

# Molecular Diagnostics Laboratory Wichita State University

CLIA Registered High Complexity Laboratory, 17D2189034

## OUR GOAL

WSU MDL's increased testing capacity enables Kansas to live with the pandemic and aid our community in returning to work and school.

**MDL processes COVID-19 test samples provided by healthcare providers. Individual samples are collected by your healthcare provider or you can call 211 to identify public testing locations.**

## REGIONAL CAPACITY ADVANTAGE

- 01 Control of testing process, prioritization and price
- 02 High-throughput
- 03 Low-cost, 40%-60% savings
- 04 Highly accurate, 24-hour response

## SAMPLE COLLECTION

Enables utilization of an unlimited number of collection sites to provide safe and nimble access to all populations.



Symptomatic

(county health dept., hospitals, health-care providers, etc.)



Schools and Childcare

Nursing Homes &  
Long -Term Care



Business and Industry



The Molecular Diagnostics Laboratory at WSU has the capability to analyze 1,500 tests per 8-hour shift (totaling 4,500 per day). The maximum analyzing capacity for 3 shifts, 7 days a week, is 31,500 tests.

FDA EUA approved **Thermo Fisher Scientific TaqPath™** - Specificity: 100% Sensitivity: 100%

FDA EUA approved **Yale SalivaDirect™** - Specificity: 100% Sensitivity: 94.6%

## SIMPLE PAPERLESS DIGITAL PROCESS

Molecular Diagnostics Laboratory utilizes secure electronic methods to quickly and seamlessly communicate information to physicians, health care providers and patients. Secure electronic tracking and communication methods are woven throughout the process to enhance reliability and user experience from start to finish.

01

Healthcare  
provider orders  
COVID-19 test



02

Specimen  
collected



03

Send  
specimen  
to lab



04

Analyze the  
specimen



05

Status Alert via  
email to Patient



06

KDHE, healthcare  
provider, and  
patient receive test  
results



If desired, patient can provide email address and elect to receive an email notification when results are completed. After registering in our patient portal, they can securely view their result.



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## TEST PROCEDURE

The WSU MDL utilizes an open analytical system allowing the flexibility to use multiple reagents and testing protocols. Currently, MDL has been authorized to use the following RT-PCR molecular testing protocols using:

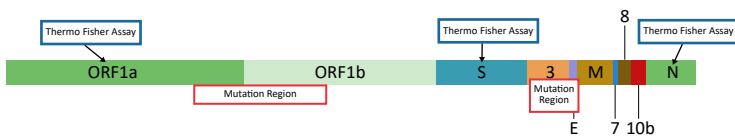
### Thermo Fisher Scientific TaqPath™



**Specificity: 100%**

**Sensitivity: 100%**

- FDA EUA approved for use on all CDC approved respiratory specimens (such as nasopharyngeal, oropharyngeal, nasal, and mid-turbinate swabs, nasopharyngeal aspirate and bronchoalveolar lavage (BAL) specimens)
- The gold standard for testing: full viral RNA extraction on the KingFisher™ Flex with real-time reverse transcription polymerase chain reaction (RT-PCR) on the QuantStudio™ 7
- Coming soon: Multiplex Assay: allows for detection of SARS-CoV-2, Influenza A, Influenza B, and RSV from one analyzed specimen
- Coming soon: Addition of approved saliva specimen for infection detection
- Targets 3 different regions of the viral genome



### Yale SalivaDirect™



Combine & mix

Heat inactivate

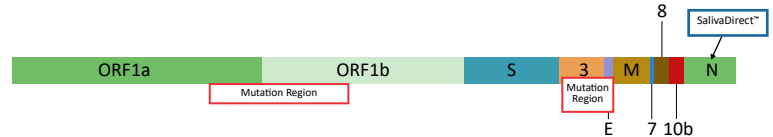
Dualplex RT-qPCR

Created with BioRender.com

**Specificity: 100%**

**Sensitivity: 94.6%**

- FDA EUA approved for saliva specimens collected in sterile cups or tubes without addition of any preservatives providing greater ease in sample collection
- Extraction-free RT-PCR: Proteinase K heat treatment followed by real time reverse transcription polymerase chain reaction (RT-PCR) on the Applied Biosystems™ 7500 Fast Dx.
- Utilizes combinations of alternate and substitute reagents, at each step adding redundancy and flexibility in the supply chain
- Enables non-invasive, frequent sampling and reduces the need for trained healthcare professionals during collection
- Targets 1 region of the viral genome



WSU MDL is supported by...



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WICHITA STATE UNIVERSITY



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