

COVID-19 TESTING PROCEDURES AND TESTS

Harrison School of Pharmacy (HSOP)

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AUBURN UNIVERSITY

HARRISON SCHOOL OF PHARMACY

COMPANY	TEST NAME	USA EUA AUTHORIZED (Date)	TECH	TESTS	SAMPLE	COLLECTION	CLIA	TIME	SENSITIVITY / SPECIFICITY*
Cepheid	Xpert Xpress SARS-CoV-2 test	3/20/20 EUA	Real-time reverse transcriptase (RT) PCR test (<i>Qualitative</i>)	Real-time RT-PCR Detection of Nucleic Acids	Mucus Secretions	Naso-pharyngeal, nasal, and mid-turbinate swabs	MODERATE, HIGH, and Waived Complexity	45 minutes	SEN= 100% SPEC= 100%
Mesa Biotech Inc.	Accula SARS-Cov-2 Test	3/23/20 EUA	Lateral flow PCR (<i>Qualitative</i>)	Real-time RT PCR Detection of Nucleic Acids	Mucus Secretions	Naso- and oro-pharyngeal swabs	MODERATE, HIGH, and Waived Complexity	30 minutes	SEN= 100% SPEC= 100%
Abbott ID now RNA	ID Now Covid-19	3/27/20 EUA	Isothermal Nucleic Acid Amplification (<i>Qualitative</i>)	COVID-19 RdRp Gene / Detection of Nucleic Acids	Mucus Secretions	Naso- and oro-pharyngeal swabs	MODERATE, HIGH, and Waived Complexity	5 - 13 minutes	SEN= 100% SPEC= 100%
Cue Health, Inc.	Cue COVID-19 Test	6/10/20 EUA	Isothermal Nucleic Acid Amplification (<i>Qualitative</i>)	COVID-19 RdRp Gene / Detection of Nucleic Acids	Mucus Secretions	Nasal swabs	MODERATE, HIGH, and Waived Complexity	25 minutes	SEN = 100% SPEC = 92%
Quidel Corporation	Sofia 2 SARS Antigen FIA	5/8/20 EUA	Antigen / Qualitative	Nucleocapsid protein from SARS-CoV and SARS-CoV-2	Mucus, secretions	Nasal or Nasopharyngeal swabs	MODERATE, HIGH, and Waived Complexity	15 minutes	SEN = 80% SPEC = 100%

SELF-COLLECTION PCR TESTS – CLIA High Complexity (Pharmacy provides sampling kit – testing completed at alternative facility)

LabCorp	COVID-19 RT-PCR Test	3/16/20 EUA	Real-time RT PCR test (Qualitative)	RT PCR Detection of Nucleic Acids	Mucus secretions	<i>Self-collected nasal swab</i>	HIGH Complexity Labs designated by LabCorp	2-4 Days	SEN = 100% SPEC = 100%
Quest Diagnostics	Quest SARS-CoV-rRT-PCR	3/17/20 EUA	Real-time RT PCR test (Qualitative)	RT PCR Detection of Nucleic Acids	Mucus secretions	<i>Self-collected nasal swab</i>	HIGH Complexity Labs designated by Quest Diagnostics	2-3 Days	SEN = 100% SPEC = 100%
Rutgers Clinical Genomics Laboratory	Rutgers Clinical Genomics Laboratory TaqPath SARS-CoV2- Assay	5/07/20 EUA	Real-time RT PCR test (Qualitative)	RT PCR Detection of Nucleic Acids	Saliva	<i>Self-collected saliva specimen</i>	HIGH Complexity Lab – Rutgers	1-2 Days	SEN = 100% SPEC = 100%
Fulgent Therapeutic s, LLC.	Fulgent COVID-19 by RT-PCR Test	5/15/20 EUA	Real-time RT PCR test (Qualitative)	RT PCR Detection of Nucleic Acids	Mucus secretions	<i>Self-collected nasal swab</i>	HIGH Complexity Lab – Fulgent Genetics' Laboratory	1-2 Days	SEN = 100% SPEC = 100%
Everlywell, Inc	Everlywell COVID-19 Test Home Collection Kit	5/15/20 EUA	Real-time RT PCR test (Qualitative)	RT PCR Detection of Nucleic Acids	Mucus secretions	<i>Self-collected nasal swab</i>	HIGH Complexity Labs designated by Everlywell, Inc.	48 Hours	SEN = 100% SPEC = 100%
P23 Labs, LLC	P23 labs TaqPath SARS-COV-2 Assay	5/21/20 EUA	Real-time RT PCR test (Qualitative)	RT PCR Detection of Nucleic Acids	Mucus secretions	<i>Supervised self-collected saliva or HCP collected Naso-, oro- pharyngeal, anterior nasal, and mid-turbinate swab; BAL fluid</i>	HIGH Complexity Lab – P23 Labs, LLC	72 Hours	SEN = 100% SPEC = 100%

PrivaPath Diagnostics, Inc.	LetsGetChecked Coronavirus COVID-19 Test	5/28/20 EUA	Real-time RT PCR test (Qualitative)	RT PCR Detection of Nucleic Acids	Mucus secretions	Self-collected nasal swab	HIGH Complexity Lab – PrivaPath Lab	24 Hours	SEN = 100% SPEC = 100%
Phosphorus Diagnostics LLC	Phosphorus COVID-19 RT-qR Test	6/4/20 EUA	Real-time RT PCR test (Qualitative)	RT PCR Detection of Nucleic Acids	Saliva	Self-collected saliva specimen	HIGH Complexity Lab – Phosphorus Diagnostics	72 Hours	SEN = 97.1% SPEC = 98.2%
Kaiser Permanente Mid-Atlantic States	KPMAS COVID-19 Test	6/13/20 EUA	Real-time RT PCR test (Qualitative)	RT PCR Detection of Nucleic Acids	Mucus secretions	Self-collected nasal swab	HIGH Complexity Lab – KPMAS Regional Lab	1-3 Days	SEN = 100% SPEC = 100%

*False negative results can occur if the sample is improperly collected, handled, or transported

LEGEND:

2019-nCoV (original name of virus) = **COVID-19** = **SARS-CoV-2** (International Committee for the Taxonomy of Viruses or ICTV)

SEN = sensitivity; the ability of a test to correctly identify those with the disease (true positive tests). A highly sensitive test has a low rate of false negative results; therefore few cases of COVID-19 are missed.

SPEC = specificity; the ability of the test to correctly identify those without the disease (true negative tests). A highly specific test means that there are few false positive results.

BAL = bronchoalveolar lavage

Updated 6/26/2020; CAO