



**MEDICAL
LABORATORY
EVALUATION**

A SERVICE OF THE AMERICAN ASSOCIATION OF BIOANALYSTS

SARS-CoV-2 USA Changes

November 2023

In 2024, some SARS-CoV-2 tests will change from CLIA Waived to Moderate complexity.

It is important that you confirm the status of your test method by contacting the manufacturer of your test kit, and/or checking the [FDA medical device database](#).

If your method is Moderate Complexity, you will need to be enrolled in a 5-challenge proficiency testing module.

REPLY TO THIS EMAIL BY TUESDAY, NOVEMBER 21, 2023

to let us know if you need to enroll in one of these NEW 5-challenge modules for 2024:

697 – SARS-CoV-2 Antigen (5-challenge) \$522

698 – SARS-CoV-2 Molecular (5-challenge) \$531

If your kit is Waived Complexity, you do not need to change. The current 2-challenge modules, 688 and 689, will still be available for CLIA-waived methods and will be renamed as “Waived.”

Please contact us with any questions. Reply to this email, or call the Technical Support Group at 800.234.5315.