

AACC Practical Recommendations for Implementing and Interpreting SARS-CoV-2 Emergency Use Authorization and Laboratory-Developed Test Serologic Testing in Clinical Laboratories.

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Clin Chem Clin Chem 3817 pheoup 9421549 clinchem Clinical Chemistry 0009-9147 1530-8561 pmc-is-collection-domain yes pmc-collection-title Oxford University Press - PMC COVID-19 Collection PMC8083777 PMC8083777.1 8083777 8083777 34470034 10.1093/clinchem/hvab051 hvab051 1 Review AACC Practical Recommendations for Implementing and Interpreting SARS-CoV-2 EUA and LDT Serologic Testing in Clinical Laboratories Zhang Y Victoria victoria_zhang@urmc.rochester.edu Wiencek Joesph Meng Qing H Theel Elitza S Babic Nikolina Sepiashvili Lusie Pecora Nicole D Slev Patricia Cameron Andrew Konforte Danijela the AACC COVID 19 Serologic Testing Task Force 1 Department of Pathology and Lab Medicine, University of Rochester Medical Center 2 Department of Pathology, Microbiology, and Immunology, Vanderbilt University Medical Center 3 Department of Laboratory Medicine, Division of Pathology and Laboratory Medicine, The University of Texas/MD Anderson Cancer Center 4 Department of Laboratory Medicine and Pathology, Mayo Clinic 5 Department of Pathology and Laboratory Medicine, Medical University of South Carolina 6 Departments of Biochemistry and Laboratory Medicine & Pathobiology The Hospital for Sick Children/University of Toronto 7 Department of Pathology and Laboratory Medicine, University of Rochester Medical Center 8 Department of Pathology, University of Utah , ARUP Laboratories 9 Department of Clinical Microbiology, University of Rochester Medical Center 10 LifeLabs Medical Laboratories Equal Contribution

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characteristics of these assays and their clinical utility continue to be defined in real-time during this pandemic. The American Association for Clinical Chemistry (AACC) convened a panel of experts from clinical chemistry, microbiology, and immunology laboratories, the in vitro diagnostics (IVD) industry, and regulatory agencies to provide practical recommendations for implementation and interpretation of these serologic tests in clinical laboratories.

The currently available EUA serologic tests and platforms, information on assay design, antibody classes including neutralizing antibodies, and the humoral immune responses to SARS-CoV-2 are discussed. Verification and validation of EUA and LDTs are described along with quality management approach. Four indications for serologic testing are outlined. Result interpretation, reporting comments, and the role of orthogonal testing are also recommended.

This document aims to provide a comprehensive reference for laboratory professionals and healthcare workers to appropriately implement SARS-CoV-2 serologic assays in the clinical laboratory and interpret test results during this pandemic. Given the more frequent occurrence of outbreaks associated with either vector-borne or respiratory pathogens, this document will be a useful resource in planning for similar scenarios in the future.