Catholic Health

TO: Catholic Health Medical Staff

FROM: Joyce A. Markiewicz, EVP, Chief Business Development Officer
James J Jarnot, MBA, MT (ASCP), SC; Technical Director, CH Laboratory

DATE: March 24, 2020

RE: Catholic Health Laboratory Memo on COVID-19 to our Practitioners

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The Catholic Health Clinical Laboratory has been actively looking for a rapid testing solution for this pandemic situation. We use a few different vendors/manufactures for our molecular testing currently. The conversations with the vendors started two weeks ago to get our laboratory on the early adopter list with them. Early Saturday morning, Cepheid[1], one of our current vendors, was granted FDA Emergency Use Authorization (EUA) for their "Xpert Xpress SARS-CoV-2 assay" developed in response to COVID-19. The Xpert Xpress SARS-CoV-2 test is a rapid, real-time RT-PCR test intended for the qualitative detection of nucleic acid from the SARS-CoV-2 in nasopharyngeal swabs. Immediately we issued a Purchase Order for testing and other related products. Because of these efforts, we are in a very good position to have testing kits and supplies delivered to us this week.
Below is a table that shows some of the attributes of this test methodology.

Cepheid Molecular Products	Catholic Health Laboratories already have the Genexpert instruments
Distributed Testing	Catholic Health Laboratory has a decentralized testing modality so we are not spending additional hours transporting samples to a central location. Sisters Main St, Sisters St Joseph's, Buffalo Mercy, Mt St Mary's, Kenmore Mercy and MACC all have instrumentation on site.
NYSDOH Permit	All CHS Laboratories have the appropriate CLIA permits already
Capacity	CHS Laboratories have a total of 48 bays across all sites which give us a testing capacity of 800 test per day. If increased capacity is required, an additional testing module can be added.
Testing Schedule	CHS laboratories use First in First out (FIFO) testing so the testing is random access not batched. And, testing is performed 24x7 at all sites
Testing personnel	All of our highly trained Medical Technologist and Medical Technicians can perform testing.
Efficiency	The Cepheid test products are "unit dose" so there is no wasted reagent
Turn-around-Time	Most National Labs and Public Health labs have TATs that vary from 2-4 days; Cepheid's assay has a 45 minute testing time.
Sample Requirement	A nasopharyngeal (NP) swab in viral transport media (VTM) is required
Multiple Test Capability	Once CHS has performed the required verifications, we will be able to test Influenza A/B, RSV and COVID-19 all from 1 sample if needed.
Test Accuracy	Current testing assays search for 1 to 2 gene targets. The Cepheid assay also searches for 2 targets.
Level of Detection (LOD)	The expected level of detection of this assay has been calculated to be 250 copies/mL
Test Reporting	Each target will be reported on the patient test report. The test will be reported as: Negative, Positive, Presumptive Positive, or Invalid

[1] Based in Sunnyvale, Calif., Cepheid is a leading molecular diagnostics company that is an operating company within Danaher Corporation's (NYSE: DHR) Diagnostics platform

Our interpretation of the results is based on the manufactures guideline

Test result	Target 1 -N2	Target 2- E	Internal Quality Control
SARS-COV-2 Positive	+	+	+
SARS-COV-2 Positive	+	-	+
SARS-COV-2 Presumptive Positive	-	+	+
SARS-COV-2 Negative	-	-	+
Invalid	-	-	-

For additional information contact our Customer Service Department at 862-1150.

Jim Jarnot
Laboratory Technical Director