Key Summary of Conference Abstract

SARS-CoV-2 IgM Detection in Relation to Reactivity in 4 SARS-CoV-2 IgG Assays

Background

- Investigators of this study previously compared the performance of the Abbott SARS-CoV-2 IgG (nucleocapsid) immunoassay to that of 3 different SARS-CoV-2 IgG (spike) immunoassays for detecting reactivity to SARS-CoV-2.[1]
- Assessment of SARS-CoV-2 IgM in these same specimens could provide additional information about the performance of the 4 IgG assays and the IgM assay.
- Because the specimens were acquired from donors relatively early in the COVID-19 pandemic (May 2020), the investigators hypothesized that specimens that were consensus-positive for IgG would also be positive for SARS-CoV-2 IgM.[1]
- **Objective:** To test this hypothesis, this study assessed how often SARS-CoV-2 IgM was detected among specimens that were consensus-positive and those that were consensus-negative for IgG.

Methods

- The study included deidentified patient specimens from the previous analysis of SARS-CoV-2 IgG reactivity, grouped as follows by Ig reactivity:
  - 73 consensus-positive: 33 positive in 3 of 4 assays, 40 positive in 4 of 4 assays
  - 87 consensus-negative: 40 positive in 0 of 4 assays, 47 positive in 1 of 4 assays
  - 6 with no consensus assignment: positive in 2 of 4 assays
- Specimens were analyzed with the Abbott Architect SARS-CoV-2 IgM chemiluminescent assay, which targets the spike protein of the virus.
  - Positivity in the test's Information for Users (ie, package insert) was defined as index ≥1.0; negativity was defined as index <1.0.

Results

- SARS-CoV-2 IgM was detected in
  - 81% (59/73) of specimens that were consensus IgG-positive
  - 3% (3/87) of specimens that were consensus IgG-negative
    - All 3 were IgG-positive in the Abbott IgG assay alone.
  - 1 of the 6 specimens that had no IgG consensus
- As part of an experimental evaluation that adjusted the assay cutoff to a lower value (0.2), it was demonstrated that IgM index values were <0.2 in
  - 96% (81/84) of IgM-negative specimens that were consensus IgG-negative
  - 0% (0/14) of IgM-negative specimens that were consensus IgG-positive; all were above 0.2

Conclusions

- As expected, SARS-CoV-2 IgM was detected much more frequently in consensus IgG-positive specimens than in consensus IgG-negative specimens.
- Sensitivity of the Abbott IgG (nucleocapsid) assay may be slightly higher than that of the other 3 IgG (spike) assays, assuming concurrent IgG and IgM positivity indicates SARS-CoV-2 infection.
- Additional studies are needed to determine if an IgM index cutoff of 0.2 has better accuracy for distinguishing between positive and negative patient specimens.

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Webpage
https://www.amli.org/2021-annual-meeting/meeting-2021-program/

Reference

1. Prince HE, Givens TS, Lapé-Nixon M, et al. Detection of SARS-CoV-2 IgG targeting nucleocapsid or spike protein by four high-throughput immunoassays authorized for emergency use. *J Clin Microbiol.* 2020;58:e01742-20. doi:10.1128/JCM.01742-20