

COVID-19 TESTING

SoftCell Laboratories employs the TaqPath™ COVID-19

Combo Kit (FDA authorized) to provide results for every sample. Both nasal swabs and saliva kits (SDNA-1000) can be processed for SARS-CoV-2

RNA detection at SoftCell Laboratories.

SALIVA KIT PERFORMANCE

LIMIT OF DETECTION: 250 COPIES/mL

SENSITIVITY: 97.50%

SPECIFICITY: 100%

POSITIVE PREDICTIVE VALUE: 100%

NEGATIVE PREDICTIVE VALUE: 97.56%

PRESERVATIVE INACTIVATES VIRUS

7-DAYS STABILITY AT AMBIENT TEMPERATURE

This test has not been FDA cleared or approved;

This test has been authorized by FDA under an EUA for use by authorized laboratories;

This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens; and

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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