

Microbiology Devices Panel of the Medical Devices Advisory Committee

FDA Questions for Panel – September 8, 2023

CDRH is seeking input from the Microbiology Devices Panel of the Medical Devices Advisory Committee on tests used in preparedness for and in response to future pandemics. Specifically, CDRH is seeking input on the following discussion points:

1. How can test developers (including both commercial manufacturers and laboratory test developers) best interact with CDRH when preparing for a future pandemic? What steps can CDRH take to strengthen its communication strategies in future pandemics with test developers, laboratories performing tests, and other stakeholders such as patients and clinicians? Were any methods of communication (town halls, telephone hotline, website FAQ, email boxes for stakeholders, EUA templates) more advantageous than others and what might CDRH consider doing differently in future pandemics?
2. What types of educational resources or communications from CDRH would be most valuable to aid test developers with respect to test development in preparation for a future pandemic?
3. Are there certain types of instrument manufacturers or test component manufacturers with whom CDRH should collaborate with in preparation for a future pandemic response to ensure test availability in a future pandemic. For example, would earlier engagement from CDRH to work with manufacturers of high throughput systems help ensure that well-designed, high-throughput tests can be made available at an appropriate volume to meet the needs of any future outbreak?
4. Are there certain types of tests or developers that should be prioritized for review in the early stages of a future pandemic? Examples include certain test types (e.g., diagnostic and high throughput), test protocol development for sharing with any laboratory, manufacturing capacity, or experienced test developers.
5. What are key features of tests or are there certain test designs that would be helpful in a future pandemic?
6. What other lessons from the recent COVID-19 pandemic and mpox emergencies might CDRH take into consideration in preparing for future pandemics?