Technical Bulletin

Saliva Testing for SARS-CoV-2 (COVID-19) for Non-Medical Purposes

TO: Medical Staff and Clients

FROM: Dr. Wesley Kim, MD
Medical Director, DLS and QMC West

Dr. Amy Woron, PhD
Manager, DLS Molecular

Dr. A. Christian Whelen, PhD
VP & Technical Director
Microbiology & Molecular

Dr. Ana Ortega-Lopez, MD
Medical Director QMC Punchbowl,
North Hawaii and Molokai

DATE: February 23, 2021

SUBJECT: Saliva testing for SARS-CoV-2 (COVID-19) validated at DLS Central for Non-Medical purposes ONLY

On March 1, 2021, DLS will begin performing COVID-19 testing on saliva specimens. Saliva has been shown to be a desirable specimen for COVID-19 testing because collection is simple, convenient, and less invasive than swab sampling, requires fewer supplies, and performs well compared to other specimen types. This is a laboratory developed test and its performance characteristics were validated by DLS; it has not been reviewed or approved by the FDA for emergency use.

Testing is only performed at the DLS Central Halawa facility. It is only available for non-medical purposes. Saliva cannot be used on the rapid Nucleic Acid Amplification Test (NAAT) platforms (e.g., PCR on Roche Liat, Cepheid GeneXpert, and BD Max or isothermal amplification on Abbott ID Now).

Saliva collection kits are available from DLS that include a screw cap tube, labels, instructions, and alcohol wipes.

Saliva testing can be used for non-medical, asymptomatic, COVID screening (e.g., schools, businesses, etc.). It is not intended for symptomatic patients suspected of having an infection with SARS-COV-2 at this time. Saliva can only be used for COVID testing. It cannot be used to test for other agents like influenza, RSV, or Group A *Streptococcus*.

Internal validation at DLS showed a limit of detection of 64 copies per reaction at an average adjusted cycle threshold of 32.4. Saliva from 23 known COVID-19 positive inpatients and 26 negative individuals were tested. Following discrepant analysis, percent agreement was 97.7%. Sensitivity was 94.1% (95% CI was 77.8%-94.1%) and Specificity was 100% (95% CI was 89.3%-100%). DLS internal validation data agrees with most published studies indicating high categorical agreement between saliva and swabs. However, based on published data that shows higher cycle threshold values for saliva in general, it is likely there is about a ten-fold lower quantity of virus in saliva compared to swab specimens. As such, in asymptomatic individuals who happen to have a low viral load at the time of testing, false negative results on saliva can occur when compared to nasal swabs. Any result on saliva should be correlated with risk factors, exposure history, other circumstances, etc. before making a decision on the status of the individual or if additional NAAT based testing on swabs is indicated.

Tests (DLS Order codes):	Saliva SARS-CoV-2 / COVID-19 (#7230),
Specimen:	Saliva
Transport/Stability:	Refrigerated for 72 HOURS **or Frozen at -70ºF**
Turnaround time:	<3 days, usually within 24 hrs of receipt
	Clients will be notified of a "Detected" result

Please refer any questions to DLS Client Services at 589-5101 or Dr. Amy Woron, Manager - DLS Microbiology Lab at 441-5436