Comparison of rapid detection tests for SARS-CoV-2

Not all SARS-CoV-2 tests are equal—know which type of test you are using or receiving

	Rapid RT-PCR	Rapid isothermal	Rapid antigen
Detection target and technology	**Viral RNA Thermal cycling amplification**	Viral RNA Isothermal amplification	Viral protein No amplification
Confirmatory testing	**Not required** (Single test confidence)	Recommended (Especially if inconsistent with the clinical context)	Recommended (If inconsistent with the clinical context)
Sensitivity	**LOD = 475–54,000 NDU/mL* [4,5]**	LOD = 60,000–300,000 NDU/mL [4]	LOD = not defined (No FDA reference panel exists for antigen tests; lower sensitivity than NAATs [7])
Detection ability	**Early infection** (A low LOD can enable detection of virus before symptoms develop [1,2,6])	Symptomatic infection (Higher LOD makes test suboptimal for detection of early infection [6,8])	Symptomatic infection (Suboptimal for early infections; optimal within 7 days of symptom onset [7])
Sample method	Nasal swab**		
Where testing occurs	Point-of-care	Point-of-care or home	
Time to result	25 to 45 min	5 to 65 min	10 to 30 min
Result type	Qualitative		

* NDU is an FDA-defined measure of the amount of viral material in a sample. NDU/mL stands for NAAT (nucleic acid amplification test) detectable units/mL and is the metric used by the FDA to allow for a more precise comparison of the analytical performance of different molecular *in vitro* diagnostic (IVD) assays intended to detect SARS-CoV-2 [1].

** Refer to product-specific IFU for details on specimen collection swab.

This table was created based on information from product IFUs for EUA authorized devices in the US.

References

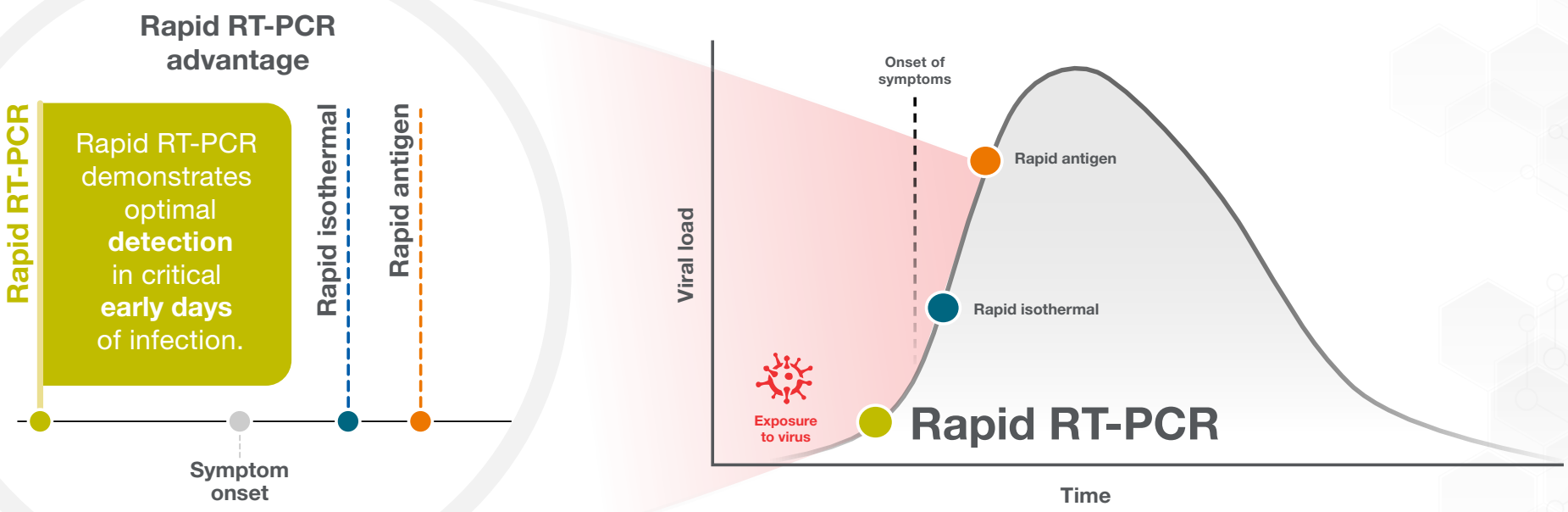
1. Arons MM, Hatfield KM, Reddy SC et al. (2020) Presymptomatic SARS-CoV-2 infections and transmission in a skilled nursing facility. *N Engl J Med* 382(22):2081–90. https://doi.org/10.1056/NEJMoa2008457
2. Nissen K, Hagbom M, Krambrich J et al. (2021) Presymptomatic viral shedding and infective ability of SARS-CoV-2; a case report. *Heliyon* 7(2):e06328. https://doi.org/10.1016/j.heliyon.2021.e06328
3. COVID-19 Real-Time Learning Network. Rapid testing. https://www.idsociety.org/covid-19-real-time-learning-network/diagnostics/rapid-testing/. Accessed September 24, 2021.
4. U.S. FDA (2020) SARS-CoV-2 reference panel comparative data. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference -panel-comparative-data
5. Thermo Fisher Scientific. Accula SARS-CoV-2 Test Instructions for Use. 60061-8 (2022-05). https://www.fda.gov/media/136355/download
6. Arnaout R, Lee RA, Lee GR et al. (2020) SARS-CoV-2 testing: the limit of detection matters. bioRxiv (preprint). https://doi.org/10.1101/2020.06.02.131144.
7. Hanson KE, Altayar O, Caliendo AM et al. (2021) Infectious Diseases Society of America Guidelines on the diagnosis of COVID-19: antigen testing. https://www.idsociety.org/practice-guide line/covid-19-guideline-antigen testing/. Accessed September 24, 2021.
8. Hanson KE, Altayar O, Caliendo AM et al. (2021) Infectious Diseases Society of America Guidelines on the diagnosis of COVID-19: molecular diagnostic testing. https://www.idsociety.org/practice-guideline/covid-19-guideline-diagnostics/. Accessed September 24, 2021.

Learn more about the rapid RT-PCR Thermo Fisher Scientific™ Accula™ SARS-CoV-2 Test at **thermofisher.com/accula**

Rapid RT-PCR can detect earliest in infection cycle

Reliable and accurate detection of early infection is key to preventing spread

Highly sensitive rapid RT-PCR tests can enable detection of SARS-CoV-2 days before symptoms [1,2] and other rapid tests [3].



References

1. Arons MM, Hatfield KM, Reddy SC et al. (2020) Presymptomatic SARS-CoV-2 infections and transmission in a skilled nursing facility. *N Engl J Med* 382(22):2081–90. https://doi.org/10.1056/NEJMoa2008457
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3. COVID-19 Real-Time Learning Network. Rapid testing. https://www.idsociety.org/covid-19-real-time-learning-network/diagnostics/rapid-testing/. Accessed September 24, 2021.

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The Accula SARS-CoV-2 Test has not been FDA cleared or approved but has been authorized for emergency use by FDA for use by laboratories certified under the Clinical Laboratory Improvement Amendments (CLIA) of 1988, 42 U.S.C. §263a, that meet requirements to perform high, moderate, or waived complexity tests. The test is authorized for use at the Point of Care (POC), i.e., in patient care settings operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. The emergency use of this test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of *in vitro* diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.