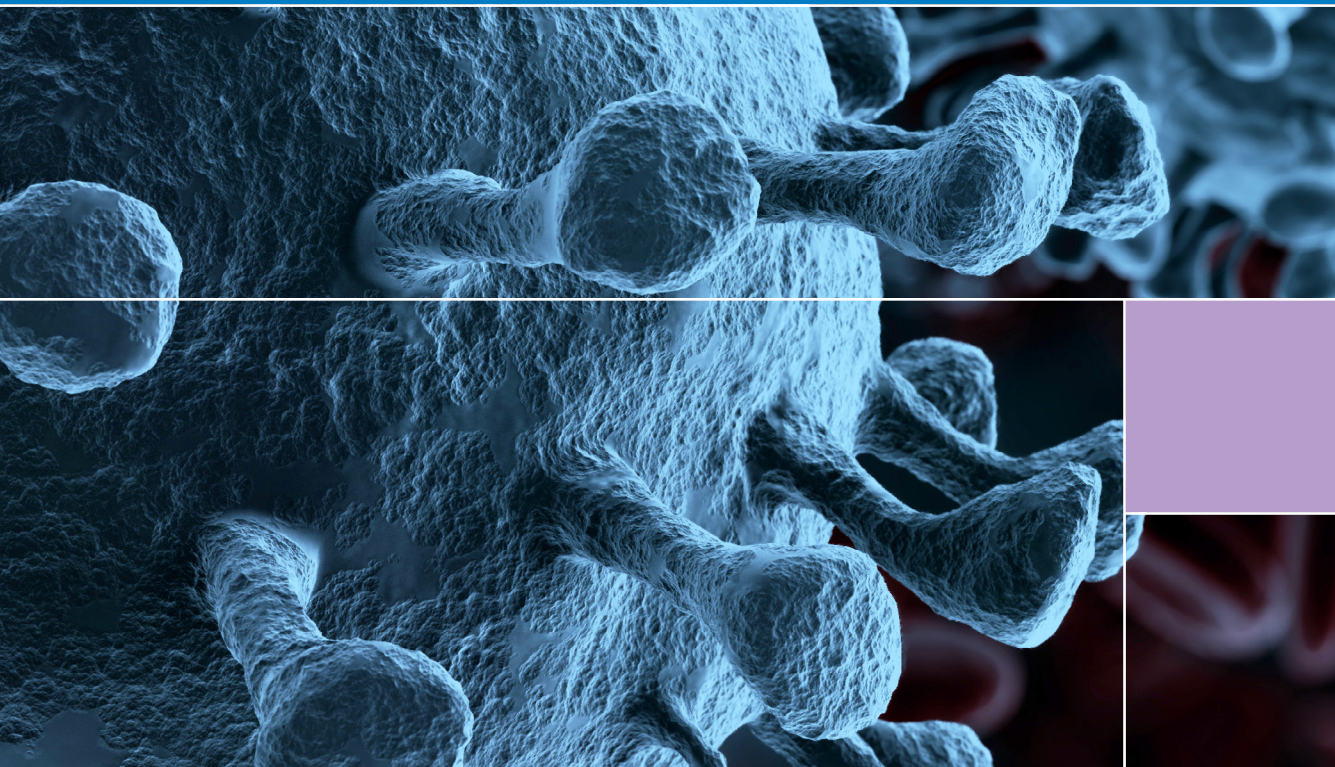


9 Tips to Bring Your COVID-19 Test to the Clinic



9 Tips for COVID-19 test developers and providers

1. Check your resources daily—even twice daily! FDA is updating its website frequently. For example, in a matter of 2 days the FDA moved from central oversight to decentralized oversight of lab-developed and diagnostic manufacturer tests. [Click here to learn more.](#)
2. Read the FDA FAQs carefully. Did you know, for example, that FDA has provided alternatives for sourcing viral transport media, but cautions against use of swabs with wooden shafts? [Click here to learn more.](#)
3. Remember that reports from laboratory testing on unapproved products must carry a disclaimer, ie, for use under FDA's Emergency Use Authorization (EUA), or this is a laboratory developed test and has not been cleared or approved by FDA.
4. Emergency Use Authorization templates are evolving daily, and in some cases, EUAs are not necessary to begin testing clinical samples.
5. Validation for your assay and instrumentation may be distinct from others—and navigating the requirements may be challenging. The CDC FDA is an excellent reference, but make sure you're certain what this means for your product.
6. Ensure your validation study designs comply with FDA recommendations for the specific scientific technology of the assay, eg, molecular, antigen, or serology, as different studies are required to show performance.
7. CMS has created 2 HCPCS codes to bill for COVID-19 testing: U0001 and U0002. Remember that U0001 applies only to tests developed by the CDC. All other COVID-19 tests—regardless of the technique used—are billed using U0002.
8. CMS Medicare Administrative Contractors (MACs) now have set uniform payment rates for U0001 (\$35.91) and U0002 (\$51.31), and commercial insurers are expected to establish similar rates. These are the payments to the testing lab, so keep that in mind when setting your test price.
9. Congress has passed legislation making COVID-19 testing free to patients, including associated provider visits, though how this will be implemented is not yet clear. (Generally, there is currently no beneficiary cost sharing for lab tests under original Medicare.) Check the websites for your MAC and key commercial payers frequently to get the latest instructions. [Click here to learn more.](#)

Precision's team of experts has significant experience in all aspects of bringing diagnostics, companion diagnostics, and their associated therapeutics to market. During these unprecedented times, we are committed to supporting the critical work you do. Contact david.parker@precisionformedicine.com.