

## Molecular PCR Summary Lab Report

	NFORMATION	PATIENT	INFORMATION		SPECIMEN INFORMATION	
Name:	Assurance Pathology Laboratory	Name:	Test, Copia	0	Lab Accession Number:	ASL-12102110191 12/09/21 1:43:00 PM
Address:	Suite 207 BIRMINGHAM, AL 35243	DOB: Phone: Address:	10/28/2000 (999)999-9999 123 Test St	Sex: M	Date Collected: Date Accessioned: Date Reported:	12/10/2021 12/10/2021
Provider:			BIRMINGHAM, AI	L 35243	Faxed to:	18777966185
	Extraction Control 1	PASS	(2) Positive contro	l is synthetic in		
Endogenous Positive Control <sup>1</sup> PASS Pathogen Positive Control <sup>2</sup> PASS						

(4) A "Detected" result indicates the presence of a pathogen (99.99% confidence) above the assay cutoff.

Test Performed

Pathogen Negative Control <sup>3</sup>

**Test Results** 

PASS

Comments

COVID-19		Collection Type: Nasopharyngeal Swab		
COVID-19	DETECTED	[12/10/21 2:39:39 PM] COVID-19 assay reviewed and approved under FDA Emergency Use Authorization #200522. Laboratory will immediately notify appropriate Federal, State, or local public health agencies of all positive results.		
nCoV_N1 (CT Value)	25.36	[12/10/21 2:39:39 PM] CT value indicates the number of amplification cycles of real-time PCR needed to detect COVID-19, a specific SARS-CoV-2 gene sequence. CT values are inversely proportional to the amount of target nucleic acid in the sample (i.e. the lower the CT level, the greater the amount of target nucleic acid in the sample). The reference range for Assurance Scientific Laboratories RT-PCR assays is <40 cycles of amplification.		

Clinic Name: Assurance Pathology Laboratory

Patient name: Test, Copia

Lab Director: Ty Thomas, MD

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Test results must be evaluated with clinical symptoms to diagnose disease. All tests established and validated by Laboratory and not FDA approved unless otherwise indicated. Methodology statement: Real-time PCR assays are designed to detect pathogens with clinical significance and analytical sensitivity and specificity greater than 99%. Limitations: While these assays are very sensitive and specific, theoretically these assays could detect pathogens not listed, resulting in a false positive. In addition, while these assays are very specific, there may be target pathogen sequences with unknown sequence variability which may not be detected, resulting in a false negative result.