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Analytical Sensitivity and Specificity of Four Point of Care Rapid Antigen Diagnostic Tests for SARS-CoV-2 Using Real-Time Quantitative PCR, Quantitative Droplet Digital PCR, and a Mass Spectrometric Antigen Assay as Comparator Methods

[Brad S Karon](#)¹, [Leslie J Donato](#)¹, [Amber R Bridgeman](#)³, [Joseph H Blommel](#)⁴, [Benjamin Kipp](#)¹, [Anthony Maus](#)¹, [Santosh Renuse](#)^{1,2}, [Jennifer Kemp](#)¹, [Anil K Madugundu](#)^{1,3,4,5}, [Patrick M Vanderboom](#)¹, [Sandip Chavan](#)¹, [Surendra Dasari](#)⁶, [Ravinder J Singh](#)¹, [Stefan K Grebe](#)^{1,7}, [Akhilesh Pandey](#)^{1,2}

Affiliations collapse

Affiliations

¹Department of Laboratory Medicine and Pathology, Mayo Clinic, Rochester, MN, USA.

²Center for Individualized Medicine, Bangalore, Mayo Clinic, Rochester, MN, USA.

³Institute of Bioinformatics, International Technology Park, Bangalore, Karnataka, India.

⁴Manipal Academy of Higher Education (MAHE), Manipal, Karnataka, India.

⁵Center for Molecular Medicine, National Institute of Mental Health and Neurosciences, Bangalore, Karnataka, India.

⁶Division of Biomedical Statistics and Informatics, Department of Health Sciences Research, Mayo Clinic, Rochester, MN, USA.

⁷Department of Medicine, Division of Endocrinology, Mayo Clinic, Rochester, MN, USA.

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Abstract

Background: We evaluated the analytical sensitivity and specificity of 4 rapid antigen diagnostic tests (Ag RDTs) for severe acute respiratory syndrome coronavirus 2, using reverse transcription quantitative PCR (RT-qPCR) as the reference method and further characterizing samples using droplet digital quantitative PCR (ddPCR) and a mass spectrometric antigen test.

Methods: Three hundred fifty (150 negative and 200 RT-qPCR positive) residual PBS samples were tested for antigen using the BD Veritor lateral flow (LF), ACON LF, ACON fluorescence immunoassay (FIA), and LumiraDx FIA. ddPCR was performed on RT-qPCR-positive samples to quantitate the viral load in copies/mL applied to each Ag RDT. Mass spectrometric antigen testing was performed on PBS samples to obtain a set of RT-qPCR-positive, antigen-positive samples for further analysis.

Results: All Ag RDTs had nearly 100% specificity compared to RT-qPCR. Overall analytical sensitivity varied from 66.5% to 88.3%. All methods detected antigen in samples with viral load >1 500 000 copies/mL RNA, and detected ≥75% of samples with viral load of 500 000 to 1 500 000 copies/mL. The BD Veritor LF detected only 25% of samples with viral load between 50 000 to 500 000 copies/mL, compared to 75% for the ACON LF device and >80% for LumiraDx and ACON FIA. The ACON FIA detected significantly more samples with viral load <50 000 copies/mL compared to the BD Veritor. Among samples with detectable antigen and viral load <50 000 copies/mL, sensitivity of the Ag RDT varied between 13.0% (BD Veritor) and 78.3% (ACON FIA).

Conclusions: Ag RDTs differ significantly in analytical sensitivity, particularly at viral load <500 000 copies/mL.

Keywords: SARS-CoV-2; antigen; point of care; rapid diagnostic test.

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