Supplemental Online Content

TEXT S1. MATERIALS AND METHODS

Fig. S1. Sensitivity and Specificity by Panel.

Fig. S2. Sensitivity and Specificity by Assay Type.

Table S1. Serology assay performance data for each evaluation

This supplemental material has been provided by the authors to give readers additional information about their work.

TEXT S1.

1. Performance Evaluation Panels

1.1. Panel Samples

Three evaluation panels were created; each panel composition and size were selected to provide reasonable estimates and confidence intervals for test performance in the context of limited sample availability for laboratory-based evaluations. The evaluation panels were composed of 30 anti-SARS-CoV-2 antibody positive serum samples from patients with confirmed SARS-CoV-2 infection by a nucleic acid amplification test, as well as 80 antibody negative peripheral blood samples, collected prior to December 1, 2019, which includes samples from 10 individuals living with HIV infection. HIV samples were included as those samples have previously demonstrated potential for cross-reactivity, particularly in the RBD assay. The samples were obtained from multiple sources (Mount Sinai Health System, The Biodefense and Emerging Infections Research Resources Repository (BEI), Vitalant, Northwestern University, Boca Biolistics, and CDC) and were collected under approved protocols. For each evaluation panel, samples were not randomly selected; rather, they were selected to maintain similar characteristics between panels, including sample SARS-CoV-2 spike IgM and IgG titer profile, days post symptom onset (17-46 days), and sample matrix (anti-SARS-CoV-2 antibody positive samples were all serum). Two laboratories (CDC and NCI-FNLCR) were used to confirm the presence or absence of anti-SARS-CoV-2 antibodies for IgM, IgG, and pan-Ig. All SARS-CoV-2 negative samples were serum or plasma obtained from blood collected into Anticoagulant Citrate Dextrose Solution, Solution A (ACD-A plasma). Samples from each panel were aliquoted in 50 µL aliquots and frozen at -80°C until testing. All samples were subjected to no more than two freeze/thaw events prior to testing.

1.2. Serology Assays for Sample Characterization

The sequences used for both the RBD and spike proteins were based on the genomic sequence of the first isolate, Wuhan-Hu-1 (GenBank: MN908947.3). Sequences were codon-optimized for mammalian cell expression, and the full-length spike sequence was modified to remove the polybasic cleavage site for optimal expression. The plasmid pCAGGS was used for mammalian expression of the SARS Coronavirus 2, Wuhan-Hu-1 spike gene RBD with C-terminal hexa-histidine tag (BEI Resources #NR-52309) and the SARS Coronavirus 2, Wuhan-Hu-1 ectodomain spike gene with C-terminal hexa-histidine tag (BEI Resources #NR-52394).

1.2.1. NCI-FNLCR SARS-CoV-2 Spike RBD ELISA Testing

An Immulon 4 HBX 96-well plate (ThermoScientific Cat#3855) was coated with 50 µL of SARS-CoV-2 RBD (2 µg/mL) and incubated overnight at 4°C. Following incubation, the plate was washed three times (350 µL per wash cycle) with an automated plate washer (Biotek, Winooski, VT). The wash buffer consisted of PBS + 0.05% Tween 20 (Millipore Sigma, Cat# P3563). The plate was blocked (200 µL per well, 3% skim milk [American Bio, Cat# AB10109-01000], 0.1% Tween 20 [Fisher Bioreagents, Cat# BP337-500] in PBS [Gibco, Cat# 10010-023]) for 60-240 min at room temperature, and then washed three times. Heat-inactivated samples (diluted 1:50 in sample buffer; 1% skim milk with 0.1% Tween-20 in PBS) were then added in singlet (100 µL per well) to the plate and incubated at room temperature for 120-240 min. Next, the plate was washed three times, and 50 µL of diluted HRP-conjugate (1:3000; Sigma, Cat# A0293) was added to each well and the plate was incubated at room temperature for 50-65 min. The plate was then washed three times, and 100 µL of SigmaFast OPD solution (Sigma-Aldrich, Cat# P9187) was added to each well. Following a 10-min room temperature incubation, 50 µL of 3M HCl (Fisher Scientific, Cat# S25856) was added to each well and the plate was read at 490 nm on a

Spectramax plate reader (Molecular Devices). Data analyses were performed using SoftMax Pro GxP 7.0.3 and Microsoft Excel. Positive samples were defined as having an optical density (OD) value higher than the negative controls (a set of pre-COVID-19 samples) + 3 standard deviations.

1.2.2. NCI-FNLCR SARS-CoV-2 Spike ELISA Screen (Pan-Ig) Testing

NCI-FNLCR measured anti-spike antibody levels using the assays' standard operating procedures provided by CDC [1]. Initially, samples were screened for anti-SARS-CoV-2 spike antibodies with a pan-Ig conjugate-HRP antibody. Briefly, an Immulon 2 HB 96-well plate (ThermoScientific Cat# 3455) was coated with 100 µL of SARS-CoV-2 spike protein (1 µg/mL) and incubated overnight (up to 1 week) at 4°C. Following incubation, the plate was washed three times using the procedure described above. The plate was blocked (150 µL per well, 5% skim milk [BD, Cat# 232100], 0.1% Tween-20 [Fisher Bioreagents, Cat# BP337-500] in PBS [Gibco, Cat# 10010-023]) for 60 min at 37°C (humidified), then washed three times. Heat-inactivated samples (diluted 1:100 in blocking buffer; 5% skim milk [BD, Cat# 232100], 0.1% Tween-20 [Fisher Bioreagents, Cat# BP337-500] in PBS [Gibco, Cat# 10010-023]) were then added in singlet (100 µL per well) to the plate and incubated at 37°C (humidified) for 60 min. Next, the plate was washed three times, and 100 µL of diluted goat anti-human IgG/IgA/IgM (pan-Ig) HRP-conjugate (1:4000; KPL, Cat# 074-1007) was added to each well and incubated at 37°C (humidified) for 60 min. The plate was washed three times, and then 100 µL of ABTS Peroxidase Substrate (Seracare, Cat# 5120-0035 and 5120-0038) was added to each well. Following a 15-min 37°C (humidified) incubation, 100 µL of 1X ABTS Peroxidase Stop Solution (Seracare, Cat# 5150-0017) was added to each well, and the plate was read at 405 nm and 490 nm on a Spectramax plate reader (Molecular Devices). Data analyses were performed as previously described using SoftMax Pro GxP 7.0.3 and Microsoft Excel.

1.2.3. NCI-FNLCR SARS-CoV-2 Spike IgG and IgM ELISA Testing

All positive samples were further evaluated to determine anti-spike IgG and IgM antibody titers. Briefly, rows 1-4 of an Immulon 2 HB 96-well plate (ThermoScientific Cat# 3455) were coated with 100 µL of SARS-CoV-2 spike protein (0.15 µg/mL) and incubated overnight (up to 1 week) at 4°C. Following incubation, the plate was washed three times as previously described. The plate was blocked (150 µL per well, 5% skim milk (BD, Cat# 232100), 0.1% Tween-20 (Fisher Bioreagents, Cat# BP337-500) in PBS (Gibco, Cat# 10010-023) for 60 min at 37°C (humidified), then washed three times. Blocking Buffer (150 µL) was added to all rows of the 96-well plate, then 50 µL of each heat-inactivated sample (diluted 1:25 in Blocking Buffer; 5% skim milk [BD, Cat# 232100], 0.1% Tween-20 [Fisher Bioreagents, Cat# BP337-500] in PBS [Gibco, Cat# 10010-023] was added to the first and fifth rows of the plate. Next, four-fold serial dilutions ranging from 1:100 to 1:6400 were performed for each sample. The plate was incubated at 37°C (humidified), for 60 min, then washed three times, and 100 µL of diluted goat anti-human IgM HRP-conjugate (1:2000; Jackson Immunoresearch Cat# 109-036-129) or 100 µL of diluted goat anti-human IgG HRP-conjugate (1:2000; Seracare, Cat# 5220-0390 for) was added to each well and incubated at 37°C (humidified), for 60 min. The plate was washed three times, and then 100 µL of ABTS Peroxidase Substrate (Seracare, Cat# 5120-0035 and 5120-0038) was added to each well. Following a 15-min, 37°C (humidified) incubation, 100 µL of 1X ABTS Peroxidase Stop Solution (Seracare, Cat# 5150-0017) was added to each well, and the plate was read at 405 nm and 490 nm on a Spectramax plate reader (Molecular Devices). Data analyses were performed using SoftMax Pro GxP 7.0.3 and Microsoft Excel. To deduct non-specific background reactivity, corrected OD values were calculated by subtracting the ODs of uncoated wells from ODs at corresponding wells coated with SARS-CoV-2 spike protein. Positive samples were defined as having a signal higher than negative control, pre-COVID-19 samples + 3 standard deviations, and the end point titer was reported based on the range from 1:100 to 1:6400 for each sample.

1.2.4. CDC SARS-CoV-2 Spike Testing

At CDC, all specimens were tested to assess the presence of pan-Ig, IgG and IgM antibodies by ELISA [1] using the pre-fusion stabilized ectodomain of the SARS-CoV-2 spike protein expressed in suspension adapted HEK-293 cells as previously described [2]. ELISA plates were prepared as described previously [1] using 100 µL of SARS-CoV-2 spike protein diluted to 0.15 µg/mL in PBS or PBS alone (to determine background reactivity). All specimens were initially tested to determine the presence of pan-Ig antibodies. Serum or plasma samples, as well as positive and negative controls, were tested at a final dilution of 1:100 (diluent contained PBS with 0.05% Tween 20 [PBS-T] containing 5% skim milk). Samples and controls were added to both antigen-coated and blank wells as described above. Plates were incubated at 37°C (humidified) for 60 min and washed three times with PBS-Tween 20. HRP (horseradish peroxidase) conjugated goat anti-human IgA + IgG + IgM (pan-Ig) antibodies (Cat# 074 1007, KPL) diluted at 1:2000 in serum diluent were added to washed plates and incubated at 37°C (humidified) for 60 min. Plates were washed three times with PBS-T, 100 µl of ABTS peroxidase substrate (Cat# for Solution A is 5120-0035 and Solution B is 5120-0038, KPL) was added to each well, and plates were incubated for 30 min at 37°C. After 30 min, 100 µl of ABTS stop solution (Cat# 5150-0017, KPL) was added to each well, and each plate was read at 405 and 490 nm using a PerkinElmer Victor XV plate reader. Final background corrected ODs were calculated as 490-405, by subtracting the ODs of PBS coated well for each specimen. Data analyses were performed using GraphPad Prism software (7.04). Samples that were reactive at a 1:100 dilution using the pan-Ig secondary antibody (background corrected OD >0.4), were then tested using the same plates and protocol except the sera were diluted four-fold (1:100 to 1:6400), and anti-human IgG (Cat# 5220-0330, KPL) and anti-human IgM (Cat# 5220-0457, KPL) were used as secondary antibodies. Samples that were positive at a dilution greater than 1:6400 were assigned a titer of 6400.

Antibody levels are presented as titers for all the FNLCR and CDC data.

2. Antibody Assays Evaluated

In FDA's guidance, Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency, reissued May 11, 2020, FDA outlined recommendations for validation studies to be conducted by test developers for SARS-CoV-2 serology assays and submitted in an EUA request [3]. Final EUA for the serology assays evaluated was determined by FDA based on the totality of scientific evidence available for each test including the data from the studies that were conducted and submitted to FDA by the test developer in addition to the independent evaluation data from this trans-government collaboration. Most companies submitted their assay kits for evaluation in this program under a Material Transfer Agreement. In many cases, FDA requested that serology tests from commercial manufacturers, including lateral flow assays and manual ELISAs, be independently evaluated under this program prior to authorization. In addition, six evaluations were conducted post-market for tests that were already EUA-authorized. Due to limited resources and availability of specimens, assays were prioritized for testing based on several factors, such as the public health need at the time, and to help facilitate timely completion of FDA review. A total of 91 assay evaluations were performed at the NCI-FNLCR, NIH Clinical Center, and/or CDC, for which the independent evaluation data are publicly available as of January 2021. The tests included 78 lateral flow assays and 10 ELISAs that were evaluated at the NCI-FNLCR, three automated chemiluminescent immunoassays (CIAs) that were evaluated at the CDC (Architect SARS-CoV-2 IgG, and VITROS Immunodiagnostic Products Anti-SARS-CoV-2 Total Reagent Pack), and one CIA that was evaluated at the NIH Clinical Center (Elecsys Anti-SARS-CoV-2). Details on the devices evaluated, such as manufacturer, kit lot number, target antigen (spike and/or nucleocapsid (N)) are provided in Supplementary Table 1.

3. Statistical Analyses

Commercial serology assays submitted for evaluation by this program were evaluated for two main performance parameters: 1) sensitivity estimates (positive percent agreement [PPA]), representing the percent of positive performance evaluation samples with a positive test result; and

2) specificity estimates (negative percent agreement [NPA]), representing the percent of negative panel samples with a negative test result. These performance estimates may not be indicative of real-world sensitivity or specificity performance of these assays as samples used in the evaluations were not randomly selected. In addition, the PPA of each test was assessed for each claimed antibody type (e.g., IgG, IgM, and/or pan-Ig) in accordance with the assay's intended use and in a combined manner, where a positive result for any antibody type was considered a positive result, as that would be indicative of a sample from an individual with a detectable immune response to the virus. NPA was assessed in a combined manner as well, where a negative result meant a sample was negative for all antibodies a test was intended to detect.

87 individual assays were evaluated under this program. Four of the 87 assays were evaluated twice for a total of 91 evaluations. For the four assays that were evaluated twice, the results of the evaluation were also assessed in a combined manner (n = 95). Combining results from multiple evaluations was appropriate because the study protocol did not change, including the inclusion and exclusion criteria, and because the same assays were used in the evaluations.

Some of the serum and plasma samples, with large volumes available, were used in multiple panels. Serum and plasma samples that were shared between panels have the same Sample ID in the line data for the evaluations. If an assay was evaluated more than once, and a serum or plasma sample was shared between the two panels, then only one result was reported for the combined evaluations. If the results on the sample were discrepant between the evaluations, the result showing the worst-case performance was used. Combining the results of multiple evaluations in this way enabled us to reduce the width of the 95% confidence interval for PPA and NPA for these assays.

References

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3. FDA. Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised). Secondary Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) 2020. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.
4. Altman D, Machin D, Bryant T, Gardner M. *Statistics with Confidence: Confidence Intervals and Statistical Guidelines, 2nd Edition*: BMJ Books, 2000.

Fig. S1. Sensitivity and Specificity by Panel.

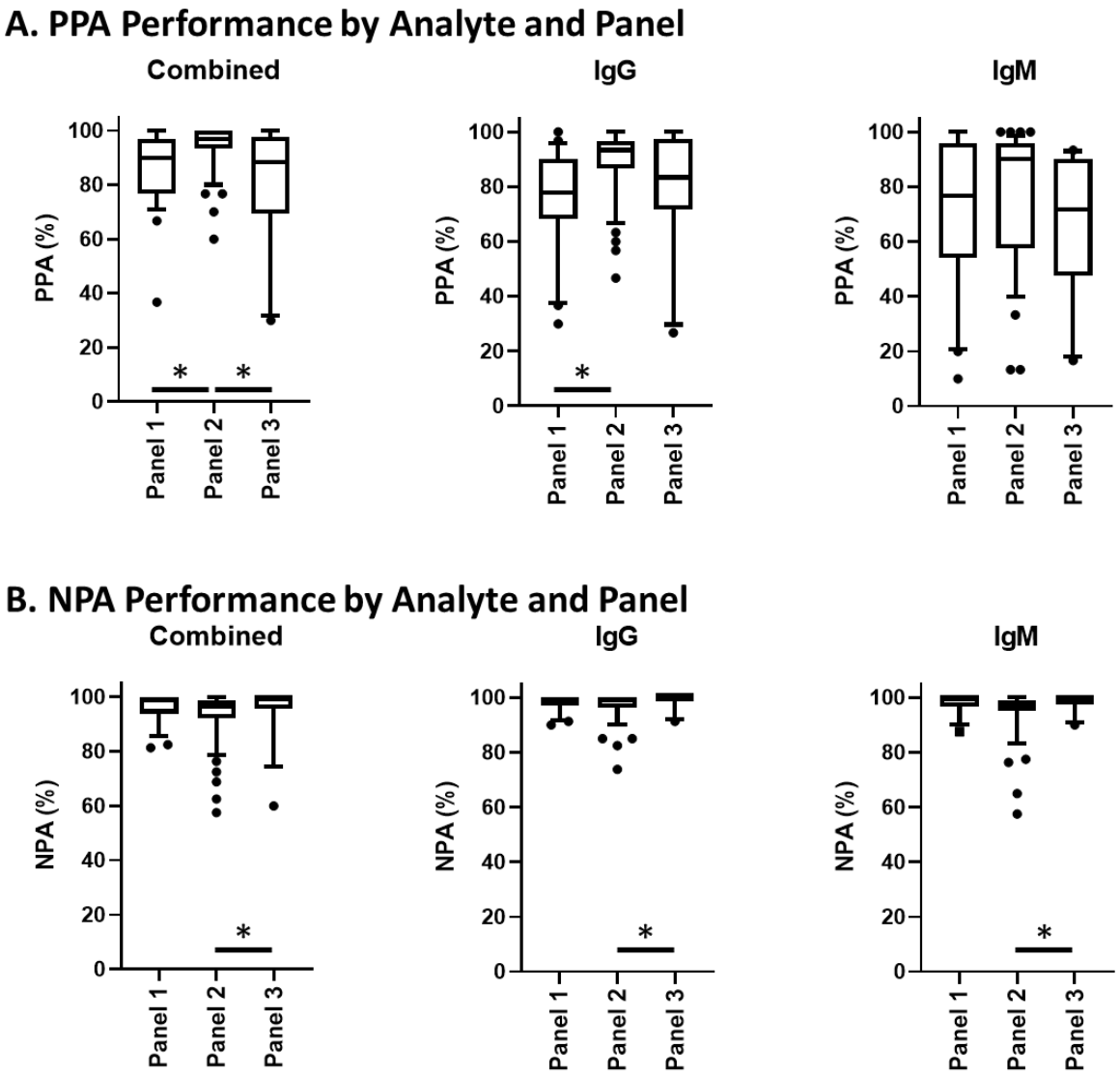

Fig. S1. Sensitivity and Specificity by Panel. A) The positive percent agreement (PPA, sensitivity) for each assay is grouped based on panel used for testing for combined, IgG, and IgM detection. B) The negative percent agreement (NPA, specificity) for each assay is grouped based on panel used for testing for combined, IgG, and IgM detection. The bar graphs indicate the median, 25% to 75% range of true call percentages for each titer group value, and the vertical lines represent the 10% to 90% range. Wilcoxon Method was used to evaluate comparisons between each panel and significant ($p<0.05$) differences between panels are indicated by *.

Fig. S2. Sensitivity and Specificity by Assay Type.

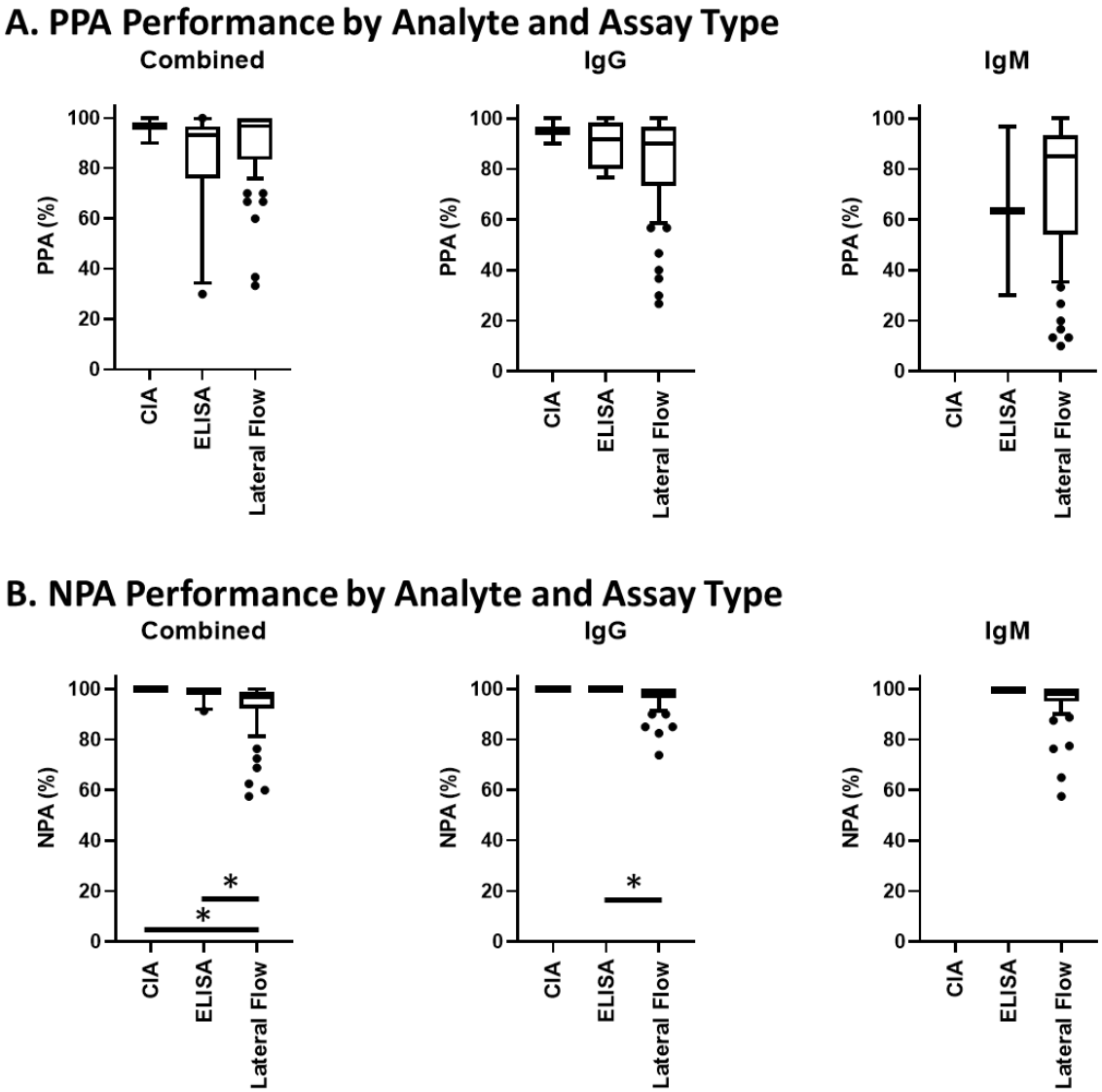

Fig. S2. Sensitivity and Specificity by Assay Type. A) The positive percent agreement (PPA, sensitivity) for each assay is grouped based on assay type tested for combined, IgG, and IgM detection. B) The negative percent agreement (NPA, specificity) for each assay is grouped based on assay type tested for combined, IgG, and IgM detection. The bar graphs indicate the median, 25% to 75% range of true call percentages for each titer group value, and the vertical lines represent the 10% to 90% range. Wilcoxon Method was used to evaluate comparisons between each assay type and significant ($p<0.05$) differences between assay types are indicated by *.

Table S1. Serology assay performance data for each evaluation

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3305-a001	Abbott	Architect i1000 SARS-CoV-2 IgG	15016M800	Panel 1	CIA	Nucleocapsid	EUA Authorized	Combined	90.0	(95% CI: 74.4%; 96.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 46.1%; 100%)	99.5	(95% CI: 98.6%; 99.8%)
maf3305-a001	Abbott	Architect i1000 SARS-CoV-2 IgG	15016M800	Panel 1	CIA	Nucleocapsid	EUA Authorized	IgG	90.0	(95% CI: 74.4%; 96.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 46.1%; 100%)	99.5	(95% CI: 98.6%; 99.8%)
maf3246-a001	Euroimmun	SARS-COV-2 ELISA (IgG)	E200330DT	Panel 1	ELISA	Spike	EUA Authorized	Combined	90.0	(95% CI: 74.4%; 96.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 46.1%; 100%)	99.5	(95% CI: 98.6%; 99.8%)
maf3246-a001	Euroimmun	SARS-COV-2 ELISA (IgG)	E200330DT	Panel 1	ELISA	Spike	EUA Authorized	IgG	90.0	(95% CI: 74.4%; 96.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 46.1%; 100%)	99.5	(95% CI: 98.6%; 99.8%)
maf3268-a001	Euroimmun	SARS-COV-2 ELISA (IgA)	E200330AS	Panel 1	ELISA	Unknown	Not Authorized	Combined	93.3	(95% CI: 78.7%; 98.2%)	91.3	(95% CI: 83.0%; 95.7%)	36.0	(95% CI: 19.6%; 54.6%)	99.6	(95% CI: 98.7%; 99.9%)
maf3268-a001	Euroimmun	SARS-COV-2 ELISA (IgA)	E200330AS	Panel 1	ELISA	Unknown	Not Authorized	IgA	93.3	(95% CI: 78.7%; 98.2%)	91.3	(95% CI: 83.0%; 95.7%)	36.0	(95% CI: 19.6%; 54.6%)	99.6	(95% CI: 98.7%; 99.9%)
maf3247-a001	Healgen	COVID-19 IgG/IgM Rapid Test Cassette	2003292	Panel 1	Lateral Flow	Spike	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	97.5	(95% CI: 91.3%; 99.3%)	67.8	(95% CI: 35.0%; 88.4%)	100.0	(95% CI: 99.4%; 100%)
maf3247-a001	Healgen	COVID-19 IgG/IgM Rapid Test Cassette	2003292	Panel 1	Lateral Flow	Spike	EUA Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	97.5	(95% CI: 91.3%; 99.3%)	67.1	(95% CI: 33.6%; 88.4%)	99.8	(95% CI: 99.0%; 100%)
maf3247-a001	Healgen	COVID-19 IgG/IgM Rapid Test Cassette	2003292	Panel 1	Lateral Flow	Spike	EUA Authorized	IgM	100.0	(95% CI: 88.6%; 100%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 50.5%; 100%)	100.0	(95% CI: 99.4%; 100%)
maf3248-a001	Biomedomics	COVID-19 IgM-IgG Rapid Test kit	51-200404	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	97.1	(95% CI: 90.2%; 99.2%)	64.0	(95% CI: 30.8%; 86.9%)	99.8	(95% CI: 99.0%; 100%)
maf3248-a001	Biomedomics	COVID-19 IgM-IgG Rapid Test kit	51-200404	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	73.3	(95% CI: 55.6%; 85.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 39.0%; 100%)	98.6	(95% CI: 97.6%; 99.3%)
maf3248-a001	Biomedomics	COVID-19 IgM-IgG Rapid Test kit	51-200404	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	86.7	(95% CI: 70.3%; 94.7%)	97.1	(95% CI: 90.2%; 99.2%)	61.5	(95% CI: 27.3%; 86.4%)	99.3	(95% CI: 98.3%; 99.7%)
maf3249-a001	Phamatech	COVID19 RAPID TEST	NCP 20030239	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	86.7	(95% CI: 70.3%; 94.7%)	93.8	(95% CI: 86.2%; 97.3%)	42.2	(95% CI: 21.1%; 64.9%)	99.3	(95% CI: 98.2%; 99.7%)
maf3249-a001	Phamatech	COVID19 RAPID TEST	NCP 20030239	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	86.7	(95% CI: 70.3%; 94.7%)	96.3	(95% CI: 89.5%; 98.7%)	54.9	(95% CI: 26.1%; 79.5%)	99.3	(95% CI: 98.3%; 99.7%)
maf3249-a001	Phamatech	COVID19 RAPID TEST	NCP 20030239	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	26.7	(95% CI: 14.2%; 44.4%)	97.5	(95% CI: 91.3%; 99.3%)	36.0	(95% CI: 7.9%; 77.3%)	96.2	(95% CI: 95.3%; 97.1%)
maf3251-a001	Tianjin Beroni Biotechnology Co., Ltd.	SARS-COV-2 IgG/IgM Antibody Detection Kit	20200405 (Test Strip)	Panel 1	Lateral Flow	S1	Not Authorized	Combined	90.0	(95% CI: 74.4%; 96.5%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 42.9%; 100%)	99.5	(95% CI: 98.6%; 99.8%)
maf3251-a001	Tianjin Beroni Biotechnology Co., Ltd.	SARS-COV-2 IgG/IgM Antibody Detection Kit	20200405 (Test Strip)	Panel 1	Lateral Flow	S1	Not Authorized	IgG	30.0	(95% CI: 16.7%; 47.9%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 16.1%; 100%)	96.4	(95% CI: 95.6%; 97.3%)
maf3251-a001	Tianjin Beroni Biotechnology Co., Ltd.	SARS-COV-2 IgG/IgM Antibody Detection Kit	20200405 (Test Strip)	Panel 1	Lateral Flow	S1	Not Authorized	IgM	83.3	(95% CI: 66.4%; 92.7%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 40.2%; 100%)	99.1	(95% CI: 98.2%; 99.6%)
maf3265-a001	ChemBio	DPP COVID-19 IgM/IgG System	204IG001Z	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	82.1	(95% CI: 64.4%; 92.1%)	81.3	(95% CI: 71.3%; 88.3%)	18.7	(95% CI: 10.6%; 29.3%)	98.9	(95% CI: 97.4%; 99.5%)
maf3265-a001	ChemBio	DPP COVID-19 IgM/IgG System	204IG001Z	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	78.6	(95% CI: 60.5%; 89.8%)	91.3	(95% CI: 83.0%; 95.7%)	32.1	(95% CI: 15.8%; 52.3%)	98.8	(95% CI: 97.6%; 99.4%)
maf3265-a001	ChemBio	DPP COVID-19 IgM/IgG System	204IG001Z	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	57.1	(95% CI: 39.1%; 73.5%)	90.0	(95% CI: 80.8%; 95.1%)	23.1	(95% CI: 9.7%; 44.0%)	97.6	(95% CI: 96.2%; 98.6%)
maf3277-a001	TESTSEALABS	SARS-COV-2-IgG/IgM Test Cassette	20200320	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	83.3	(95% CI: 66.4%; 92.7%)	92.5	(95% CI: 84.6%; 96.5%)	36.9	(95% CI: 18.5%; 58.3%)	99.1	(95% CI: 98.0%; 99.6%)
maf3277-a001	TESTSEALABS	SARS-COV-2-IgG/IgM Test Cassette	20200320	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	40.0	(95% CI: 24.6%; 57.7%)	93.8	(95% CI: 86.2%; 97.3%)	25.2	(95% CI: 8.6%; 52.9%)	96.7	(95% CI: 95.6%; 97.8%)
maf3277-a001	TESTSEALABS	SARS-COV-2-IgG/IgM Test Cassette	20200320	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	73.3	(95% CI: 55.6%; 85.8%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 36.0%; 100%)	98.6	(95% CI: 97.6%; 99.3%)
maf3252-a001	Hangzhou Biotest Biotech, Co., Ltd.	Covid-19 IgG/IgM Rapid Test Cassette	COV 20030071	Panel 1	Lateral Flow	Spike	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 50.5%; 100%)	100.0	(95% CI: 99.4%; 100%)
maf3252-a001	Hangzhou Biotest Biotech, Co., Ltd.	Covid-19 IgG/IgM Rapid Test Cassette	COV 20030071	Panel 1	Lateral Flow	Spike	EUA Authorized	IgG	93.3	(95% CI: 78.7%; 98.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 47.5%; 100%)	99.7	(95% CI: 98.8%; 99.9%)

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3252-a001	Hangzhou Biotest Biotech, Co., Ltd.	Covid-19 IgG/IgM Rapid Test Cassette	COV 20030071	Panel 1	Lateral Flow	Spike	EUA Authorized	IgM	100.0	(95% CI: 88.6%; 100%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 50.5%; 100%)	100.0	(95% CI: 99.4%; 100%)
maf3254-a001	Accudiagnostics	Covid-19 IgM/IgG Test Kit	NA	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	82.5	(95% CI: 72.7%; 89.3%)	23.1	(95% CI: 14.6%; 32.9%)	100.0	(95% CI: 99.2%; 100%)
maf3254-a001	Accudiagnostics	Covid-19 IgM/IgG Test Kit	NA	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	92.5	(95% CI: 84.6%; 96.5%)	41.2	(95% CI: 23.2%; 60.2%)	100.0	(95% CI: 99.3%; 100%)
maf3254-a001	Accudiagnostics	Covid-19 IgM/IgG Test Kit	NA	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	100.0	(95% CI: 88.6%; 100%)	87.5	(95% CI: 78.5%; 93.1%)	29.6	(95% CI: 17.8%; 43.2%)	100.0	(95% CI: 99.2%; 100%)
maf3267-a001	W.H.P.M, Inc.	Covisure Covid-19 IgM/IgG Rapid Test	P0406203922	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	76.7	(95% CI: 59.1%; 88.2%)	97.1	(95% CI: 90.2%; 99.2%)	58.5	(95% CI: 24.0%; 85.5%)	98.8	(95% CI: 97.7%; 99.4%)
maf3267-a001	W.H.P.M, Inc.	Covisure Covid-19 IgM/IgG Rapid Test	P0406203922	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	70.0	(95% CI: 52.1%; 83.3%)	97.1	(95% CI: 90.2%; 99.2%)	56.3	(95% CI: 21.8%; 84.8%)	98.4	(95% CI: 97.3%; 99.1%)
maf3267-a001	W.H.P.M, Inc.	Covisure Covid-19 IgM/IgG Rapid Test	P0406203922	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	76.7	(95% CI: 59.1%; 88.2%)	97.1	(95% CI: 90.2%; 99.2%)	58.5	(95% CI: 24.0%; 85.5%)	98.8	(95% CI: 97.7%; 99.4%)
maf3272-a001	Atlas-Link (Beijing)	Nova COVID-19 IgG/IgM Antibody Rapid Test	20200305	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	90.0	(95% CI: 74.4%; 96.5%)	90.0	(95% CI: 81.5%; 94.8%)	32.1	(95% CI: 17.5%; 49.6%)	99.4	(95% CI: 98.4%; 99.8%)
maf3272-a001	Atlas-Link (Beijing)	Nova COVID-19 IgG/IgM Antibody Rapid Test	20200305	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	90.0	(95% CI: 74.4%; 96.5%)	90.0	(95% CI: 81.5%; 94.8%)	32.1	(95% CI: 17.5%; 49.6%)	99.4	(95% CI: 98.4%; 99.8%)
maf3272-a001	Atlas-Link (Beijing)	Nova COVID-19 IgG/IgM Antibody Rapid Test	20200305	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	90.0	(95% CI: 74.4%; 96.5%)	90.0	(95% CI: 81.5%; 94.8%)	32.1	(95% CI: 17.5%; 49.6%)	99.4	(95% CI: 98.4%; 99.8%)
maf3255-a001	Alfa Scientific Designs Inc.	Covid-19 IgG/IgM Antibody Test	PD200420A	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	93.8	(95% CI: 86.2%; 97.3%)	45.7	(95% CI: 25.3%; 66.1%)	100.0	(95% CI: 99.3%; 100%)
maf3255-a001	Alfa Scientific Designs Inc.	Covid-19 IgG/IgM Antibody Test	PD200420A	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	80.0	(95% CI: 62.7%; 90.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 41.9%; 100%)	99.0	(95% CI: 98.0%; 99.5%)
maf3255-a001	Alfa Scientific Designs Inc.	Covid-19 IgG/IgM Antibody Test	PD200420A	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	100.0	(95% CI: 88.6%; 100%)	93.8	(95% CI: 86.2%; 97.3%)	45.7	(95% CI: 25.3%; 66.1%)	100.0	(95% CI: 99.3%; 100%)
maf3259-a001	Invenio Medical Inc.	COVID-19 IgG/IgM Ab Rapid Test	COVID 20200424	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	80.0	(95% CI: 62.7%; 90.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 41.9%; 100%)	99.0	(95% CI: 98.0%; 99.5%)
maf3259-a001	Invenio Medical Inc.	COVID-19 IgG/IgM Ab Rapid Test	COVID 20200424	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	80.0	(95% CI: 62.7%; 90.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 41.9%; 100%)	99.0	(95% CI: 98.0%; 99.5%)
maf3259-a001	Invenio Medical Inc.	COVID-19 IgG/IgM Ab Rapid Test	COVID 20200424	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	76.7	(95% CI: 59.1%; 88.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 40.4%; 100%)	98.8	(95% CI: 97.8%; 99.4%)
maf3280-a001	Zhuhai Livzon Diagnostic Inc.	IgM/IgG Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-COV-2)	CK 2004240410	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	93.3	(95% CI: 78.7%; 98.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 47.5%; 100%)	99.7	(95% CI: 98.8%; 99.9%)
maf3280-a001	Zhuhai Livzon Diagnostic Inc.	IgM/IgG Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-COV-2)	CK 2004240410	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	63.3	(95% CI: 45.5%; 78.1%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 34.3%; 100%)	98.1	(95% CI: 97.1%; 98.9%)
maf3280-a001	Zhuhai Livzon Diagnostic Inc.	IgM/IgG Diagnostic Kit for IgM/IgG Antibody to Coronavirus (SARS-COV-2)	CK 2004240410	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	93.3	(95% CI: 78.7%; 98.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 47.5%; 100%)	99.7	(95% CI: 98.8%; 99.9%)
maf3257-a001	Abacus Pharma International	SARS-CoV-2 IgM/IgG AB Antibody Rapid Test (Immunochromatography)	COV 1252003C	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	76.7	(95% CI: 59.1%; 88.2%)	98.8	(95% CI: 93.3%; 99.8%)	76.3	(95% CI: 31.5%; 95.5%)	98.8	(95% CI: 97.7%; 99.4%)
maf3257-a001	Abacus Pharma International	SARS-CoV-2 IgM/IgG AB Antibody Rapid Test (Immunochromatography)	COV 1252003C	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	73.3	(95% CI: 55.6%; 85.8%)	98.8	(95% CI: 93.3%; 99.8%)	75.5	(95% CI: 30.2%; 95.3%)	98.6	(95% CI: 97.6%; 99.3%)
maf3257-a001	Abacus Pharma International	SARS-CoV-2 IgM/IgG AB Antibody Rapid Test (Immunochromatography)	COV 1252003C	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	53.3	(95% CI: 36.1%; 69.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 29.3%; 100%)	97.6	(95% CI: 96.6%; 98.4%)
maf3258-a001	Aurora Biomed Inc	COVID-19 IgG/IgM Rapid Test	COVID 20200424	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	76.7	(95% CI: 59.1%; 88.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 40.4%; 100%)	98.8	(95% CI: 97.8%; 99.4%)
maf3258-a001	Aurora Biomed Inc	COVID-19 IgG/IgM Rapid Test	COVID 20200424	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	76.7	(95% CI: 59.1%; 88.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 40.4%; 100%)	98.8	(95% CI: 97.8%; 99.4%)
maf3258-a001	Aurora Biomed Inc	COVID-19 IgG/IgM Rapid Test	COVID 20200424	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	66.7	(95% CI: 48.8%; 80.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 35.9%; 100%)	98.3	(95% CI: 97.3%; 99.0%)

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3263-a001	BTNX, Inc.	COVID-19 IgG/IgM Test Cassettes (Whole Blood/Serum/Plasma)	I2004027	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 47.3%; 100%)	100.0	(95% CI: 99.4%; 100%)
maf3263-a001	BTNX, Inc.	COVID-19 IgG/IgM Test Cassettes (Whole Blood/Serum/Plasma)	I2004027	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	86.7	(95% CI: 70.3%; 94.7%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 44.7%; 100%)	99.3	(95% CI: 98.4%; 99.7%)
maf3263-a001	BTNX, Inc.	COVID-19 IgG/IgM Test Cassettes (Whole Blood/Serum/Plasma)	I2004027	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	96.7	(95% CI: 83.3%; 99.4%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 45.7%; 100%)	99.8	(95% CI: 99.1%; 100%)
maf3266-a001	Chemtron Biotech, Inc.	Rapid COVID-19 IgM/IgG Antibody Screen Test	DA05507401	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	66.7	(95% CI: 48.8%; 80.8%)	98.8	(95% CI: 93.3%; 99.8%)	73.7	(95% CI: 27.6%; 95.1%)	98.3	(95% CI: 97.2%; 99.0%)
maf3266-a001	Chemtron Biotech, Inc.	Rapid COVID-19 IgM/IgG Antibody Screen Test	DA05507401	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	63.3	(95% CI: 45.5%; 78.1%)	98.8	(95% CI: 93.3%; 99.8%)	72.7	(95% CI: 26.2%; 94.9%)	98.1	(95% CI: 97.0%; 98.9%)
maf3266-a001	Chemtron Biotech, Inc.	Rapid COVID-19 IgM/IgG Antibody Screen Test	DA05507401	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	20.0	(95% CI: 9.5%; 37.3%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 9.8%; 100%)	96.0	(95% CI: 95.2%; 96.8%)
maf3269-a001	Shanghai Fosun Long March Medical Science Co., Ltd.	Fosun COVID-19 IgG/IgM Rapid Antibody Detection Kit	20200302	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	36.7	(95% CI: 21.9%; 54.5%)	95.0	(95% CI: 87.8%; 98.0%)	27.8	(95% CI: 8.6%; 59.4%)	96.6	(95% CI: 95.5%; 97.6%)
maf3269-a001	Shanghai Fosun Long March Medical Science Co., Ltd.	Fosun COVID-19 IgG/IgM Rapid Antibody Detection Kit	20200302	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	36.7	(95% CI: 21.9%; 54.5%)	98.8	(95% CI: 93.3%; 99.8%)	60.7	(95% CI: 14.6%; 92.8%)	96.7	(95% CI: 95.8%; 97.7%)
maf3269-a001	Shanghai Fosun Long March Medical Science Co., Ltd.	Fosun COVID-19 IgG/IgM Rapid Antibody Detection Kit	20200302	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	10.0	(95% CI: 3.5%; 25.6%)	96.3	(95% CI: 89.5%; 98.7%)	12.3	(95% CI: 1.7%; 51.2%)	95.3	(95% CI: 94.6%; 96.2%)
maf3270-a001	GP Getein Biotech, Inc.	One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)	PGGM 20015W	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	76.7	(95% CI: 59.1%; 88.2%)	98.8	(95% CI: 93.3%; 99.8%)	76.3	(95% CI: 31.5%; 95.5%)	98.8	(95% CI: 97.7%; 99.4%)
maf3270-a001	GP Getein Biotech, Inc.	One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)	PGGM 20015W	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	73.3	(95% CI: 55.6%; 85.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 39.0%; 100%)	98.6	(95% CI: 97.6%; 99.3%)
maf3270-a001	GP Getein Biotech, Inc.	One Step Test for Novel Coronavirus (2019-nCoV) IgM/IgG antibody (Colloidal Gold)	PGGM 20015W	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	56.7	(95% CI: 39.2%; 72.6%)	98.8	(95% CI: 93.3%; 99.8%)	70.5	(95% CI: 23.4%; 94.5%)	97.7	(95% CI: 96.7%; 98.6%)
maf3274-a001	SD BIOSENSOR, Inc.	STANDARD Q COVID-19 IgM/IgG Duo	QC01020007/ sub : A-2	Panel 1	Lateral Flow	Unknown	Not Authorized	Combined	76.7	(95% CI: 59.1%; 88.2%)	98.8	(95% CI: 93.3%; 99.8%)	76.3	(95% CI: 31.5%; 95.5%)	98.8	(95% CI: 97.7%; 99.4%)
maf3274-a001	SD BIOSENSOR, Inc.	STANDARD Q COVID-19 IgM/IgG Duo	QC01020007/ sub : A-2	Panel 1	Lateral Flow	Unknown	Not Authorized	IgG	73.3	(95% CI: 55.6%; 85.8%)	98.8	(95% CI: 93.3%; 99.8%)	75.5	(95% CI: 30.2%; 95.3%)	98.6	(95% CI: 97.6%; 99.3%)
maf3274-a001	SD BIOSENSOR, Inc.	STANDARD Q COVID-19 IgM/IgG Duo	QC01020007/ sub : A-2	Panel 1	Lateral Flow	Unknown	Not Authorized	IgM	53.3	(95% CI: 36.1%; 69.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 29.3%; 100%)	97.6	(95% CI: 96.6%; 98.4%)
maf3358-a001	Roche Diagnostic Corporation	Elecsys Anti-SARS-CoV-2	50726001	Panel 2	CIA	Nucleocapsid	EUA Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 48.9%; 100%)	99.8	(95% CI: 99.1%; 100%)
maf3358-a001	Roche Diagnostic Corporation	Elecsys Anti-SARS-CoV-2	50726001	Panel 2	CIA	Nucleocapsid	EUA Authorized	Pan Ig	96.7	(95% CI: 83.3%; 99.4%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 48.9%; 100%)	99.8	(95% CI: 99.1%; 100%)
maf3315-a001	InBios International Inc.	SCoV-2 Detect™ IgG ELISA	DFT1172	Panel 2	ELISA	Spike	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 50.5%; 100%)	100.0	(95% CI: 99.4%; 100%)
maf3315-a001	InBios International Inc.	SCoV-2 Detect™ IgG ELISA	DFT1172	Panel 2	ELISA	Spike	EUA Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 50.5%; 100%)	100.0	(95% CI: 99.4%; 100%)
maf3316-a001	InBios International Inc.	SCoV-2 Detect™ IgM ELISA	DFT1170	Panel 2	ELISA	Spike	EUA Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	98.8	(95% CI: 93.3%; 99.8%)	80.3	(95% CI: 39.4%; 95.9%)	99.8	(95% CI: 99.1%; 100%)
maf3316-a001	InBios International Inc.	SCoV-2 Detect™ IgM ELISA	DFT1170	Panel 2	ELISA	Spike	EUA Authorized	IgM	96.7	(95% CI: 83.3%; 99.4%)	98.8	(95% CI: 93.3%; 99.8%)	80.3	(95% CI: 39.4%; 95.9%)	99.8	(95% CI: 99.1%; 100%)
maf3312-a001	Arbor Vita Corporation	CoVisa™ IgG Test	RD20060803	Panel 2	ELISA	Unknown	Not Authorized	Combined	76.7	(95% CI: 59.1%; 88.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 40.4%; 100%)	98.8	(95% CI: 97.8%; 99.4%)
maf3312-a001	Arbor Vita Corporation	CoVisa™ IgG Test	RD20060803	Panel 2	ELISA	Unknown	Not Authorized	IgG	76.7	(95% CI: 59.1%; 88.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 40.4%; 100%)	98.8	(95% CI: 97.8%; 99.4%)

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3319-a001	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab ELISA	NCOA 20200401	Panel 2	ELISA	Spike	EUA Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	97.5	(95% CI: 91.3%; 99.3%)	67.1	(95% CI: 33.6%; 88.4%)	99.8	(95% CI: 99.0%; 100%)
maf3319-a001	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab ELISA	NCOA 20200401	Panel 2	ELISA	Spike	EUA Authorized	Pan Ig	96.7	(95% CI: 83.3%; 99.4%)	97.5	(95% CI: 91.3%; 99.3%)	67.1	(95% CI: 33.6%; 88.4%)	99.8	(95% CI: 99.0%; 100%)
maf3327-a001	Zeus Scientific, Inc.	SARS-CoV-2 IgG Test System	20060295	Panel 2	ELISA	Spike and Nucleocapsid	EUA Authorized	Combined	93.3	(95% CI: 78.7%; 98.2%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 44.3%; 100%)	99.7	(95% CI: 98.8%; 99.9%)
maf3327-a001	Zeus Scientific, Inc.	SARS-CoV-2 IgG Test System	20060295	Panel 2	ELISA	Spike and Nucleocapsid	EUA Authorized	IgG	93.3	(95% CI: 78.7%; 98.2%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 44.3%; 100%)	99.7	(95% CI: 98.8%; 99.9%)
maf3260-a001	Biohit Healthcare (Hefei) Co., Ltd.	SARS-CoV-2 IgM/IgG Antibody Test Kit	SA200301	Panel 2	Lateral Flow	Nucleocapsid	EUA Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	95.0	(95% CI: 87.8%; 98.0%)	50.4	(95% CI: 26.5%; 72.7%)	99.8	(95% CI: 99.0%; 100%)
maf3260-a001	Biohit Healthcare (Hefei) Co., Ltd.	SARS-CoV-2 IgM/IgG Antibody Test Kit	SA200301	Panel 2	Lateral Flow	Nucleocapsid	EUA Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	95.0	(95% CI: 87.8%; 98.0%)	50.4	(95% CI: 26.5%; 72.7%)	99.8	(95% CI: 99.0%; 100%)
maf3260-a001	Biohit Healthcare (Hefei) Co., Ltd.	SARS-CoV-2 IgM/IgG Antibody Test Kit	SA200301	Panel 2	Lateral Flow	Nucleocapsid	EUA Authorized	IgM	96.7	(95% CI: 83.3%; 99.4%)	95.0	(95% CI: 87.8%; 98.0%)	50.4	(95% CI: 26.5%; 72.7%)	99.8	(95% CI: 99.0%; 100%)
maf3261-a001	Biolidics Ltd	2019-nCoV IgG/IgM Detection Kit (Colloidal Gold)	V5020041352 A	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	96.2	(95% CI: 89.4%; 98.7%)	57.3	(95% CI: 29.3%; 80.1%)	99.8	(95% CI: 99.0%; 100%)
maf3261-a001	Biolidics Ltd	2019-nCoV IgG/IgM Detection Kit (Colloidal Gold)	V5020041352 A	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	96.2	(95% CI: 89.4%; 98.7%)	57.3	(95% CI: 29.3%; 80.1%)	99.8	(95% CI: 99.0%; 100%)
maf3261-a001	Biolidics Ltd	2019-nCoV IgG/IgM Detection Kit (Colloidal Gold)	V5020041352 A	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	33.3	(95% CI: 19.2%; 51.2%)	97.5	(95% CI: 91.2%; 99.3%)	40.9	(95% CI: 10.3%; 79.5%)	96.5	(95% CI: 95.5%; 97.5%)
maf3275-a001	Sugentech, Inc.	Sugentech SGTi-flex COVID-19 IgM/IgG	COVT20906	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	90.0	(95% CI: 81.5%; 94.8%)	34.5	(95% CI: 20.1%; 50.5%)	100.0	(95% CI: 99.3%; 100%)
maf3275-a001	Sugentech, Inc.	Sugentech SGTi-flex COVID-19 IgM/IgG	COVT20906	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	93.3	(95% CI: 78.7%; 98.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 47.5%; 100%)	99.7	(95% CI: 98.8%; 99.9%)
maf3275-a001	Sugentech, Inc.	Sugentech SGTi-flex COVID-19 IgM/IgG	COVT20906	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	93.3	(95% CI: 78.7%; 98.2%)	90.0	(95% CI: 81.5%; 94.8%)	32.9	(95% CI: 18.3%; 50.1%)	99.6	(95% CI: 98.6%; 99.9%)
maf3262-a001	Xiamen Biotime Biotechnology Co., Ltd.	Biotime SARS-CoV-2 IgG/IgM Rapid Qualitative Test	X2003602	Panel 2	Lateral Flow	Spike	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	96.3	(95% CI: 89.5%; 98.7%)	58.4	(95% CI: 30.9%; 80.4%)	100.0	(95% CI: 99.3%; 100%)
maf3262-a001	Xiamen Biotime Biotechnology Co., Ltd.	Biotime SARS-CoV-2 IgG/IgM Rapid Qualitative Test	X2003602	Panel 2	Lateral Flow	Spike	EUA Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	97.5	(95% CI: 91.3%; 99.3%)	67.1	(95% CI: 33.6%; 88.4%)	99.8	(95% CI: 99.0%; 100%)
maf3262-a001	Xiamen Biotime Biotechnology Co., Ltd.	Biotime SARS-CoV-2 IgG/IgM Rapid Qualitative Test	X2003602	Panel 2	Lateral Flow	Spike	EUA Authorized	IgM	100.0	(95% CI: 88.6%; 100%)	98.8	(95% CI: 93.3%; 99.8%)	80.8	(95% CI: 40.9%; 96.0%)	100.0	(95% CI: 99.4%; 100%)
maf3278-a001	Nanjing Vazyme Medical Technology Co. LTD	Vazyme 2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)	5020042252B	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	68.8	(95% CI: 57.9%; 77.8%)	14.0	(95% CI: 9.4%; 19.1%)	99.7	(95% CI: 98.5%; 100%)
maf3278-a001	Nanjing Vazyme Medical Technology Co. LTD	Vazyme 2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)	5020042252B	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	90.0	(95% CI: 81.5%; 94.8%)	33.7	(95% CI: 19.2%; 50.4%)	99.8	(95% CI: 98.9%; 100%)
maf3278-a001	Nanjing Vazyme Medical Technology Co. LTD	Vazyme 2019-nCoV IgG/IgM Detection Kit (Colloidal Gold-Based)	5020042252B	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	66.7	(95% CI: 48.8%; 80.8%)	77.5	(95% CI: 67.2%; 85.3%)	13.5	(95% CI: 7.3%; 22.4%)	97.8	(95% CI: 96.1%; 98.8%)
maf3283-a001	MEDsan GmbH	MEDsan biological health solutions, MEDsan COVID-19 IgM/IgG Rapid Test	NA	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	90.0	(95% CI: 74.4%; 96.5%)	92.5	(95% CI: 84.6%; 96.5%)	38.7	(95% CI: 20.3%; 59.3%)	99.4	(95% CI: 98.4%; 99.8%)
maf3283-a001	MEDsan GmbH	MEDsan biological health solutions, MEDsan COVID-19 IgM/IgG Rapid Test	NA	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	90.0	(95% CI: 74.4%; 96.5%)	93.8	(95% CI: 86.2%; 97.3%)	43.1	(95% CI: 22.1%; 65.3%)	99.4	(95% CI: 98.5%; 99.8%)
maf3283-a001	MEDsan GmbH	MEDsan biological health solutions, MEDsan COVID-19 IgM/IgG Rapid Test	NA	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	90.0	(95% CI: 74.4%; 96.5%)	96.3	(95% CI: 89.5%; 98.7%)	55.8	(95% CI: 27.2%; 79.8%)	99.5	(95% CI: 98.5%; 99.8%)

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3287-a001	RayBiotech	Novel Coronavirus (SARS-CoV-2) IgM and IgG Dual Combined Antibody Detection Kit (Colloidal Gold Method)	505202977	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	70.0	(95% CI: 52.1%; 83.3%)	57.5	(95% CI: 46.6%; 67.7%)	8.0	(95% CI: 4.9%; 12.0%)	97.3	(95% CI: 94.9%; 98.7%)
maf3287-a001	RayBiotech	Novel Coronavirus (SARS-CoV-2) IgM and IgG Dual Combined Antibody Detection Kit (Colloidal Gold Method)	505202977	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	46.7	(95% CI: 30.2%; 63.9%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 25.8%; 100%)	97.3	(95% CI: 96.3%; 98.1%)
maf3287-a001	RayBiotech	Novel Coronavirus (SARS-CoV-2) IgM and IgG Dual Combined Antibody Detection Kit (Colloidal Gold Method)	505202977	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	60.0	(95% CI: 42.3%; 75.4%)	57.5	(95% CI: 46.6%; 67.7%)	6.9	(95% CI: 4.0%; 11.0%)	96.5	(95% CI: 93.9%; 98.1%)
maf3282-a001	Innovita (Tangshan) Biological Technology Co., Ltd.	One Step Rapid Test 2019-nCoV Ab Test (Colloidal Gold) IgM/IgG Whole Blood/Serum/Plasma Combo	20200405	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	97.5	(95% CI: 91.3%; 99.3%)	67.8	(95% CI: 35.0%; 88.4%)	100.0	(95% CI: 99.4%; 100%)
maf3282-a001	Innovita (Tangshan) Biological Technology Co., Ltd.	One Step Rapid Test 2019-nCoV Ab Test (Colloidal Gold) IgM/IgG Whole Blood/Serum/Plasma Combo	20200405	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgG	93.3	(95% CI: 78.7%; 98.2%)	98.8	(95% CI: 93.3%; 99.8%)	79.7	(95% CI: 38.0%; 95.9%)	99.6	(95% CI: 98.8%; 99.9%)
maf3282-a001	Innovita (Tangshan) Biological Technology Co., Ltd.	One Step Rapid Test 2019-nCoV Ab Test (Colloidal Gold) IgM/IgG Whole Blood/Serum/Plasma Combo	20200405	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgM	93.3	(95% CI: 78.7%; 98.2%)	98.8	(95% CI: 93.3%; 99.8%)	79.7	(95% CI: 38.0%; 95.9%)	99.6	(95% CI: 98.8%; 99.9%)
maf3299-a001	Access Bio Inc.	CareStart COVID-19 IgM/IgG Rapid Diagnostic Test for the Detection of SARS-CoV-2 IgM/IgG Ab	C120E68	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	97.5	(95% CI: 91.3%; 99.3%)	67.8	(95% CI: 35.0%; 88.4%)	100.0	(95% CI: 99.4%; 100%)
maf3299-a001	Access Bio Inc.	CareStart COVID-19 IgM/IgG Rapid Diagnostic Test for the Detection of SARS-CoV-2 IgM/IgG Ab	C120E68	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	98.8	(95% CI: 93.3%; 99.8%)	80.8	(95% CI: 40.9%; 96.0%)	100.0	(95% CI: 99.4%; 100%)
maf3299-a001	Access Bio Inc.	CareStart COVID-19 IgM/IgG Rapid Diagnostic Test for the Detection of SARS-CoV-2 IgM/IgG Ab	C120E68	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgM	90.0	(95% CI: 74.4%; 96.5%)	98.8	(95% CI: 93.3%; 99.8%)	79.1	(95% CI: 36.7%; 95.8%)	99.5	(95% CI: 98.6%; 99.8%)
maf3328-a001	BioMedomics, Inc.	BioMedomics COVID-19 IgM-IgG Rapid Test	51-200511	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	92.5	(95% CI: 84.6%; 96.5%)	41.2	(95% CI: 23.2%; 60.2%)	100.0	(95% CI: 99.3%; 100%)
maf3328-a001	BioMedomics, Inc.	BioMedomics COVID-19 IgM-IgG Rapid Test	51-200511	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	96.3	(95% CI: 89.5%; 98.7%)	57.6	(95% CI: 29.6%; 80.3%)	99.8	(95% CI: 99.0%; 100%)
maf3328-a001	BioMedomics, Inc.	BioMedomics COVID-19 IgM-IgG Rapid Test	51-200511	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	86.7	(95% CI: 70.3%; 94.7%)	97.1	(95% CI: 90.2%; 99.2%)	61.5	(95% CI: 27.3%; 86.4%)	99.3	(95% CI: 98.3%; 99.7%)
maf3285-a001	Zhuhai Livzon Diagnostics Inc	Livzon IgM/IgG Diagnostic Kit for IgM/IgG Antibody to Coronovirus (SARS-Cov-2) Lateral Flow	CK 2004350410	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	86.7	(95% CI: 70.3%; 94.7%)	97.5	(95% CI: 91.3%; 99.3%)	64.6	(95% CI: 29.9%; 87.9%)	99.3	(95% CI: 98.3%; 99.7%)
maf3285-a001	Zhuhai Livzon Diagnostics Inc	Livzon IgM/IgG Diagnostic Kit for IgM/IgG Antibody to Coronovirus (SARS-Cov-2) Lateral Flow	CK 2004350410	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	66.7	(95% CI: 48.8%; 80.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 35.9%; 100%)	98.3	(95% CI: 97.3%; 99.0%)
maf3285-a001	Zhuhai Livzon Diagnostics Inc	Livzon IgM/IgG Diagnostic Kit for IgM/IgG Antibody to Coronovirus (SARS-Cov-2) Lateral Flow	CK 2004350410	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	86.7	(95% CI: 70.3%; 94.7%)	97.5	(95% CI: 91.3%; 99.3%)	64.6	(95% CI: 29.9%; 87.9%)	99.3	(95% CI: 98.3%; 99.7%)

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3288-a001	Zhongshan Bio-Tech Co LTD	SARS-CoV-2 IgM-IgG (GICA)	2020007	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	83.8	(95% CI: 74.2%; 90.3%)	23.8	(95% CI: 14.5%; 34.9%)	99.8	(95% CI: 98.8%; 100%)
maf3288-a001	Zhongshan Bio-Tech Co LTD	SARS-CoV-2 IgM-IgG (GICA)	2020007	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	85.0	(95% CI: 75.6%; 91.2%)	25.3	(95% CI: 15.2%; 37.3%)	99.8	(95% CI: 98.9%; 100%)
maf3288-a001	Zhongshan Bio-Tech Co LTD	SARS-CoV-2 IgM-IgG (GICA)	2020007	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	50.0	(95% CI: 33.2%; 66.8%)	97.5	(95% CI: 91.3%; 99.3%)	51.3	(95% CI: 16.8%; 83.6%)	97.4	(95% CI: 96.3%; 98.3%)
maf3290-a001	Biocan Diagnostics Inc	biocan Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test	B251CB 170320	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	Combined	93.3	(95% CI: 78.7%; 98.2%)	96.2	(95% CI: 89.4%; 98.7%)	56.4	(95% CI: 28.1%; 79.9%)	99.6	(95% CI: 98.8%; 99.9%)
maf3290-a001	Biocan Diagnostics Inc	biocan Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test	B251CB 170320	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgG	93.3	(95% CI: 78.7%; 98.2%)	96.2	(95% CI: 89.4%; 98.7%)	56.4	(95% CI: 28.1%; 79.9%)	99.6	(95% CI: 98.8%; 99.9%)
maf3290-a001	Biocan Diagnostics Inc	biocan Tell Me Fast Novel Coronavirus (COVID-19) IgG/IgM Antibody Test	B251CB 170320	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgM	90.0	(95% CI: 74.4%; 96.5%)	98.7	(95% CI: 93.2%; 99.8%)	78.9	(95% CI: 36.4%; 95.8%)	99.5	(95% CI: 98.6%; 99.8%)
maf3320-a001	LumiQuick Diagnostics	Quick Profile 2019-nCoV IgG/IgM Test Card	20042919	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	90.0	(95% CI: 81.5%; 94.8%)	33.7	(95% CI: 19.2%; 50.4%)	99.8	(95% CI: 98.9%; 100%)
maf3320-a001	LumiQuick Diagnostics	Quick Profile 2019-nCoV IgG/IgM Test Card	20042919	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	96.3	(95% CI: 89.5%; 98.7%)	57.6	(95% CI: 29.6%; 80.3%)	99.8	(95% CI: 99.0%; 100%)
maf3320-a001	LumiQuick Diagnostics	Quick Profile 2019-nCoV IgG/IgM Test Card	20042919	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	86.7	(95% CI: 70.3%; 94.7%)	93.8	(95% CI: 86.2%; 97.3%)	42.2	(95% CI: 21.1%; 64.9%)	99.3	(95% CI: 98.2%; 99.7%)
maf3281-a001	Guangzhou Fenghua Bioengineering Co., Ltd.	SARS-COV-2 IgM/IgG Combo Rapid Test Kit	20200508	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	80.0	(95% CI: 62.7%; 90.5%)	62.5	(95% CI: 51.5%; 72.3%)	10.1	(95% CI: 6.4%; 14.7%)	98.3	(95% CI: 96.3%; 99.3%)
maf3281-a001	Guangzhou Fenghua Bioengineering Co., Ltd.	SARS-COV-2 IgM/IgG Combo Rapid Test Kit	20200508	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	70.0	(95% CI: 52.1%; 83.3%)	95.0	(95% CI: 87.8%; 98.0%)	42.4	(95% CI: 18.4%; 69.1%)	98.4	(95% CI: 97.2%; 99.1%)
maf3281-a001	Guangzhou Fenghua Bioengineering Co., Ltd.	SARS-COV-2 IgM/IgG Combo Rapid Test Kit	20200508	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	70.0	(95% CI: 52.1%; 83.3%)	65.0	(95% CI: 54.1%; 74.5%)	9.5	(95% CI: 5.6%; 14.7%)	97.6	(95% CI: 95.5%; 98.8%)
maf3284-a001	Abbexa	COVID-19 IgG/IgM Rapid Test Kit	L20Z4852X	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	92.5	(95% CI: 84.6%; 96.5%)	40.4	(95% CI: 22.2%; 60.0%)	99.8	(95% CI: 99.0%; 100%)
maf3284-a001	Abbexa	COVID-19 IgG/IgM Rapid Test Kit	L20Z4852X	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	96.3	(95% CI: 89.5%; 98.7%)	57.6	(95% CI: 29.6%; 80.3%)	99.8	(95% CI: 99.0%; 100%)
maf3284-a001	Abbexa	COVID-19 IgG/IgM Rapid Test Kit	L20Z4852X	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	53.3	(95% CI: 36.1%; 69.8%)	96.3	(95% CI: 89.5%; 98.7%)	42.8	(95% CI: 15.4%; 74.1%)	97.5	(95% CI: 96.4%; 98.4%)
maf3286-a001	PCL, Inc.	PCL COVID19 IgG/IgM Rapid Gold	COV03-200325	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 45.7%; 100%)	99.8	(95% CI: 99.1%; 100%)
maf3286-a001	PCL, Inc.	PCL COVID19 IgG/IgM Rapid Gold	COV03-200325	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	80.0	(95% CI: 62.7%; 90.5%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 38.8%; 100%)	99.0	(95% CI: 98.0%; 99.5%)
maf3286-a001	PCL, Inc.	PCL COVID19 IgG/IgM Rapid Gold	COV03-200325	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	93.3	(95% CI: 78.7%; 98.2%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 44.3%; 100%)	99.7	(95% CI: 98.8%; 99.9%)
maf3297-a001	Jiangsu Dablood Pharmaceutical Co. Ltd	COVID-19 IgM/IgG One Step Rapid Test	NA	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	81.3	(95% CI: 71.3%; 88.3%)	21.9	(95% CI: 14.0%; 31.0%)	100.0	(95% CI: 99.2%; 100%)
maf3297-a001	Jiangsu Dablood Pharmaceutical Co. Ltd	COVID-19 IgM/IgG One Step Rapid Test	NA	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	82.5	(95% CI: 72.7%; 89.3%)	23.1	(95% CI: 14.6%; 32.9%)	100.0	(95% CI: 99.2%; 100%)
maf3297-a001	Jiangsu Dablood Pharmaceutical Co. Ltd	COVID-19 IgM/IgG One Step Rapid Test	NA	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	93.3	(95% CI: 78.7%; 98.2%)	97.5	(95% CI: 91.3%; 99.3%)	66.3	(95% CI: 32.3%; 88.2%)	99.6	(95% CI: 98.8%; 99.9%)
maf3292-a001	H-Guard (China) Co., Ltd.	Novel Coronavirus COVID-19 IgM/IgG Test Kit (colloidal gold)	20200406	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	93.8	(95% CI: 86.2%; 97.3%)	44.9	(95% CI: 24.1%; 66.0%)	99.8	(95% CI: 99.0%; 100%)
maf3292-a001	H-Guard (China) Co., Ltd.	Novel Coronavirus COVID-19 IgM/IgG Test Kit (colloidal gold)	20200406	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	93.3	(95% CI: 78.7%; 98.2%)	97.5	(95% CI: 91.3%; 99.3%)	66.3	(95% CI: 32.3%; 88.2%)	99.6	(95% CI: 98.8%; 99.9%)

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3292-a001	H-Guard (China) Co., Ltd.	Novel Coronavirus COVID-19 IgM/IgG Test Kit (colloidal gold)	20200406	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	53.3	(95% CI: 36.1%; 69.8%)	96.3	(95% CI: 89.5%; 98.7%)	42.8	(95% CI: 15.4%; 74.1%)	97.5	(95% CI: 96.4%; 98.4%)
maf3293-a001	Salofa Oy	Sienna COVID-19 IgG/IgM Rapid Test Cassette (whole blood/serum/plasma)	20052003	Panel 2	Lateral Flow	Spike	EUA Authorized	Combined	93.3	(95% CI: 78.7%; 98.2%)	98.8	(95% CI: 93.3%; 99.8%)	79.7	(95% CI: 38.0%; 95.9%)	99.6	(95% CI: 98.8%; 99.9%)
maf3293-a001	Salofa Oy	Sienna COVID-19 IgG/IgM Rapid Test Cassette (whole blood/serum/plasma)	20052003	Panel 2	Lateral Flow	Spike	EUA Authorized	IgG	93.3	(95% CI: 78.7%; 98.2%)	98.8	(95% CI: 93.3%; 99.8%)	79.7	(95% CI: 38.0%; 95.9%)	99.6	(95% CI: 98.8%; 99.9%)
maf3293-a001	Salofa Oy	Sienna COVID-19 IgG/IgM Rapid Test Cassette (whole blood/serum/plasma)	20052003	Panel 2	Lateral Flow	Spike	EUA Authorized	IgM	90.0	(95% CI: 74.4%; 96.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 46.1%; 100%)	99.5	(95% CI: 98.6%; 99.8%)
maf3289-a001	Assure Tech. (Hangzhou) Co., Ltd.	FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test	I2003183	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	98.8	(95% CI: 93.3%; 99.8%)	80.8	(95% CI: 40.9%; 96.0%)	100.0	(95% CI: 99.4%; 100%)
maf3289-a001	Assure Tech. (Hangzhou) Co., Ltd.	FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test	I2003183	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgG	90.0	(95% CI: 74.4%; 96.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 46.1%; 100%)	99.5	(95% CI: 98.6%; 99.8%)
maf3289-a001	Assure Tech. (Hangzhou) Co., Ltd.	FaStep Rapid Diagnostic Test Coronavirus Disease 2019/ (COVID-2019) IgG/IgM Rapid Test	I2003183	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgM	100.0	(95% CI: 88.6%; 100%)	98.8	(95% CI: 93.3%; 99.8%)	80.8	(95% CI: 40.9%; 96.0%)	100.0	(95% CI: 99.4%; 100%)
maf3291-a001	Hangzhou Laihe Biotech Co., Ltd.	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	2005037	Panel 2	Lateral Flow	Spike	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	98.8	(95% CI: 93.3%; 99.8%)	80.8	(95% CI: 40.9%; 96.0%)	100.0	(95% CI: 99.4%; 100%)
maf3291-a001	Hangzhou Laihe Biotech Co., Ltd.	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	2005037	Panel 2	Lateral Flow	Spike	EUA Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	98.8	(95% CI: 93.3%; 99.8%)	80.8	(95% CI: 40.9%; 96.0%)	100.0	(95% CI: 99.4%; 100%)
maf3291-a001	Hangzhou Laihe Biotech Co., Ltd.	Novel Coronavirus (2019-nCoV) IgM/IgG Antibody Combo Test Kit (Colloidal Gold)	2005037	Panel 2	Lateral Flow	Spike	EUA Authorized	IgM	96.7	(95% CI: 83.3%; 99.4%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 48.9%; 100%)	99.8	(95% CI: 99.1%; 100%)
maf3298-a001	Tianjin New Bay Bioresearch C. #1	Quik Pac II COVID-19 IgG & IgM Test	2005059	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	97.5	(95% CI: 91.3%; 99.3%)	67.1	(95% CI: 33.6%; 88.4%)	99.8	(95% CI: 99.0%; 100%)
maf3298-a001	Tianjin New Bay Bioresearch C. #1	Quik Pac II COVID-19 IgG & IgM Test	2005059	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	73.3	(95% CI: 55.6%; 85.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 39.0%; 100%)	98.6	(95% CI: 97.6%; 99.3%)
maf3298-a001	Tianjin New Bay Bioresearch C. #1	Quik Pac II COVID-19 IgG & IgM Test	2005059	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	93.3	(95% CI: 78.7%; 98.2%)	97.5	(95% CI: 91.3%; 99.3%)	66.3	(95% CI: 32.3%; 88.2%)	99.6	(95% CI: 98.8%; 99.9%)
maf3300-a001	GenBody Inc.	GenBody COVID-19 IgM/IgG	FJFB30201	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	60.0	(95% CI: 42.3%; 75.4%)	98.8	(95% CI: 93.3%; 99.8%)	71.6	(95% CI: 24.8%; 94.7%)	97.9	(95% CI: 96.8%; 98.7%)
maf3300-a001	GenBody Inc.	GenBody COVID-19 IgM/IgG	FJFB30201	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	56.7	(95% CI: 39.2%; 72.6%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 31.0%; 100%)	97.8	(95% CI: 96.8%; 98.6%)
maf3300-a001	GenBody Inc.	GenBody COVID-19 IgM/IgG	FJFB30201	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	40.0	(95% CI: 24.6%; 57.7%)	98.8	(95% CI: 93.3%; 99.8%)	62.7	(95% CI: 16.1%; 93.2%)	96.9	(95% CI: 95.9%; 97.8%)
maf3304-a001	Wuhan Easy Diagnosis Biomedicine Co. Ltd.	COVID-19 (SARS-CoV-2) IgM/IgG Antibody Test Kit	20030401	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	87.5	(95% CI: 78.5%; 93.1%)	29.6	(95% CI: 17.8%; 43.2%)	100.0	(95% CI: 99.2%; 100%)
maf3304-a001	Wuhan Easy Diagnosis Biomedicine Co. Ltd.	COVID-19 (SARS-CoV-2) IgM/IgG Antibody Test Kit	20030401	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	98.8	(95% CI: 93.3%; 99.8%)	80.3	(95% CI: 39.4%; 95.9%)	99.8	(95% CI: 99.1%; 100%)
maf3304-a001	Wuhan Easy Diagnosis Biomedicine Co. Ltd.	COVID-19 (SARS-CoV-2) IgM/IgG Antibody Test Kit	20030401	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	100.0	(95% CI: 88.6%; 100%)	88.8	(95% CI: 80.0%; 94.0%)	31.9	(95% CI: 18.9%; 46.6%)	100.0	(95% CI: 99.3%; 100%)

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3303-a001	BTNX Inc	COVID-19 IgG/IgM Test Cassettes (Whole Blood/Serum/Plasma)	I2004027	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	97.5	(95% CI: 91.3%; 99.3%)	67.8	(95% CI: 35.0%; 88.4%)	100.0	(95% CI: 99.4%; 100%)
maf3303-a001	BTNX Inc	COVID-19 IgG/IgM Test Cassettes (Whole Blood/Serum/Plasma)	I2004027	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 50.5%; 100%)	100.0	(95% CI: 99.4%; 100%)
maf3303-a001	BTNX Inc	COVID-19 IgG/IgM Test Cassettes (Whole Blood/Serum/Plasma)	I2004027	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	100.0	(95% CI: 88.6%; 100%)	97.5	(95% CI: 91.3%; 99.3%)	67.8	(95% CI: 35.0%; 88.4%)	100.0	(95% CI: 99.4%; 100%)
maf3325-a001	Hangzhou Realy Tech Co., LTD	COVID-19 IgG/IgM Rapid Device Test	N01G17T	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	93.7	(95% CI: 86.0%; 97.3%)	44.6	(95% CI: 23.9%; 65.7%)	99.8	(95% CI: 99.0%; 100%)
maf3325-a001	Hangzhou Realy Tech Co., LTD	COVID-19 IgG/IgM Rapid Device Test	N01G17T	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	86.7	(95% CI: 70.3%; 94.7%)	97.5	(95% CI: 91.2%; 99.3%)	64.3	(95% CI: 29.7%; 87.7%)	99.3	(95% CI: 98.3%; 99.7%)
maf3325-a001	Hangzhou Realy Tech Co., LTD	COVID-19 IgG/IgM Rapid Device Test	N01G17T	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	96.7	(95% CI: 83.3%; 99.4%)	94.9	(95% CI: 87.7%; 98.0%)	50.1	(95% CI: 26.3%; 72.5%)	99.8	(95% CI: 99.0%; 100%)
maf3307-a001	TBG Biotechnology Corp	SARS-CoV-2 IgG/IgM Rapid Test Kit	FRS20051K	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	Combined	93.3	(95% CI: 78.7%; 98.2%)	95.0	(95% CI: 87.8%; 98.0%)	49.6	(95% CI: 25.4%; 72.5%)	99.6	(95% CI: 98.7%; 99.9%)
maf3307-a001	TBG Biotechnology Corp	SARS-CoV-2 IgG/IgM Rapid Test Kit	FRS20051K	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgG	93.3	(95% CI: 78.7%; 98.2%)	96.3	(95% CI: 89.5%; 98.7%)	56.7	(95% CI: 28.4%; 80.1%)	99.6	(95% CI: 98.8%; 99.9%)
maf3307-a001	TBG Biotechnology Corp	SARS-CoV-2 IgG/IgM Rapid Test Kit	FRS20051K	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgM	93.3	(95% CI: 78.7%; 98.2%)	95.0	(95% CI: 87.8%; 98.0%)	49.6	(95% CI: 25.4%; 72.5%)	99.6	(95% CI: 98.7%; 99.9%)
maf3308-a001	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab Rapid Test	JNB 20200406	Panel 2	Lateral Flow	Spike	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	98.8	(95% CI: 93.3%; 99.8%)	80.8	(95% CI: 40.9%; 96.0%)	100.0	(95% CI: 99.4%; 100%)
maf3308-a001	Beijing Wantai Biological Pharmacy Enterprise Co., Ltd.	WANTAI SARS-CoV-2 Ab Rapid Test	JNB 20200406	Panel 2	Lateral Flow	Spike	EUA Authorized	Pan Ig	100.0	(95% CI: 88.6%; 100%)	98.8	(95% CI: 93.3%; 99.8%)	80.8	(95% CI: 40.9%; 96.0%)	100.0	(95% CI: 99.4%; 100%)
maf3313-a001	Jiangsu Well Biotech Co, Ltd.	COVID-19 IgM/IgG Rapid Test (Colloidal gold)	2005202	Panel 2	Lateral Flow	Spike	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	93.8	(95% CI: 86.2%; 97.3%)	45.7	(95% CI: 25.3%; 66.1%)	100.0	(95% CI: 99.3%; 100%)
maf3313-a001	Jiangsu Well Biotech Co, Ltd.	COVID-19 IgM/IgG Rapid Test (Colloidal gold)	2005202	Panel 2	Lateral Flow	Spike	EUA Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	98.8	(95% CI: 93.3%; 99.8%)	80.8	(95% CI: 40.9%; 96.0%)	100.0	(95% CI: 99.4%; 100%)
maf3313-a001	Jiangsu Well Biotech Co, Ltd.	COVID-19 IgM/IgG Rapid Test (Colloidal gold)	2005202	Panel 2	Lateral Flow	Spike	EUA Authorized	IgM	96.7	(95% CI: 83.3%; 99.4%)	95.0	(95% CI: 87.8%; 98.0%)	50.4	(95% CI: 26.5%; 72.7%)	99.8	(95% CI: 99.0%; 100%)
maf3318-a001	Jiangsu Superbio Biomedical (Nanjing) Co Ltd	SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)	SYG202027	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	83.8	(95% CI: 74.2%; 90.3%)	24.5	(95% CI: 15.3%; 35.1%)	100.0	(95% CI: 99.2%; 100%)
maf3318-a001	Jiangsu Superbio Biomedical (Nanjing) Co Ltd	SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)	SYG202027	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	85.0	(95% CI: 75.6%; 91.2%)	26.0	(95% CI: 16.0%; 37.4%)	100.0	(95% CI: 99.2%; 100%)
maf3318-a001	Jiangsu Superbio Biomedical (Nanjing) Co Ltd	SARS-CoV-2 (COVID-19) IgM/IgG Antibody Fast Detection Kit (Colloidal Gold)	SYG202027	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	40.0	(95% CI: 24.6%; 57.7%)	98.8	(95% CI: 93.3%; 99.8%)	62.7	(95% CI: 16.1%; 93.2%)	96.9	(95% CI: 95.9%; 97.8%)
maf3306-a001	AutoBio Diagnostics Co., LTD	Anti-SARS-CoV-2 Rapid Test	20E22-J01	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	93.3	(95% CI: 78.7%; 98.2%)	98.8	(95% CI: 93.3%; 99.8%)	79.7	(95% CI: 38.0%; 95.9%)	99.6	(95% CI: 98.8%; 99.9%)
maf3306-a001	AutoBio Diagnostics Co., LTD	Anti-SARS-CoV-2 Rapid Test	20E22-J01	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	93.3	(95% CI: 78.7%; 98.2%)	98.8	(95% CI: 93.3%; 99.8%)	79.7	(95% CI: 38.0%; 95.9%)	99.6	(95% CI: 98.8%; 99.9%)
maf3306-a001	AutoBio Diagnostics Co., LTD	Anti-SARS-CoV-2 Rapid Test	20E22-J01	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	50.0	(95% CI: 33.2%; 66.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 27.6%; 100%)	97.4	(95% CI: 96.4%; 98.3%)
maf3314-a001	Nirmidas Biotech, Inc	COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit	15038	Panel 2	Lateral Flow	Spike	EUA Authorized	Combined	93.3	(95% CI: 78.7%; 98.2%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 44.3%; 100%)	99.7	(95% CI: 98.8%; 99.9%)

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3314-a001	Nirmidas Biotech, Inc	COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit	15038	Panel 2	Lateral Flow	Spike	EUA Authorized	IgG	86.7	(95% CI: 70.3%; 94.7%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 44.7%; 100%)	99.3	(95% CI: 98.4%; 99.7%)
maf3314-a001	Nirmidas Biotech, Inc	COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit	15038	Panel 2	Lateral Flow	Spike	EUA Authorized	IgM	93.3	(95% CI: 78.7%; 98.2%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 44.3%; 100%)	99.7	(95% CI: 98.8%; 99.9%)
maf3321-a001	Megna Health Inc.	Megna Rapid COVID-19 IgM/IgG Combo Test Kit	NA	Panel 2	Lateral Flow	Nucleocapsid	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	95.0	(95% CI: 87.8%; 98.0%)	51.3	(95% CI: 27.7%; 72.9%)	100.0	(95% CI: 99.3%; 100%)
maf3321-a001	Megna Health Inc.	Megna Rapid COVID-19 IgM/IgG Combo Test Kit	NA	Panel 2	Lateral Flow	Nucleocapsid	EUA Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	97.5	(95% CI: 91.3%; 99.3%)	67.8	(95% CI: 35.0%; 88.4%)	100.0	(95% CI: 99.4%; 100%)
maf3321-a001	Megna Health Inc.	Megna Rapid COVID-19 IgM/IgG Combo Test Kit	NA	Panel 2	Lateral Flow	Nucleocapsid	EUA Authorized	IgM	83.3	(95% CI: 66.4%; 92.7%)	97.5	(95% CI: 91.3%; 99.3%)	63.7	(95% CI: 28.8%; 87.6%)	99.1	(95% CI: 98.1%; 99.6%)
maf3322-a001	Hangzhou AllTest Biotech Co. Ltd	2019-nCoV IgG/IgM Rapid Test Cassette(Whole Blood/Serum/Plasma)	NCP 20050100U	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	96.3	(95% CI: 89.5%; 98.7%)	58.4	(95% CI: 30.9%; 80.4%)	100.0	(95% CI: 99.3%; 100%)
maf3322-a001	Hangzhou AllTest Biotech Co. Ltd	2019-nCoV IgG/IgM Rapid Test Cassette(Whole Blood/Serum/Plasma)	NCP 20050100U	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	97.5	(95% CI: 91.3%; 99.3%)	67.1	(95% CI: 33.6%; 88.4%)	99.8	(95% CI: 99.0%; 100%)
maf3322-a001	Hangzhou AllTest Biotech Co. Ltd	2019-nCoV IgG/IgM Rapid Test Cassette(Whole Blood/Serum/Plasma)	NCP 20050100U	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	83.3	(95% CI: 66.4%; 92.7%)	98.8	(95% CI: 93.3%; 99.8%)	77.8	(95% CI: 34.1%; 95.7%)	99.1	(95% CI: 98.1%; 99.6%)
maf3323-a001	Genobio Pharmaceutical Co. Ltd	Virusee® COVID-19 IgM/IgG Lateral Flow Assay	VMG200331	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	80.0	(95% CI: 62.7%; 90.5%)	76.3	(95% CI: 65.9%; 84.2%)	15.1	(95% CI: 8.8%; 23.2%)	98.6	(95% CI: 97.1%; 99.4%)
maf3323-a001	Genobio Pharmaceutical Co. Ltd	Virusee® COVID-19 IgM/IgG Lateral Flow Assay	VMG200331	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	63.3	(95% CI: 45.5%; 78.1%)	98.8	(95% CI: 93.3%; 99.8%)	72.7	(95% CI: 26.2%; 94.9%)	98.1	(95% CI: 97.0%; 98.9%)
maf3323-a001	Genobio Pharmaceutical Co. Ltd	Virusee® COVID-19 IgM/IgG Lateral Flow Assay	VMG200331	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	56.7	(95% CI: 39.2%; 72.6%)	76.3	(95% CI: 65.9%; 84.2%)	11.2	(95% CI: 5.7%; 19.5%)	97.1	(95% CI: 95.4%; 98.3%)
maf3329-a001	Abbott Rapid Diagnostics Jena GmbH	COVID-19 IgG Rapid Test Device	COV0062057	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	83.3	(95% CI: 66.4%; 92.7%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 43.3%; 100%)	99.1	(95% CI: 98.2%; 99.6%)
maf3329-a001	Abbott Rapid Diagnostics Jena GmbH	COVID-19 IgG Rapid Test Device	COV0062057	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	83.3	(95% CI: 66.4%; 92.7%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 43.3%; 100%)	99.1	(95% CI: 98.2%; 99.6%)
maf3333-a001	Xiamen AmonMed Biotechnology Co., Ltd	COVID-19 IgM/IgG Test Kit (colloidal gold)	3120200501	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	93.3	(95% CI: 78.7%; 98.2%)	98.8	(95% CI: 93.3%; 99.8%)	79.7	(95% CI: 38.0%; 95.9%)	99.6	(95% CI: 98.8%; 99.9%)
maf3333-a001	Xiamen AmonMed Biotechnology Co., Ltd	COVID-19 IgM/IgG Test Kit (colloidal gold)	3120200501	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	86.7	(95% CI: 70.3%; 94.7%)	98.8	(95% CI: 93.3%; 99.8%)	78.5	(95% CI: 35.4%; 95.8%)	99.3	(95% CI: 98.4%; 99.7%)
maf3333-a001	Xiamen AmonMed Biotechnology Co., Ltd	COVID-19 IgM/IgG Test Kit (colloidal gold)	3120200501	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	70.0	(95% CI: 52.1%; 83.3%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 37.5%; 100%)	98.4	(95% CI: 97.4%; 99.1%)
maf3355-a001	CTK Biotech, Inc.	OnSite COVID-19 IgG/IgM Rapid Test	F0507R1C00	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	98.8	(95% CI: 93.3%; 99.8%)	80.8	(95% CI: 40.9%; 96.0%)	100.0	(95% CI: 99.4%; 100%)
maf3355-a001	CTK Biotech, Inc.	OnSite COVID-19 IgG/IgM Rapid Test	F0507R1C00	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	73.3	(95% CI: 55.6%; 85.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 39.0%; 100%)	98.6	(95% CI: 97.6%; 99.3%)
maf3355-a001	CTK Biotech, Inc.	OnSite COVID-19 IgG/IgM Rapid Test	F0507R1C00	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	96.7	(95% CI: 83.3%; 99.4%)	98.8	(95% CI: 93.3%; 99.8%)	80.3	(95% CI: 39.4%; 95.9%)	99.8	(95% CI: 99.1%; 100%)
maf3338-a001	Beijing Kewei Clinical Diagnostic Reagent Inc.	Genonto Rapid Test10 COVID-19 IgG/IgM Rapid Test Kit	202004004	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	93.3	(95% CI: 78.7%; 98.2%)	91.3	(95% CI: 83.0%; 95.7%)	36.0	(95% CI: 19.6%; 54.6%)	99.6	(95% CI: 98.7%; 99.9%)
maf3338-a001	Beijing Kewei Clinical Diagnostic Reagent Inc.	Genonto Rapid Test10 COVID-19 IgG/IgM Rapid Test Kit	202004004	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	93.3	(95% CI: 78.7%; 98.2%)	96.3	(95% CI: 89.5%; 98.7%)	56.7	(95% CI: 28.4%; 80.1%)	99.6	(95% CI: 98.8%; 99.9%)

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3338-a001	Beijing Kewei Clinical Diagnostic Reagent Inc.	Genonto Rapid Test10 COVID-19 IgG/IgM Rapid Test Kit	202004004	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	93.3	(95% CI: 78.7%; 98.2%)	91.3	(95% CI: 83.0%; 95.7%)	36.0	(95% CI: 19.6%; 54.6%)	99.6	(95% CI: 98.7%; 99.9%)
maf3350-a001	Polymedco, Inc.	Polystat SARS-CoV-2 Antibody Test	20200303	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	76.7	(95% CI: 59.1%; 88.2%)	91.3	(95% CI: 83.0%; 95.7%)	31.6	(95% CI: 15.5%; 51.9%)	98.7	(95% CI: 97.5%; 99.4%)
maf3350-a001	Polymedco, Inc.	Polystat SARS-CoV-2 Antibody Test	20200303	Panel 2	Lateral Flow	Unknown	Not Authorized	(IgM / IgA)	50.0	(95% CI: 33.2%; 66.8%)	93.8	(95% CI: 86.2%; 97.3%)	29.6	(95% CI: 11.2%; 56.6%)	97.3	(95% CI: 96.1%; 98.2%)
maf3350-a001	Polymedco, Inc.	Polystat SARS-CoV-2 Antibody Test	20200303	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	60.0	(95% CI: 42.3%; 75.4%)	97.5	(95% CI: 91.3%; 99.3%)	55.8	(95% CI: 20.5%; 85.2%)	97.9	(95% CI: 96.8%; 98.7%)
maf3339-a001	MOKOBIO Biotechnology R&D Center, INC.	SARS-CoV-2 IgM & IgG Quantum Dot Immunoassay	20200324	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	72.5	(95% CI: 61.9%; 81.1%)	16.1	(95% CI: 10.9%; 21.8%)	100.0	(95% CI: 99.0%; 100%)
maf3339-a001	MOKOBIO Biotechnology R&D Center, INC.	SARS-CoV-2 IgM & IgG Quantum Dot Immunoassay	20200324	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	93.3	(95% CI: 78.7%; 98.2%)	73.8	(95% CI: 63.2%; 82.1%)	15.8	(95% CI: 10.1%; 22.4%)	99.5	(95% CI: 98.3%; 99.9%)
maf3339-a001	MOKOBIO Biotechnology R&D Center, INC.	SARS-CoV-2 IgM & IgG Quantum Dot Immunoassay	20200324	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	66.7	(95% CI: 48.8%; 80.8%)	91.3	(95% CI: 83.0%; 95.7%)	28.6	(95% CI: 13.1%; 49.7%)	98.1	(95% CI: 96.9%; 99.0%)
maf3341-a001	Changzhou Confucius Biotechnology Co Ltd	COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)	20200313	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	92.5	(95% CI: 84.6%; 96.5%)	40.4	(95% CI: 22.2%; 60.0%)	99.8	(95% CI: 99.0%; 100%)
maf3341-a001	Changzhou Confucius Biotechnology Co Ltd	COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)	20200313	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	96.3	(95% CI: 89.5%; 98.7%)	57.6	(95% CI: 29.6%; 80.3%)	99.8	(95% CI: 99.0%; 100%)
maf3341-a001	Changzhou Confucius Biotechnology Co Ltd	COVID-19 IgG/IgM Rapid Test Cassette (WB/S/P)	20200313	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	13.3	(95% CI: 5.3%; 29.7%)	95.0	(95% CI: 87.8%; 98.0%)	12.3	(95% CI: 2.2%; 44.3%)	95.4	(95% CI: 94.6%; 96.4%)
maf3348-a001	Sugentech, Inc.	SGTi-flex COVID-19 IgG	COGT20104	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 48.9%; 100%)	99.8	(95% CI: 99.1%; 100%)
maf3348-a001	Sugentech, Inc.	SGTi-flex COVID-19 IgG	COGT20104	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 48.9%; 100%)	99.8	(95% CI: 99.1%; 100%)
maf3351-a001	NanoEntek Inc	FREND™ COVID-19 IgG/IgM Duo test	730023	Panel 2	Lateral Flow	Nucleocapsid	EUA Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	98.8	(95% CI: 93.3%; 99.8%)	80.3	(95% CI: 39.4%; 95.9%)	99.8	(95% CI: 99.1%; 100%)
maf3351-a001	NanoEntek Inc	FREND™ COVID-19 IgG/IgM Duo test	730023	Panel 2	Lateral Flow	Nucleocapsid	EUA Authorized	(IgM / IgG)	96.7	(95% CI: 83.3%; 99.4%)	98.8	(95% CI: 93.3%; 99.8%)	80.3	(95% CI: 39.4%; 95.9%)	99.8	(95% CI: 99.1%; 100%)
maf3347-a001	Predictive Laboratories, Inc.	Assurance AB COVID-19 IgM/IgG Rapid Antibody Test	2020AB12	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	90.0	(95% CI: 74.4%; 96.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 46.1%; 100%)	99.5	(95% CI: 98.6%; 99.8%)
maf3347-a001	Predictive Laboratories, Inc.	Assurance AB COVID-19 IgM/IgG Rapid Antibody Test	2020AB12	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	90.0	(95% CI: 74.4%; 96.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 46.1%; 100%)	99.5	(95% CI: 98.6%; 99.8%)
maf3347-a001	Predictive Laboratories, Inc.	Assurance AB COVID-19 IgM/IgG Rapid Antibody Test	2020AB12	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	50.0	(95% CI: 33.2%; 66.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 27.6%; 100%)	97.4	(95% CI: 96.4%; 98.3%)
maf3349-a001	Boditech Med Incorporated	iChroma COVID-19 Ab	WHQEA88	Panel 2	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	95.0	(95% CI: 87.8%; 98.0%)	50.4	(95% CI: 26.5%; 72.7%)	99.8	(95% CI: 99.0%; 100%)
maf3349-a001	Boditech Med Incorporated	iChroma COVID-19 Ab	WHQEA88	Panel 2	Lateral Flow	Unknown	Not Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	96.3	(95% CI: 89.5%; 98.7%)	57.6	(95% CI: 29.6%; 80.3%)	99.8	(95% CI: 99.0%; 100%)
maf3349-a001	Boditech Med Incorporated	iChroma COVID-19 Ab	WHQEA88	Panel 2	Lateral Flow	Unknown	Not Authorized	IgM	13.3	(95% CI: 5.3%; 29.7%)	98.8	(95% CI: 93.3%; 99.8%)	36.0	(95% CI: 4.0%; 87.6%)	95.6	(95% CI: 94.9%; 96.4%)
maf3396-a001	Acon Biotech (Hangzhou) Co., LTD	Acon SARS-CoV2 IgG/IgM Rapid Test	COV0109007	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	96.3	(95% CI: 89.5%; 98.7%)	58.4	(95% CI: 30.9%; 80.4%)	100.0	(95% CI: 99.3%; 100%)
maf3396-a001	Acon Biotech (Hangzhou) Co., LTD	Acon SARS-CoV2 IgG/IgM Rapid Test	COV0109007	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	97.5	(95% CI: 91.3%; 99.3%)	67.8	(95% CI: 35.0%; 88.4%)	100.0	(95% CI: 99.4%; 100%)
maf3396-a001	Acon Biotech (Hangzhou) Co., LTD	Acon SARS-CoV2 IgG/IgM Rapid Test	COV0109007	Panel 2	Lateral Flow	Spike and Nucleocapsid	EUA Authorized	IgM	96.7	(95% CI: 83.3%; 99.4%)	98.8	(95% CI: 93.3%; 99.8%)	80.3	(95% CI: 39.4%; 95.9%)	99.8	(95% CI: 99.1%; 100%)

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3371-a001	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack	130	Panel 3	CIA	Spike	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 50.5%; 100%)	100.0	(95% CI: 99.4%; 100%)
maf3371-a001	Ortho-Clinical Diagnostics, Inc.	VITROS Immunodiagnostic Products Anti-SARS-CoV-2 IgG Reagent Pack	130	Panel 3	CIA	Spike	EUA Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 50.5%; 100%)	100.0	(95% CI: 99.4%; 100%)
maf3362-a001	Fisher Diagnostics	OmniPATH COVID-19 Total Antibody ELISA Test	20200523	Panel 3	ELISA	Spike	EUA Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	97.5	(95% CI: 91.3%; 99.3%)	67.1	(95% CI: 33.6%; 88.4%)	99.8	(95% CI: 99.0%; 100%)
maf3362-a001	Fisher Diagnostics	OmniPATH COVID-19 Total Antibody ELISA Test	20200523	Panel 3	ELISA	Spike	EUA Authorized	Pan Ig	96.7	(95% CI: 83.3%; 99.4%)	97.5	(95% CI: 91.3%; 99.3%)	67.1	(95% CI: 33.6%; 88.4%)	99.8	(95% CI: 99.0%; 100%)
maf3377-a001	EUROIMMUN Medizinische Labordiagnostika AG	Anti-SARS-CoV-2-NCP ELISA (IgM)	E200703AO	Panel 3	ELISA	Unknown	Not Authorized	Combined	30.0	(95% CI: 16.7%; 47.9%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 14.4%; 100%)	96.4	(95% CI: 95.6%; 97.3%)
maf3377-a001	EUROIMMUN Medizinische Labordiagnostika AG	Anti-SARS-CoV-2-NCP ELISA (IgM)	E200703AO	Panel 3	ELISA	Unknown	Not Authorized	IgM	30.0	(95% CI: 16.7%; 47.9%)	100.0	(95% CI: 94.8%; 100%)	100.0	(95% CI: 14.4%; 100%)	96.4	(95% CI: 95.6%; 97.3%)
maf3387-a001	Plexense, Inc.	ACCEL ELISA COVID-19	PXCOV 061820	Panel 3	ELISA	Unknown	Not Authorized	Combined	73.3	(95% CI: 55.6%; 85.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 39.0%; 100%)	98.6	(95% CI: 97.6%; 99.3%)
maf3387-a001	Plexense, Inc.	ACCEL ELISA COVID-19	PXCOV 061820	Panel 3	ELISA	Unknown	Not Authorized	Pan Ig	73.3	(95% CI: 55.6%; 85.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 39.0%; 100%)	98.6	(95% CI: 97.6%; 99.3%)
maf3354-a001	Nirmidas Biotech, Inc	COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit	15038	Panel 3	Lateral Flow	Spike	EUA Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	97.5	(95% CI: 91.3%; 99.3%)	67.1	(95% CI: 33.6%; 88.4%)	99.8	(95% CI: 99.0%; 100%)
maf3354-a001	Nirmidas Biotech, Inc	COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit	15038	Panel 3	Lateral Flow	Spike	EUA Authorized	IgG	86.7	(95% CI: 70.3%; 94.7%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 44.7%; 100%)	99.3	(95% CI: 98.4%; 99.7%)
maf3354-a001	Nirmidas Biotech, Inc	COVID-19 (SARS-CoV-2) IgM/IgG Antibody Detection Kit	15038	Panel 3	Lateral Flow	Spike	EUA Authorized	IgM	90.0	(95% CI: 74.4%; 96.5%)	97.5	(95% CI: 91.3%; 99.3%)	65.5	(95% CI: 31.1%; 88.1%)	99.5	(95% CI: 98.5%; 99.8%)
maf3356-a001	Jiangsu Well Biotech Co., Ltd.	COVID-19 IgM/IgG Rapid Test	2005202	Panel 3	Lateral Flow	Spike	EUA Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 50.5%; 100%)	100.0	(95% CI: 99.4%; 100%)
maf3356-a001	Jiangsu Well Biotech Co., Ltd.	COVID-19 IgM/IgG Rapid Test	2005202	Panel 3	Lateral Flow	Spike	EUA Authorized	IgG	100.0	(95% CI: 88.6%; 100%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 50.5%; 100%)	100.0	(95% CI: 99.4%; 100%)
maf3356-a001	Jiangsu Well Biotech Co., Ltd.	COVID-19 IgM/IgG Rapid Test	2005202	Panel 3	Lateral Flow	Spike	EUA Authorized	IgM	90.0	(95% CI: 74.4%; 96.5%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 46.1%; 100%)	99.5	(95% CI: 98.6%; 99.8%)
maf3373-a001	Shenzhen JetMay Care Limited	COVID-19 IgM & IgG Test	20200401	Panel 3	Lateral Flow	Unknown	Not Authorized	Combined	66.7	(95% CI: 48.8%; 80.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 35.9%; 100%)	98.3	(95% CI: 97.3%; 99.0%)
maf3373-a001	Shenzhen JetMay Care Limited	COVID-19 IgM & IgG Test	20200401	Panel 3	Lateral Flow	Unknown	Not Authorized	IgG	56.7	(95% CI: 39.2%; 72.6%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 31.0%; 100%)	97.8	(95% CI: 96.8%; 98.6%)
maf3373-a001	Shenzhen JetMay Care Limited	COVID-19 IgM & IgG Test	20200401	Panel 3	Lateral Flow	Unknown	Not Authorized	IgM	53.3	(95% CI: 36.1%; 69.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 29.3%; 100%)	97.6	(95% CI: 96.6%; 98.4%)
maf3375-a001	Accel Diagnostics, LLC	Rapid C2T Total Antibodies (IgG/IgM) Card	07.20.005	Panel 3	Lateral Flow	Unknown	Not Authorized	Combined	70.0	(95% CI: 52.1%; 83.3%)	60.0	(95% CI: 49.0%; 70.0%)	8.4	(95% CI: 5.1%; 12.8%)	97.4	(95% CI: 95.1%; 98.8%)
maf3375-a001	Accel Diagnostics, LLC	Rapid C2T Total Antibodies (IgG/IgM) Card	07.20.005	Panel 3	Lateral Flow	Unknown	Not Authorized	(IgM / IgG)	70.0	(95% CI: 52.1%; 83.3%)	60.0	(95% CI: 49.0%; 70.0%)	8.4	(95% CI: 5.1%; 12.8%)	97.4	(95% CI: 95.1%; 98.8%)
maf3378-a001	Top Biotech Sdn. Bhd.	Top Rapid COVID-19 Rapid Antibody IgG/IgM Test Kit	TBCV 04007001T	Panel 3	Lateral Flow	Unknown	Not Authorized	Combined	100.0	(95% CI: 88.6%; 100%)	90.0	(95% CI: 81.5%; 94.8%)	34.5	(95% CI: 20.1%; 50.5%)	100.0	(95% CI: 99.3%; 100%)
maf3378-a001	Top Biotech Sdn. Bhd.	Top Rapid COVID-19 Rapid Antibody IgG/IgM Test Kit	TBCV 04007001T	Panel 3	Lateral Flow	Unknown	Not Authorized	IgG	83.3	(95% CI: 66.4%; 92.7%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 43.3%; 100%)	99.1	(95% CI: 98.2%; 99.6%)
maf3378-a001	Top Biotech Sdn. Bhd.	Top Rapid COVID-19 Rapid Antibody IgG/IgM Test Kit	TBCV 04007001T	Panel 3	Lateral Flow	Unknown	Not Authorized	IgM	93.3	(95% CI: 78.7%; 98.2%)	90.0	(95% CI: 81.5%; 94.8%)	32.9	(95% CI: 18.3%; 50.1%)	99.6	(95% CI: 98.6%; 99.9%)

Evaluation ID	Manufacturer	Device	Lot Number	Panel	Assay Type	Target	Regulatory Status	Analyte	PPA (%)	PPA CI	NPA (%)	NPA CI	PPV (%)	PPV CI	NPV (%)	NPV CI
maf3383-a001	Doctorspot Technologies Inc,	COVID-19 SARS-CoV-2 IgM/IgG Antibody Rapid Test Kit (Colloidal Gold)	S060012010	Panel 3	Lateral Flow	Unknown	Not Authorized	Combined	33.3	(95% CI: 19.2%; 51.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 18.1%; 100%)	96.6	(95% CI: 95.7%; 97.5%)
maf3383-a001	Doctorspot Technologies Inc,	COVID-19 SARS-CoV-2 IgM/IgG Antibody Rapid Test Kit (Colloidal Gold)	S060012010	Panel 3	Lateral Flow	Unknown	Not Authorized	IgG	26.7	(95% CI: 14.2%; 44.4%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 14.0%; 100%)	96.3	(95% CI: 95.5%; 97.2%)
maf3383-a001	Doctorspot Technologies Inc,	COVID-19 SARS-CoV-2 IgM/IgG Antibody Rapid Test Kit (Colloidal Gold)	S060012010	Panel 3	Lateral Flow	Unknown	Not Authorized	IgM	16.7	(95% CI: 7.3%; 33.6%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 7.8%; 100%)	95.8	(95% CI: 95.1%; 96.6%)
maf3390-a001	Artron Laboratories, Inc.	OTO-Artron COVID-19 IgG/IgM Antibody Test	200606	Panel 3	Lateral Flow	Unknown	Not Authorized	Combined	93.3	(95% CI: 78.7%; 98.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 47.5%; 100%)	99.7	(95% CI: 98.8%; 99.9%)
maf3390-a001	Artron Laboratories, Inc.	OTO-Artron COVID-19 IgG/IgM Antibody Test	200606	Panel 3	Lateral Flow	Unknown	Not Authorized	IgG	83.3	(95% CI: 66.4%; 92.7%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 43.3%; 100%)	99.1	(95% CI: 98.2%; 99.6%)
maf3390-a001	Artron Laboratories, Inc.	OTO-Artron COVID-19 IgG/IgM Antibody Test	200606	Panel 3	Lateral Flow	Unknown	Not Authorized	IgM	76.7	(95% CI: 59.1%; 88.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 40.4%; 100%)	98.8	(95% CI: 97.8%; 99.4%)
maf3391-a001	SurExam Bio-Tech Co. Ltd.	Surplex COVID-19 IgM/IgG Rapid Test	20052901	Panel 3	Lateral Flow	Unknown	Not Authorized	Combined	76.7	(95% CI: 59.1%; 88.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 40.4%; 100%)	98.8	(95% CI: 97.8%; 99.4%)
maf3391-a001	SurExam Bio-Tech Co. Ltd.	Surplex COVID-19 IgM/IgG Rapid Test	20052901	Panel 3	Lateral Flow	Unknown	Not Authorized	IgG	76.7	(95% CI: 59.1%; 88.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 40.4%; 100%)	98.8	(95% CI: 97.8%; 99.4%)
maf3391-a001	SurExam Bio-Tech Co. Ltd.	Surplex COVID-19 IgM/IgG Rapid Test	20052901	Panel 3	Lateral Flow	Unknown	Not Authorized	IgM	76.7	(95% CI: 59.1%; 88.2%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 40.4%; 100%)	98.8	(95% CI: 97.8%; 99.4%)
maf3394-a001	Vincitek LLC	Vincitek S2-AB Test Card	S2AB200914	Panel 3	Lateral Flow	Unknown	Not Authorized	Combined	83.3	(95% CI: 66.4%; 92.7%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 43.3%; 100%)	99.1	(95% CI: 98.2%; 99.6%)
maf3394-a001	Vincitek LLC	Vincitek S2-AB Test Card	S2AB200914	Panel 3	Lateral Flow	Unknown	Not Authorized	IgG	83.3	(95% CI: 66.4%; 92.7%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 43.3%; 100%)	99.1	(95% CI: 98.2%; 99.6%)
maf3394-a001	Vincitek LLC	Vincitek S2-AB Test Card	S2AB200914	Panel 3	Lateral Flow	Unknown	Not Authorized	IgM	53.3	(95% CI: 36.1%; 69.8%)	100.0	(95% CI: 95.4%; 100%)	100.0	(95% CI: 29.3%; 100%)	97.6	(95% CI: 96.6%; 98.4%)
maf3398-a001	MP Biomedicals Asia Pacific Pte. Ltd.	MP Diagnostics Assure SARS-CoV-2 IgG/IgM Rapid Test	DC0005	Panel 3	Lateral Flow	Unknown	Not Authorized	Combined	96.7	(95% CI: 83.3%; 99.4%)	88.8	(95% CI: 80.0%; 94.0%)	31.1	(95% CI: 18.0%; 46.4%)	99.8	(95% CI: 98.9%; 100%)
maf3398-a001	MP Biomedicals Asia Pacific Pte. Ltd.	MP Diagnostics Assure SARS-CoV-2 IgG/IgM Rapid Test	DC0005	Panel 3	Lateral Flow	Unknown	Not Authorized	IgG	96.7	(95% CI: 83.3%; 99.4%)	91.3	(95% CI: 83.0%; 95.7%)	36.8	(95% CI: 20.5%; 54.9%)	99.8	(95% CI: 99.0%; 100%)
maf3398-a001	MP Biomedicals Asia Pacific Pte. Ltd.	MP Diagnostics Assure SARS-CoV-2 IgG/IgM Rapid Test	DC0005	Panel 3	Lateral Flow	Unknown	Not Authorized	IgM	66.7	(95% CI: 48.8%; 80.8%)	97.5	(95% CI: 91.3%; 99.3%)	58.4	(95% CI: 22.9%; 86.1%)	98.2	(95% CI: 97.1%; 99.0%)

PPA= Positive Percent Agreement

NPA= Negative Percent Agreement

CI= Confidence Interval

PPV= Positive Predictive Value

NPV= Negative Predictive Value