



Detects IgG & IgM anti-SARS-CoV-2 in 10 minutes



## PRODUCT FEATURES

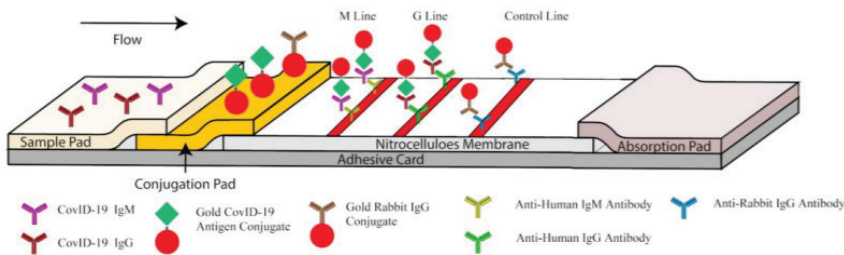
- ▶ Whole blood specimen allows testing at point-of-care, saving crucial time.
- ▶ Results in 10 minutes allow doctors to take immediate action.
- ▶ 96.9% sensitivity, 99.4% specificity (vs. PCR-confirmed specimens)
- ▶ Complementary to PCR by removing false negatives caused by specimen collection issue
- ▶ Compatible with Rapid Test Reader (RTR-1)

- 200 tests per hour in batch mode
- Capable of connecting to Laboratory Information System (LIS)
- Built-in barcode reader provides faster test set up
- Store up to 1,000 results, presented on screen, via printout, or uploaded to database

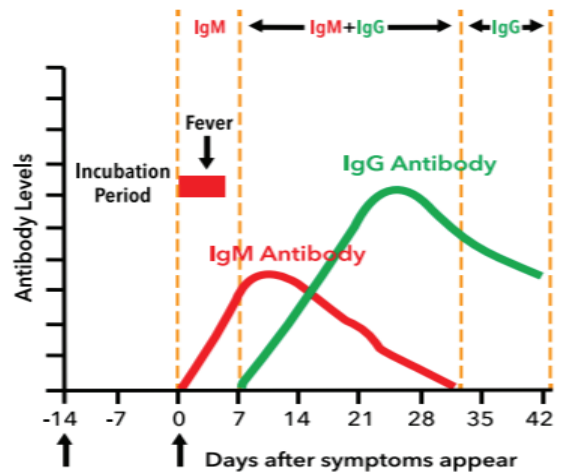




# COVID-19 IgG/IgM Rapid Test CE



## TEST PRINCIPLE



## COVID-19 INFECTION CHART

### NEED OF RAPID DIAGNOSTIC TEST FOR COVID-19

- ▶ Long Turn around Time, complicated in operation of RT-PCR and other methods.
- ▶ PCR Test required certified laboratories, expensive technique and trained technicians to operate.
- ▶ There are some number of false negatives in RT-PCR of COVID-19. (Gallagher et al., Feb 2020)
- ▶ Hence, there is an urgent need for a rapid, simple to ease, sensitive and accurate test to quickly identify infected patients of SARS-CoV-2

### CLINICAL PERFORMANCE

PCR Test	COVID-19 IgG/IgM Rapid Test IgG Results		COVID-19 IgG/IgM Rapid Test IgM Results	
	Positive	Negative	Positive	Negative
Positive	216	7	174	49
Negative	0	328	2	326
Total	216	335	176	375

Relative IgG Sensitivity: 96.86% (95% CI: 93.66%-98.47%), Relative IgG Specificity: 100% (95% CI: 98.84%-100%)  
 Relative IgM Sensitivity: 78.03% (95% CI: 72.14%-82.96%), Relative IgM Specificity: 99.39% (95% CI: 97.80%-99.83%)  
 Relative Test Sensitivity: 96.86% (95% CI: 93.66%-98.47%), Relative Test Specificity: 99.39% (95% CI: 97.80%-99.83%)  
 Overall Agreement: 98.37% (95% CI: 96.93%- 99.14%)



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