

Are rapid point of care antigen tests sufficient for diagnosing COVID-19?

Clinical Question	How accurate are rapid point-of-care antigen tests, to determine if a person presenting in the community or in primary or secondary care has current SARS-CoV-2 infection?
Bottom Line	<p>Overall, this review suggests that in symptomatic individuals in the first few days of symptoms, the most accurate rapid antigen tests are a useful alternative to laboratory-based RT-PCR where immediate results are required for timely patient management. However, Rapid antigen tests are only sufficiently sensitive in the first week from onset of symptoms. At 80% sensitivity compared to RT-PCR, the probability that infected individuals are missed is 20% higher than for RT-PCR. Thus the possibility of false negative results should be considered in those with a high clinical suspicion of COVID-19, particularly if tested several days after onset of symptoms when viral load levels may have fallen.</p> <p>Rapid antigen tests may be used simultaneously in combination with RT-PCR for symptomatic people, particularly where RT-PCR turn-around times are slow, to exploit the benefits of earlier results and consequent contact-tracing and isolation.</p> <p>For antigen test evaluations in symptomatic participants, this review observed considerable heterogeneity in sensitivities (and to a lesser extent the specificities). WHO have set a minimum 'acceptable' sensitivity requirement of 80%, and acceptable and ideal (or 'desirable') specificity requirements of 97% and 99% respectively. For the two tests available in New Zealand from the list of tests studied (SD Biosensor, Abbott PanBio) only SD Biosensor met the WHO acceptable criterion for sensitivity based on pooled results of several studies whilst Abbott PanBio met the sensitivity criterion in some individual studies but not overall. Both Abbott Panbio and SD Biosensor met the desirable criterion of more than 99% specificity.</p>
Caveat	Around a quarter (18/78) of the studies included in this review are currently only available as preprints, and as yet, have not undergone peer review. None of the included studies were judged to have overall low risk of bias, although in 11 of 78 studies the only concern was that a single negative RT-PCR was used to confirm absence of COVID infection rather than the preferred two negative tests.
Context	As point-of-care tests are more accessible and provide a result more quickly than RT-PCR, theoretically their use may increase detection and speed up isolation and contact-tracing, leading to reduction in disease spread and reduce the burden on laboratory services.
Cochrane Systematic Review	Dinnes J, Deeks JJ, Berhane S, Taylor M, Adriano A, Davenport C, Dittrich S, Emperador D, Takwoingi Y, Cunningham J, Beese S, Domen J, Dretzke J, Ferrante di Ruffano L, Harris IM, Price MJ, Taylor-Phillips

S, Hooft L, Leeflang MMG, McInnes MDF, Spijker R, Van den Bruel A. Rapid, point-of-care antigen and molecular-based tests for diagnosis of SARS-CoV-2 infection. Cochrane Database of Systematic Reviews 2021, Issue 3. Art. No.: CD013705. DOI: 10.1002/14651858.CD013705.pub2. This review contains 78 diagnostic trials with a total of 24,087 samples (7,415 with confirmed SARS-CoV-2).

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Systematic review link:

<https://www.cochranelibrary.com/cdsr/doi/10.1002/14651858.CD013705.pub2/full>