Accepted Non-YNHHS COVID-19 Tests

With the expansion of COVID-19 tests, testing sites, and home testing, this document updates which tests are acceptable for use in specific medical decisions for patients, based on recommendations from the YNHHS/YM Testing Stewardship Committee.

Guidelines for Indications Requiring Highly Sensitive Tests

COVID-19 testing at Yale New Haven Health affiliated laboratories is *typically* preferred for work within the health system, particularly for indications that require highly sensitive testing, such as for admission status, pre-procedure planning, facility clearance, and healthcare worker screening and exposure management in unvaccinated/unboostered individuals. In general these situations require highly-sensitive assays for confidence that a **negative result** is true and accurate. Further, these situations typically require that results are promptly and easily available in the Epic electronic health record. COVID-19 nucleic acid amplification tests (NAAT) performed at non-YNHHS facilities may be considered for these indications if there are exceptional circumstances that prevent the patient from being tested at a YNHHS-affiliated laboratory. In these situations, the external test result may be acceptable for clinical decisions and actions if 1) the test process/validation meets YNHHS internal lab-defined standards and 2) the result is visible and functions appropriately in Epic so that the healthcare team is aware. The time frame for test acceptability is not changed if testing is performed outside YNHHS.

Acceptable specimen collection for tests for these purposes include:

- A nasopharyngeal (NP) specimen collected by a healthcare provider
- A nasal mid-turbinate swab collected by a healthcare provider or by observed self-collection
- An anterior nares (nasal swab) specimen collected by a healthcare provider or observed self-collection

Acceptable non-YNHHS NAAT should be authorized by the FDA either through an EUA or non-EUA pathway (i.e. De Novo, 510(K), or PMA).

Current EUAs are available at this website https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-molecular

Hospitals or laboratories may be using multiple different platforms for patient testing, and individual testing methods should be reviewed rather than relying upon a known laboratory. The platform is generally listed in the notes of the result and can be cross-referenced with the following list.

Acceptable Tests and/or Testing Platforms		
• Abbott m2000 • Abbott Alinity • BD Max • Biofire • Broad / CRSP Assay • CDC Assay • Cepheid Xpert	• Diasorin Simplexa • GenMark Diagnostics • Hologic Panther TMA • Hologic Panther Fusion • Luminex MagPx • Luminex Aries • NeuMoDx	• Perkin Elmer • ThermoFisher Taqpath • Quidel Lyra • Qiagen Qiastat • Roche Cobas LiaT • Roche Cobas 6800/8800

Tests performed at home, saliva tests, and some rapid or point-of-care tests performed in health care settings are, at this time, **NOT** acceptable for applications requiring highly sensitive assays to provide accurate and true negative results, even if results may be available in EPIC. The Laboratory COVID-19 preparedness group may defer consideration of small, independent laboratories within, or affiliated with, physician practice groups for whom it lacks the resources to evaluate the background, performance and reputation.

Laboratories and/or platforms that are not included or approved by a YNHHS laboratory should not be presumed to be deemed acceptable for applications requiring highly sensitive assays.

This statement is based on current information, recommendations, and evidence and will be subject to revision or retraction based on continued monitoring by the Committee.

Guidelines for Other Indications

Tests performed at home as well as some rapid or point-of-care tests performed in health care settings may be appropriate for the indications of diagnosing COVID-19 in symptomatic individuals, post-exposure testing in the community (excluding unvaccinated healthcare workers at YNHHS), or testing prior to social events.

These tests include but are not limited to:

• Abbott ID Now • Binax Now	• Veritor • Sofia

These other types of tests, when positive, can be considered for the purposes of confirming/diagnosing Covid-19. Symptomatic patients who test positive by any FDA-authorized method should be considered to have COVID-19, adhere to applicable institutional or CDC recommendations for isolation, and seek assessment for treatment as needed. Repeat or confirmatory NAAT/PCR is not necessary. For patients with positive results outside of EPIC, the clinical scenario (type and date of symptoms, test result, type and date of test) should be recorded in the medical record.