MicroGen DX
Next-Gen DNA Sequencing
FOR ACCURATE MICROBIAL IDENTIFICATION
Superior Diagnostics. Targeted Treatments. Better Outcomes.

Substitution Study: Sterile Saline in place of VTM/UTM

Due to extreme shortages of Viral Transfer Media (VTM) and Universal Transfer Media (UTM) the FDA has recommended that a dry swab in sterile saline could be used to collect and transport samples for molecular RT-PCR SARS-CoV-2 assays (link below). Sterile saline was tested to determine if viral RNA integrity could be maintained at room temperature (15ºC-25ºC) for up to 72 hours.

The test was carried out by spiking inactivated Coronavirus 229E into tubes containing a PurFlock Ultra 6" Sterile Ultrafine Flock Swab w/ Plastic Handle and either 350 or 500 µL sterile saline and incubating at room temperature for 72 hours. RNA integrity after 72 hours was assessed using the FDA-approved Biofire FilmArray Respiratory Panel. While this method differs from the SARS-CoV-2 rRT-PCR assay developed by MicroGen DX, the testing principle (RT-PCR) remains the same.

Result Summary	Coronavirus 229E with 350 µL sterile saline	Coronavirus 229E with 500µL sterile saline
Result Summary	Detected	Not detected

These results indicate that swabs in 350 µL sterile saline collected from suspected COVID-19 patients are capable of maintaining viral RNA integrity for up to 72 hours between 15ºC and 25ºC during shipping to the testing facility.

MicroGen DX believes the ability to use sterile saline when VTM/UTM are not available will help clinicians and their patients to continue to receive state-of-the-art testing in a time of great need. The SARS-CoV-2 rRT-PCR assay offered by MicroGen DX uses stringent assay controls that monitor specimen integrity and samples reported as inconclusive or invalid will be re-extracted and repeated before issuing specimen recollection requests.

FDA FAQS: https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2