Test Bulletin

ACL Laboratories
We are AdvocateAuroraHealth

March 2021

Reporting of SARS-COV-2 Cycle Threshold (Ct) Values for Rapid SARS-COV-2 Testing (Advocate Aurora Health rapid testing *only)*

Effective Thursday, March 4, 2021, ACL Laboratories will report the Cycle Threshold (Ct) value for rapid SARS-COV-2 BY PCR. For qualitative real-time PCR tests, such as the rapid SARS-COV-2 tests performed on the Cepheid instrumentation, the Ct value can provide a semi-qualitative estimation of "how positive" a SARS-COV-2 PCR test is. This value is not routinely reported; however, due to limited resources and expensive antivirals utilized to treat COVID-19 patients, it has been shown to add value. Some studies indicate that knowledge of the Ct value can benefit providers when determining the appropriate course of therapy for their patients.

Tests Impacted

- RAPID SARS-COV-2 BY PCR (Test Order Code LAB10644)
- COVID/FLU/RSV PANEL (Test Order Code LAB10789)

Result Reporting Changes

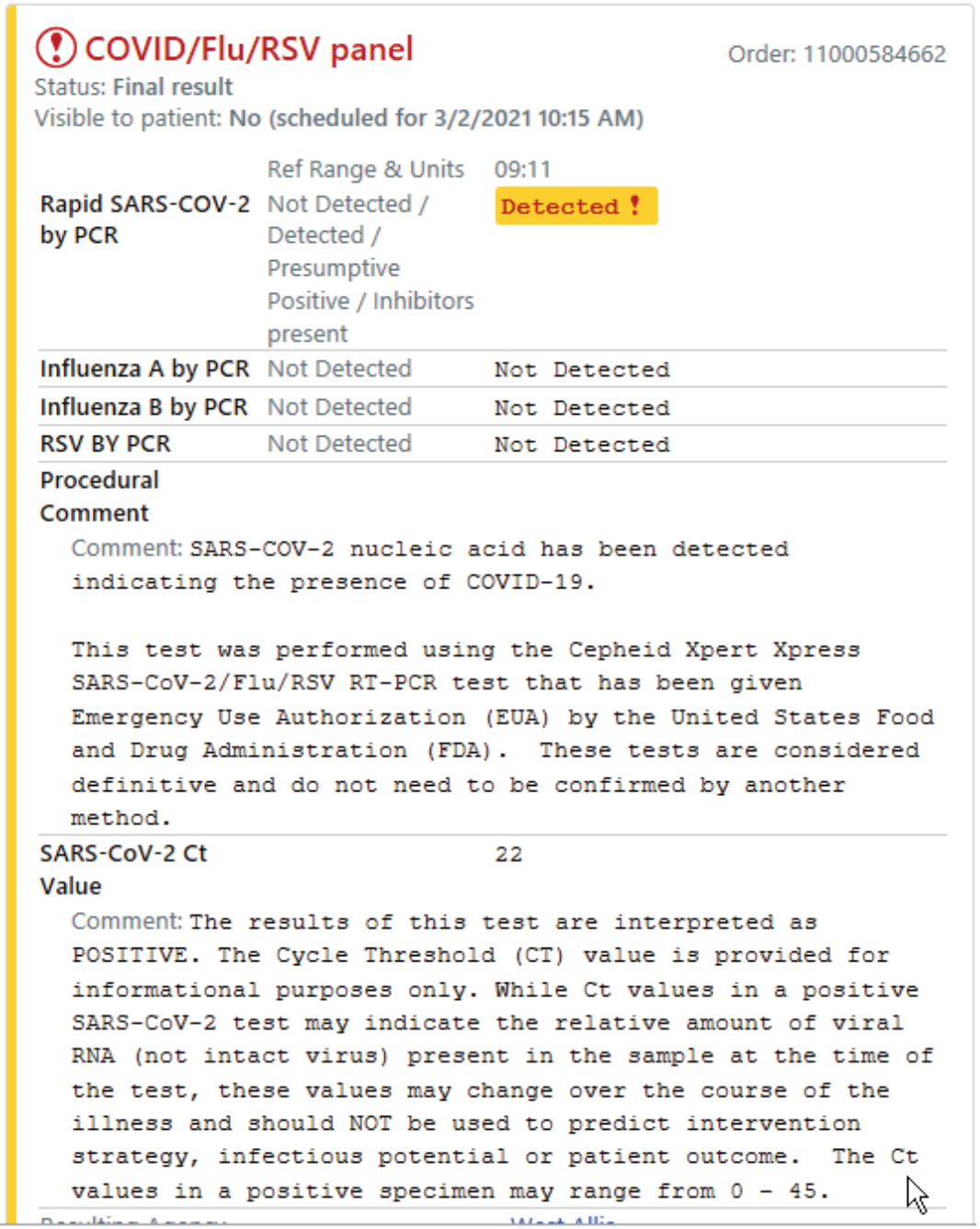
Positive tests will have a Ct value reported that will automatically cross the Cepheid interfaces into EPIC Beaker.

Negative tests will have no change. The Ct value field will not be present on SARS-COV-2 negative results.

The template on the right shows how a SARS-COV-2 result from the Cepheid instrument will look with a Ct value reported.

Interpretation of Results

ACL Laboratories will **not** provide specific interpretive criteria around the Ct value as the interpretation is dependent on the patient's clinical condition.



COVID/Flu/RSV panel Order: 11000584662

Status: **Final result**

Visible to patient: **No (scheduled for 3/2/2021 10:15 AM)**

	Ref Range & Units	09:11
Rapid SARS-COV-2 by PCR	Not Detected / Detected / Presumptive Positive / Inhibitors present	**Detected !**
Influenza A by PCR	Not Detected	Not Detected
Influenza B by PCR	Not Detected	Not Detected
RSV BY PCR	Not Detected	Not Detected

Procedural Comment

Comment: SARS-COV-2 nucleic acid has been detected indicating the presence of COVID-19.

This test was performed using the Cepheid Xpert Xpress SARS-CoV-2/Flu/RSV RT-PCR test that has been given Emergency Use Authorization (EUA) by the United States Food and Drug Administration (FDA). These tests are considered definitive and do not need to be confirmed by another method.

SARS-CoV-2 Ct Value	22

Comment: The results of this test are interpreted as POSITIVE. The Cycle Threshold (CT) value is provided for informational purposes only. While Ct values in a positive SARS-CoV-2 test may indicate the relative amount of viral RNA (not intact virus) present in the sample at the time of the test, these values may change over the course of the illness and should NOT be used to predict intervention strategy, infectious potential or patient outcome. The Ct values in a positive specimen may range from 0 - 45.

Below are general characteristics for your knowledge and awareness:

1) The possible range for Ct values is 0 – 45.
2) The Ct value is inversely related to viral concentration in a specimen (greater Ct values correlate to less viral nucleic acid).
3) Patients can have high Ct values (low levels of virus) at the beginning and at the end of their infection so clinical context is necessary for interpretation.
4) The Ct value is most commonly used by Infectious Disease and Critical Care Providers to help with difficult treatment decisions.

Provider Inquiries/Resources

Providers needing additional insight in interpretation of a Ct value should discuss the results with an Infectious Disease Provider or with the Technical Director for Microbiology, Dr. Eric Beck who can be contacted at 414-328-6124.

Organic Acids Screen, Urine (Test Order Code ORGUR) - New Performing Laboratory

Effective immediately, Organic Acids Screen, Urine (Test Order Code ORGUR) will be performed by ARUP Laboratories. Specimen requirements are identified below.

Specimen Requirements	Effective immediately -- ARUP	Previous Requirements – Mayo (discontinued)
Volume (preferred)	9.0 mL of urine in an aliquot tube	10.0 mL
Volume (minimum)	3.0 mL of urine in an aliquot tube	4.0 mL
Temperature	Frozen	Frozen
Required information	Patient History for Biochemical Genetic Testing https://ltd.aruplab.com/api/ltd/pdf/16	Patient's age, family, clinical history
	Reports include age appropriate reference intervals and interpretation.	

For additional information regarding this test, please contact ACL Client Services at 1.800.877.7016 or visit our website at acllaboratories.com/test-catalog/.

ACL Announces Test Methodology Change for Inhibin B (Test Order Code INHIBB)

Effective immediately, the testing methodologies for Inhibin B (Test Order code INHIBB) have changed.

Effective immediately and through Sunday, May 16, 2021, laboratory results will identify results using ***both*** methods to help establish a new baseline in existing patients.

Changes include modifications in the reference ranges and specimen collection requirements highlighted below.

- **Patient Preparation:** For premenopausal females, collection is preferred during the follicular phase of the menstrual cycle.
- **Collect:** Gold gel or plain red.
- **Specimen Preparation:** Transport 0.5 mL serum. (Min: 0.2 mL)
- **Storage/Transport Temperature:** Frozen.
- **Unacceptable Conditions:** Room temperature specimens.***Grossly hemolyzed specimens. Plasma***
- **Stability** (collection to initiation of testing) – After separation from cells:
  Ambient: Unacceptable;
  Refrigerated: 72 hours;
  Frozen: 1 month

Current reference ranges, effective immediately.

Male	Female
<15 days: 68-373 pg/mL	1 day-12 years: 1-182 pg/mL
15 days-6 months: 42-516 pg/mL	13-41 years (regular cycle, follicular phase): 8-223 pg/mL
7 months-7 years: 24-300 pg/mL	42-51 years (regular cycle, follicular phase): 1-107 pg/mL
8-30 years: 47-383 pg/mL	51-76 years (postmenopausal): 1-11 pg/mL
31-72 years: 10-357 pg/mL	

Previous reference ranges.

Male	Female
0-6 yrs: 40-630 pg/mL	0-6 years: less than 73 pg/mL
7-10 yrs: 35-170 pg/mL	7-10 years: less than 130 pg/mL
11-18 yrs: 50-475 pg/mL	11-12 years: less than 186 pg/mL
19-45 yrs: 40-450 pg/mL	13-18 years: less than 360 pg/mL
> 46 years: less than 200 pg/mL	Pre-menopausal: less than 290 pg/mL
	Follicular phase: 10-290 pg/mL
	Post-menopausal: less than or equal to 16 pg/mL

For additional information regarding this test, please contact ACL Client Services at 1.800.877.7016 or visit our website at acllaboratories.com/test-catalog/.