Exciting Update from Dynix Diagnostix

SALIVADIRECT™

Tired of being swabbed?

Dynix Diagnostix is proud to announce our designation as a SalivaDirect approved provider for testing SARS-CoV-2 via RT-PCR. The SalivaDirect method was developed by the Yale School of Medicine and has been granted Emergency Use Authorization by the FDA. The method requires no invasive swabs, only .5ml's of saliva.

SalivaDirect is only permitted to be offered by high complexity CLIA certified laboratories located in the United States of America. Dynix Diagnostix underwent vigorous correlation studies and has attested to comply with the collection requirements set forth in the IFU. This test is now available to all of our clients effective immediately.

Accuracy

The SalivaDirect method reflects **100%** Clinical Specificity and **94%** Clinical Sensitivity.

Stability

The sample is stable for up to 7 days refrigerated.

Specimen Type

"Normal" saliva of at least .5ml. Sniffing or coughing up deeper material is not necessary

Turnaround Time

Less than 24 hours*

Testing Platform

RT-PCR via the BioRad CFX 96

FDA Authorization Letter

https://www.fda.gov/media/141194/download

For more information visit

https://publichealth.yale.edu/salivadirect/about

turnaround times are based on the time the sample is received at the laboratory, not the time of collection.

For more information, please contact your designated sales representative or our Chief Marketing Officer Anthony Galgano at (954)292-7952. On behalf of the entire Dynix Diagnostix team, we value your business.

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https://www.linkedin.com/company/16225081/admin/

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SalivaDirect™has not been FDA cleared or approved. It has been authorized by the FDA under an emergency use authorization for use by authorized laboratories. The test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

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