



Serology Test Evaluation Report for “Megna Rapid COVID-19 IgM/IgG Combo Test Kit” from Megna Health Inc.

July 13, 2020

Contents

1	Introduction	2
1.1	Panel composition	2
1.2	Analysis	4
1.3	Important caveats	4
1.4	Notes about the evaluation procedure	4
1.5	Additional notes, anomalies, and clarifications	5
2	Results	6
3	Line Data	7

List of Tables

1	Summary Results	6
2	Summary Statistics	6
3	Line Data	7

2 Results

Table 1: Summary Results

	Comparator Method			Collected pre-2020		Total
	Antibody Positive			Antibody Negative		
Megna Rapid COVID-19 IgM/IgG Combo Test Kit	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	
IgM+, IgG+	25					25
IgM+, IgG-				2		2
IgM-, IgG+	5			2		7
IgM-, IgG-				66	10	76
Total	30			70	10	110

Table 2: Summary Statistics

Measure	Estimate	Confidence Interval
IgM Sensitivity	83.3% (25/30)	(66.4%; 92.7%)
IgM Specificity	97.5% (78/80)	(91.3%; 99.3%)
IgG Sensitivity	100% (30/30)	(88.7%; 100%)
IgG Specificity	97.5% (78/80)	(91.3%; 99.3%)
Combined Sensitivity	100% (30/30)	(88.7%; 100%)
Combined Specificity	95.0% (76/80)	(87.8%; 98%)
Combined PPV for prevalence = 5.0%	51.3%	(27.7%; 72.9%)
Combined NPV for prevalence = 5.0%	100%	(99.3%; 100%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	