Analysis of Multiple Serology Test Evaluations of the "Advaite RapCov Rapid COVID-19 Test" from Advaite Inc.

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1 Introduction

The Advaite RapCov Rapid COVID-19 Test from Advaite Inc. was evaluated more than once at the Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center (FFRDC) sponsored by the National Cancer Institute (NCI). Combining results from multiple evaluations is appropriate because the study protocol did not change, including the inclusion and exclusion criteria used to select the samples used for each evaluation, and because the devices used in the evaluations were the same. The Advaite RapCov Rapid COVID-19 Test is intended to qualitatively detect IgG. For the details of the individual evaluations, see the corresponding evaluation reports.

Table 1: Evaluation results included in this analysis

Evaluation ID	Date(s) Performed	Lot Number(s)	Panel
maf3382-a001	2020-10-06	P0904	Panel 3
maf3397-a001	2020-11-02	P0904	Panel 2

1.1 Panel composition

For detailed information on the panels used in these evaluations, see the evaluation test reports. The serum and plasma samples used in each evaluation panel have not been restricted for use to only a single panel. Serum and plasma samples shared between panels have the same Sample ID in the line data for the evaluations. Where a serum or plasma sample was tested more than once, only one result was reported for the calculations in this report. If the results on the sample were the same between/amongst evaluations, the result with the earliest date was reported. If the results on the sample were not the same between/amongst evaluations, the result showing the worst-case performance was reported. For antibody-positive samples, this resulted in the combined panel composition shown in Figure 1.
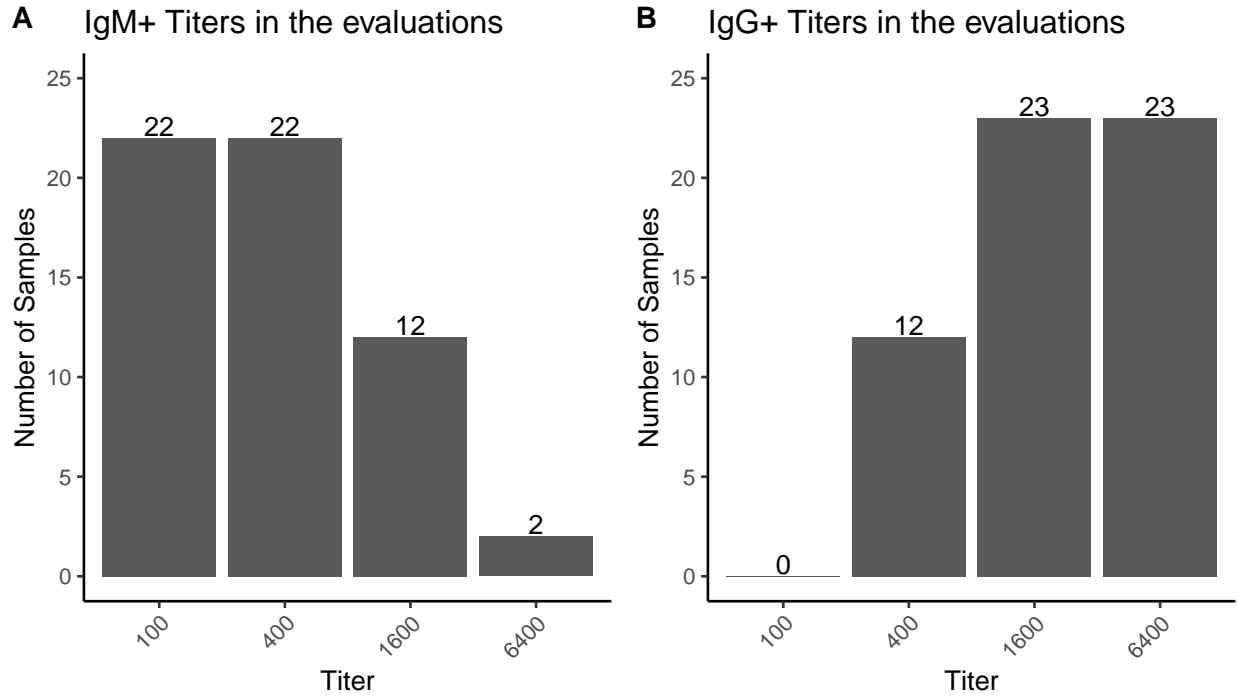
Figure 1: Titer levels for (A) IgM+ and (B) IgG+ samples according to the CDC SARS-CoV-2 Spike antigen assay

1.2 Analysis

Samples used in these evaluations were not randomly selected, and sensitivity (PPA) and specificity (NPA) estimates in this report may not be indicative of the real-world performance of the Advaite Inc. Advaite RapCov Rapid COVID-19 Test. Sensitivity and specificity were calculated for each antibody (e.g., IgM, IgG, IgA, and Pan-Ig, as applicable) separately. In addition, sensitivity and specificity were estimated in a combined manner, where a positive result for any antibody the Advaite Inc. Advaite RapCov Rapid COVID-19 Test is intended to detect was considered as a positive test result and a negative result meant that a sample tested negative for all antibodies the Advaite Inc. Advaite Rap-Cov Rapid COVID-19 Test is intended to detect. Positive and negative predictive values were calculated for combined sensitivity and specificity assuming a prevalence of 5%. Cross-reactivity with HIV+ was evaluated, and results are presented separately. If cross-reactivity was detected, the samples with HIV+ were not included in calculations of specificity.

Confidence intervals for sensitivity and specificity were calculated per a score method described in CLSI EP12-A2 (2008).[1] Confidence intervals for PPV and NPV were calculated using the values from

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[1]CLSI. *User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline—Second Edition*. CLSI document EP12-A2. Wayne, PA: Clinical and Laboratory Standards Institute; 2008. See `https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/detail.cfm?standard__identification_no=31791`.

the 95% confidence intervals for sensitivity and specificity. For evaluation of cross-reactivity with HIV+, it was evaluated whether an increased false positive rate among antibody negative samples with HIV was statistically higher than the false positive rate among antibody negative samples without HIV (for this, a confidence interval for the difference in false positive rates was calculated per a score method described by Altman.[2])

1.3 Important caveats

Sensitivity and specificity estimates in this report may not be indicative of the real world performance of the Advaite Inc. Advaite RapCov Rapid COVID-19 Test.

These results are based on serum and plasma samples only and may not be indicative of performance with other sample types, such as whole blood, including finger stick blood.

The number of samples in the panel is a minimally viable sample size that still provides reasonable estimates and confidence intervals for test performance, and the samples used may not be representative of the antibody profile observed in patient populations.

For more detailed information on the evaluation procedure, including any deviations, please see the individual test reports for each evaluation.

1.4 Additional notes, anomalies, and clarifications for maf3382-a001

The FNLCR provided the following additional information:

Sample number 38 had to be tested three times because the control line on the cassette failed twice. Instructions for Use only describe the use of serum, but Product Information sheet supplied by company describes the use of plasma and serum. Contract Manufacturer is Frontida Biopharm Inc. as described on Product Information sheet.

1.5 Additional notes, anomalies, and clarifications for maf3397-a001

The FNLCR provided the following additional information:

Instructions for Use only describe the use of serum.

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[2]Statistics with Confidence: Confidence Intervals and Statistical Guidelines. (2013). Wiley.

2 Results

Table 2: Summary Results

Advaite RapCov Rapid COVID-19 Test	Comparator Method			Collected pre-2020		
	Antibody Positive			Antibody Negative		
	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	Total
IgG+	52			2		54
IgG-	6			85	10	101
Total	58			87	10	155

Table 3: Summary Statistics

Measure	Estimate	Confidence Interval
IgG Sensitivity	89.7% (52/58)	(79.2%; 95.2%)
IgG Specificity	97.9% (95/97)	(92.8%; 99.4%)
Combined Sensitivity	89.7% (52/58)	(79.2%; 95.2%)
Combined Specificity	97.9% (95/97)	(92.8%; 99.4%)
Combined PPV for prevalence = 5.0%	69.6%	(36.6%; 89.8%)
Combined NPV for prevalence = 5.0%	99.4%	(98.8%; 99.7%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

3 Line Data (all)

In the table below, "Days" refers to "Days from symptom onset to blood collection."

Table 4: Line Data (all)

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3397-a001	C0031	Positive	Pass	Serum	1600	400	6400	21	Positive
maf3397-a001	C0049	Positive	Pass	Serum	400	400	400	23	Positive
maf3397-a001	C0053	Positive	Pass	Serum	1600	1600	1600	28	Positive
maf3397-a001	C0064	Positive	Pass	Serum	1600	1600	6400	20	Positive
maf3397-a001	C0071	Positive	Pass	Serum	6400	1600	6400	20	Positive
maf3397-a001	C0080	Positive	Pass	Serum	1600	400	1600	29	Positive
maf3397-a001	C0127	Positive	Pass	Serum	400	400	1600	23	Positive
maf3397-a001	C0132	Positive	Pass	Serum	1600	1600	6400		Positive
maf3397-a001	C0144	Positive	Pass	Serum	6400	1600	6400	21	Positive
maf3397-a001	C0145	Positive	Pass	Serum	6400	1600	6400	17	Positive
maf3397-a001	C0152	Positive	Pass	Serum	400	400	6400	24	Positive
maf3397-a001	C0153	Negative	Pass	Serum	400	100	400	31	Positive
maf3397-a001	C0172	Positive	Pass	Serum	1600	400	1600	19	Positive
maf3397-a001	C0187	Positive	Pass	Serum	6400	6400	6400	29	Positive
maf3397-a001	D0012	Positive	Pass	Serum	6400	100	6400	28	Positive
maf3382-a001	D0020	Positive	Pass	Serum	1600	400	6400	42	Positive
maf3397-a001	D0020	Positive	Pass	Serum	1600	400	6400	42	Positive
maf3397-a001	D0022	Negative	Pass	Serum	400	100	1600	46	Positive
maf3397-a001	D0028	Positive	Pass	Serum	6400	400	6400	32	Positive
maf3382-a001	D0038	Positive	Pass	Serum	400	100	1600	44	Positive
maf3382-a001	D0040	Positive	Pass	Serum	100	100	400	43	Positive
maf3397-a001	D0084	Positive	Pass	Serum	1600	100	1600	41	Positive

Table 4: Line Data (all) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3382-a001	D0090	Positive	Pass	Serum	1600	400	6400	45	Positive
maf3382-a001	D0091	Positive	Pass	Serum	400	100	1600	40	Positive
maf3382-a001	D0102	Positive	Pass	Serum	400	100	400	24	Positive
maf3397-a001	D0104	Positive	Pass	Serum	400	100	400	17	Positive
maf3397-a001	D0149	Positive	Pass	Serum	400	100	400	43	Positive
maf3382-a001	D0159	Positive	Pass	Serum	100	100	400	24	Positive
maf3397-a001	D0159	Positive	Pass	Serum	100	100	400	24	Positive
maf3397-a001	D0161	Positive	Pass	Serum	1600	100	1600	44	Positive
maf3382-a001	D0168	Positive	Pass	Serum	400	100	400	24	Positive
maf3397-a001	D0180	Positive	Pass	Serum	6400	400	6400	39	Positive
maf3382-a001	D0182	Positive	Pass	Serum	6400	1600	6400	17	Positive
maf3397-a001	D0188	Positive	Pass	Serum	400	400	1600	24	Positive
maf3397-a001	D0201	Positive	Pass	Serum	100	100	400	33	Positive
maf3397-a001	D0205	Positive	Pass	Serum	400	400	1600	26	Positive
maf3397-a001	D0206	Positive	Pass	Serum	1600	100	1600	25	Positive
maf3397-a001	D0208	Positive	Pass	Serum	400	100	1600	22	Positive
maf3382-a001	D0209	Positive	Pass	Serum	6400	1600	6400	42	Positive
maf3397-a001	D0210	Positive	Pass	Serum	1600	100	1600	26	Positive
maf3382-a001	D0231	Positive	Pass	Serum	6400	1600	6400	19	Positive
maf3382-a001	D0254	Positive	Pass	Serum	400	400	1600	34	Positive
maf3382-a001	D0268	Negative	Pass	Serum	400	100	1600		Positive
maf3382-a001	D0270	Positive	Pass	Serum	1600	100	1600	20	Positive
maf3382-a001	D0297	Positive	Pass	Serum	1600	400	6400	20	Positive
maf3382-a001	D0307	Positive	Pass	Serum	6400	1600	6400	41	Positive
maf3382-a001	D0326	Negative	Pass	Serum	400	400	1600		Positive
maf3382-a001	D0344	Positive	Pass	Serum	6400	1600	6400	27	Positive

Table 4: Line Data (all) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3382-a001	D0349	Positive	Pass	Serum	1600	400	6400	19	Positive
maf3382-a001	D0367	Negative	Pass	Serum	400	400	400	37	Positive
maf3382-a001	D0386	Negative	Pass	Serum	6400	6400	6400	20	Positive
maf3382-a001	D0396	Positive	Pass	Serum	100	100	400	26	Positive
maf3382-a001	D0405	Positive	Pass	Serum	400	400	400	32	Positive
maf3382-a001	D0451	Positive	Pass	Serum	1600	400	1600	35	Positive
maf3382-a001	D0455	Positive	Pass	Serum	1600	1600	6400	23	Positive
maf3382-a001	D0465	Positive	Pass	Serum	1600	100	6400	31	Positive
maf3382-a001	D0466	Positive	Pass	Serum	400	100	1600	19	Positive
maf3382-a001	D0493	Positive	Pass	Serum	1600	400	1600	43	Positive
maf3382-a001	D0497	Positive	Pass	Serum	400	400	1600	25	Positive
maf3382-a001	D0498	Positive	Pass	Serum	1600	400	1600	17	Positive
maf3382-a001	C0004	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0004	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0005	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0005	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0008	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0008	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0019	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0019	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0026	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0026	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0032	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0032	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0041	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0041	Negative	Pass	Plasma	0	0	0		Negative

Table 4: Line Data (all) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3382-a001	C0051	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0051	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0059	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0059	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0063	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0063	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0065	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0065	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0075	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0075	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0079	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0079	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0095	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0095	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0098	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0098	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0101	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0101	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0103	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0103	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0105	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0105	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0109	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0109	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0117	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0117	Negative	Pass	Plasma	0	0	0		Negative

Table 4: Line Data (all) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3382-a001	C0121	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0121	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0133	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0133	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0134	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0134	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0137	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0137	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0140	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0140	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0156	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0156	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0162	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0162	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0179	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0179	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0185	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0185	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0193	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0193	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0196	Positive	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0196	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0198	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	C0198	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0199	Negative	Pass	Plasma	0	0	0		Negative

Table 4: Line Data (all) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3397-a001	C0199	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0003	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0006	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0007	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0007	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0011	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0015	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0015	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0023	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0025	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0027	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0031	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0034	Negative	Pass	Serum	0	0	0		Negative
maf3397-a001	D0047	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0049	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0049	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0053	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0056	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0056	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0058	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0060	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0064	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0064	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0073	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0077	Negative	Pass	Plasma	0	0	0		Negative

Table 4: Line Data (all) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3382-a001	D0080	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0083	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0085	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0086	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0086	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0094	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0097	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0097	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0112	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0113	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0115	Negative	Pass	Serum	0	0	0		Negative
maf3397-a001	D0120	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0123	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0123	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0126	Positive	Pass	Serum	0	0	0		Negative
maf3397-a001	D0128	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0129	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0130	Negative	Pass	Serum	0	0	0		Negative
maf3397-a001	D0131	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0132	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0132	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0135	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0135	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0141	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0141	Negative	Pass	Plasma	0	0	0		Negative

Table 4: Line Data (all) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3382-a001	D0142	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0142	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0145	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0145	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0148	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0148	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0153	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0153	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0154	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0154	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0158	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0166	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0166	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0169	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0170	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0170	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0172	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0173	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0178	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0183	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0184	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0184	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0187	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0187	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0192	Negative	Pass	Plasma	0	0	0		Negative

Table 4: Line Data (all) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3382-a001	C0018	Negative	Pass	Plasma	0	0	0		HIV+
maf3397-a001	C0018	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0054	Negative	Pass	Plasma	0	0	0		HIV+
maf3397-a001	C0054	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0089	Negative	Pass	Plasma	0	0	0		HIV+
maf3397-a001	C0089	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0093	Negative	Pass	Plasma	0	0	0		HIV+
maf3397-a001	C0093	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0099	Negative	Pass	Plasma	0	0	0		HIV+
maf3397-a001	C0099	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0138	Negative	Pass	Plasma	0	0	0		HIV+
maf3397-a001	C0138	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0150	Negative	Pass	Plasma	0	0	0		HIV+
maf3397-a001	C0150	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0155	Negative	Pass	Plasma	0	0	0		HIV+
maf3397-a001	C0155	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0182	Negative	Pass	Plasma	0	0	0		HIV+
maf3397-a001	C0182	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0197	Negative	Pass	Plasma	0	0	0		HIV+
maf3397-a001	C0197	Negative	Pass	Plasma	0	0	0		HIV+

4 Line Data (independent samples)

In the table below, "Days" refers to "Days from symptom onset to blood collection."

Table 5: Line Data (independent samples)

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3397-a001	C0031	Positive	Pass	Serum	1600	400	6400	21	Positive
maf3397-a001	C0049	Positive	Pass	Serum	400	400	400	23	Positive
maf3397-a001	C0053	Positive	Pass	Serum	1600	1600	1600	28	Positive
maf3397-a001	C0064	Positive	Pass	Serum	1600	1600	6400	20	Positive
maf3397-a001	C0071	Positive	Pass	Serum	6400	1600	6400	20	Positive
maf3397-a001	C0080	Positive	Pass	Serum	1600	400	1600	29	Positive
maf3397-a001	C0127	Positive	Pass	Serum	400	400	1600	23	Positive
maf3397-a001	C0132	Positive	Pass	Serum	1600	1600	6400		Positive
maf3397-a001	C0144	Positive	Pass	Serum	6400	1600	6400	21	Positive
maf3397-a001	C0145	Positive	Pass	Serum	6400	1600	6400	17	Positive
maf3397-a001	C0152	Positive	Pass	Serum	400	400	6400	24	Positive
maf3397-a001	C0153	Negative	Pass	Serum	400	100	400	31	Positive
maf3397-a001	C0172	Positive	Pass	Serum	1600	400	1600	19	Positive
maf3397-a001	C0187	Positive	Pass	Serum	6400	6400	6400	29	Positive
maf3397-a001	D0012	Positive	Pass	Serum	6400	100	6400	28	Positive
maf3382-a001	D0020	Positive	Pass	Serum	1600	400	6400	42	Positive
maf3397-a001	D0022	Negative	Pass	Serum	400	100	1600	46	Positive
maf3397-a001	D0028	Positive	Pass	Serum	6400	400	6400	32	Positive
maf3382-a001	D0038	Positive	Pass	Serum	400	100	1600	44	Positive
maf3382-a001	D0040	Positive	Pass	Serum	100	100	400	43	Positive
maf3397-a001	D0084	Positive	Pass	Serum	1600	100	1600	41	Positive
maf3382-a001	D0090	Positive	Pass	Serum	1600	400	6400	45	Positive

Table 5: Line Data (independent samples) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3382-a001	D0091	Positive	Pass	Serum	400	100	1600	40	Positive
maf3382-a001	D0102	Positive	Pass	Serum	400	100	400	24	Positive
maf3397-a001	D0104	Positive	Pass	Serum	400	100	400	17	Positive
maf3397-a001	D0149	Positive	Pass	Serum	400	100	400	43	Positive
maf3382-a001	D0159	Positive	Pass	Serum	100	100	400	24	Positive
maf3397-a001	D0161	Positive	Pass	Serum	1600	100	1600	44	Positive
maf3382-a001	D0168	Positive	Pass	Serum	400	100	400	24	Positive
maf3397-a001	D0180	Positive	Pass	Serum	6400	400	6400	39	Positive
maf3382-a001	D0182	Positive	Pass	Serum	6400	1600	6400	17	Positive
maf3397-a001	D0188	Positive	Pass	Serum	400	400	1600	24	Positive
maf3397-a001	D0201	Positive	Pass	Serum	100	100	400	33	Positive
maf3397-a001	D0205	Positive	Pass	Serum	400	400	1600	26	Positive
maf3397-a001	D0206	Positive	Pass	Serum	1600	100	1600	25	Positive
maf3397-a001	D0208	Positive	Pass	Serum	400	100	1600	22	Positive
maf3382-a001	D0209	Positive	Pass	Serum	6400	1600	6400	42	Positive
maf3397-a001	D0210	Positive	Pass	Serum	1600	100	1600	26	Positive
maf3382-a001	D0231	Positive	Pass	Serum	6400	1600	6400	19	Positive
maf3382-a001	D0254	Positive	Pass	Serum	400	400	1600	34	Positive
maf3382-a001	D0268	Negative	Pass	Serum	400	100	1600		Positive
maf3382-a001	D0270	Positive	Pass	Serum	1600	100	1600	20	Positive
maf3382-a001	D0297	Positive	Pass	Serum	1600	400	6400	20	Positive
maf3382-a001	D0307	Positive	Pass	Serum	6400	1600	6400	41	Positive
maf3382-a001	D0326	Negative	Pass	Serum	400	400	1600		Positive
maf3382-a001	D0344	Positive	Pass	Serum	6400	1600	6400	27	Positive
maf3382-a001	D0349	Positive	Pass	Serum	1600	400	6400	19	Positive
maf3382-a001	D0367	Negative	Pass	Serum	400	400	400	37	Positive

Table 5: Line Data (independent samples) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3382-a001	D0386	Negative	Pass	Serum	6400	6400	6400	20	Positive
maf3382-a001	D0396	Positive	Pass	Serum	100	100	400	26	Positive
maf3382-a001	D0405	Positive	Pass	Serum	400	400	400	32	Positive
maf3382-a001	D0451	Positive	Pass	Serum	1600	400	1600	35	Positive
maf3382-a001	D0455	Positive	Pass	Serum	1600	1600	6400	23	Positive
maf3382-a001	D0465	Positive	Pass	Serum	1600	100	6400	31	Positive
maf3382-a001	D0466	Positive	Pass	Serum	400	100	1600	19	Positive
maf3382-a001	D0493	Positive	Pass	Serum	1600	400	1600	43	Positive
maf3382-a001	D0497	Positive	Pass	Serum	400	400	1600	25	Positive
maf3382-a001	D0498	Positive	Pass	Serum	1600	400	1600	17	Positive
maf3382-a001	C0004	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0005	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0008	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0019	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0026	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0032	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0041	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0051	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0059	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0063	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0065	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0075	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0079	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0095	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0098	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0101	Negative	Pass	Plasma	0	0	0		Negative

Table 5: Line Data (independent samples) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3382-a001	C0103	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0105	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0109	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0117	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0121	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0133	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0134	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0137	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0140	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0156	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0162	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0179	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0185	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0193	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0196	Positive	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0198	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0199	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0003	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0006	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0007	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0011	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0015	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0023	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0025	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0027	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0031	Negative	Pass	Plasma	0	0	0		Negative

Table 5: Line Data (independent samples) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3397-a001	D0034	Negative	Pass	Serum	0	0	0		Negative
maf3397-a001	D0047	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0049	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0053	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0056	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0058	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0060	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0064	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0073	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0077	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0080	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0083	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0085	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0086	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0094	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0097	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0112	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0113	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0115	Negative	Pass	Serum	0	0	0		Negative
maf3397-a001	D0120	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0123	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0126	Positive	Pass	Serum	0	0	0		Negative
maf3397-a001	D0128	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0129	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0130	Negative	Pass	Serum	0	0	0		Negative

Table 5: Line Data (independent samples) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3397-a001	D0131	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0132	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0135	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0141	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0142	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0145	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0148	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0153	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0154	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0158	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0166	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0169	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0170	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0172	Negative	Pass	Plasma	0	0	0		Negative
maf3397-a001	D0173	Negative	Pass	Serum	0	0	0		Negative
maf3382-a001	D0178	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0183	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0184	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0187	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	D0192	Negative	Pass	Plasma	0	0	0		Negative
maf3382-a001	C0018	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0054	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0089	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0093	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0099	Negative	Pass	Plasma	0	0	0		HIV+

Table 5: Line Data (independent samples) *(continued)*

Evaluation ID	Sample ID	IgG Result	Control	Type	CDC Spike Pan-Ig Titer	CDC Spike IgM Titer	CDC Spike IgG Titer	Days	Group
maf3382-a001	C0138	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0150	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0155	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0182	Negative	Pass	Plasma	0	0	0		HIV+
maf3382-a001	C0197	Negative	Pass	Plasma	0	0	0		HIV+