Analysis of Multiple Serology Test Evaluations of the “Novel Coronavirus (COVID-19) IgG/IgM Antibody Test” from Biocan Diagnostics Inc

March 2, 2021

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1 Introduction

The Novel Coronavirus (COVID-19) IgG/IgM Antibody Test from Biocan Diagnostics 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 Novel Coronavirus (COVID-19) IgG/IgM Antibody Test is intended to qualitatively detect IgM and IgG separately. For the details of the individual evaluations, see the corresponding evaluation reports.

<table>
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<tr>
<th>Evaluation ID</th>
<th>Date(s) Performed</th>
<th>Lot Number(s)</th>
<th>Panel</th>
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<td>2020-12-01</td>
<td>B251SB150720</td>
<td>Panel 3</td>
</tr>
<tr>
<td>maf3428-a001</td>
<td>2021-02-23</td>
<td>B251SB150720</td>
<td>Panel 2</td>
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</tbody>
</table>

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 Biocan Diagnostics Inc Novel Coronavirus (COVID-19) IgG/IgM Antibody 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 Biocan Diagnostics Inc Novel Coronavirus (COVID-19) IgG/IgM Antibody 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 Biocan Diagnostics Inc Novel Coronavirus (COVID-19) IgG/IgM Antibody 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

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 Biocan Diagnostics Inc Novel Coronavirus (COVID-19) IgG/IgM Antibody 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 maf3428-a001

The FNLCR provided the following additional information:

While the package insert specifies the use of human serum, plasma (EDTA, citrate, Heparin), or venipuncture whole blood specimens (including finger prick), this evaluation used antibody-positive serum samples and antibody-negative ACD-A plasma and serum samples. Red streaks/haze were noticed on several devices following the incubation period.
2 Results

Table 2: Summary Results

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<th>Collected pre-2020</th>
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Table 3: Summary Statistics

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<th>Estimate</th>
<th>Confidence Interval</th>
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<td>(37.5%; 62.5%)</td>
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<td>IgM Specificity</td>
<td>95.9% (93/97)</td>
<td>(89.9%; 98.4%)</td>
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<td>IgG Sensitivity</td>
<td>84.5% (49/58)</td>
<td>(73.1%; 91.6%)</td>
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<tr>
<td>IgG Specificity</td>
<td>99.0% (96/97)</td>
<td>(94.4%; 99.8%)</td>
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<tr>
<td>Combined Sensitivity</td>
<td>84.5% (49/58)</td>
<td>(73.1%; 91.6%)</td>
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<tr>
<td>Combined Specificity</td>
<td>94.8% (92/97)</td>
<td>(88.5%; 97.8%)</td>
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<td>Combined PPV for prevalence = 5.0%</td>
<td>46.3%</td>
<td>(25.1%; 68.5%)</td>
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<tr>
<td>Combined NPV for prevalence = 5.0%</td>
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<tr>
<td>Cross-reactivity with HIV+</td>
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## 3 Line Data (all)

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

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<th>IgG Result</th>
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<th>CDC Spike IgM Titer</th>
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### 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)**

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

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

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