

Subject: Alternative External Quality Control Testing for the Metrix™ COVID-19 Test

Affected Products: Metrix™ COVID-19 Test
Distributed by SEKISUI Diagnostics

Effective Date: January 17, 2024

When using the Metrix™ COVID-19 Test in laboratory settings, good laboratory practice suggests the use of external positive and negative control materials to ensure that reagents are functional and that the testing procedure is performed correctly.

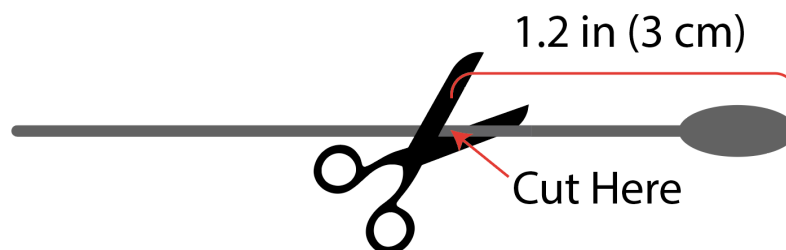
In addition to the external controls listed in the IFU for the Metrix™ COVID-19 Test, the following external control swabs from Microbix Biosystems Inc. were tested and found to be compatible for use with the Metrix™ COVID-19 Test. The links below lead to the product data sheets for the Controls:

- [REDx™ FLOQ® SARS-CoV-2 Swab Positive Control \(RED-S-19-1\)](#)
- [REDx™ FLOQ® SARS-CoV-2 Swab Negative Control \(RED-S-99-M4\)](#)

The REDx™ FLOQ® SARS-CoV-2 Swab Positive Control and the REDx™ FLOQ® SARS-CoV-2 Swab Negative Controls, available from Microbix Biosystems Inc., provide an alternative option for External Quality Control that follows the same process as testing a patient sample and does not require any sample preparation. Refer to the control package inserts for all information including intended use.

Procedure:

When running the REDx™ FLOQ® SARS-CoV-2 Swab Positive and Negative Controls with the Metrix™ COVID-19 Test, the swab handle must first be cut to size. Using scissors, cut the swab handle 1.2 inches (3 cm) from the swab tip (see below). Insert the cut swab into the collector with the swab tip pointed downward into the center of the collector (see Step 2 of the Metrix™ COVID-19 Test QRI/IFU for a picture of the swab orientation). This is required to fit the Cap onto the Collector without spilling the blue neutralization buffer. The remainder of the test procedure (from Step 3 of the Metrix™ COVID-19 Test QRI/IFU) can be performed normally.



Results:

If the correct control results are not obtained, repeat the control tests using new control swabs and test components. Results from the repeated assay(s) must be acceptable to proceed. If acceptable results are not obtained, do not perform patient tests or report patient results. Contact SEKISUI Diagnostics Technical Support at +1.888.341.7206 or techservices@sekisuidiagnostics.com.

Aptitude recommends that the external controls be run:

- once for each new lot or shipment of tests received,
- once for each new operator,
- when problems with testing are suspected or identified,
- as deemed additionally necessary in order to conform with the laboratory's internal quality control procedures, with local, state and/or federal regulations, or accrediting groups.

Ordering Information:

To facilitate use with the Metrix test, the REDx™ FLOQ® SARS-CoV-2 Control Swabs are available in a 2-swab set, **Catalog# RED-S-19/99-P-01**, containing 1 Positive Control swab and 1 Negative Control swab. The Control set can be ordered through your Distribution partner in the same manner as the Metrix Reader and Metrix COVID-19 test. For additional information contact SEKISUI Diagnostics Customer Service at +1.800.332.1042 or USCS@sekisuidiagnostics.com.

Disclaimer: This bulletin was developed to provide assistance with External Quality Control testing for customers using the test in professional settings. It is the responsibility of the facility to ensure that an adequate external control program is in place, in accordance with federal, state, and local laws.