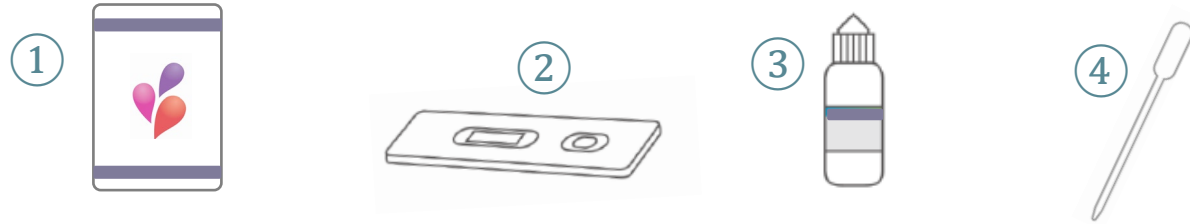


KIT COMPONENTS

1) Instructions for Use	1 Piece
2) Test Card	25 Cassettes
3) Sample Diluent	1 Vial
4) Dropper	25 Droppers



ORDERING INFORMATION

Catalog No.	Product Name	Sample Type	Storage Temperature	Packaging Size
80115	SARS-CoV-2 IgM/IgG Antibody Test	Serum, Plasma, Whole Blood	2°C – 30°C	25 Test/Kit

ThermoGenesis®

SARS-COV-2 IgM/IgG Antibody Test Kit

The SARS-CoV-2 IgM/IgG Antibody Test Kit is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2.

- ✓ **FDA Authorized**
- ✓ **Sample Volume: 10uL**
- ✓ **Rapid Test Time: 15 minutes**
- ✓ **Dual Results: IgM and IgG Antibody**

ThermoGenesis®

2711 Citrus Road | Rancho Cordova, CA 95742

Toll-Free: 800.783.8357

Local: 916.858.5100

Fax: 916.858.5199

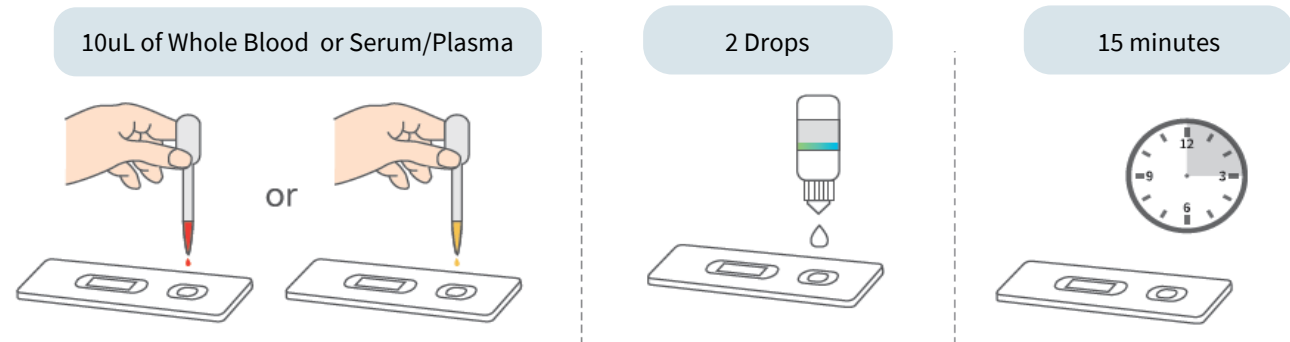
www.ThermoGenesis.com

customerservice@thermogenesis.com



Accessible COVID-19 Antibody Test Kits

OPERATION PROCEDURE



PERFORMANCE EVALUATION

Retrospective study with 186 samples from a local hospital during the COVID-19 pandemic

	Reference Method	NPA	95% Confidence Limit
SARS-CoV-2-IgM	SARS-CoV-2 PCR	99.46% (185/186)	97.04% - 99.99%
SARS-CoV-2-IgG	SARS-CoV-2 PCR	100% (186/186)	98.04% - 100%

Performance evaluation of coincidence rate of IgM / IgG over time with 197 samples

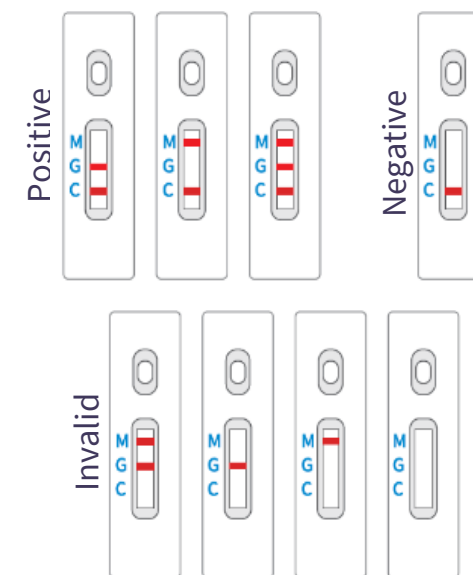
Days from onset of symptoms	PCR Positive at any time	Samples with Positive result (Serum)	PPA	IgG		IgM	
				95% CI	Samples with Positive result (Serum)	PPA	95% CI
≤ 5	12	0	0		4	33.33%	13.81- 60.93%
8 - 14	53	30	56.6%	43.26 - 69.05%	44	83.02%	70.78 - 90.80%
≥ 15	132	127	96.21%	91.43 - 98.37%	129	97.73%	93.53 - 99.22%
Total	197						

	SARS-CoV-2 IgM	SARS-CoV-2 IgG	SARS-CoV-2 IgM/IgG
*Sensitivity	96.7%	96.7%	96.7%
*Specificity	95.0%	95.0%	95.0%

*Source: Validation of the SARS-CoV-2 IgM/IgG Antibody Test at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI)

Together we can help stop the spread

RESULT INTERPRETATION



- A IgM (-) & IgG (-) Negative
- B IgM (+) & IgG (-) Positive for IgM antibody
- C IgM (+) & IgG (+) Positive for IgM and IgG antibodies
- D IgM (-) & IgG (+) Positive for IgG antibody



PRODUCT CHARACTERISTICS

- ✓ **Precision** The sensitivity of the test can reach 97.5%
- ✓ **Simple** Easy to operate with only 15 minutes to read results
- ✓ **Flexibility** Serum, plasma, and whole blood can be tested
- ✓ **Low risk** Detection of antibodies reduced the risk from sampling

