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FDA sets up SARS-CoV-2 reference panel for diagnostic tests

01 June 2020 | News

Reference panels are an additional step to ensure the quality of the tests

The U.S. Food and Drug Administration took a new step to support the agency's evaluation of diagnostic tests for COVID-19, by providing a SARS-CoV-2 reference panel.

Reference panels are an additional step to ensure the quality of the tests, validation of new assays, test calibration, and monitoring of assay performance.

Nucleic acid tests identify infection by confirming the presence of a virus' genetic material (RNA) and the FDA-supplied reference panel provides developers access to this material.

The FDA's reference panel is an independent performance validation step for diagnostic tests of SARS-CoV-2 infection that are being used for clinical, not research, purposes.

The FDA panel is available to commercial and laboratory developers who are interacting with the FDA through the pre-emergency use authorization (EUA) process.

These types of reference panels have proven to be an invaluable resource in the development of accurate, reliable, and validated diagnostic tests for detecting infectious diseases. The FDA has provided similar tools to assist industry in developing tests for other infectious diseases.

By providing this new tool to aid in the evaluation of diagnostic tests for SARS-CoV-2, the FDA continues its public health mandate in combatting this pandemic.