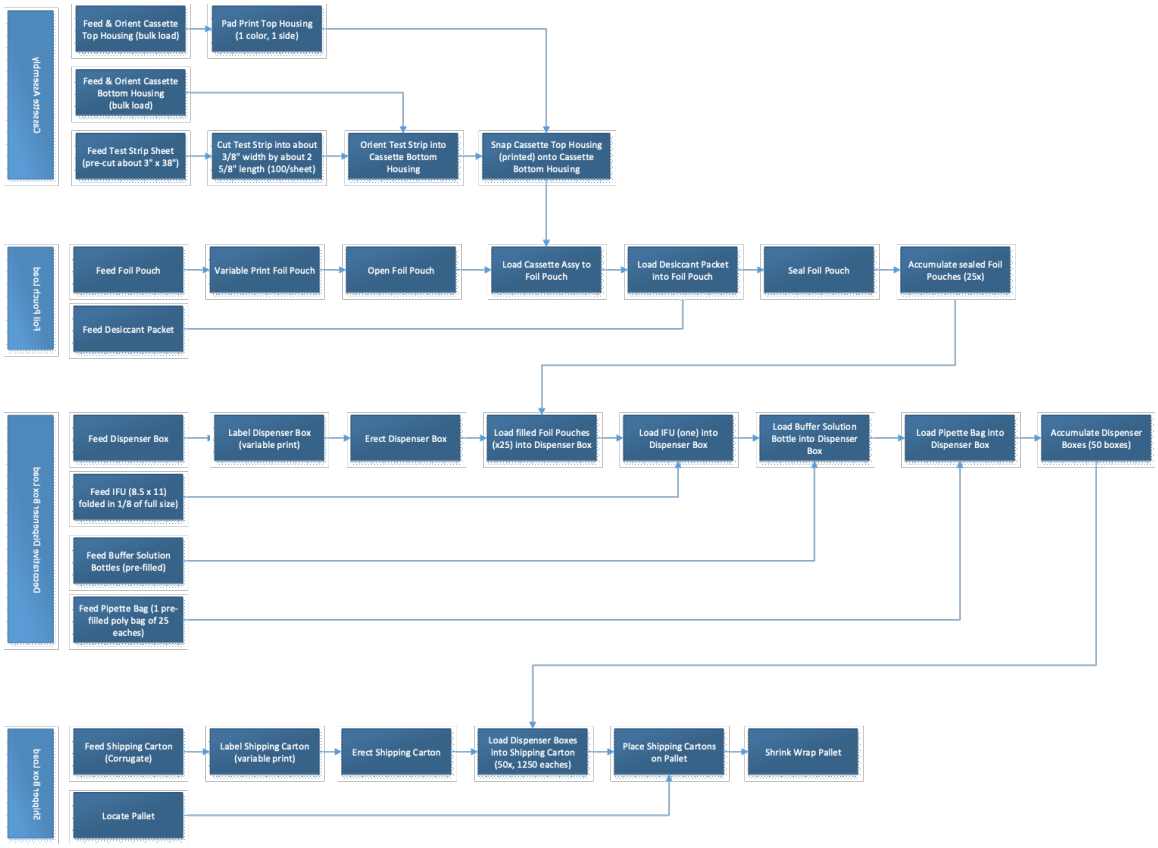
Figure 85. Invalid Cases



9. Product Manufacturing

The product is manufactured by Pinnacle IVD Corporation. The **c**ov-ID NEO IgG/IgM Rapid Test has been validated using only the components referenced in this submission and shall not be changed without prior concurrence from the FDA.

9.1 Overview of Manufacturing



Each test kit box is supplied with sufficient components for 25 tests. Up to 25 different samples can be tested using one text box, or fewer samples can be tested more than 1 times. The product will be distributed by Feltwell Holding, S.A.

9.2 Components Included with the Test

Components supplied with the test kit box include:

- 25 Individually wrapped test cassette device(s)
- Precision 10 uL Disposable pipettes (25)
- 5 mL buffer
- Instructions for Use
- Results Interpretation Quick Guide.

9.3 Components Required but Not Included with the Test

Components required but not included with the test: Timer

9.4 Testing Capabilities

Total time of 15-20 minutes is required to complete each test.

9.5 Reagent Stability

Stability testing of in vitro diagnostic reagents are described in detail in Appendix 13.2

10. Performance Evaluation

The clinical trial test implementation and result statistics are detailed in Appendix 13.1. A total of 61 positive and 105 negative serum or venous whole blood samples were collected at 4 different study sites, including Tianjin Centers for Disease Control and Prevention, The Eighth Hospital Of Xi'an. Tianjin Second People' Hospital, and Teda International Cardiovascular Hospital at Shenzhen Blood Center.These samples were tested with both RT-PCR method for SARS-CoV-2 infection and Pinnacle cov-ID NEO IgG/IgM Rapid Test for antibodies. The obtained sensitivity and specificity results are summarized in following tables.

Table 1. IgG PPA for the Pinnacle cov-ID NEO IgG/IgM Rapid Test

Site	Days post symptom onset	# PCR Positive at any time	Pinnacle cov-ID NEO IgG/IgM Rapid Test		
			#Positive Results	PPA	95%CI
(Site 1+3+4) Serum	≤7	8	7	87.5%	52.9%-97.8%
	8-14	15	13	86.7%	62.1%-96.3%
	≥15	25	25	100%	86.7%-100%
(Site 2) Venous Whole Blood	≤7	1	1	100%	20.7%-100%
	8-14	3	3	100%	43.9%-100%
	≥15	9	9	100%	70.1%-100%
Combined Sites (Serum + Blood)	-	61	58	95.1%	86.5%-98.3%

Table 2. IgG NPA for the Pinnacle cov-ID NEO IgG/IgM Rapid Test

Site	# PCR Negative	Pinnacle cov-ID NEO IgG/IgM Rapid Test		
		#Negative Results	NPA	95%CI
(Site 1+3+4) Serum	96	96	100%	96.2%-100%
(Site 2) Venous Whole Blood	9	9	100%	70.1%-100%
Combined Sites (Serum + Blood)	105	105	100%	96.5%-100%

Table 3. IgM PPA for the Pinnacle cov-ID NEO IgG/IgM Rapid Test

Site	Days post symptom onset	# PCR Positive at any time	Pinnacle cov-ID NEO IgG/IgM Rapid Test		
			#Positive Results	PPA	95%CI
(Site 1+3+4) Serum	≤7	8	8	100%	67.6%-100%
	8-14	15	13	86.7%	62.1%-96.3%
	≥15	25	21	84%	65.3%-93.6%
(Site 2) Venous Whole Blood	≤7	1	1	100%	20.7%-100%
	8-14	3	3	100%	43.9%-100%
	≥15	9	9	100%	70.1%-100%
Combined Sites (Serum + Blood)	-	61	55	90.2%	80.2%-95.4%

Table 4. IgM NPA for the Pinnacle cov-ID NEO IgG/IgM Rapid Test

Site	# PCR Negative	Pinnacle cov-ID NEO IgG/IgM Rapid Test		
		#Negative Results	NPA	95%CI
(Site 1+3+4) Serum	96	94	97.9%	92.7%-99.4%
(Site 2) Venous Whole Blood	9	9	100%	70.1%-100%
Combined Sites (Serum + Blood)	105	103	98.1%	93.3%-99.5%

11. Package Label:

The label for the package is provided in Figure 111.

Figure 111. Package Label

12. **Record Keeping** and Reporting Information to FDA:

Pinnacle IVD Corporation will track adverse events and report to FDA under 21 CFR Part 803. A website will be available to report on adverse events, and this website will be referenced in the Fact Sheet for Health Care providers as well as through the "COVID-19 (Sars-Cov-2) IgM/IgG test" Product Support website: https://pblabs.com/. Each report of an adverse event will be processed according to Pinnacle IVD Corporation Non-Conformance Reporting Requirements, and Medical Device Reports will be filed with the FDA as required. Through a process of inventory control, Pinnacle IVD Corporation will also maintain records of device usage/purchase. Pinnacle IVD Corporation will collect information on the performance of the test, and report to FDA any suspected occurrence of false positive or false negative results of which Pinnacle IVD Corporation becomes aware. Pinnacle IVD Corporation will maintain records associated with this EUA and ensure these records are maintained until notified by FDA. Such records will be made available to FDA for inspection upon request.

13. APPENDIX

13.1. Test Implementation and Result Statistics

13.1.1. Statistics of test results

For the assay verification 166 clinical specimen from Novel Coronavirus infected patients, include 61 cases of blood specimen from confirmed Positive Novel Coronavirus infected patients and 105 cases from confirmed negative Novel Coronavirus infected patients by an independent laboratory at Tianjin Centers for Disease Control and Prevention.The Eighth Hospital Of Xi'an. Tianjin Second People' Hospital. Teda International Cardiovascular Hospital and the Shenzhen Blood Center. Capillary specimens, while included in the assay verification, were excluded from the data set (attached) as we are not making a capillary blood claim at this time.

13.1.2. Statistics of Positive Specimen

Since IgM is released first followed by IgG a few days later in the course of an infection, the detection of IgM and IgG can indicate the stage of infection in an individual. The positive diagnosis based on sampling time were classified as Table 1 and 3 shows.

Table 131. Positive Diagnosis Based on Sampling Time

The 61 positive specimens were further classified according to the time when the specimens were taken. Samples were divided into samples taken less than 7 days after the positive diagnosis, samples taken 8-15 days after the positive diagnosis, and samples taken more than 15 days after the positive diagnosis (Table 1-4). PPA of IgG was 87.5%, 86.7% and 100% respectively for IGG and 100%, 86.7% and 87.5% for IgM. Combined PPA across all days post infection and specimen types was 100%.

Figure 131. Classification Statistics of Positive Test Results

13.1.3. Classification and analysis of positive specimen from clinical positive confirmed to sampling date

A total of 61 specimens were tested from 7-+15 days, the IgM positive rate was 90.2% and the IgG positive rate was 95.1%. A total of 14 specimens were tested from 4 to 7 days, the IgM positive rate was 85.7% and the IgG positive rate was 92.8%. A total of 10 specimens were tested in the range of more than 8 days, the IgM positive rate was 95% and the IgG positive rate was 90.1%. Overall PPA with both IgG and IgM considered was 100%.

	IgM		IgG	
Number of Specimens	**Positive**	**Negative**	**Positive**	**Negative**
61	58	3	55	6

13.1.4. Statistical analysis of confirmed negative specimens

105 cases of confirmed negative specimens were tested from serum collected prior to December 2019, when the first known cases of novel Coronavirus presented and the negative coincidence rate was 100%. Statistics are shown in Table 2 and 4.

Table 133. Confirmed Negative Cases

	IgM		IgG	
Number of Specimens	**Positive**	**Negative**	**Positive**	**Negative**
105	0	105	0	105

13.2. Stability testing of in vitro diagnostic reagents

13.2.1. Unsealing Stability study

Before starting the unsealing stability study, the design scheme of shelf life stability study of Cov-ID NEO IgG/IgM Rapid Test needed to be followed according to the requirements of EN13640:2002. The specific design scheme is shown in Table 134:

Table 134. Unsealing stability study plan

Responsibilities	R & D department is responsible for the implementation of the plan
Presumed storage condition	-4 °C, 2 °C, 30 °C, 40 °C -20-16 °C, -4-0 °C, 2-8 °C, 20-30 °C, 36-40 °C (humidity are all below 30%) and humidity 10-30%, 40-60%, 70-90% (The temperature is in the range of 20 °C)
Objective and purpose of testing	Study the stability of unsealed product
Information about the samples	20200203, 20200205, 20200208 three lots
Storage conditions recommended for the samples	Store at 2-8°C
Simulation of transport as appropriate	Unsealing stability does not consider the transportation process
Intervals between examination	Every 30 minutes, select 5 cassette d to restore the room temperature
Examinations to be performed at the end of each interval	Collect serum,plasma and whole blood from positive Novel Coronavirus infection patient
Stability criteria to be met	Collect serum,plasma and whole blood from negative Novel Coronavirus infection patien
Interpretation of data	Statistical analysis of the data

The results of the unsealing stability study are shown in Table 135.

Table 135. Unsealing stability study results

	Temperature as below Humility ＜30%				Temperature 20℃ Humility as below		
Time (hrs)	**-4℃**	**2℃**	**30℃**	**40℃**	**10-30%**	**40-60%**	**70-90%**
Onset	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●
0.5	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●
1	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●
1.5	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●
2.0	+ ●	+ ●	+ ●	+ ●	+ ●	+ ●	- ●
2.5	+ ●	+ ●	+ ●	+ ●	+ ●	- ●	- ○
3.0	+ ●	+ ●	+ ●	+ ●	+ ●	- ○	- ○
3.5	+ ●	+ ●	+ ●	+ ●	+ ●	- ○	- ○
4.0	+ ●	+ ●	+ ●	+ ●	+ ●	- ○	- ○
4.5	+ ●	+ ●	+ ●	+ ●	+ ●	- ○	- ○
5.0	+ ●	+ ●	+ ●	+ ●	+ ●	- ○	- ○
5.5	+ ●	+ ●	+ ●	- ●	+ ●	- ○	- ○

6.0	- ●	+ ●	+ ●	- ●	+ ●	- ○	- ○
6.5	- ●	+ ●	+ ●	- ○	+ ●	- ○	- ○
7.0	- ○	+ ●	+ ●	- ○	+ ●	- ○	- ○
7.5	- ○	- ●	- ●	- ○	- ●	- ○	- ○
8.0	- ○	- ○	- ○	- ○	- ○	- ○	- ○

Note: "+" indicates the sensitivity test is qualified, and "-" indicates the sensitivity test is unqualified.
"●" indicates the negative test is qualified, and "○" indicates the negative test is unqualified.

According to the analysis of the test results, the unsealed test cassette was very sensitive to humidity and slightly less sensitive to temperature. The best storage temperature for the unsealed test cassette was 2-30°C, and the environmental humidity is preferably not more than 40%, the best is less than 30%. Under this condition, the unsealed test cassette can be stored for at least 7 hours. Excessive humidity and high or low temperature will make the test cassette lose efficacy rapidly. In actual use, the test cassette should be used as soon as possible after sealing to prevent failure.

The extraction buffer in this kit is mainly composed of phosphate buffered saline and preservative, which is not sensitive to temperature or humidity. In the actual use process, the extraction solution shall be used as soon as possible after unsealing.

13.2.2. Accelerated Stability Study

Before starting the stability study, the design scheme of the accelerated stability study of Cov-ID NEO IgG/IgM Rapid Test needed to be followed according to the requirements of EN ISO 23640: 2015. The specific design scheme is shown in Table 136.

Table 136. Accelerated Stability Study Plan

Responsibilities	R & D department is responsible for the implementation of the plan
Presumed storage conditions	30°C，34°C，37°C，40°C，45°C
Accelerating contrast reagent	HP antibody detection kit Registration certificate: 20163402241

Objective and purpose of testing	Study of Shelf life and stability during transportation
Information about the samples	20200285, 20200286, 20200287 three lots
Storage conditions recommended for the samples	Stored at 2-8°C
Simulation of transport as appropriate	Analyze the stability of the product during transportation according to the transportation conditions
Intervals between examinations	Take out the kits from storage for testing each day
Examinations to be performed at the end of each interval	Collect serum,plasma and whole blood from positive Novel Coronavirus infection patient
Stability criteria to be met	Collect serum,plasma and whole blood from negative Novel Coronavirus infection patient
Interpretation of data	Statistical analysis of the data

The results of the accelerated stability study are detailed in table

Table 137. Accelerated Stability Study Results

	cov-ID NEO IgG/IgM Rapid Test kit					**HP antibody detection kit**				
Time (Days)	**Temperature °C**									
	30	**34**	**37**	**40**	**45**	**30**	**34**	**37**	**40**	**45**
Start	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
1	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
2	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
3	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
4	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
5	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○

6	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
7	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
8	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
9	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
10	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
11	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
12	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
13	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
14	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
15	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
16	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
17	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
18	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
19	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
20	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
21	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
22	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
23	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
24	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
25	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
26	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
27	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○
28	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	+ ○	- ○
29	+ ○	+ ○	+ ○	+ ○	- ○	+ ○	+ ○	+ ○	+ ○	- ○
30	+ ○	+ ○	+ ○	+ ○	- ○	+ ○	+ ○	+ ○	+ ○	- ○

Note: "+" indicates the sensitivity test is qualified, and "-" indicates the sensitivity test is unqualified.
“○” indicates the specificity test is qualified.

A comparison of the accelerated stability results of Cov-ID NEO IgG/IgM Rapid Test and HP antibody detection kit shows that the Cov-ID NEO IgG/IgM Rapid Test product stability reached the level of HP antibody detection kit stability. HP antibody detection kit has a shelf life of up to 24 months from the shelf life stability Test, so a shelf life of 24 months for Cov-ID NEO IgG/IgM Rapid Test is appropriate.

13.2.3. Transportation Stability Analysis

Pinnacle IVD Corporation, through the WERKSMART platform, had the Sodium Azide PBS buffer solution independently studied by Underwriter Laboratories for Transportation stability. WERKSMART issues a Pass/Fail grading system and the cov-ID NEO PBS was issued a PASS certificate on file with Underwriter Laboratories (UL Listed).

13.2.3.1. Method of Transportation

Products are transported by cars and trains for short distance, transported by sea and air for long distance.

13.2.3.2. Lighting Effect

The product is sealed and packaged during transportation. The inner material is aluminum foil pouch; light will not affect the product.

13.2.3.3. Humidity Effect

Each component in the kit is sealed and is not sensitive to humidity during transportation, that is, the humidity will not affect the validity of the kit during transportation. Based on the above analysis, the main factors such as light, humidity, and temperature which will affect product performance during the entire transportation process, are under control and will not affect the product performance.

13.2.4. HP Antibody Detection Kit Stability Experimental Data

The stability results for the HP antibody detection kit are described in table.

Table 138. HP antibody detection kit stability results

Time (weeks)	**Temperature (°C)**			
	-4	**2**	**30**	**40**
Start	+○	+○	+○	+○
1	+○	+○	+○	+○
2	+○	+○	+○	+○
3	+○	+○	+○	+○
4	+○	+○	+○	+○
8	+○	+○	+○	+○
12	+○	+○	+○	+○
16	+○	+○	+○	+○
20	+○	+○	+○	+○
24	+○	+○	+○	+○
28	+○	+○	+○	+○
32	+○	+○	+○	+○
36	−○	+○	+○	+○
40	−○	+○	+○	−○
44	−○	+○	+○	−○
48	−○	+○	+○	−○
52	−○	+○	+○	−○
56	−○	+○	+○	−○
60	−○	+○	+○	−○
64	−○	+○	+○	−○
68	−○	+○	+○	−○
72	−○	+○	+○	−○
76	−○	+○	+○	−○

Time (weeks)	Temperature (°C)			
	-4	**2**	**30**	**40**
80	−○	+○	+○	−○
84	−○	+○	+○	−○
88	−○	+○	+○	−○
92	−○	+○	+○	−○
96	−○	+○	+○	−○
100	−○	+○	+○	−○
104	−○	+○	+○	−○
108	−○	+○	+○	−○
114	−○	+○	+○	- ○

Note: "+" indicates the sensitivity test is qualified, and "-" indicates the sensitivity test is unqualified.
“○” indicates the specificity test is qualified.

According to the analysis of the test results, under the freezing condition, the effectiveness of the kit decreases rapidly, and the high temperature will also have a certain impact on the effectiveness of the kit. The best storage temperature is 2-30 °C, and the validity of the kit can be set as 24 months. Compared to the storage condition of 2-30 ° C, the storage temperature of -4 ° C will accelerate product aging time by 82 weeks, When stored at a temperature of 40° C product aging is accelerated by 78 weeks .The temperature has a great effect on the aging of the product. When stored at 2-30 °C, the quality of the product is stable for 24 months.

14. Cross Reactivity

An initial cross-reactivity study was performed on VER 1 of the Assay by the State of Delaware Public Health Laboratory. Assay performance yielded no cross-reactivity with HIV, ANA, RSV, or certain influenza specimens (Attached) An additional cross reactivity study was performed, which yielded no cross reactivity from specimens banked at the Shenzen Hospital.

Cross Reactivity

There was no cross-reactivity with plasma specimens meeting the disease state shown below. No IgM or IgG false positive results were observed with the following potential cross-reactants:

Table 7. Cross-reactivity Study Data of Pinnacle cov-ID NEO IgG/IgM Rapid Test

Conditions	Number of samples	Conditions	Number of samples
Anti-HAV IgM +	5	Lyme disease+	5
Anti-HEV IgG +	2	P. falciparum +	5
HBsAg +	5	P. vivax +	5
Anti-HCV +	5	Toxoplasma IgM +	5
Anti-HIV +	5	HAMA +	1
Anti-Rubella IgM +	5	RF +	5
Anti-CMV IgM +	5	ANA+	5
Anti-HSV-I IgM +	5	Anti-Influenza A IgM +	3
Anti-HSV-II IgM +	5	Anti-Influenza B IgM +	1
EBV IgM +	4	Anti-RSV IgM +	3
Anti-Dengue IgM +	5	Legionella pneumophila IgM+	2
Anti-Yellow fever +	5	Anti-Adenovirus IgM +	1
Anti-Zika IgG +	5	Anti-Mycoplasma pneumonia IgM +	3
Chagas Ab+	5	Anti-Chlamydia pneumonia IgM +	3
Anti-Syphilis IgG +	4	Anti-Chlamydia pneumonia IgG +	2
Anti-Tuberculosis +	5	Measles IgG +	1
Typhoid IgM +	5	Mumps IgG +	1

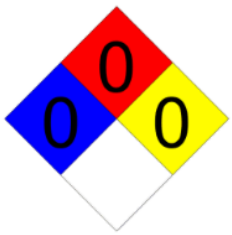
Safety Data Sheet

SECTION 1 - PRODUCT IDENTIFICATION

Trade Name: cov-ID NEO IgG/IgM Rapid Test
Part number: cov25

Manufactured by: Pinnacle IVD Corporation
Street Address: 315 Deaderick Street, 15th Floor
City, State, Zip, Country: Nashville, TN 37208 USA
Telephone Number: 1-800-609-6419
Fax Number: 1-800-609-9321
email: lab@PBLabs.com

SECTION 2 — HAZARDS IDENTIFICATION

Primary Routes of Exposure	Ingestion, skin and/or eye contact.
Inhalation	Inhalation of mists or sprays of these components may irritate the nose, throat and lungs. Symptoms are generally alleviated upon breathing fresh air.
Ingestion	Ingestion of this product, especially in large quantities, may cause nausea or vomiting.
Skin Contact	This product is not considered hazardous according to OSHA Hazcom 2012.
Eye Contact	This product is not considered hazardous according to OSHA Hazcom 2012.
Chronic Exposure	None known
Medical Conditions aggravated by exposure	None known
Additional Information	NFPA Rating: 

SECTION 3 — COMPOSITION / INFO ON HAZARDOUS INGREDIENTS

CHEMICAL NAME	CAS #	%W/V	OSHA PEL	OSHA STEL	ACGIH TLV	ACGIH STEL
No hazardous components > 1%, ≥ 0.1% carcinogen	NONE	N/A	N/A	N/A	N/A	N/A

SECTION 4 — FIRST AID MEASURES

Inhalation	If breathing becomes difficult, remove victim to fresh air. Seek medical attention.
Skin Contact	Rinse with plenty of water. If skin irritation persists, seek medical attention.
Ingestion	Seek medical attention. Do not induce vomiting without medical advice.
Eye Contact	Immediately flush with plenty of water and seek medical attention.
Notes to Physician	None determined

SECTION 5 — FIRE FIGHTING MEASURES

Suitable Extinguishing Media	Use fire extinguishing media appropriate for site conditions.
Special Hazards from the Substance	None known
Advice for Firefighters	Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6 — ACCIDENTAL RELEASE MEASURES

Personal Precautions	Use personal protective equipment.
Environmental Precautions	Prevent further leakage or spillage if safe to do so. Prevent product from entering sanitary drains.
Methods for Clean Up	Never return spills to original containers for re-use. Wear lab coat or apron, chemical safety goggles and disposable gloves. This product should be handled as potentially biohazardous. Take up with absorbent material and place in a biohazard container. Wipe up area with damp paper towel and discard into biohazard container. Disinfect spill areas with a 10% bleach solution.

SECTION 7 — HANDLING AND STORAGE

Handling	Protect from contamination. Wear personal protective equipment.
Storage	Store Bottles as directed in package insert or product labeling.

SECTION 8 — EXPOSURE CONTROL / PERSONAL PROTECTION

Respiratory Protection	Respiratory protection is not required under normal use of this product.
Hand Protection	Wear appropriate protective gloves to prevent skin contact.
Skin and Body Protection	Wear appropriate body protection to prevent skin contact.
Eye Protection	Wear appropriate eye protection to prevent eye contact.
Hygiene Measures	Avoid contact with eyes, skin and clothing.

SECTION 9 — PHYSICAL AND CHEMICAL PROPERTIES

Physical State	Liquid
Appearance	Yellow – Green colored
Odor	Odorless
pH	8.5 +/- 0.1

SECTION 10 — STABILITY AND REACTIVITY

Stability	Stable under recommended storage conditions.
Polymerization	N/A
Hazardous Decomposition Products	Thermal decomposition may emit carbon oxides.
Conditions to Avoid	Excess heat, flame or pressure.

SECTION 11 — TOXICOLOGICAL INFORMATION

Presently no toxicological data available for this kit or its components.

SECTION 12 — ECOLOGICAL INFORMATION

Bioaccumulation	Not determined
Aquatic Toxicity	No data is available on the product itself.
Ecotoxicity Effects	No data is available on the product itself.

SECTION 13 — DISPOSAL CONSIDERATIONS

Dispose according to local, state, and national regulations.

SECTION 14 — TRANSPORT INFORMATION

This product is not hazardous to ship.

SECTION 15 — REGULATORY INFORMATION

This product and its contents are not classified as dangerous under any regulations.
No Chemical Safety Assessment has been carried out on the components of this product.

SECTION 16 - OTHER INFORMATION

The information, data and recommendations contained on the following SDS are based on information believed by Pinnacle BioLabs after reasonable investigation and research to be accurate. However, Pinnacle BioLabs does not warrant the accuracy of this information.

Serology Test Evaluation Report for “COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test” from Pinnacle BioLabs

May 28, 2020

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1 Introduction

The COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test from Pinnacle BioLabs was tested on 2020-05-06 through 2020-05-08 at the Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center (FFRDC) sponsored by the National Cancer Institute (NCI). Tests were from lot number 2003201. The COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test is intended to qualitatively detect IgM and IgG separately.

1.1 Panel composition

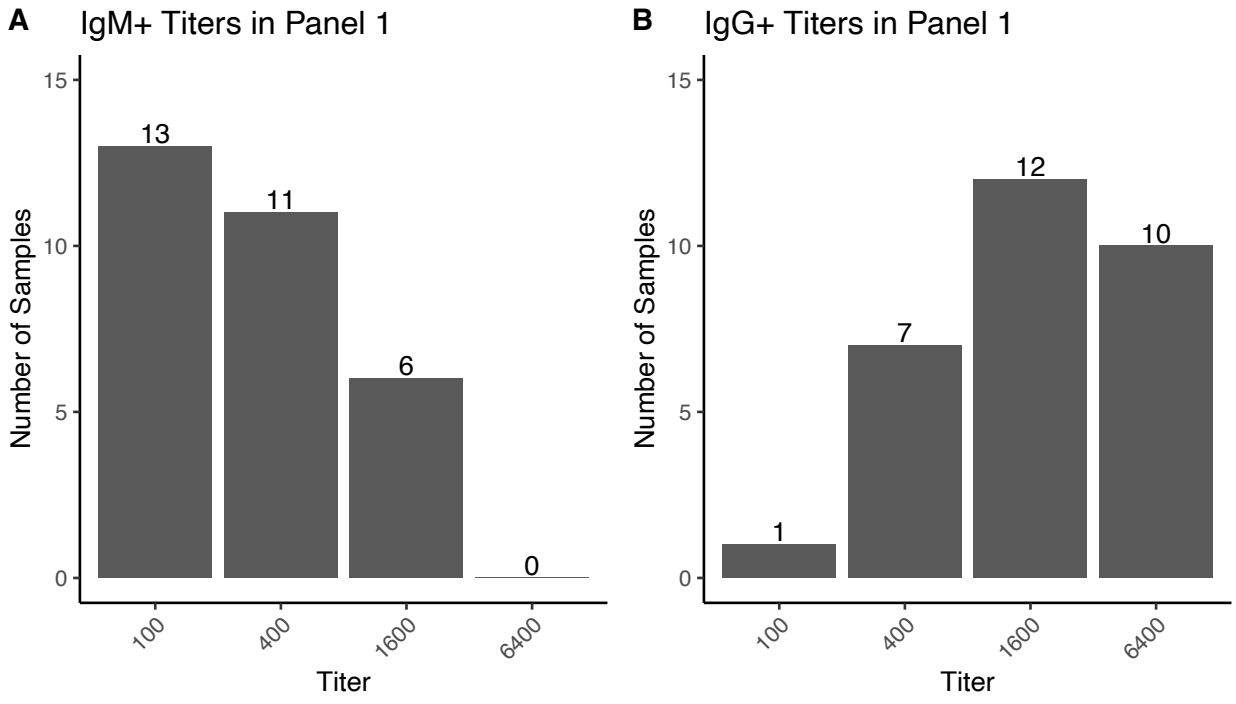

Figure 1: Titer levels for (A) IgM+ and (B) IgG+ samples according to the CDC SARS-CoV-2 Spike antigen assay

The test was evaluated against “Panel 1,” which includes frozen SARS-CoV-2 antibody-positive serum samples ($n = 30$) and frozen antibody-negative serum and plasma samples ($n = 80$). The panel size and composition were chosen to enable a laboratory-based evaluation and to provide reasonable estimates and confidence intervals for test performance in the context of limited sample availability. The sample size is comparable to that of a typical sample size used to support Emergency Use Authorization (EUA) by FDA for tests of this type.

1.1.1 Positive samples

Positive samples used in Panel 1 were from patients previously confirmed to have SARS-CoV-2 infection with a nucleic acid amplification test (NAAT). Time between symptom onset, NAAT testing, and sample collection is not known for all samples. Both SARS-CoV-2 IgM and IgG antibodies are present in all Panel 1 positive samples. The Centers for Disease Control and prevention (CDC) detected the presence of IgG and IgM antibodies at their laboratory using their SARS-CoV-2 spike enzyme-linked immunosorbent assay (ELISA) tests.[1] The presence of antibodies was confirmed at FNLCR using CDC's developed ELISAs (Pan-Ig, IgG, and IgM) as well as an IgG Receptor Binding Domain (RBD) ELISA developed by the Krammer Laboratory at the Icahn School of Medicine at Mount Sinai.[2] The positive samples selected may not reflect the distribution of antibody levels in patient populations that would be evaluated by such a test. Because all samples are positive for both IgM and IgG, this evaluation cannot verify that tests intended to detect IgM and IgG antibodies separately detect these antibodies independently.

Positive samples were assessed at dilutions of 1:100, 1:400, 1:1600, and 1:6400 by CDC on their Pan-Ig assay, their IgM assay, and their IgG assay. Some samples were run at additional dilutions. Any samples that were positive at a dilution greater than 1:6400 were assigned a titer of 6400 because 1:6400 was the highest dilution at which all Panel 1 positive samples were assessed. Two of these samples, C0107 and C0176, were positive for IgG antibodies at a dilution of 1:25600.

1.1.2 Negative samples

All Panel 1 negative samples were collected prior to 2020, before the SARS-CoV-2 virus is known to have circulated in the United States. Panel 1 groups include:

- "Negatives" ($n = 70$): selected without regard for clinical status. This group includes a sample, C0063, that showed reactivity in the Pan-Ig CDC spike ELISA at FNLCR. It includes another sample, C0087, that showed reactivity in the IgG RBD ELISA at FNLCR.
- "HIV+" ($n = 10$): selected from banked serum from HIV+ patients.[3] This group includes 3 samples, C0018, C0155, and C0182, that showed reactivity in the IgG RBD ELISA at FNLCR.

All Panel 1 negative samples were assessed at dilutions of 1:100 and 1:400 by CDC on their Pan-Ig assay. A subset of samples was assessed in parallel at additional dilutions and on the CDC IgM

[1] See `https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html`, which notes "CDC's serologic test is designed and validated for broad-based surveillance and research that will give us information needed to guide the response to the pandemic and protect the public's health. The test is not currently designed to test individuals who want to know if they have been previously infected with COVID-19."

[2] An implementation of this test, the COVID-19 ELISA IgG Antibody Test, has been granted an EUA authorization by FDA for use at the Mount Sinai Laboratory (MSL), Center for Clinical Laboratories, a division of the Department of Pathology, Molecular, and Cell-Based Medicine, New York, NY. See `https://www.fda.gov/media/137029/download`.

[3] HIV+ samples were deemed appropriate for inclusion in the panel: (1) to increase the sample size and reduce the confidence interval; and (2) to identify any possibility of cross-reactivity with HIV+ samples. It is anticipated that other types of samples, as they become available, may also be evaluated in any future analyses.

and IgG assays. All Panel 1 negative samples were negative at a dilution of 1:100 on the CDC Pan-Ig assay. These samples were assigned an undetectable titer (represented as zero (0) in the line data) for the Pan-Ig assay, the IgM assay, and the IgG assay.

1.2 Analysis

Samples used in this evaluation were not randomly selected, and sensitivity (PPA) and specificity (NPA) estimates in this report may not be indicative of the real-world performance of the Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test. Sensitivity and specificity were calculated for each antibody (e.g., IgM, IgG, IgA, and Pan-Ig, as applicable) separately. In addition, sensitivity and specificity were estimated in a combined manner, where a positive result for any antibody the Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test is intended to detect was considered as a positive test result and a negative result meant that a sample tested negative for all antibodies the Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test is intended to detect. Positive and negative predictive values were calculated for combined sensitivity and specificity assuming a prevalence of 5%. Cross-reactivity with HIV+ was evaluated, and results are presented separately. If cross-reactivity was detected, the samples with HIV+ were not included in calculations of specificity.

Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).[4] Confidence intervals for PPV and NPV were calculated using the values from the 95% confidence intervals for sensitivity and specificity. For evaluation of cross-reactivity with HIV+, it was evaluated whether an increased false positive rate among antibody negative samples with HIV was statistically higher than the false positive rate among antibody negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman.[5])

1.3 Important caveats

Sensitivity and specificity estimates in this report may not be indicative of the real world performance of the Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test.

These results are based on serum and plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including finger stick blood.

Information about anticoagulants used is not known.

The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.

[4] CLSI. *User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition*. CLSI document EP12-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2008. See `https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=31791`.

[5] Statistics with Confidence: Confidence Intervals and Statistical Guidelines. (2013). Wiley.

1.4 Notes about the evaluation procedure

- The Pinnacle BioLabs COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test was used per the manufacturer's package insert.
- Devices were tested within any expiration dates provided.
- Devices were not obviously defective / compromised.
- Devices were stored at FNLCR within their labeled conditions.
- A single operator conducted and read the test.
- The personnel who performed the testing were blinded to the identity / code of the sample and the expected results.
- The testing was performed in a non-clinical laboratory environment.
- Negative and positive samples were ordered randomly and then tested serially.
- The operator trained on the COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test with positive and negative controls prior to testing.

1.5 Additional notes, anomalies, and clarifications

FNLCR provided the following additional information:

> Sample Nos. 1-20 were repeated on 08MAY20 due to a separate Kit lot number being tested and samples were exhausted on 06MAY20, so same day repeat could not occur. Sample No. 82 was tested on 08MAY20 because the original aliquot on 06MAY20 did not have enough volume to support testing. The data results presented in the Pinnacle data file are based on the same Kit Lot number.

2 Results

Table 1: Summary Results

	Comparator Method			Collected pre-2020		
	Antibody Positive			Antibody Negative		
COVID-19 Novel Coronavirus Dual IgG/IgM Rapid Test	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	Total
IgM+, IgG+	27			6		33
IgM+, IgG-				1		1
IgM-, IgG+						
IgM-, IgG-	3			63	10	76
Total	30			70	10	110

Table 2: Summary Statistics

Measure	Estimate	Confidence Interval
IgM Sensitivity	90.0% (27/30)	(74.4%; 96.5%)
IgM Specificity	91.2% (73/80)	(83%; 95.7%)
IgG Sensitivity	90.0% (27/30)	(74.4%; 96.5%)
IgG Specificity	92.5% (74/80)	(84.6%; 96.5%)
Combined Sensitivity	90.0% (27/30)	(74.4%; 96.5%)
Combined Specificity	91.2% (73/80)	(83%; 95.7%)
Combined PPV for prevalence = 5.0%	35.1%	(18.7%; 54.1%)
Combined NPV for prevalence = 5.0%	99.4%	(98.4%; 99.8%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

3 Line Data

In the table below, “Days” refers to “Days from symptom onset to blood collection.”

Table 3: Line Data

Sample Number	IgM Result	IgG Result	IgA Result	Pan Ig Result	(IgM / IgG) Result	Control	Sample ID	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
1	Negative	Negative				Pass	C0001	Serum	0	0	0		Negatives
2	Negative	Negative				Pass	C0002	Serum	0	0	0		Negatives
3	Positive	Positive				Pass	C0004	Plasma	0	0	0		Negatives
4	Negative	Negative				Pass	C0005	Plasma	0	0	0		Negatives
5	Negative	Negative				Pass	C0008	Plasma	0	0	0		Negatives
6	Positive	Positive				Pass	C0010	Serum	1600	400	1600	29	Positives
7	Negative	Negative				Pass	C0011	Serum	0	0	0		Negatives
8	Negative	Negative				Pass	C0012	Serum	0	0	0		Negatives
9	Positive	Positive				Pass	C0014	Serum	0	0	0		Negatives
10	Negative	Negative				Pass	C0016	Serum	0	0	0		Negatives
11	Negative	Negative				Pass	C0018	Plasma	0	0	0		HIV+
12	Negative	Negative				Pass	C0020	Serum	0	0	0		Negatives
13	Negative	Negative				Pass	C0024	Serum	0	0	0		Negatives
14	Negative	Negative				Pass	C0027	Serum	0	0	0		Negatives
15	Negative	Negative				Pass	C0029	Serum	0	0	0		Negatives
16	Negative	Negative				Pass	C0032	Plasma	0	0	0		Negatives
17	Negative	Negative				Pass	C0033	Serum	0	0	0		Negatives
18	Negative	Negative				Pass	C0034	Serum	0	0	0		Negatives
19	Positive	Positive				Pass	C0037	Serum	400	100	1600	19	Positives
20	Positive	Positive				Pass	C0038	Serum	100	100	100	20	Positives

Table 3: Line Data *(continued)*

Sample Number	IgM Result	IgG Result	IgA Result	Pan Ig Result	(IgM / IgG) Result	Control	Sample ID	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
21	Positive	Positive				Pass	C0040	Serum	1600	400	1600	24	Positives
22	Negative	Negative				Pass	C0041	Plasma	0	0	0		Negatives
23	Negative	Negative				Pass	C0043	Serum	0	0	0		Negatives
24	Negative	Negative				Pass	C0044	Serum	0	0	0		Negatives
25	Negative	Negative				Pass	C0048	Serum	0	0	0		Negatives
26	Positive	Positive				Pass	C0049	Serum	1600	400	400	23	Positives
27	Negative	Negative				Pass	C0050	Serum	0	0	0		Negatives
28	Negative	Negative				Pass	C0051	Plasma	0	0	0		Negatives
29	Positive	Positive				Pass	C0053	Serum	1600	1600	1600	28	Positives
30	Negative	Negative				Pass	C0054	Plasma	0	0	0		HIV+
31	Negative	Negative				Pass	C0058	Serum	0	0	0		Negatives
32	Negative	Negative				Pass	C0059	Plasma	0	0	0		Negatives
33	Positive	Positive				Pass	C0061	Serum	1600	100	1600	26	Positives
34	Negative	Negative				Pass	C0062	Serum	0	0	0		Negatives
35	Negative	Negative				Pass	C0063	Plasma	0	0	0		Negatives
36	Positive	Positive				Pass	C0064	Serum	1600	1600	6400	20	Positives
37	Negative	Negative				Pass	C0065	Plasma	0	0	0		Negatives
38	Negative	Negative				Pass	C0066	Serum	0	0	0		Negatives
39	Negative	Negative				Pass	C0067	Serum	0	0	0		Negatives
40	Negative	Negative				Pass	C0069	Serum	0	0	0		Negatives
41	Negative	Negative				Pass	C0070	Serum	0	0	0		Negatives
42	Positive	Positive				Pass	C0071	Serum	6400	1600	6400	20	Positives
43	Negative	Negative				Pass	C0072	Serum	0	0	0		Negatives
44	Positive	Positive				Pass	C0073	Serum	0	0	0		Negatives

Table 3: Line Data *(continued)*

Sample Number	IgM Result	IgG Result	IgA Result	Pan Ig Result	(IgM / IgG) Result	Control	Sample ID	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
45	Positive	Positive				Pass	C0074	Serum	400	100	400	24	Positives
46	Negative	Negative				Pass	C0079	Plasma	0	0	0		Negatives
47	Positive	Positive				Pass	C0080	Serum	1600	400	1600	29	Positives
48	Negative	Negative				Pass	C0081	Serum	0	0	0		Negatives
49	Negative	Negative				Pass	C0083	Serum	0	0	0		Negatives
50	Positive	Positive				Pass	C0084	Serum	6400	100	6400	24	Positives
51	Negative	Negative				Pass	C0087	Serum	0	0	0		Negatives
52	Negative	Negative				Pass	C0089	Plasma	0	0	0		HIV+
53	Positive	Positive				Pass	C0090	Serum	1600	100	1600	22	Positives
54	Positive	Positive				Pass	C0092	Serum	1600	100	1600		Positives
55	Negative	Negative				Pass	C0093	Plasma	0	0	0		HIV+
56	Negative	Negative				Pass	C0094	Serum	0	0	0		Negatives
57	Negative	Negative				Pass	C0095	Plasma	0	0	0		Negatives
58	Negative	Negative				Pass	C0098	Plasma	0	0	0		Negatives
59	Negative	Negative				Pass	C0099	Plasma	0	0	0		HIV+
60	Positive	Positive				Pass	C0100	Serum	0	0	0		Negatives
61	Negative	Negative				Pass	C0101	Plasma	0	0	0		Negatives
62	Negative	Negative				Pass	C0102	Serum	400	400	400	25	Positives
63	Positive	Positive				Pass	C0107	Serum	6400	400	6400	36	Positives
64	Negative	Negative				Pass	C0109	Plasma	0	0	0		Negatives
65	Negative	Negative				Pass	C0110	Serum	0	0	0		Negatives
66	Negative	Negative				Pass	C0115	Serum	0	0	0		Negatives
67	Positive	Positive				Pass	C0116	Serum	0	0	0		Negatives
68	Negative	Negative				Pass	C0117	Plasma	0	0	0		Negatives

Table 3: Line Data *(continued)*

Sample Number	IgM Result	IgG Result	IgA Result	Pan Ig Result	(IgM / IgG) Result	Control	Sample ID	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
69	Negative	Negative				Pass	C0118	Serum	0	0	0		Negatives
70	Positive	Positive				Pass	C0119	Serum	1600	100	1600	20	Positives
71	Negative	Negative				Pass	C0120	Serum	0	0	0		Negatives
72	Negative	Negative				Pass	C0121	Plasma	0	0	0		Negatives
73	Negative	Negative				Pass	C0122	Serum	400	100	400	24	Positives
74	Negative	Negative				Pass	C0126	Serum	0	0	0		Negatives
75	Positive	Positive				Pass	C0127	Serum	400	400	1600	23	Positives
76	Negative	Negative				Pass	C0128	Serum	0	0	0		Negatives
77	Positive	Negative				Pass	C0131	Serum	0	0	0		Negatives
78	Positive	Positive				Pass	C0132	Serum	1600	1600	6400		Positives
79	Positive	Positive				Pass	C0136	Serum	6400	400	6400		Positives
80	Negative	Negative				Pass	C0138	Plasma	0	0	0		HIV+
81	Negative	Negative				Pass	C0139	Serum	0	0	0		Negatives
82	Negative	Negative				Pass	C0140	Plasma	0	0	0		Negatives
83	Positive	Positive				Pass	C0144	Serum	6400	1600	6400	21	Positives
84	Negative	Negative				Pass	C0146	Serum	0	0	0		Negatives
85	Negative	Negative				Pass	C0150	Plasma	0	0	0		HIV+
86	Negative	Negative				Pass	C0153	Serum	400	100	400	31	Positives
87	Negative	Negative				Pass	C0155	Plasma	0	0	0		HIV+
88	Negative	Negative				Pass	C0156	Plasma	0	0	0		Negatives
89	Negative	Negative				Pass	C0158	Serum	0	0	0		Negatives
90	Positive	Positive				Pass	C0160	Serum	1600	100	1600	17	Positives
91	Positive	Positive				Pass	C0161	Serum	400	100	400	25	Positives
92	Positive	Positive				Pass	C0164	Serum	1600	400	6400	23	Positives

Table 3: Line Data *(continued)*

Sample Number	IgM Result	IgG Result	IgA Result	Pan Ig Result	(IgM / IgG) Result	Control	Sample ID	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
93	Negative	Negative				Pass	C0165	Serum	0	0	0		Negatives
94	Negative	Negative				Pass	C0169	Serum	0	0	0		Negatives
95	Positive	Positive				Pass	C0172	Serum	1600	400	1600	19	Positives
96	Negative	Negative				Pass	C0173	Serum	0	0	0		Negatives
97	Negative	Negative				Pass	C0174	Serum	0	0	0		Negatives
98	Positive	Positive				Pass	C0176	Serum	6400	400	6400	19	Positives
99	Negative	Negative				Pass	C0179	Plasma	0	0	0		Negatives
100	Positive	Positive				Pass	C0180	Serum	6400	1600	6400	24	Positives
101	Negative	Negative				Pass	C0181	Serum	0	0	0		Negatives
102	Negative	Negative				Pass	C0182	Plasma	0	0	0		HIV+
103	Positive	Positive				Pass	C0185	Plasma	0	0	0		Negatives
104	Negative	Negative				Pass	C0186	Serum	0	0	0		Negatives
105	Positive	Positive				Pass	C0191	Serum	400	100	400	22	Positives
106	Negative	Negative				Pass	C0193	Plasma	0	0	0		Negatives
107	Negative	Negative				Pass	C0197	Plasma	0	0	0		HIV+
108	Negative	Negative				Pass	C0198	Plasma	0	0	0		Negatives
109	Negative	Negative				Pass	C0199	Plasma	0	0	0		Negatives
110	Negative	Negative				Pass	C0200	Serum	0	0	0		Negatives

Clinical Report

Purpose: Assay verification of the Pinnacle cov-ID NEO Lateral Flow Immunoassay v2.

Technician: Tianjin Centers for Disease Control and Prevention.The Eighth Hospital Of Xi'an. Tianjin Second People' Hospital. Teda International Cardiovascular Hospital at Shenzhen Blood Center.

Test Procedure: Collect 10 μL capilarry plasma or serum sample, add into the sample well of test cassette and add 2 drops of buffer solution into the buffer well. Read result after 15minutes.

Test Result

NO.	Rapid Test	PCR
1	—	Positive
2	++	Positive
3	+	Positive
4	+	Positive
5	++	Positive
6	+++	Positive
7	++	Positive
8	++	Positive
9	+	Positive
10	+++	Positive
11	+	Positive
12	+	Positive
13	++	Positive
14	+	Positive
15	++	Positive
16	+	Positive
17	+	Positive
18	++	Positive
19	+++	Positive
20	++	Positive
21	++	Positive
22	+++	Positive
23	—	Positive
24	+	Positive
25	+++	Positive
26	++	Positive
27	+	Positive
28	+	Positive
29	—	Positive

30	+	Positive
31	+	Positive
32	++	Positive
33	++	Positive
34	+	Positive
35	+++	Positive
36	++	Positive
37	+	Positive
38	++	Positive
39	+++	Positive
40	+	Positive
41	+++	Positive
42	+	Positive
43	+++	Positive
44	++	Positive
45	+++	Positive
46	—	Positive
47	+++	Positive
48	++	Positive
49	+	Positive
50	+++	Positive
51	+++	Positive
52	+++	Positive
53	+++	Positive
54	+++	Positive
55	+++	Positive
56	+++	Positive
57	+++	Positive
58	+++	Positive
59	+++	Positive
60	—	Positive
61	+	Positive
62	+++	Positive
63	++	Positive
64	+	Positive
65	—	Positive
66	—	Positive
67	+	Positive
68	—	Positive
69	++	Positive
70	+	Positive
71	—	Positive
72	+++	Positive
73	++	Positive

74	+	Positive
75	++	Positive
76	+++	Positive
77	+	Positive
78	+++	Positive
79	+	Positive
80	+++	Positive
81	+	Positive
82	+	Positive
83	+	Positive
84	—	Positive
85	+	Positive
86	+	Positive
87	+	Positive
88	—	Positive
89	+	Positive
90	+	Positive
91	—	Positive
92	—	Positive
93	—	Positive
94	+	Positive
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105	+	Positive
106	+	Positive
107	+	Positive
108	+	Positive
109	+	Positive
110	+	Positive
111	+	Positive
112	+	Positive
113	+	Positive
114	+	Positive
115	+	Positive
116	+	Positive
117	+	Positive

118	++	Positive
119	++	Positive
120	++	Positive
121	++	Positive
122	++	Positive
123	++	Positive
124	++	Positive
125	++	Positive
126	++	Positive
127	++	Positive
128	++	Positive
129	++	Positive
130	++	Positive
131	++	Positive
132	++	Positive
133	++	Positive
134	+++	Positive
135	+++	Positive
136	+++	Positive
137	+++	Positive
138	+++	Positive
139	+++	Positive
140	+++	Positive
141	+++	Positive
142	+++	Positive

NO.	RAPID TEST	PCR
1	—	Negative
2	—	Negative
3	—	Negative
4	—	Negative
5	—	Negative
6	—	Negative
7	—	Negative
8	—	Negative
9	—	Negative
10	—	Negative
11	—	Negative
12	—	Negative
13	—	Negative
14	—	Negative
15	—	Negative
16	—	Negative

17	—	Negative
18	—	Negative
19	—	Negative
20	—	Negative
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22	—	Negative
23	—	Negative
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364	—	Negative
365	—	Negative
366	—	Negative
367	—	Negative
368	—	Negative

369	—	Negative
370	—	Negative
371	—	Negative
372	—	Negative
373	—	Negative
374	—	Negative
375	—	Negative
376	—	Negative
377	—	Negative
378	—	Negative
379	—	Negative
380	—	Negative
381	—	Negative

Result interpretation:

—indicates negativeresult

+ indicates VISUAL slightly positive result

++ indicates VISUAL moderate positive result

+++ indicates VISUAL strong positive result

Result analysis

Rapid Test	Clinical sample information				Total	
	Positive		Negative			
Positive	A	129	B	0	A+B	129
Negative	C	13	D	381	C+D	391
Total	A+C	142	B+D	381	A+B+C+D	523

Sensitivity:

A/(A+C)% = 90.85%(95% credibility interval: 84.85% ~ 95.04%)

Specificity:

D/(B+D)% = 100.00%(95% credibility interval: 99.04% ~ 100.00%)

Total Accuracy:

(A+D)/(A+B+C+D)% = 97.51%(95% credibility interval: 95.79% ~ 98.67%)

For and on behalf of
SPAN BIOTECH LIMITED
眾鑫生物技術有限公司

Authorized Signature(s)

Issued date : 28/07/2020

5 May 2020

Pinnacle Biolabs SARS-CoV-2 IgM/IgG Antibody Assay Verification

Extensive verification of the Pinnacle Biolabs COVID-19 Novel Coronavirus IgM/IgG Rapid Test, a lateral flow chromatographic immunoassay, was performed to confirm the specificity and sensitivity of the assay. In particular, verification studies were undertaken to assess:

- Cross-Reactivity/Analytical Specificity
- Analytical Sensitivity
- Clinical Experience

Cross Reactivity/Analytical Specificity

A panel of negative specimens were obtained including 80 serum samples (frozen serum samples stored pre-pandemic), 1 sample (EDTA whole blood) from an individual confirmed to be negative for SARS-CoV-2 via rt-PCR, and 10 fresh fingerstick samples (capillary blood) from individuals confirmed to be negative for SARS-CoV-2 via rt-PCR. All samples were drawn from a population with a high prevalence of vaccination against influenza, HBV, and *Haemophilus influenzae*. The sample were drawn from a population known to contain a high prevalence of HCV. Testing of the samples was performed in accordance with the manufacturer-supplied package insert. Of these samples, 90/91 showed no T1 or T2 bands, indicating a negative result (98.9% overall specificity). 1/91 showed a T2 band only, indicating a negative result for IgM and positive result for IgG (100% specificity for IgM, 98.9% specificity for IgG).

In addition, 5 stored serum samples known to contain anti-RSV IgM and IgG as well as 5 stored serum samples known to contain ANA from individuals were tested. Of these samples, 10/10 showed no T1 or T2 bands, indicating a negative result (100% specificity).

In total, 100/101 samples showed no T1 or T2 bands, indicating a negative result (99% specificity).

Sample	**IgM**	**IgG**	**Comments**
WB-01	Neg	Neg	Negative by rt-PCR
CB-01	Neg	Neg	Negative by rt-PCR
CB-02	Neg	Neg	Negative by rt-PCR
CB-03	Neg	Neg	Negative by rt-PCR
CB-04	Neg	Neg	Negative by rt-PCR
CB-05	Neg	Neg	Negative by rt-PCR
CB-06	Neg	Neg	Negative by rt-PCR
CB-07	Neg	Neg	Negative by rt-PCR
CB-08	Neg	Neg	Negative by rt-PCR
CB-09	Neg	Neg	Negative by rt-PCR
CB-10	Neg	Neg	Negative by rt-PCR
Serum-1	Neg	Neg	

Serum-2	Neg	Neg	
Serum-3	Neg	Neg	
Serum-4	Neg	Neg	
Serum-5	Neg	Neg	
Serum-6	Neg	Neg	
Serum-7	Neg	Neg	
Serum-8	Neg	Neg	
Serum-9	Neg	Neg	
Serum-10	Neg	Neg	
Serum-11	Neg	Neg	
Serum-12	Neg	Neg	
Serum-13	Neg	Neg	
Serum-14	Neg	Neg	
Serum-15	Neg	Neg	
Serum-16	Neg	Neg	
Serum-17	Neg	Neg	
Serum-18	Neg	Neg	
Serum-19	Neg	Pos	Negative for IgG by Abbott Microparticle
Serum-19R	Neg	Neg	
Serum-20	Neg	Neg	
Serum-21	Neg	Neg	
Serum-22	Neg	Neg	
Serum-23	Neg	Neg	
Serum-24	Neg	Neg	
Serum-25	Neg	Neg	
Serum-26	Neg	Neg	
Serum-27	Neg	Neg	
Serum-28	Neg	Neg	
Serum-29	Neg	Neg	
Serum-30	Neg	Neg	
Serum-31	Neg	Neg	
Serum-32	Neg	Neg	
Serum-33	Neg	Neg	

Serum-34	Neg	Neg	
Serum-35	Neg	Neg	
Serum-36	Neg	Neg	
Serum-37	Neg	Neg	
Serum-38	Neg	Neg	
Serum-39	Neg	Neg	
Serum-40	Neg	Neg	
Serum-41	Neg	Neg	
Serum-42	Neg	Neg	
Serum-43	Neg	Neg	
Serum-44	Neg	Neg	
Serum-45	Neg	Neg	
Serum-46	Neg	Neg	
Serum-47	Neg	Neg	
Serum-48	Neg	Neg	
Serum-49	Neg	Neg	
Serum-50	Neg	Neg	
Serum-51	Neg	Neg	
Serum-52	Neg	Neg	
Serum-53	Neg	Neg	
Serum-54	Neg	Neg	
Serum-55	Neg	Neg	
Serum-56	Neg	Neg	
Serum-57	Neg	Neg	
Serum-58	Neg	Neg	
Serum-59	Neg	Neg	
Serum-60	Neg	Neg	
Serum-61	Neg	Neg	
Serum-62	Neg	Neg	
Serum-63	Neg	Neg	
Serum-64	Neg	Neg	
Serum-65	Neg	Neg	
Serum-66	Neg	Neg	

Serum-67	Neg	Neg	
Serum-68	Neg	Neg	
Serum-69	Neg	Neg	
Serum-70	Neg	Neg	
Serum-71	Neg	Neg	
Serum-72	Neg	Neg	
Serum-73	Neg	Neg	
Serum-74	Neg	Neg	
Serum-75	Neg	Neg	
Serum-76	Neg	Neg	
Serum-77	Neg	Neg	
Serum-78	Neg	Neg	
Serum-79	Neg	Neg	
Serum-RSV-1	Neg	Neg	
Serum-RSV-2	Neg	Neg	
Serum-RSV-3	Neg	Neg	
Serum-RSV-4	Neg	Neg	
Serum-RSV-5	Neg	Neg	
Serum-ANA-1	Neg	Neg	
Serum-ANA-2	Neg	Neg	
Serum-ANA-3	Neg	Neg	
Serum-ANA-4	Neg	Neg	
Serum-ANA-5	Neg	Neg	

Analytical Sensitivity

A panel of 15 known positive specimens (whole blood, EDTA) were obtained from Christiana Hospital. Immune status of the individuals or length of active infection was not known or collected. Of the 15 known positive specimens, 12 demonstrated a positive IgM and IgG band on the rapid test (80% sensitivity).

Discussion

Consistent with FDA guidance, docket FDA-2020-D-0987, the State of Delaware has identified point-of-care lateral flow immunoassays (“rapid tests”) as useful diagnostic adjuncts for COVID-19 and subsequently developed guidance for use of these tests. Use of rapid tests is contingent upon implementation in appropriate clinical scenarios, leveraging high analytical specificity (>99%) in a “PCR-sparing” testing strategy.

Over a period 4/7/2020-4/29/2020, DPH monitored samples as part of a prospective observational effort to ensure satisfactory performance of Pinnacle Biolabs COVID-19 Novel Coronavirus IgM/IgG Rapid Tests in a real-world setting. IRB approval was not required as testing was performed under executive authority consistent with the Eleventh Modification of the Declaration of a State of Emergency for the State of Delaware Due to a Public Health Threat.

Specimens were deployed by Delaware Division of Public Health personnel, principally within post-acute care facilities. Tests were administered by licensed registered nurses (RNs) or physicians (MD/DOs) following training performed in-person or via instructional video. Specimens were collected in accordance with the manufacturer-supplied package insert. Specimens were collected simultaneously with nasopharyngeal swabs and compared to rt-PCR results.

Of these specimens, high specificity was maintained with no false positives identified by rt-PCR. Most specimens were identified to manifest both IgM and IgG, with some specimens showing IgM only and only a few showing IgG only. Multiple patients known to have remote infection with SARS-CoV-2 via positive rt-PCR testing manifested both IgM and IgG, and were found to have both IgM and IgG. Repeat PCR testing showed threshold cycle values ranging from low (17) to high (34).

Rapid tests may be deployed first in symptomatic individuals and a positive IgM is a reasonable surrogate to identify infection with COVID-19, and follow-up PCR is not necessary, as the sensitivity of widely available PCR and negative predictive value given high-pretest probability with positive serology would not be sufficient to change recommendations for isolation. Those individuals with negative rapid tests should then proceed to molecular testing via PCR.

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Pinnacle BioLabs covID Neo 2 Assay Verification Protocol

Background- After being assessed by the NCI laboratory in collaboration with the US FDA, and after multiple discussions with FDA on same, Pinnacle chose to resubmit an Emergency Use Authorization pursuant to 21 CFR 807.81(a)(3). We have developed a proprietary protocol to verify the assay to FDA's specifications. All testing will be performed at George Mason University in Manassas, Virginia.

1. Panel Composition

The panel size and composition is chosen to enable a laboratory-based evaluation and to provide reasonable estimates and confidence intervals for test performance in the context of limited sample availability. The sample size is comparable to that of a typical sample size used to support Emergency Use Authorization (EUA) by FDA for tests of this type.

Clinical agreement data for SARS-CoV-2 antibody tests with at the minimum 30 positive samples and 75 negative samples generally should demonstrate a minimum overall positive percent agreement (PPA), or sensitivity, of 90%; a minimum overall negative percent agreement (NPA), or specificity, of 95%; and for tests that report specifically IgM and IgG, a minimum PPA/sensitivity for IgG of 90% and a minimum PPA/sensitivity for IgM of 70%.

Under this current thinking, clinical agreement data for SARS-CoV-2 antibody tests with greater than 30 positives and 75 negative samples generally should demonstrate a minimum IgG and overall (i.e., combined IgM/IgG) PPA of 87% with a lower bound of the 95% confidence interval greater than 74.4%, a minimum IgM PPA of 67% with a lower bound of the 95% confidence interval greater than 52.1%, and a minimum overall (i.e., combined IgM/IgG) NPA of 93% with a lower bound of the 95% confidence interval greater than 87.8%.

2. Number of Samples

This protocol will assess a total of 30 positive samples from patients previously confirmed to have SARS-CoV-2 infection with a nucleic acid amplification test (NAAT) as well as 80 confirmed negative samples (including 10 HIV^+ samples) collected prior to 2020. This number of samples is needed for each sample matrix. For example, a set of 30 positive and 80 negative should be used each for serum, plasma and blood samples since any of these samples types may be used in the real world setting.

1. Positive Samples

After the panel composition has been determined and an appropriate panel selected, positive samples (n=30) will be used from patients previously confirmed to have SARS-CoV-2 infection with a nucleic acid amplification test (NAAT). Both SARS-CoV-2 IgM and IgG antibodies are to be present in all positive samples confirmed by validated ELISA tests (Pan-Ig, IgG, and IgM) as well as an IgG Receptor Binding Domain (RBD). The positive samples selected may not reflect the distribution of antibody levels in patient populations that would be evaluated by such a test. Because all samples are to be positive for both IgM and IgG, this evaluation cannot verify that tests intended to detect IgM and IgG antibodies separately detect these antibodies independently.

Positive samples will be assessed at dilutions of 1:100, 1:400, 1:1600, and 1:6400.

2. Negative Samples

All negative samples are to be collected prior to 2020, before the SARS-CoV-2 virus is known to have circulated. Negative samples will include:

- "Negatives" (n = 70) will be selected without regard for clinical status
- "HIV^+" (n=10) selected from banked serum from HIV+ patients

HIV^+ samples are deemed appropriate for inclusion in the panel for the following reasons:

- To increase the sample size and reduce the confidence interval
- To identify any possibility of cross-reactivity with HIV+ samples

All negative samples were assessed at dilutions of 1:100 and 1:40

3. Analysis of Samples

Samples will be tested using Pinnacle BioLabs covID Neo 2 Assay. Sensitivity and specificity will be calculated for each antibody (e.g., IgM, IgG, and Pan-Ig, as applicable) separately. In addition, sensitivity and specificity will be estimated in a combined manner, where a positive result for any antibody the Pinnacle BioLabs covID Neo 2 Assay is intended to detect will be considered a positive test result and a negative result will be considered negative for all antibodies the Pinnacle BioLabs covID Neo 2 Assay is intended to detect. Positive and negative predictive values will be calculated for combined sensitivity and specificity assuming a prevalence of 5%. Cross-reactivity with HIV^+ will be evaluated, and results will be presented separately. If cross-reactivity is detected, the samples with HIV^+ will not be included in calculations of specificity.

Confidence intervals for sensitivity and specificity will be calculated per a score method described in CLSI EP12-A2, 2008. Confidence intervals for PPV and NPV will be calculated using the values from the 95% confidence intervals for sensitivity and specificity. For evaluation of cross-reactivity with HIV^+, it will be evaluated whether an increased false positive rate among antibody negative samples with HIV is statistically higher than the false positive rate among antibody negative samples without HIV. A confidence interval for the difference in false positive rates will be calculated per a score method described by Altman, 2013.

4. Procedure

The Pinnacle BioLabs covID Neo V2 Assay will used according to test steps described in the manufacturer's recommendations. Devices will be tested within any expiration dates provided. Any devices that are obviously defective or otherwise compromised in any way will not be used. Devices will be stored according to the labeled conditions.

A single operator that is trained on the Pinnacle BioLabs covID Neo V2 Assay with positive and negative controls prior to testing will conduct and read the test. This operator will be blinded to the identity/code of the sample and the expected results. Negative and positive samples will be ordered randomly and then tested serially.

5. Interpretation of Results

Since the samples are positive for both IgG and IgM, the following results are expected with these samples:

Table 51. Interpretation of Results

	Control Line	IgM Line	IgG Line	Test Result Interpretation
1	Not present	Any	Any	Invalid test. The specimen must be retested with another device (test strip)
2	+	-	-	Valid test, negative for antibodies to SARS-CoV-2
3	+	+	+	Valid test, IgM and IgG positive antibodies to SARS-CoV-2

The results for the test can be read as follows:

Negative for antibodies to SARS-CoV-2

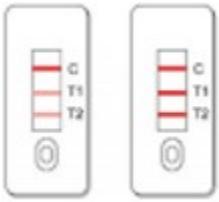
Only control line (C) is visible. No IgG or IgM antibodies to SARS-CoV-2 were detected.

Figure 51. Negative

Positive for IgM and IgG:

Colored bands appear at the control line (C) and both test lines (T1 and T2). The test is positive for IgM and IgG antibodies.

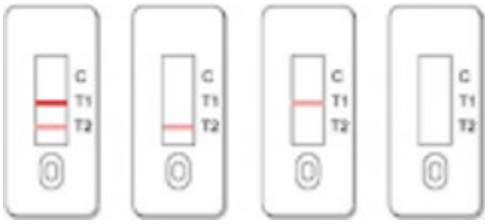
Figure 54. Positive IgG and IgM



Invalid:

Control line (C) is absent. If this occurs, irrespective of the appearance of the IgM or IgG lines, the assay should be repeated using a new test cassette.

Figure 55. Invalid



6. Appendices

3. User Instructions for Pinnacle BioLabs covID Neo 2 Assay