ACCOBiotech ACCO COVID-19 IgM/IgG COVID-19 Test
US Testing and Validation Summary

The ACCO COVID-19 IgM/IgG validation test was performed at Memorial Medical Center Lab certified under CLIA # 14D0646999 and Decatur Memorial Hospital Lab certified under CLIA # 14D0662403

The **ACCO COVID-19 IgM/IgG TEST** is an immunoassay based test intended for the qualitative detection of IgM and/or IgG antibodies in whole blood or serum or plasma from individuals with signs and symptoms of infection who are suspected of COVID-19, and also from asymptomatic individuals who may have been exposed to SARS-CoV-2 and are potential carriers of the virus.

This kit has been previously evaluated per the test guidance and regulatory documents of the European harmonised standard EN 13612:2002 and EN23640:2015, NCCLS (EP17-A2, EP06-A, EP07-A2, MM17-A, EP05-A3, EP12-A2, EP10-A3, EP09-A2). The previous study was performed on March 2, 2020 using a total of 159 sera (39 positive and 120 negatives) that were collected by Dankook University Hospital (under IRB approval) and DonAccoang Hospital Shanghai.

As of this writing, over 200,000 kits have been used successfully in several jurisdictions including Singapore, Hong Kong, Cambodia, Iran and Thailand.

In order to validate the test for FDA emergency use authorization, a US-based clinical study was conducted to evaluate the performance of the ACCO COVID-19 IgM/IgG Rapid Detection Test Kit. A total of 32 individual tests were performed on known RT-PCR COVID-19 positive samples. The positive samples included whole blood, plasma and serum. There were 27 unique samples; five individuals had samples of both serum and whole blood tested from specimens collected on the same date. Three (3) of the 27 individuals were hospitalized patients tested with serum and then tested 6-8 days later with new samples of whole blood. All individuals tested positive for RT-PCR for SARS CoV-2; these results are on file. The preparation and performance of the testing was performed in accordance with the IFU provided to the laboratory performing the clinical study. A result photo was provided with each test result.

For all tests performed, IgG was present in 18 of the 32 samples and IgM was present in 27 of the 32 samples. 31 samples included IgG, IgM, or both antibodies. One (1) test was negative for both antibodies.

Subject 022 was severely ill with respiratory failure requiring ventilation and symptoms consistent with COVID-19. The individual was tested twice by RT-PCR for SARS CoV-2 and found negative both times from a nasopharyngeal swab. He had an extensive clinical workup for a source of infectious agents and was found negative for all of the following tests: Influenza A and B by respiratory panel, throat cultures for Group A and beta strep, blood cultures, urine for Legionella antigen, Streptococcus pneumoniae, Mycoplasma antibody, sputum culture with Gram stain, and MRSA by PCR. A second respiratory panel (BioFire® Film Array) was performed that ruled out infection by Bordetella pertussis, Chlamydophila pneumoniae, Mycoplasma pneumoniae, Adenovirus, Coronavirus HKU1, Coronavirus NL63, Coronavirus 229E, Coronavirus OC43, Influenza A, Influenza A subtype H1, Influenza A subtype H3, Influenza A subtype 2009 H1, Influenza B, Metapneumovirus, Parainfluenza 1, Parainfluenza 2, Parainfluenza 3, Parainfluenza 4, RSV, Rhinovirus/Enterovirus. Three (3) days after the second negative RT-PCR for SARS CoV-2, he was found positive for both IgG and IgM antibodies using the ACCO COVID-19 test. On that same date he had a bronchoscopy performed and had fluid tested for the virus from the bronchalveolar lavage (BAL). This third sample was found positive by RT-PCR.

Test results are summarized in Table 1 below:

Study #	# Days since RT-PCR (+)	*IgM	*IgG	Gender	Fever
1	8	+	+	F	No
2	10	-	-	F	No
3	2	+	+	M	Yes
4	10	+	+	F	No
5	12	+	+	F	No
6	3	+	+	F	No
7	4	-	+	M	Yes
8	3	+	-	M	No
9	7	+	+	F	No
10	4	+	+	F	No
11	7	+	+	F	No
12	6	+	+	F	No
13	5	-	+	F	No
14	3	-	+	F	Yes
15	3	+	+	F	No
16	0	+	+	F	No
17	18	+	-	F	No
18	14	+	-	M	No
19	21	+	-	F	No
20	11	+	+	M	No
21	11	+	-	F	No
22	3	+	+	M	Yes
23	18	+	+	F	No
24	9	+	-	F	No
25	16	+	+	M	No
26	3	+	-	M	No
27	3	+	-	M	No
28	0	+	-	F	No
29	18	+	-	F	No
30	14	+	+	M	No
31	21	+	-	F	No
32	11	+	-	F	No

Table 1: Individual Sample Results for IgG /IgM by Days Since RT-PCR Results to Antibody Testing

Summary Conclusions:

There were 4 groups of results obtained from the study.

1) RT-PCR (+) / IgM (+) / IgG (+)

Fifteen (15) out of 32 samples tested positive for all 3 markers tested. This result indicated that antibodies SARS-CoV-2-specific IgM and IgG were present in the blood of patients that were exposed to the SARS-CoV-2.

2) RT-PCR (+) / IgM (-) / IgG (+)

Four (4) samples (sample 007, 013, 014 and 026) out of 32 samples tested negative for IgM but positive for IgG. Since patients present for care and testing depending on their individual symptoms, it is unknown if samples were taken in the active or recovery period of the illness. Several individuals did not have fever or symptoms at the time of antibody testing. Testing during the recovery period could explain the presence of IgG when IgM is not detectable. Another explanation (that would probably be highly unlikely considering how new infection caused by is SARS-CoV-2) is a secondary infection (due to fever present), but perhaps the primary infection was caused by another coronavirus.

3) RT-PCR (+) / IgM (+) / IgG (-)

Twelve (12) out of 32 samples tested negative for IgG but positive for IgM. Individuals in this category are thought to be early in the development of antibodies and showing IgM in the early active phase of the disease.

4) RT-PCR (+) / IgM (-) / IgG (-)

One (1) (sample 002) out of 32 samples tested negative for IgG and for IgM. For this patient, the situation was quite unique in that the patient was severely immunocompromised because she is a cancer patient undergoing intensive chemotherapy. This may have explained the lack of IgM and IgG in this particular patient who tested positive for the presence of RNA for SARS-CoV-2.