COVID-19 RAPID TEST KIT

CORONAVIRUS IGG / IGM RAPID TEST

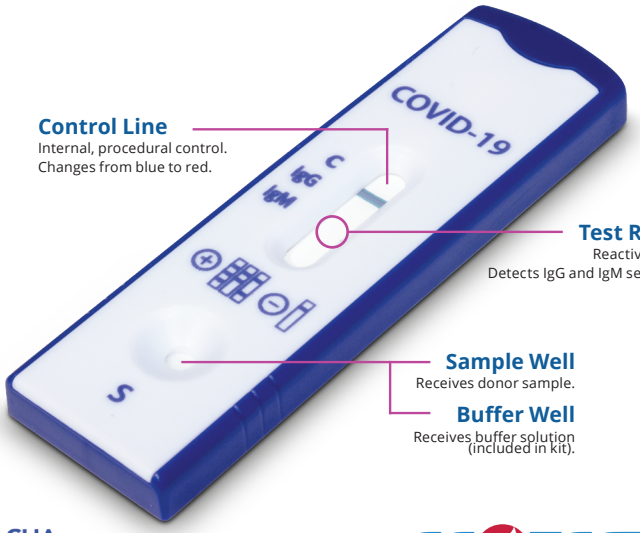
FDA EMERGENCY USE AUTHORIZATION (EUA) / CLIA WAIVED

PLYMOUTH MEDICAL

The COVID-19 IgG/IgM Rapid Test Device is an in vitro immunoassay for the direct and qualitative detection of anti-SARS-CoV-2 IgM and anti-SARS-CoV-2 IgG in human whole blood, serum, or plasma as an aid in the diagnosis of primary and second SARS-COV-2 infections. The test is for professional use only. The COVID-19 IgG/IgM Rapid Test Device detects anti-SARS-CoV-2 IgG/IgM antibody through visual interpretation of color development. Anti-human IgG and anti-human IgM are used to detect specific antibodies in the human whole blood, serum, or plasma specimen. When specimen is added to the sample well, specific IgM and/or IgG antibodies, if present, will bind to the SARS-CoV-2 antigens conjugated to colored particles on the conjugate pad.

FEATURES:

- Detection Window (IgM): Symptomatic 3-5 days, Asymptomatic 7 days
- Dual band results for simple interpretation
- Multivariable analysis of both IgG & IgM
- Room temperature storage or refrigerated
- Procedural internal control included
- Buffer included
- Box of 25 Tests and 25 Pipettes



SPECIFICATIONS:

- Sensitivity: IgG 90%; IgM 100%
- Specificity: IgG 100%; IgM 98.8%
- Specimen: Whole Blood, Serum, Plasma
- Time to Results: 10 minutes
- Shelf Life: 24 months from the date of manufacture

CLIA WAIVED

ECOTEST®

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgM	Sensitivity (PPA)	(30/30) 100%	(88.7%; 100%)
IgM	Specificity (NPA)	(79/80) 98.8%	(93.3%; 98.8%)
IgG	Sensitivity (PPA)	(27/30) 90.0%	(74.4%; 96.5%)
IgG	Specificity (NPA)	(80/80) 100%	(95.4%; 100%)
Combined	Sensitivity	(30/30) 100%	(88.7%; 100%)
Combined	Specificity	(79/80) 98.8%	(93.3%; 98.8%)
Combined	PPV at prevalence = 5%	80.8%	(40.9%; 96%)
Combined	NPV at prevalence = 5%	100%	(99.4%; 100%)
Cross-reactivity	with HIV+	(0/10) 0% not detected	----------

*Performance results from National Institute of Health study

CLIA WAIVED/FOR PROFESSIONAL USE ONLY: These tests are available for Medical Healthcare professionals only and are NOT intended for home use. Please call for more information.

PLYMOUTH MEDICAL

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FOR TECHNICAL SUPPORT, PLEASE CALL (888) 392 - 5076 Ext. 1