SalivaDirect™ SARS-CoV-2 Assay Validation Summary

The SalivaDirect™ test is an RNA-extraction free, real-time reverse transcription polymerase chain reaction (RT-PCR) test for the qualitative detection of nucleic acid from SARS-CoV-2 (the causative agent of COVID-19) for use with saliva specimens that are collected in the presence of a trained adult observer from individuals suspected of COVID-19 by their health care provider. It is also for use with saliva specimens that are self-collected by individuals 18 years of age or older unsupervised at home and dropped off at a collection site, using the SalivaDirect™ Unsupervised Collection Kit when determined to be appropriate by a health care provider or unsupervised at home using the SalivaDirect™ At-Home Collection Kit and mailed to a testing laboratory, when used consistent with its authorization. This test is also intended for use in individuals without symptoms or other epidemiological reasons to suspect COVID-19, using supervised saliva collection, or unsupervised saliva self collection with the SalivaDirect™ Unsupervised Collection Kit or the SalivaDirect™ At-Home Collection Kit.

Detection of viral RNA is carried out using the Applied Biosystems™ QuantStudio 7 Flex following the Yale School of Public Health, Department of Epidemiology of Microbial Diseases SalivaDirect™ instructions for use. The assay targets the SARS-CoV-2 nucleocapsid (N1) gene and the human RNase P gene, and includes positive and negative plate level controls to allow the laboratory to assess the acceptability of sample collection and PCR amplification.

Validation of the SalivaDirect™ test at Tempus Labs was performed on saliva specimens in our CLIA-certified, high-complexity, CAP-accredited laboratory. Precision and limit of detection (LOD) were determined using contrived positive and negative samples and dilution series. Accuracy was determined by testing 30 known positive and 30 known negative saliva samples for concordance. Positive samples showed 92.6% concordance and negative samples showed 100% concordance between Yale's SalivaDirect™ and Tempus SalivaDirect™. These results demonstrate the high accuracy of the test. Intra-run and inter-run precision testing showed 100% concordance between samples. Lastly, the test can detect 6 copies per µL with 99.9% sensitivity.

Tempus' COVID-19 tests are either validated in accordance with FDA policies or have received an EUA authorization from FDA. The EUA authorized test:

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

TABLE 1: Performance specifications in saliva samples

Test Characteristic	Results
Limit of detection	6 copies per µL
Sensitivity	99.9%
Specificity	99.9%
Accuracy - positive samples	92.6%
Accuracy - negative samples	100%