Does performance differ between SARS-CoV-2 IgG assays that target different viral proteins?

**Background**
Different SARS-CoV-2 IgG assays may test for antibodies against different viral proteins. Whether this affects the performance of SARS-CoV-2 IgG assays relative to each other was unknown.

**Methods and Results**

The results of 4 different IgG assays were compared to consensus

Assay performance: % agreement with consensus results

<table>
<thead>
<tr>
<th>Viral protein</th>
<th>Assay #1</th>
<th>Assay #2</th>
<th>Assay #3</th>
<th>Assay #4</th>
</tr>
</thead>
<tbody>
<tr>
<td>spike 1</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>spike 1 &amp; 2</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
<tr>
<td>nucleocapsid</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>100</td>
</tr>
</tbody>
</table>

Comparisons were done for 1,200 specimens. The graph below shows the results.

All 4 assays performed comparably, regardless of the viral protein used to detect SARS-CoV-2 IgG antibodies.

For more information about Quest Diagnostics publications, please visit the Clinical Education Center at [Education.Questdiagnostics.com/publications](http://Education.Questdiagnostics.com/publications).
Article Title: Detection of SARS-CoV-2 IgG Targeting Nucleocapsid or Spike Protein by Four High Throughput Immunoassays Authorized for Emergency Use

Harry E Prince,1 Tara S Givens,2 Mary Lapé-Nixon,1 Dale A Schwab,1 Hollis J Batterman,1 Robert S Jones,2 William A Meyer III,3 Hema Kapoor,1 Charles M Rowland,1 Farnoosh Haji-Sheikhi,1 Elizabeth M Marlowe1
1Quest Diagnostics, San Juan Capistrano, CA, USA; 2Quest Diagnostics, Chantilly, VA, USA; 3Quest Diagnostics, Baltimore, MD USA; 4Quest Diagnostics, Secaucus, NJ, USA


Background

- Nucleic acid amplification testing (NAAT) is the main method of diagnosing acute SARS-CoV-2 infections. However, antibody testing is another method that has important uses, such as identifying people exposed to the virus and assessing infection prevalence.
- Multiple SARS-CoV-2 antibody assays have received FDA Emergency Use Authorization (EUA). The antigen targets and methods vary between assays, which could cause inconsistency between the assays.
- The extent of agreement of results from different assays is still being explored.1-3

Objective: In this study, investigators compared results from 4 different SARS-CoV-2 antibody assays that are being used in the United States.

Methods

- A total of 1,200 serum specimens (600 positive and 600 negative) that were tested using an Abbot Architect™ nucleocapsid-targeting chemiluminescent immunoassay (CIA) were further analyzed using 3 spike protein-targeting immunoassays: DiaSorin Liaison® CIA, Ortho VITROS® CIA, and EUROIMMUN enzyme-linked immunosorbent assay (ELISA).
- Consensus interpretation was defined as agreement between at least 3 of 4 assay results.
- The results of each assay were compared to the consensus results.
- Inhibition assays were developed to assess true- vs false-positivity for specimens with consensus-negative interpretations in which 1 of the assays gave a positive result.

Results

- For 581 consensus-positive and 610 consensus-negative interpretations, agreement between assay results and consensus interpretations was high:
  - Consensus-positive interpretations: 94.3% to 100%
  - Consensus-negative interpretations: 96.7% to 100%
- Among the 610 specimens with consensus-negative interpretations, 49 (4% of all specimens tested) were positive in 1 assay. Among these 49, only 2 (4%) were true positives.
  - For the individual assays, false-positive results accounted for ≤1.7% of all specimens tested.

Conclusions

- All 4 evaluated SARS-CoV-2 IgG immunoassays demonstrated a high level of agreement and low false-positivity rates, regardless of target antigen or assay method (CIA versus ELISA).
- These study findings should help assure healthcare professionals that results from these 4 EUA assays are comparable.

Reference