COVID- 19 testing at Yale New Haven Health System Laboratories is strongly preferred. COVID-19 nucleic acid amplification tests performed at non-YNHHS facilities may be considered if there are exceptional circumstances that prevent the patient from being tested at a YNHHS Lab. In these situations, the external test 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.

Acceptable specimen collection for these tests include

- A nasopharyngeal (NP) and/or oropharyngeal 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 Nucleic Acid Amplification Tests should meet the following criteria:

The test should be performed under an EUA from the FDA. 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 **AND**

- Be performed at established reference laboratories to whom YNHHS laboratories refer specimens for laboratory testing and/or academic medical centers with established microbiology/ virology departments and/or performed on an acceptable testing platform. Examples (not a comprehensive list) of reference laboratories and platforms are included below. Other laboratories may also be considered if testing is performed on an acceptable platform. Additional questions about a laboratory or attesting platform should be directed to the laboratory within each delivery network. ***Laboratories and/or platforms that are not included or approved by a YNHHS laboratory should not be presumed to be deemed acceptable.***

Hospitals / Labs		Tests / Platforms
▪ ARUP Laboratories ▪ Brigham and Women's Hospital ▪ CDC Laboratories ▪ Columbia University ▪ Connecticut State Department of Public Health laboratories ▪ Dana Farber Cancer Center ▪ Day Kimball Hospital ▪ Genesys ▪ Griffin Hospital ▪ Hartford Hospital ▪ JAX Lab ▪ Lab Corp of America ▪ Landmark Hospital ▪ Massachusetts General Hospital ▪ Mayo Clinic Laboratories ▪ Memorial Sloan Kettering ▪ Mercy Hospital ▪ Middletown Hospital	▪ Montefiore Medical Center ▪ Mt. Sinai Hospital Laboratory ▪ Northwell Health Laboratories ▪ Rhode Island Hospital ▪ Sema 4 ▪ St. Francis Hospital ▪ St. Mary's Hospital ▪ Sunrise Medical Laboratories ▪ The Broad Institute ▪ Quest Diagnostics ▪ University of Connecticut Health Center ▪ Veterans Affairs Hospital Laboratories/ Medical Center ▪ Weill Cornell Medicine ▪ Women and Infants (Genmark or Roche only) ▪ Yale Pathology Lab	• Abbott m2000 • Abbott Alinity • Biofire • Cepheid Xpert • Diasorin Simplexa • GenMark Diagnostics • Hologic Panther TMA • Hologic Panther Fusion • Luminex MagPx • NeuMoDx • Perkin Elmer • ThermoFisher Taqpath • Quidel Lyra • Qiagen Qiastat • Roche Cobas LiaT • Roche Cobas 6800/8800

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.

Negative results from some currently available POC Mobile platforms such as Abbott ID NOW and BINAX, although available in Epic, must be confirmed by a more sensitive YNHHS nucleic acid amplification test.