Nucleocapsid and Spike Protein-Based Anti-SARS-CoV-2 Assay Performance in the Minority and Rural Coronavirus Insights Study

Overview

COVID-19 has had a devastating impact on Black, Hispanic, and other underserved, disadvantaged populations. Here anti-SARS-CoV-2 tests are characterized in disadvantaged patients to examine equivalence in US populations. **The recently published findings from the MRCIS study clearly demonstrate that despite concerns and mistrust from certain communities, antibody tests for detecting SARS-CoV-2 infection do not discriminate by race/ethnicity and age.**

Study Design and Participants

A full description of the participant population and accompanying serum biobank has been published elsewhere. **Approximately 66% of the MRCIS participants who contributed samples to the biobank were selected at random for inclusion in this study**; the MRCIS subset of samples included here is coined the "MRCIS SARS-CoV-2 Antibody Cohort."

Briefly, eligible participants included adults (age > 18 years) from underserved populations who were at risk for SARS-CoV-2 infection. Participants were enrolled as a convenience cohort of adults between November 2020 and April 2021 at 5 federally qualified health centers in **California, Florida, Louisiana, Illinois, and Ohio** funded by the Health Resources & Services Administration.

> This analysis only included SARS-CoV-2 unvaccinated participants

Race and ethnicity were categorized as:

- **53%** Hispanic/Latino
- **21%** Non-Hispanic White
- **26%** Non-Hispanic Black/African American

Non-Hispanic individuals in the "other" category were excluded due to small numbers.

Different tests that were examined

R-anti-N
The Roche Elecsys Anti-SARS-CoV-2 assay detects polyvalent antibodies against the nucleocapsid protein in serum, was utilized with the cobas e 601 analyzer
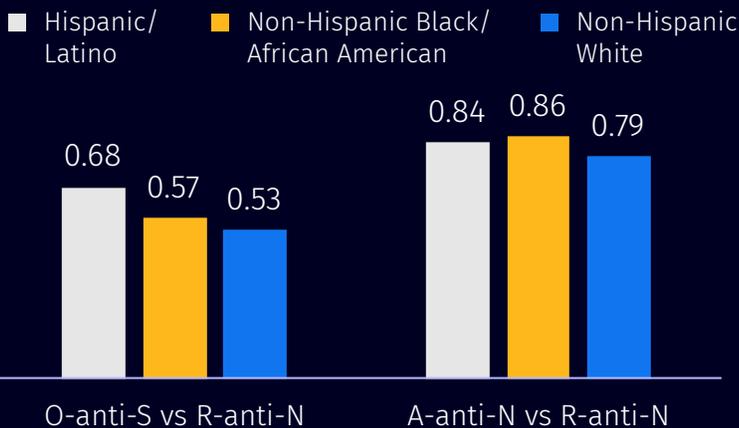
A-anti-N
The Abbott Architect SARS-CoV-2 IgG assay detects IgG antibodies against the nucleocapsid protein in serum and plasma, was utilized on the Architect 2000 system

O-anti-S
The Ortho Clinical Diagnostics VITROS Anti-SARS-CoV-2 IgG assay detects IgG antibodies against the spike protein in serum and plasma using the 5600 analyzer
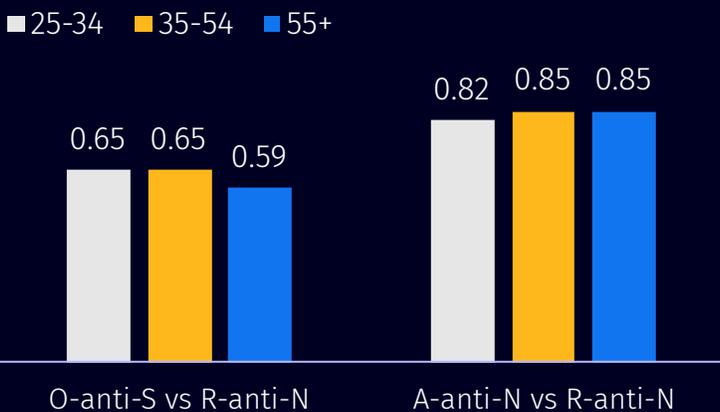
Results (Values represented here are Kappa (95% CI))

Race/Ethnicity Based

Legend:
- Hispanic/Latino
- Non-Hispanic Black/African American
- Non-Hispanic White

O-anti-S vs R-anti-N: 0.68, 0.57, 0.53
A-anti-N vs R-anti-N: 0.84, 0.86, 0.79

The Kappa for non-Hispanic Whites was **lowest at 0.53** for the O-anti-S test results.

Age Based

Legend:
- 25-34
- 35-54
- 55+

O-anti-S vs R-anti-N: 0.65, 0.65, 0.59
A-anti-N vs R-anti-N: 0.82, 0.85, 0.85

The Kappa for participants >55 years of age was **lowest at 0.59** for the O-anti-S test results.

This demonstrated **no significant variability in agreement between results** from the anti-SARS-CoV-2 assay methods examined by race/ethnicity or age.