

Sofia SARS Antigen FIA and Reverse-Transcriptase Polymerase Chain Reaction: Comparing Diagnostic Methods

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Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the virus that causes coronavirus disease 19 (Covid-19), emerged in December 2019 and led to a global pandemic. Timely and accurate diagnostic methods became an absolute necessity and remain a critical tool for detecting Covid-19 cases. Two primary methods for detecting active SARS-CoV-2 infection are currently in use: reverse-transcriptase polymerase chain reaction (RT-PCR) molecular testing and antigen testing. RT-PCR is considered the “gold standard” method for detecting SARS-CoV-2 infection. It is highly sensitive, but requires a molecular testing facility, has a longer turnaround time, and is more expensive than antigen testing. Clinicians and public health authorities must consider these factors when selecting appropriate testing methods for patients and communities.

Methods

1285 nasopharyngeal samples were collected from 1282 individuals at Springfield Hospital and Dartmouth-Hitchcock Medical Center between July 2020 and February 2021. Of the 1282 individuals in study population, 2 were known to be symptomatic, 16 had a known exposure, and 14 were healthcare workers being tested for surveillance. The remaining samples were collected from out-patients and in-patients for screening. Samples were analyzed using both Sofia SARS antigen FIA test and RT-PCR. Comparing Sofia to RT-PCR with RT-PCR as the gold standard, positive percent agreement and negative percent agreement were calculated.

Results

Compared to RT-PCR, Sofia rapid antigen test has a positive percent agreement of 72.7% and a negative percent agreement of 98.9%. Eighteen tested negative by Sofia, but tested positive by RT-PCR.

Table 1: Comparing RT-PCR and Sofia Antigen Results

	PCR POSITIVE	PCR NEGATIVE	Total
Sofia POSITIVE	48	13	61
Sofia NEGATIVE	18	1206	1224
Total	66	1219	1285

Conclusion

Compared to RT-PCR, Sofia FIA rapid antigen testing shows high negative percent agreement and reasonable positive percent agreement. Previous studies have compared RT-PCR and Sofia FIA methods in study populations comprised only of symptomatic patients^{1,2}. In these studies the positive percent agreements values were between 54.5% and 97.6%. Additionally, studies have shown that that Sofia FIA testing is significantly less sensitive than RT-PCR in detecting SARS-CoV-2 infection in asymptomatic individuals². Our results and results from previous studies indicate that Sofia FIA testing should be used with caution for screening and in asymptomatic individuals.

Sources

1. Beck ET, et al. Comparison of the Quidel Sofia SARS FIA Test to the Hologic Aptima SARS-CoV-2 TMA Test for Diagnosis of COVID-19 in Symptomatic Outpatients. *J Clin Microbiol.* 2021;59(2):e02727-20. 2021 Jan 21. doi:10.1128/JCM.02727-20
2. Brihn A, et al. Diagnostic Performance of an Antigen Test with RT-PCR for the Detection of SARS-CoV-2 in a Hospital Setting - LA County, CA, Jun-Aug 2020. *MMWR Morb Mortal Wkly Rep.* 2021;70(19):702-706. 2021 May 14. doi:10.15585/mmwr.mm7019a3