



Serology Test Evaluation Report for “COVID-19 IgG/IgM Rapid Test Cassette” from Healgen

Updated

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1 Introduction

The COVID-19 IgG/IgM Rapid Test Cassette from Healgen was tested on 2020-04-21 at the Frederick National Laboratory for Cancer Research (FNLCR), a Federally Funded Research and Development Center (FFRDC) sponsored by the National Cancer Institute (NCI). Tests were from lot number 2003292. The COVID-19 IgG/IgM Rapid Test Cassette is intended to qualitatively detect IgM and IgG separately.

1.1 Panel composition

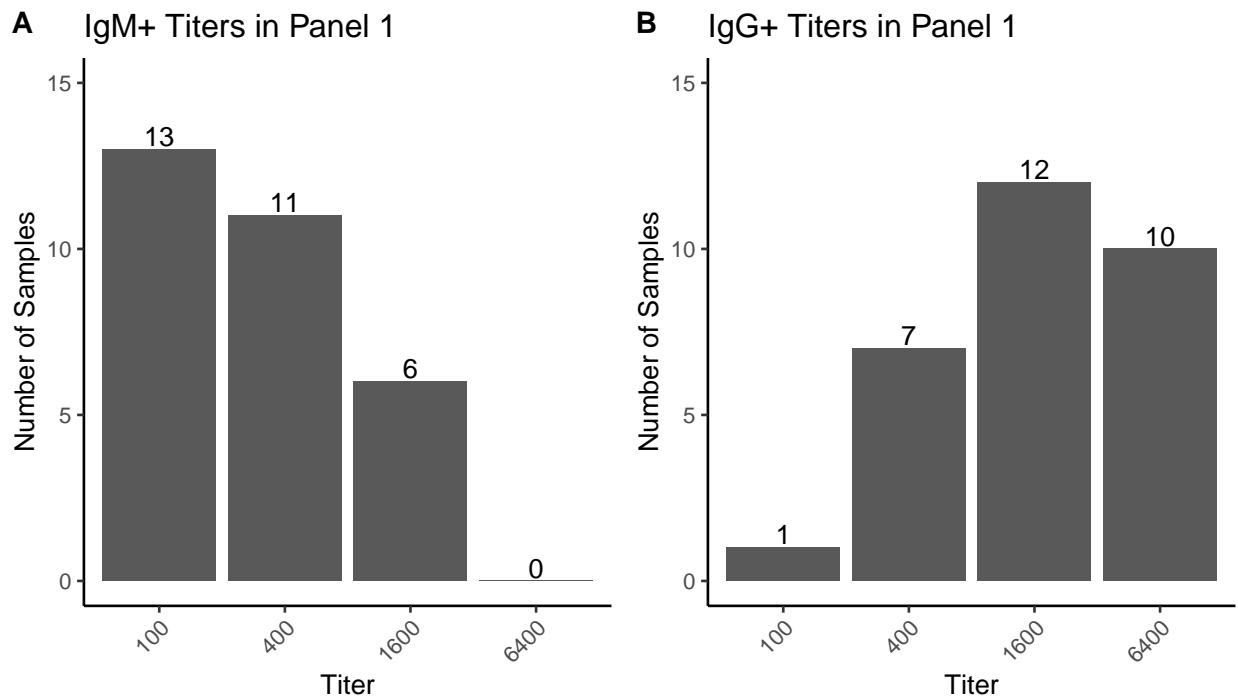


Figure 1: Titer levels for (A) IgM+ and (B) IgG+ samples according to the CDC SARS-CoV-2 Spike antigen assay

The test was evaluated against “Panel 1,” which includes frozen SARS-CoV-2 antibody-positive serum samples ($n = 30$) and frozen antibody-negative serum and plasma samples ($n = 80$). The panel size and composition were chosen to enable a laboratory-based evaluation and to provide reasonable estimates and confidence intervals for test performance in the context of limited sample availability. The sample size is comparable to that of a typical sample size used to support Emergency Use Authorization (EUA) by FDA for tests of this type.

1.1.1 Positive samples

Positive samples used in Panel 1 were from patients previously confirmed to have SARS-CoV-2 infection with a nucleic acid amplification test (NAAT). Time between symptom onset, NAAT testing, and sample collection is not known for all samples. Both SARS-CoV-2 IgM and IgG antibodies are present in all Panel 1 positive samples. The Centers for Disease Control and prevention (CDC) detected the presence of IgG and IgM antibodies at their laboratory using their SARS-CoV-2 spike enzyme-linked immunosorbent assay (ELISA) tests.¹ The presence of antibodies was confirmed at FNLCR using CDC's developed ELISAs (Pan-Ig, IgG, and IgM) as well as an IgG Receptor Binding Domain (RBD) ELISA developed by the Krammer Laboratory at the Icahn School of Medicine at Mount Sinai.² The positive samples selected may not reflect the distribution of antibody levels in patient populations that would be evaluated by such a test. Because all samples are positive for both IgM and IgG, this evaluation cannot verify that tests intended to detect IgM and IgG antibodies separately detect these antibodies independently.

Positive samples were assessed at dilutions of 1:100, 1:400, 1:1600, and 1:6400 by CDC on their Pan-Ig assay, their IgM assay, and their IgG assay. Some samples were run at additional dilutions. Any samples that were positive at a dilution greater than 1:6400 were assigned a titer of 6400 because 1:6400 was the highest dilution at which all Panel 1 positive samples were assessed. Two of these samples, C0107 and C0176, were positive for IgG antibodies at a dilution of 1:25600.

1.1.2 Negative samples

All Panel 1 negative samples were collected prior to 2020, before the SARS-CoV-2 virus is known to have circulated in the United States. Panel 1 groups include:

- “Negatives” ($n = 70$): selected without regard for clinical status. This group includes a sample, C0063, that showed reactivity in the Pan-Ig CDC spike ELISA at FNLCR. It includes another sample, C0087, that showed reactivity in the IgG RBD ELISA at FNLCR.
- “HIV+” ($n = 10$): selected from banked serum from HIV+ patients.³ This group includes 3 samples, C0018, C0155, and C0182, that showed reactivity in the IgG RBD ELISA at FNLCR.

All Panel 1 negative samples were assessed at dilutions of 1:100 and 1:400 by CDC on their Pan-Ig assay. A subset of samples was assessed in parallel at additional dilutions and on the CDC IgM

¹See <https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html>, which notes “CDC’s serologic test is designed and validated for broad-based surveillance and research that will give us information needed to guide the response to the pandemic and protect the public’s health. The test is not currently designed to test individuals who want to know if they have been previously infected with COVID-19.”

²An implementation of this test, the COVID-19 ELISA IgG Antibody Test, has been granted an EUA authorization by FDA for use at the Mount Sinai Laboratory (MSL), Center for Clinical Laboratories, a division of the Department of Pathology, Molecular, and Cell-Based Medicine, New York, NY. See <https://www.fda.gov/media/137029/download>.

³HIV+ samples were deemed appropriate for inclusion in the panel: (1) to increase the sample size and reduce the confidence interval; and (2) to identify any possibility of cross-reactivity with HIV+ samples. It is anticipated that other types of samples, as they become available, may also be evaluated in any future analyses.

and IgG assays. All Panel 1 negative samples were negative at a dilution of 1:100 on the CDC Pan-Ig assay. These samples were assigned an undetectable titer (represented as zero (0) in the line data) for the Pan-Ig assay, the IgM assay, and the IgG assay.

1.2 Analysis

Samples used in this evaluation 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 Healgen COVID-19 IgG/IgM Rapid Test Cassette. 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 Healgen COVID-19 IgG/IgM Rapid Test Cassette 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 Healgen COVID-19 IgG/IgM Rapid Test Cassette 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).⁴ Confidence intervals for PPV and NPV were calculated using the values from 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.⁵)

1.3 Important caveats

Sensitivity and specificity estimates in this report may not be indicative of the real world performance of the Healgen COVID-19 IgG/IgM Rapid Test Cassette.

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.

Information about anticoagulants used is not known.

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.

⁴CLSI. *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.

⁵Statistics with Confidence: Confidence Intervals and Statistical Guidelines. (2013). Wiley.

1.4 Notes about the evaluation procedure

- The Healgen COVID-19 IgG/IgM Rapid Test Cassette was used per the manufacturer's package insert.
- Devices were tested within any expiration dates provided.
- Devices were not obviously defective / compromised.
- Devices were stored at FNLCR within their labeled conditions.
- A single operator conducted and read the test.
- The personnel who performed the testing were blinded to the identity / code of the sample and the expected results.
- The testing was performed in a non-clinical laboratory environment.
- Negative and positive samples were ordered randomly and then tested serially.
- The operator trained on the COVID-19 IgG/IgM Rapid Test Cassette with positive and negative controls prior to testing.

2 Results

Table 1: Summary Results

| COVID-19 IgG/IgM Rapid Test Cassette | Comparator Method | | | Collected pre-2020 | | Total |
|--|-------------------|---------------|---------------|--------------------|------|-------|
| | Antibody Positive | | | Antibody Negative | | |
| | IgM+, IgG+ | IgM+, IgG- | IgM-, IgG+ | Negative | HIV+ | |
| IgM+, IgG+ | 29 | | | | | 29 |
| IgM+, IgG- | 1 | | | | | 1 |
| IgM-, IgG+ | | | | 2 | | 2 |
| IgM-, IgG- | | | | 68 | 10 | 78 |
| Total | 30 | | | 70 | 10 | 110 |

Table 2: Summary Statistics

| Measure | Estimate | Confidence Interval |
|---------------------------------------|------------------------------|---------------------|
| IgM Sensitivity | 100% (30/30) | (88.7%; 100%) |
| IgM Specificity | 100% (80/80) | (95.4%; 100%) |
| IgG Sensitivity | 96.7% (29/30) | (83.3%; 99.4%) |
| IgG Specificity | 97.5% (78/80) | (91.3%; 99.3%) |
| Combined Sensitivity | 100% (30/30) | (88.7%; 100%) |
| Combined Specificity | 97.5% (78/80) | (91.3%; 99.3%) |
| Combined PPV for prevalence = 5.0% | 67.8% | (35%; 88.4%) |
| Combined NPV for prevalence = 5.0% | 100% | (99.4%; 100%) |
| Cross-reactivity with HIV+ | 0.0% (0/10), not detected | |

3 Line Data

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

Table 3: Line Data

| Sample Number | IgM Result | IgG Result | IgA Result | Pan Ig Result | (IgM / IgG) Result | Control | Sample ID | Type | CDC Spike Pan-Ig Titer | CDC Spike IgM Titer | CDC Spike IgG Titer | Days | Group |
|---------------|------------|------------|------------|---------------|--------------------|---------|-----------|--------|------------------------|---------------------|---------------------|------|-----------|
| 1 | Negative | Negative | | | | Pass | C0001 | Serum | 0 | 0 | 0 | | Negatives |
| 2 | Negative | Negative | | | | Pass | C0002 | Serum | 0 | 0 | 0 | | Negatives |
| 3 | Negative | Negative | | | | Pass | C0004 | Plasma | 0 | 0 | 0 | | Negatives |
| 4 | Negative | Negative | | | | Pass | C0005 | Plasma | 0 | 0 | 0 | | Negatives |
| 5 | Negative | Negative | | | | Pass | C0008 | Plasma | 0 | 0 | 0 | | Negatives |
| 6 | Positive | Positive | | | | Pass | C0010 | Serum | 1600 | 400 | 1600 | 29 | Positives |
| 7 | Negative | Negative | | | | Pass | C0011 | Serum | 0 | 0 | 0 | | Negatives |
| 8 | Negative | Negative | | | | Pass | C0012 | Serum | 0 | 0 | 0 | | Negatives |
| 9 | Negative | Negative | | | | Pass | C0014 | Serum | 0 | 0 | 0 | | Negatives |
| 10 | Negative | Negative | | | | Pass | C0016 | Serum | 0 | 0 | 0 | | Negatives |
| 11 | Negative | Negative | | | | Pass | C0018 | Plasma | 0 | 0 | 0 | | HIV+ |
| 12 | Negative | Negative | | | | Pass | C0020 | Serum | 0 | 0 | 0 | | Negatives |
| 13 | Negative | Negative | | | | Pass | C0024 | Serum | 0 | 0 | 0 | | Negatives |
| 14 | Negative | Negative | | | | Pass | C0027 | Serum | 0 | 0 | 0 | | Negatives |
| 15 | Negative | Negative | | | | Pass | C0029 | Serum | 0 | 0 | 0 | | Negatives |
| 16 | Negative | Negative | | | | Pass | C0032 | Plasma | 0 | 0 | 0 | | Negatives |
| 17 | Negative | Negative | | | | Pass | C0033 | Serum | 0 | 0 | 0 | | Negatives |
| 18 | Negative | Negative | | | | Pass | C0034 | Serum | 0 | 0 | 0 | | Negatives |
| 19 | Positive | Positive | | | | Pass | C0037 | Serum | 400 | 100 | 1600 | 19 | Positives |
| 20 | Positive | Positive | | | | Pass | C0038 | Serum | 100 | 100 | 100 | 20 | Positives |

Table 3: Line Data (continued)

| Sample Number | IgM Result | IgG Result | IgA Result | Pan Ig Result | (IgM / IgG) Result | Control | Sample ID | Type | CDC Spike Pan-Ig Titer | CDC Spike IgM Titer | CDC Spike IgG Titer | Days | Group |
|---------------|------------|------------|------------|---------------|--------------------|---------|-----------|--------|------------------------|---------------------|---------------------|------|-----------|
| 21 | Positive | Positive | | | | Pass | C0040 | Serum | 1600 | 400 | 1600 | 24 | Positives |
| 22 | Negative | Negative | | | | Pass | C0041 | Plasma | 0 | 0 | 0 | | Negatives |
| 23 | Negative | Negative | | | | Pass | C0043 | Serum | 0 | 0 | 0 | | Negatives |
| 24 | Negative | Negative | | | | Pass | C0044 | Serum | 0 | 0 | 0 | | Negatives |
| 25 | Negative | Negative | | | | Pass | C0048 | Serum | 0 | 0 | 0 | | Negatives |
| 26 | Positive | Negative | | | | Pass | C0049 | Serum | 1600 | 400 | 400 | 23 | Positives |
| 27 | Negative | Negative | | | | Pass | C0050 | Serum | 0 | 0 | 0 | | Negatives |
| 28 | Negative | Negative | | | | Pass | C0051 | Plasma | 0 | 0 | 0 | | Negatives |
| 29 | Positive | Positive | | | | Pass | C0053 | Serum | 1600 | 1600 | 1600 | 28 | Positives |
| 30 | Negative | Negative | | | | Pass | C0054 | Plasma | 0 | 0 | 0 | | HIV+ |
| 31 | Negative | Negative | | | | Pass | C0058 | Serum | 0 | 0 | 0 | | Negatives |
| 32 | Negative | Negative | | | | Pass | C0059 | Plasma | 0 | 0 | 0 | | Negatives |
| 33 | Positive | Positive | | | | Pass | C0061 | Serum | 1600 | 100 | 1600 | 26 | Positives |
| 34 | Negative | Negative | | | | Pass | C0062 | Serum | 0 | 0 | 0 | | Negatives |
| 35 | Negative | Negative | | | | Pass | C0063 | Plasma | 0 | 0 | 0 | | Negatives |
| 36 | Positive | Positive | | | | Pass | C0064 | Serum | 1600 | 1600 | 6400 | 20 | Positives |
| 37 | Negative | Negative | | | | Pass | C0065 | Plasma | 0 | 0 | 0 | | Negatives |
| 38 | Negative | Negative | | | | Pass | C0066 | Serum | 0 | 0 | 0 | | Negatives |
| 39 | Negative | Negative | | | | Pass | C0067 | Serum | 0 | 0 | 0 | | Negatives |
| 40 | Negative | Negative | | | | Pass | C0069 | Serum | 0 | 0 | 0 | | Negatives |
| 41 | Negative | Negative | | | | Pass | C0070 | Serum | 0 | 0 | 0 | | Negatives |
| 42 | Positive | Positive | | | | Pass | C0071 | Serum | 6400 | 1600 | 6400 | 20 | Positives |
| 43 | Negative | Negative | | | | Pass | C0072 | Serum | 0 | 0 | 0 | | Negatives |
| 44 | Negative | Negative | | | | Pass | C0073 | Serum | 0 | 0 | 0 | | Negatives |

Table 3: Line Data (continued)

| Sample Number | IgM Result | IgG Result | IgA Result | Pan Ig Result | (IgM / IgG) Result | Control | Sample ID | Type | CDC Spike Pan-Ig Titer | CDC Spike IgM Titer | CDC Spike IgG Titer | Days | Group |
|---------------|------------|------------|------------|---------------|--------------------|---------|-----------|--------|------------------------|---------------------|---------------------|------|-----------|
| 45 | Positive | Positive | | | | Pass | C0074 | Serum | 400 | 100 | 400 | 24 | Positives |
| 46 | Negative | Negative | | | | Pass | C0079 | Plasma | 0 | 0 | 0 | | Negatives |
| 47 | Positive | Positive | | | | Pass | C0080 | Serum | 1600 | 400 | 1600 | 29 | Positives |
| 48 | Negative | Negative | | | | Pass | C0081 | Serum | 0 | 0 | 0 | | Negatives |
| 49 | Negative | Positive | | | | Pass | C0083 | Serum | 0 | 0 | 0 | | Negatives |
| 50 | Positive | Positive | | | | Pass | C0084 | Serum | 6400 | 100 | 6400 | 24 | Positives |
| 51 | Negative | Negative | | | | Pass | C0087 | Serum | 0 | 0 | 0 | | Negatives |
| 52 | Negative | Negative | | | | Pass | C0089 | Plasma | 0 | 0 | 0 | | HIV+ |
| 53 | Positive | Positive | | | | Pass | C0090 | Serum | 1600 | 100 | 1600 | 22 | Positives |
| 54 | Positive | Positive | | | | Pass | C0092 | Serum | 1600 | 100 | 1600 | | Positives |
| 55 | Negative | Negative | | | | Pass | C0093 | Plasma | 0 | 0 | 0 | | HIV+ |
| 56 | Negative | Negative | | | | Pass | C0094 | Serum | 0 | 0 | 0 | | Negatives |
| 57 | Negative | Negative | | | | Pass | C0095 | Plasma | 0 | 0 | 0 | | Negatives |
| 58 | Negative | Negative | | | | Pass | C0098 | Plasma | 0 | 0 | 0 | | Negatives |
| 59 | Negative | Negative | | | | Pass | C0099 | Plasma | 0 | 0 | 0 | | HIV+ |
| 60 | Negative | Negative | | | | Pass | C0100 | Serum | 0 | 0 | 0 | | Negatives |
| 61 | Negative | Negative | | | | Pass | C0101 | Plasma | 0 | 0 | 0 | | Negatives |
| 62 | Positive | Positive | | | | Pass | C0102 | Serum | 400 | 400 | 400 | 25 | Positives |
| 63 | Positive | Positive | | | | Pass | C0107 | Serum | 6400 | 400 | 6400 | 36 | Positives |
| 64 | Negative | Negative | | | | Pass | C0109 | Plasma | 0 | 0 | 0 | | Negatives |
| 65 | Negative | Negative | | | | Pass | C0110 | Serum | 0 | 0 | 0 | | Negatives |
| 66 | Negative | Negative | | | | Pass | C0115 | Serum | 0 | 0 | 0 | | Negatives |
| 67 | Negative | Negative | | | | Pass | C0116 | Serum | 0 | 0 | 0 | | Negatives |
| 68 | Negative | Negative | | | | Pass | C0117 | Plasma | 0 | 0 | 0 | | Negatives |

Table 3: Line Data (continued)

| Sample Number | IgM Result | IgG Result | IgA Result | Pan Ig Result | (IgM / IgG) Result | Control | Sample ID | Type | CDC Spike Pan-Ig Titer | CDC Spike IgM Titer | CDC Spike IgG Titer | Days | Group |
|---------------|------------|------------|------------|---------------|--------------------|---------|-----------|--------|------------------------|---------------------|---------------------|------|-----------|
| 69 | Negative | Negative | | | | Pass | C0118 | Serum | 0 | 0 | 0 | | Negatives |
| 70 | Positive | Positive | | | | Pass | C0119 | Serum | 1600 | 100 | 1600 | 20 | Positives |
| 71 | Negative | Negative | | | | Pass | C0120 | Serum | 0 | 0 | 0 | | Negatives |
| 72 | Negative | Negative | | | | Pass | C0121 | Plasma | 0 | 0 | 0 | | Negatives |
| 73 | Positive | Positive | | | | Pass | C0122 | Serum | 400 | 100 | 400 | 24 | Positives |
| 74 | Negative | Negative | | | | Pass | C0126 | Serum | 0 | 0 | 0 | | Negatives |
| 75 | Positive | Positive | | | | Pass | C0127 | Serum | 400 | 400 | 1600 | 23 | Positives |
| 76 | Negative | Negative | | | | Pass | C0128 | Serum | 0 | 0 | 0 | | Negatives |
| 77 | Negative | Negative | | | | Pass | C0131 | Serum | 0 | 0 | 0 | | Negatives |
| 78 | Positive | Positive | | | | Pass | C0132 | Serum | 1600 | 1600 | 6400 | | Positives |
| 79 | Positive | Positive | | | | Pass | C0136 | Serum | 6400 | 400 | 6400 | | Positives |
| 80 | Negative | Negative | | | | Pass | C0138 | Plasma | 0 | 0 | 0 | | HIV+ |
| 81 | Negative | Negative | | | | Pass | C0139 | Serum | 0 | 0 | 0 | | Negatives |
| 82 | Negative | Negative | | | | Pass | C0140 | Plasma | 0 | 0 | 0 | | Negatives |
| 83 | Positive | Positive | | | | Pass | C0144 | Serum | 6400 | 1600 | 6400 | 21 | Positives |
| 84 | Negative | Negative | | | | Pass | C0146 | Serum | 0 | 0 | 0 | | Negatives |
| 85 | Negative | Negative | | | | Pass | C0150 | Plasma | 0 | 0 | 0 | | HIV+ |
| 86 | Positive | Positive | | | | Pass | C0153 | Serum | 400 | 100 | 400 | 31 | Positives |
| 87 | Negative | Negative | | | | Pass | C0155 | Plasma | 0 | 0 | 0 | | HIV+ |
| 88 | Negative | Negative | | | | Pass | C0156 | Plasma | 0 | 0 | 0 | | Negatives |
| 89 | Negative | Negative | | | | Pass | C0158 | Serum | 0 | 0 | 0 | | Negatives |
| 90 | Positive | Positive | | | | Pass | C0160 | Serum | 1600 | 100 | 1600 | 17 | Positives |
| 91 | Positive | Positive | | | | Pass | C0161 | Serum | 400 | 100 | 400 | 25 | Positives |
| 92 | Positive | Positive | | | | Pass | C0164 | Serum | 1600 | 400 | 6400 | 23 | Positives |

Table 3: Line Data (continued)

| Sample Number | IgM Result | IgG Result | IgA Result | Pan Ig Result | (IgM / IgG) Result | Control | Sample ID | Type | CDC Spike Pan-Ig Titer | CDC Spike IgM Titer | CDC Spike IgG Titer | Days | Group |
|---------------|------------|------------|------------|---------------|--------------------|---------|-----------|--------|------------------------|---------------------|---------------------|------|-----------|
| 93 | Negative | Negative | | | | Pass | C0165 | Serum | 0 | 0 | 0 | | Negatives |
| 94 | Negative | Negative | | | | Pass | C0169 | Serum | 0 | 0 | 0 | | Negatives |
| 95 | Positive | Positive | | | | Pass | C0172 | Serum | 1600 | 400 | 1600 | 19 | Positives |
| 96 | Negative | Negative | | | | Pass | C0173 | Serum | 0 | 0 | 0 | | Negatives |
| 97 | Negative | Negative | | | | Pass | C0174 | Serum | 0 | 0 | 0 | | Negatives |
| 98 | Positive | Positive | | | | Pass | C0176 | Serum | 6400 | 400 | 6400 | 19 | Positives |
| 99 | Negative | Negative | | | | Pass | C0179 | Plasma | 0 | 0 | 0 | | Negatives |
| 100 | Positive | Positive | | | | Pass | C0180 | Serum | 6400 | 1600 | 6400 | 24 | Positives |
| 101 | Negative | Positive | | | | Pass | C0181 | Serum | 0 | 0 | 0 | | Negatives |
| 102 | Negative | Negative | | | | Pass | C0182 | Plasma | 0 | 0 | 0 | | HIV+ |
| 103 | Negative | Negative | | | | Pass | C0185 | Plasma | 0 | 0 | 0 | | Negatives |
| 104 | Negative | Negative | | | | Pass | C0186 | Serum | 0 | 0 | 0 | | Negatives |
| 105 | Positive | Positive | | | | Pass | C0191 | Serum | 400 | 100 | 400 | 22 | Positives |
| 106 | Negative | Negative | | | | Pass | C0193 | Plasma | 0 | 0 | 0 | | Negatives |
| 107 | Negative | Negative | | | | Pass | C0197 | Plasma | 0 | 0 | 0 | | HIV+ |
| 108 | Negative | Negative | | | | Pass | C0198 | Plasma | 0 | 0 | 0 | | Negatives |
| 109 | Negative | Negative | | | | Pass | C0199 | Plasma | 0 | 0 | 0 | | Negatives |
| 110 | Negative | Negative | | | | Pass | C0200 | Serum | 0 | 0 | 0 | | Negatives |