IgG/IgM Rapid Test Device

Developer: Assure Tech. (Hangzhou Co., Ltd)
Test: Assure COVID-19 IgG/IgM Rapid Test Device
Technology: Lateral Flow
Target: Spike and Nucleocapsid

Antibody	Performance Measure	Estimate of Performance	95% Confidence Interval
IgM	Sensitivity	100% (30/30)	(88.7%; 100%)
IgM	Specificity	98.8% (79/80)	(93.3%; 99.8%)
IgG	Sensitivity	90.0% (27/30)	(74.4%; 96.5%)
IgG	Specificity	100% (80/80)	(95.4%; 100%)
Combined	Sensitivity	100% (30/30)	(88.7%; 100%)
Combined	Specificity	98.8% (79/80)	(93.3%; 99.8%)
Combined	PPV at prevalence = 5%	80.8%	(40.9%; 96.0%)
Combined	NPV at prevalence = 5%	100%	(99.4%; 100%)