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API Pharma Next Gen Antibody Test

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Manufacturer Information

Kit Name: API Pharma *Next Gen* SARS CoV-2 IgM/IgG Antibody Test
Kit Manufacturer:Division 5 Labs
Importer of Record: API Pharma USA LLC

Environmental Storage

- Store as packaged in the sealed pouch at the temperature (4-30℃).Avoid hot and sunshine, dry place, valid for 12 months.DO NOT FREEZE.Some protective measures should be taken in hot summer and cold winter to avoid high temperatures or freeze-thaw.
- Do not open the inner packaging until ready, it must be used in 1 hour if opened
- Humidity:<=60%, Temp:20C-30℃
- Please use immediately when humidity is >60%.

Specimen

The reagent can be used for the serum, plasm and whole blood samples.A serum plasma whole blood sample must be collected in a clean and dry container.EDTA, sodium citrate, heparin can be used as anticoagulants.in plasma/whole blood samples.Detect immediately after collecting blood.
Serum and plasma samples may be stored at 2-8℃ for 7 days prior to assay.If testing is delayed more than 7 days, the sample should be frozen (-20℃ or colder).Repeat freeze and thaw for no more than 3 times.
Whole blood samples with anticoagulant can be stored at 2-8℃ for 3 days and should not be frozen.Whole blood samples without anticoagulant should be used immediately (if the sample has agglutination, it can be detected as serum).

Quality Control

A procedural control is included in the test. A colored line appearing in the control region (C) considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

.Intended Use

The kit is used to detect IgG and IgM antibodies to severed acute respiratory syndrome coronavirus 2 (SARS-CoV-2) the SARS-CoV-2 virus in serum, plasma or whole blood sample qualitatively.It is to be used as an aid in the diagnosis of coronavirus infection disease (COVID-19), which is caused by SARS-CoV-2

Test Principle

This kit is an immunochromatographic assay, using capture method for quantitative detection of severe acute respiratory syndrome coronavirus 2(SARS CoV-2) IgG/IgM antibody in human serum plasma and whole blood sample.When the sample contains the SRS CoV-2 IgM antibody, it forms a complex with the gold label antigen (SARS-CoV-2 recombinant antigen.The complex moves forward under the action of chromatography and combines with the coated antibody (Mouse anti-human IgM monoclonal antibody) at the T2 line to form a complex

and develop color (T2line), which indicates positive result.When the sample does not contain the SARS-CoV-2 IgM antibody, no complex can be formed at the T2 line and no red band appears which indicates a negative test. When the sample contains the SARS CoV-2 IgG antibody, it forms a complex with the gold label antigen (SARS-CoV-2 recombinant antigen.The complex moves forward under the action of chromatography and combines with the coated antibody (Mouse anti-human IgG monoclonal antibody) at the T1 line to form a complex and develop color (T1 line), which indicates positive result.When the sample does not contain the SARS-CoV-2 IgG antibody, no complex can be formed at the T1 line and no red band appears which indicates a negative test.

Regardless of whether the SARS-CoV-2 IgM and/or IgG antibody is contained in the sample, the gold label quality control antibody (Biotinylated BSA) will bind with the coated antibody at the C line to form a complex and develop color (C Line).

API Pharma *Next Gen* IgM/IgG Antibody Test

KAI MEDICAL
— LABORATORY —

Laboratory:
Kai Medical Laboratory
8230 Elmbrook Drive - Ste 200, Dallas, TX 75247

New Method or Instrument Information	
Manufacturer	**Division 5 Labs**
Kit Name	API Pharma Next Gen SARS CoV-2 IgM/IgG Antibody Test
Control Material/Lot/Exp	Control not readily available. Correlations samples used to confirm testing specifications.
Reference Range	Normal human condition of negative for SARS-CoV-2 Antibodies.
Sample Type	Whole Blood/Serum/Plasma

Detail	Date Performed	Detail	Acceptable?
Accuracy/ Correlation Qualitative	7.3.2020	10 out of 10 negative IgG/IgM samples correlated with expected results. 10 out of 10 positive IgG samples correlated with expected results. 10 out of 10 positive IgM samples correlated with expected results.	YES
Precision 2 levels N=20 TEa 20%	7.3.2020	Control Samples not readily available. Patient testing used to perform positive and negative replicates. Testing: Neg/Pos. 10 replicates each	YES
Selectivity/Specificity	7.3.2020	Positive dilution tests was performed at 1:3, 1:5, 1:10 All dilutions demonstrated visible positive immunoglobulin bands. Hemolysis interference testing performed on positive and negative samples. No interference demonstrated.	YES
Reference Range	7.3.2020	Negative result is supported by normal human biological condition.	YES
Sample Stability	NA	See package inserts	NA
Comments:			

Sensitivity and Specificity

All samples were gathered from patients May 4 to July 2nd. Samples that were stored more than three days were frozen. Dates of symptom onset were written by clinical site. Since many patients were asymptomatic, it was not possible to determine date of onset. All patients had a nasopharyngeal swab taken at the same time as the blood sample. PCR results for each patient are listed below.

Procedure:

1. Removed the test device from the sealed pouch.
2. Added 40-50µl of serum or plasma or 80-100µl of whole blood vertically into the sample well.
3. Added two (2) drops (80-100µl) of sample buffer into the sample well.
4. Observed the test results immediately within 15~20 minutes, the result is invalid over 20 minutes.

Note: Any color change around the region of a line, even if faint or indistinct, was considered a positive result.

SARS-CoV-2 IgM/IgG Ab

		API Test Result Compared to PCR				
	Days from Symptom onset to Blood Collection	Number of samples	2019-nCoV RT PCR Resul	IgM (+)	IgG (+)	IgM (+) and/or IgG (+)

		t			
1-5 days	14	Pos	14	14	14
6-10 days	16	Pos	13	16	16
11-15 days	0				
16-20 days	0				
>20 days	0				
Asymptomatic	25	Pos	23	25	25
Total	55	Pos	50	55	55

SARS-CoV-2 IgM Ab

SARS-CoV-2 IgM Ab Rapid Test	PCR Test	Total	
Positive	Negative		
Positive	50	0	50
Negative	5	85	90
Total	55	85	140

Analysis of coincidence rate of SARS-CoV-2 IgM Ab rapid test and PCR Test in blood samples.
Positive Percent Agreement=50 / (50+5) × 100% = 90.9%
Negative Percent Agreement =85 / (85+0) × 100% = 100%

SARS-CoV-2 IgG Ab

SARS-CoV-2 IgG Ab Rapid Test	PCR Test	Total	
Positive	Negative		

	Positive	55	0	55
	Negative	0	85	85
	Total	55	85	140

Analysis of coincidence rate of SARS-CoV-2 IgG Ab rapid test and PCR Test in blood samples.
Positive Percent Agreement=50 / (55+0) × 100% = 100%
Negative Percent Agreement =85 / (85+0) × 100% = 100%

HIV + Samples

Ten asymptomatic HIV+ patients with no known exposure to COVID19 were recruited through Kai Medical in Dallas Texas. Patient HIV status was confirmed using standard of care HIV testing. Patients were given API Pharma *Rapid* testing and results were confirmed by PCR. 100% of patients tested negative for COVID19 by API Pharma *Rapid testing.*

	Patient Number	HIV test result	API Pharma *Rapid* Test Result	PCR Test Result
	Patient 1	Pos	Neg	Neg
	Patient 2	Pos	Neg	Neg
	Patient 3	Pos	Neg	Neg
	Patient 4	Pos	Neg	Neg
	Patient 5	Pos	Neg	Neg
	Patient 6	Pos	Neg	Neg
	Patient 7	Pos	Neg	Neg
	Patient 8	Pos	Neg	Neg
	Patient 9	Pos	Neg	Neg

Patient 10	Pos	Neg	Neg

This validation study has been reviewed and the performance of the **Division 5 LabsAPI Pharma *Next Gen* IgM/IgG Antibody Test** method is considered acceptable for patient testing of SARS CoV-2 IgG/IgM Antibodies.

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Technical Supervisor: Kathleen Braniff, MSA, MT(ASCP)	Date: 7.20.2020
Laboratory Director:	Date: