Technical Data

MaxSure COVID-19 IgM/IgG Antibody Test

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Intended use

MaxSure COVID-19 IgM/IgG Antibody Test is a rapid and qualitative immunochromatographic in vitro assay for differential detection of IgM and IgG antibodies to SARS-CoV-2 in human serum, plasma and whole blood samples.

The device is designed to aid in the determination of recent or previous exposure to SARS-CoV-2 virus, tracking the body's immunity status after infection by the SARS-CoV-2 virus. It only provides a preliminary result. Negative results do not exclude SARS-CoV-2 infection. Patient management decisions should combine negative results with clinical observations, patient history, and epidemiological information. A positive result does not necessarily mean a current infection but represents a different stage of the disease after infection. Current infection should be confirmed by Real-Time Reverse Transcriptase (RT-PCR) or viral gene sequencing.

The test is in vitro diagnostic (IVD) device for professional use only.

Principle of the test

MaxSure COVID-19 IgM/IgG Antibody Test is an antibody-capture immunochromatographic assay for simultaneous detection and differentiation of IgM and IgG antibodies to SARS-CoV-2 virus. When the sample (human serum, plasma or whole blood) is added in the sample well, the specific antibodies, if any in the sample, will react with the SARS-CoV-2 specific antigens conjugated to colloidal gold. As the immunocomplex migrates along the strip, IgM and IgG antibodies are captured on the respective areas where anti-human IgM and IgG antibodies were immobilized and red/violet lines appear, indicating positive results. A colored procedure control line always forms at the end of the test area marked "C". If SARS-CoV-2 antibodies are absent in the sample, no red/violet line will form in the test lines (G and M), indicating a negative result.

Materials provided with the test

- 25 test devices, individually packed
- 1 dropper bottle containing buffer reagent (3ml)
- 25 sample transfer pipettes
- Instructions for use

Other materials required

- Lancets
- Blood collection tubes
- Micropipette
- Alcohol wipe
- Timer

Storage and Stability

Test components are stored between 2°C-30°C. Do not freeze. Keep away from direct sunlight, moisture and heat. The kit can be used until the expiry date indicated on the label.

Performance evaluation

Clinical Sensitivity and Specificity

Total 1162 samples including 285 of RT-PCR confirmed SARS-CoV-2 positive serum / plasma / whole blood samples and 877 of RT-PCR confirmed SARS-CoV-2 negative serum / plasma or clinically true serum / plasma were used to evaluate MaxSure COVID-19 IgM/IgG Antibody Test. Among all the 285 positive samples, MaxSure COVID-19 IgM/IgG Antibody Test identified out 269 of COVID-19 IgM and/or IgG positive including 253 of IgM positive; 259 of IgG positive. The diagnostic sensitivity for IgM test was 88.77%; for IgG was 90.88%; the combined sensitivity was 94.39%. The diagnostic specificity for IgM was 98.40%; for IgG was 99.77%; the combined specificity was 98.18%. The overall agreement for IgM and IgG was 96.04% and 97.59%, respectively. The combined overall agreement was 97.25%. The PPV for IgM and IgG was 94.76% and 99.23%, respectively. The combined IgM & IgG PPV was 94.39%. The NPV for IgM and IgG was 96.42% and 97.11%, respectively. The combined IgM & IgG NPV was 99.42%.

		RT-PCR Confirmed/Clinically true		
		Positive	Negative	Total
MaxSure COVID-19 IgM/IgG Antibody Test	Positive	269	16	285
	Negative	16	861	877
	Total	285	877	1162

Diagnostic sensitivity of MaxSure COVID-19 IgM/IgG Antibody Test: 269/(269+16) × 100% = **94.39%**

Diagnostic specificity of MaxSure COVID-19 IgM/IgG Antibody Test: 861/(861+16) × 100% = **98.18%**

PPV: 269/(269+16) × 100% = **94.39%**

NPV: 861/(861+5) × 100% = **99.42%**

Overall agreement: (269+861)/1162 = **97.25%**

Analytical sensitivity and specificity

Inactive COVID-19 IgM/IgG sensitivity panel including 5 SARS-CoV-2 IgM positive sera (Strong, moderate and weak), 5 SARS-CoV-2 IgG positive sera (Strong, moderate and weak), and 5 negative sera was applied to validate the sensitivity of MaxSure COVID-19 IgM/IgG Antibody Test. MaxSure COVID-19 IgM/IgG Antibody Test could identify all the positive samples. No false positive or false negative results were observed.

		MaxSure COVID-19 IgM/IgG Antibody Test						
		Negative	Weak positive IgM	Moderate positive IgM	Strong positive IgM	Weak positive IgG	Moderate positive IgG	Strong positive IgG
Control Samples	Negative	5	-	-	-	-	-	-
	Weak positive IgM	-	2	-	-	-	-	-
	Moderate positive IgM	-	-	2	-	-	-	-
	Strong positive IgM	-	-	-	1	-	-	-
	Weak positive IgG	-	-	-	-	2	-	-
	Moderate positive IgG	-	-	-	-	-	2	-
	Strong positive IgG	-	-	-	-	-	-	1

Cross reactivity

Samples with the following seromarkers associated with unrelated SARS-CoV-2 medical conditions: Rheumatoid factor(RF), Anti-nuclear antibodies (ANA), Coronavirus Seasonal, Coronavirus 229E, Coronavirus NL63, Coronavirus HKU1, Coronavirus OC43, anti-Human immunodeficiency virus (HIV); Human hepatitis B virus (HBV) serum markers (HBsAg, anti-HBc IgG/IgM), Anti-Human hepatitis C virus (HCV), anti-Helicobacter pylori (HP); Anti-herpes simplex virus (HSV), anti-cytomegalovirus (CMV), anti-Chikungunya virus (CHIKV); anti-Zika virus (ZIKV); anti-mycoplasma, anti-Dengue Virus(DENV), anti-Adenovirus (ADV); anti-respiratory syncytial virus (RSV): anti-influenza A; anti-influenza B; anti-parainfluenza virus 1/2/3; anti-Epstein-Barr virus (EBV), Anti-Haemophilus influenza, anti-Streptococcus pyogenes; anti-Mycobacterium tuberculosis (TB); anti-T. pallidum (TP), total 138 samples were applied to evaluate the analytical specificity of MaxSure COVID-19 IgM/IgG Antibody Test. The results showed that only one test gave very equivocal signal on IgM with one anti-CHIKV plasma. MaxSure COVID-19 IgM/IgG Antibody Test had no cross reaction with all other 137 samples. No significant cross-reaction was observed to most of above relevant serum marker, demonstrating that MaxSure COVID-19 IgM/IgG Antibody Test has good analytical specificity.

Interference Study

Analytes commonly found in OTC, prescription and/or abuse drugs, chemical analytes, endogenous substances, and pH did not interfere MaxSure COVID-19 IgM/IgG Antibody Test.

Matrix equivalency

27 nasopharyngeal samples from patients with symptoms were tested with RT-PCR and 17 of them found positive. Serum samples were also collected from all patients. These serum samples were tested for antibodies (IgM and/or IgG) and then they were graded as low positive, high positive and negative to be used in matrix equivalency study. For each grade 5 patients were selected as donors. Venipuncture whole blood and fingerstick whole blood samples were collected from each donor (15 individual samples in total). Two operators who are not aware of the initial grading of the samples ran the tests in duplicates. Venipuncture whole blood and fingerstick samples were tested immediately after collection.

Some portion from venipuncture whole blood samples were transferred to tubes containing different types of anticoagulants (EDTA, sodium citrate and lithium heparin) and the remaining whole blood was allowed to clot and form serum. Serum and plasma samples were then tested in duplicates. Only one fingerstick sample was evaluated as weak positive although it was graded as strong positive initially. The other operator evaluated the same sample as strong positive. The results demonstrated that MaxSure COVID-19 IgM/IgG Antibody Test results do not differ significantly with different sample types and anticoagulant types.

Repeatability and Reproducibility

5 SARS-CoV-2 IgM positive sera (Strong, moderate and weak), 5 SARS-CoV-2 IgG positive sera (Strong, moderate and weak), and 5 negative sera was used to validate the repeatability and reproducibility of MaxSure COVID-19 IgM/IgG Antibody Test.

The samples were tested in duplicates by two operators at different sites.

There was no significant difference observed for the same sample when repeatedly testing 10 tests in the same batch.

When tested with three lots no appreciable intra and inter lot variation were observed among different lots, different operators at different test sites in different time for the same sample.

Tests showed positive results with all positive samples and showed negative results with negative samples.

The results demonstrated that the repeatability and reproducibility of MaxSure COVID-19 IgM/IgG Antibody Test are satisfactory.

Stability study

Test devices taken from three different production lots were taken for stability study and divided into three groups: Group 1 – stored at 2-8°C, Group 2 – stored at room temperature (20-30°C), and Group 3 – accelerated at 40°C. Samples from each group are taken and tested with negative, weak positive (for IgM and IgG) and strong positive serum (for IgM and IgG) samples in duplicates every two weeks. Correct results were obtained with all samples in all groups eight weeks. Real time stability study continues until May 2021.