Key Summary of Published Article

SARS-CoV-2 IgG Testing
Assay Comparison

Quest Diagnostics®

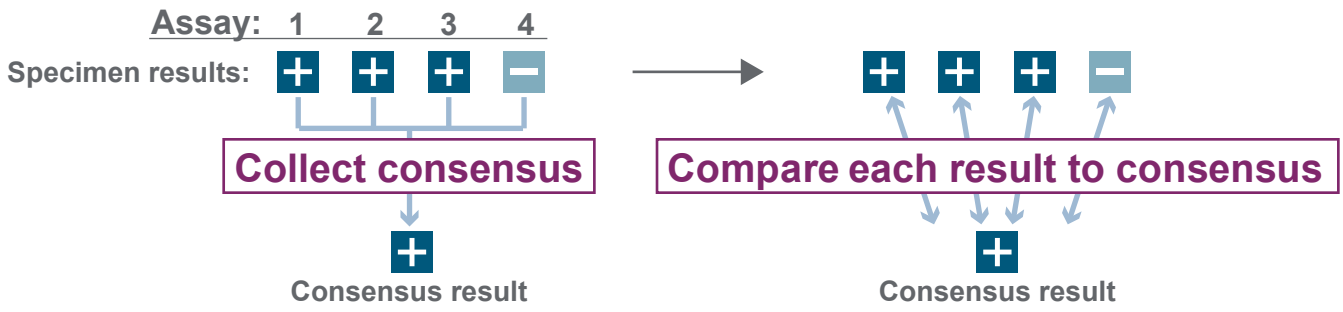
Does performance differ between SARS-CoV-2 IgG assays that target different viral proteins?

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

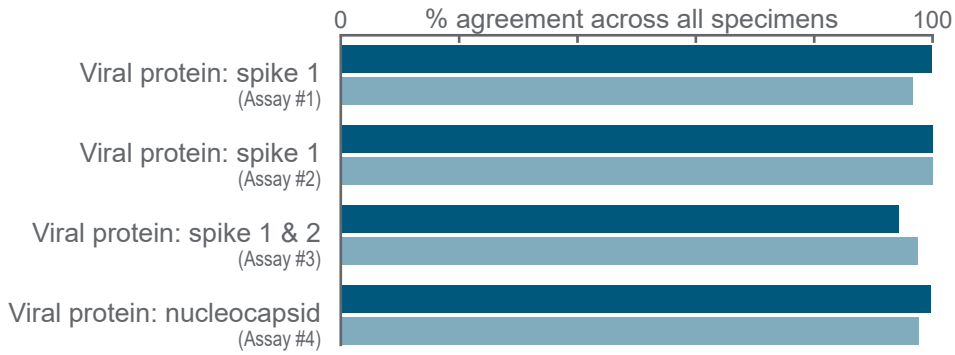
The results of 4 different IgG assays were compared to consensus



Consensus was defined as at least 3 of 4 assay results matching. In this example, the consensus is positive.

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

Assay performance: % agreement with consensus results



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

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SARS-CoV-2 IgG Testing
Assay Comparison

Article Title: Detection of SARS-CoV-2 IgG Targeting Nucleocapsid or Spike Protein by Four High Throughput Immunoassays Authorized for Emergency Use

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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

1. Liu W, Liu L, Kou G, et al. Evaluation of nucleocapsid and spike protein-based enzyme-linked immunosorbent assays for detecting antibodies against SARS-CoV-2. *J Clin Microbiol*. 2020;58(6):e00461-20. doi:10.1128/JCM.00461-20
2. Tang MS, Hock KG, Logsdon NM, et al. Clinical performance of two SARS-CoV-2 serologic assays. *Clin Chem*. 2020;66(8):1055-1062. doi:10.1093/clinchem/hvaa120
3. Burbelo PD, Riedo FX, Morishima C, et al. Detection of nucleocapsid antibody to SARS-CoV-2 is more sensitive than antibody to spike protein in COVID-19 patients. *medRxiv*. 2020;2020.04.20.20071423. doi:10.1101/2020.04.20.20071423