

SARS-CoV-2 RNA Amplification Tests Available at YNHH- Update

A variety of different test platforms are employed for SARS CoV-2 RNA detection at YNHH and differ in key features as well as in expected time to result. A table of current test options is provided on page 2.

Nucleic acid amplification tests (NAAT) for viral RNA are essential for diagnosis of acute SARS CoV-2 infections, and are much more sensitive than antigen tests. Due to limited supplies and unreliable delivery of reagents, laboratories offer **multiple NAAT “platforms”** to remain operational and meet the need for increased COVID-19 test availability. NAAT amplification methods vary. Only real-time polymerase chain reaction (PCR) tests provide a cycle threshold (Ct) value, which is an indicator of viral load.

Test differences: Tests vary in methods, viral genes targeted, instrumentation, skill level and labor required, as well as the results displayed in EPIC. Result terminology, i.e. “Detected or Not detected” versus “Positive or Negative”, and the use of “Inconclusive”, vary according to the manufacturer’s protocol and instructions.

Test selection: Since test reagents are inadequate to meet demand, priorities must be set by the YNHHS Test Stewardship Committee. The laboratory staff follow the committee’s recommendations. Thus, samples are routed to different test platforms according to patient population, sample type, turnaround time required, test reagent inventory, test supplies, and available staff trained to perform the test. Routing to the correct platform is reliant on correct test ordering by the provider, which leads to an icon on the sample label.

Most commonly used tests: Panther TMA and ThermoFisher TaqPath RT-PCR assays are currently the most commonly used platforms.

Unusual sample types: The CDC lab-developed assay is now reserved for **sputum, tracheal aspirates, and saliva** as these sample types are not approved for testing by other platforms used at YNHH. Due to the low numbers of these samples, the CDC assay is now done only once a day and often not on weekends.

Tests offered may change over time and communication is strongly encouraged. Inquiries and feedback may be directed to Marie Landry, MD, David Peaper MD, PhD, or Maureen Owen at 203-688-3524 or Maureen.owen@ynhh.org.

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Table. SARS CoV-2 Test Platforms Available as of September 4, 2020

Test ^a <i>Go live</i>	Method ^b	Samples	Time to result ^c	Workflow	Features	Utility	Patient population
GeneXpert (Cepheid) 3/29/20	Multiplex Real time RT-PCR	NP, OP, nasal, mid-turbinate	2 hrs	Sample inoculated into single cartridge and placed on instrument	Automated test Simple to train Limited inventory	Rapid result 24/7 capability Ct value available	Prioritized list of indications
Simplexa (Diasorin) 5/24/20	Multiplex Real time RT-PCR	NP, nasal, BAL	2-3 hrs	Samples inoculated into wells in 8-well wheel; 1.5 hrs to run on instrument	Automated Simple to train 1-8 samples/ batch Limited inventory	Rapid result Day and evening shifts only	Back up to GeneXpert
Panther (Hologic) 5/14/20	Transcription mediated amplification (TMA)	NP, OP, nasal, mid-turbinate	6 hrs	Samples placed on instrument singly or in batches	Up to 250-300 samples per shift Supply shortages impact availability	24/7 capability No Ct value	Inpatient and outpatient
TaqPath (Thermofisher) 5/7/20	Multiplex Real time-RT-PCR	NP, OP, nasal, mid-turbinate, NP aspirate, BAL	12-72 hrs	Batched, 96-384 samples	Potential for automation and high throughput High skill level	Large batches Ct value available Day and evening shifts only	Outpatients
CDC (Lab developed) 3/13/20	Singleplex Real time RT-PCR	NP, OP, nasal, mid-turbinate, BAL, sputum ^d , saliva ^e	24-48 hrs	Batched, 15-23 samples; 3 PCRs per sample Labor intensive	Gold standard Manual, low throughput High skill level	EUA to test BAL, tracheal aspirate, sputum^d, or saliva^e Ct value available	Uncommon sample types Backup to other tests if needed

EUA, Emergency Use Authorization obtained from the FDA to allow testing

"Throughput" refers to the amount of testing completed in a given time period (e.g. 3 tests per hour, versus 50 tests per hour)

a, Due to the volume of testing and need for multiple platforms, tests may be performed in either the Virology or Microbiology Laboratory

b, "Multiplex" indicates that multiple PCRs to detect multiple gene targets are combined in a single vial to simplify workflow

c, Time is from arrival in lab, not from sample collection

d, Sputum preferred for retesting if NP or mid-turbinate swab is negative.

e, If sputum negative and suspicion still high, saliva can be tested. Saliva is not recommended for initial screen. NP swab is the preferred sample, especially on hospitalized patients.

Note: BD Max SARS CoV-2 PCR has been discontinued.