WHITE PAPER

REDx™ FLOQ® Quality Control Protocol

Validation of sample transport medium and swabs from different vendors by using REDx™ FLOQ® SARS-CoV-2 Swab Positive Control

1. Scope

The COVID-19 pandemic has created a global supply chain crisis for patient sample collection devices (PSCD) for both swabs and viral transport medium. Globally, the current needs by clinical laboratories exceed the supply of those products and there are several vendors providing various forms of medium and types of swabs. In order to provide the needed PSCD materials, governments and regulatory bodies are often deviating from the routine IVD approval process and often given emergency use authorizations. This can lead to an increase of false positive and negative samples and possible patient misdiagnosis.

2. Rationale

By using the clinically validated quality controls that monitor the nucleic acid test workflow the labs can establish baseline performance for PSCD from various lots and various vendors.

3. Recommended basic protocol for new sample transport medium validation

a. Elute each swab (2-5 swabs in total) in 1-3 mL of standard Viral Transport Medium and/or Sample Transport Medium (VTM/STM).
b. Based on the requirements for the recommended sample volume in the IFUs of the nucleic acid assay (including the extraction) perform 10-20 repeats for establishing the baseline test performance.
c. Elute each swab (2-5 swabs in total) in 1-3 mL of the new VTM/STM under investigation.
d. Repeat step “B” again doing 10-20 repeats and compare with the baseline results. The data should be within 3 Standard Deviations (SD) from the mean of the standard VTM/STM.
e. Greater than +/- 3SD variation is an indication of interference, it is up to lab to accept the data and establish new guidelines with the new VTM/STM or reject the vendor and/or the lot of the VTM/UTM.

4. Recommended basic protocol for new swab validation

a. Elute each swab (4-10 swabs in total) in 0.5 mL of standard VTM/STM in a separate vial.
b. Dip current swabs (2-5 swabs in total) used in the lab in each vial.
c. Test the swabs by running 10-20 repeats as per the instructions for testing the patient specimen and establish a baseline with a mean and SD.
d. Dip the new swabs under investigation (2-5 swabs in total) in each vial.
e. Test the swabs by running 10-20 repeats as per the instructions for testing the patient specimen and compare the results with the previously generated baseline data.
f. The data should be within 3 SD from the mean of the standard swab.
g. Greater than +/- 3SD variation is indication of interference, it is up to lab to accept the data and establish new guidelines with the new swab or reject the vendor and/or the lot of the swab.

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