iC COVID-19 RT-PCR Validation, Atlanta

The Tempus iC COVID-19 RT-PCR assay is a real-time reverse transcription polymerase chain reaction (RT-PCR) test for the qualitative detection of nucleic acid from SARS-CoV-2 in upper respiratory tract specimens collected from individuals suspected of COVID-19 by their healthcare provider.

The highly automated test uses the RNAdvance viral Extraction kit on the Beckman i7 liquid handler to isolate RNA from upper respiratory tract specimens. Detection of viral RNA is carried out using the PerkinElmer® New Coronavirus Nucleic Acid Detection kit, a TaqMan-based RT-qPCR run on the Applied Biosystems QuantStudio12 Flex (QS12) instrument. The assay targets specific genomic regions of SARS-CoV-2: nucleocapsid (N) gene, ORF1ab and an RNA internal control (IC, bacteriophage MS2) to monitor the process from nucleic acid extraction to fluorescence detection.

Validation of the Tempus iC COVID-19 RT-PCR test was performed on nasopharyngeal (NP) and anterior nares swab specimens in our CLIA-certified, high-complexity, CAP-accredited laboratory. Accuracy, precision, and limit of detection (LOD) were determined using known positive and negative samples and dilution series. Following the Beckman Coulter i7 extraction workflow, accuracy was determined by testing 89 known positive and negative samples collected in mawi buffer and saline for concordance. Positive samples showed 100% concordance and negative samples showed 97% concordance. Lastly, the test can detect 250 viral copies per mL for both Mawi buffer and saline.

Validation of the Tempus iC COVID-19 RT-PCR test established a robust assay for the detection of SARS-CoV-2 RNA with high accuracy, sensitivity, and specificity in nasopharyngeal and nasal swab samples. This test has not been reviewed by FDA. The detection of SARS-CoV-2 RNA does not rule out co-infection with other viruses or bacteria, and negative results do not preclude an infection by SARS-CoV-2. The patient's healthcare provider should assess results along with the patient's medical information and clinical observations in order to make treatment or management decisions.

TABLE 1: Performance specifications in upper respiratory samples

Test Characteristic	Results
Limit of detection	250 viral copies per mL in both Mawi buffer and Saline
Sensitivity	99.9%
Specificity	99.9%