

mLabs[®]

SARS-CoV-2 IgG/IgM Assay

Rapid results in 4~8 minutes



MICROPOINT

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Features

- Easy to use - touch screen operation
- Fast - qualitative results in 4~8 minutes
- Stable - the signal is stable after testing and remains constant for at least 30 minutes
- Patented microfluidic technology enables highly precise and reliable qualitative fluorescence immunoassay testing

Clinical Significance

- Detects the combination of IgM and IgG
- Positive results occur after/recent infection

Clinical Data

- All samples were collected from individuals who were confirmed as positive or negative for the SARS-CoV-2 virus by various (FDA authorized) PCR tests.

Whole blood (N=111)		PCR Comparator	
		Positive	Negative
mLabs Assay	Positive	38	3
	Negative	2	68
Sens/PPA	95.00%	PPV	92.68%
Spec/NPA	95.77%	NPV	97.14%

Plasma (N=190)		PCR Comparator	
		Positive	Negative
mLabs Assay	Positive	38	3
	Negative	2	147
Sens/PPA	95.00%	PPV	92.68%
Spec/NPA	98.00%	NPV	98.66%

Product Name	SARS CoV-2 IgG/IgM Assay
Catalog Number	M101-091034
Sample Types	250 µL of whole blood/plasma
Sensitivity	95.0%(PL) 95.0%(WB)
Specificity	98.0%(PL) 95.8%(WB)
Storage Condition	2 - 8 °C
Shelf Life	12 months
Control	M101 - 091021 2 Levels lyophilized controls

ABOUT MICROPOINT

Micropoint Bioscience Inc. is a global provider of Point of Care Testing (POCT) systems and solutions. We are improving patient care by providing rapid, accurate, reliable, and low cost diagnostic products. Micropoint's patented microfluidic technologies and three proprietary POCT platforms enable testing at the same high quality level as a central lab, but with improved speed and convenience. Micropoint's products are manufactured in cGMP and ISO 13485 certified facilities.

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