ASSURETECH

ECOTEST®

KIT CONTAINS:

- 20 - In Vitro Diagnostic Devices (IVDD)
- 20 - 10 uL pipettes (for whole blood)
- 20 - Alcohol wipes
- 20 - One-time-use safety lancets (automatic, spring loaded, with retractable blade)
- 1 - Bottle of buffer
- 1 - Product insert

FOR IgM DETECTION

METHOD		PCR +	PCR -	Total
COVID-19 IgG/IgM Rapid Test	IgM+	74	2	76
	IgM -	5	255	230
TOTAL		79	227	306

Relative sensitivity: 93.7% (86.0%-97.3%)*
Relative specificity: 99.1% (96.8%-99.8%)*
Overall agreement: 97.7% (95.4%-98.9%)*
*95% Confidence Interval

FOR IgM DETECTION

METHOD		PCR +	PCR -	Total
COVID-19 IgG/IgM Rapid Test	IgG+	82	3	85
	IgG -	1	224	230
TOTAL		83	227	306

Relative sensitivity: 98.8% (93.5%-99.8%)*
Relative specificity: 98.7% (96.2%-99.5%)*
Overall agreement: 98.7% (96.7%-99.5%)*
*95% Confidence Interval

CLINICAL DATA

SARS-COV-2 ANTIGEN AND IGM/IGG ANTIBODY TEST RESULTS AND CLINICAL SIGNIFICANCE

TEST RESULTS			SIGNIFICANCE
PCR (Ag)	IgM Ab	IgG Ab	
+	−	−	Patient may be in the “window period” of SARS-COV-2 infection.
+	+	−	Patient may be in the early stages of infection, and the body’s immune response first produced the antibody IgM, but no IgG was produced or the IgG content did not reach the detection limit of the diagnostic reagent.
+	−	+	Patient may be in late or recurrent stage of infection.
+	+	+	Patient is in the active phase of infection, but the human body has developed some immunity to SARS-COVD-2 (the persistent antibody IgG has been produced).
−	+	−	Patient may be in the acute phase of SARS-COV-2 infection. At this time, nucleic acid test results need to be considered (PCR may be false negative).
−	−	+	Patient may have been infected with SARS-COVD-2 in the past, but the patient has recovered or the virus in the body has been cleared.
−	+	+	Patient has recently been infected with SARS-COVD-2 and is in the recovery stage, or the nucleic acid test result is false negative and the patient is in the active infection stage.

MEDIGUARD SYSTEMS

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