Center for Devices and Radiological Health (CDRH)
Microbiology Devices Panel of the Medical Devices Advisory Committee

General Issues Meeting on Use of Pathogen-Agnostic Sequencing In Vitro Diagnostic Devices for Emergency Preparedness and Response Efforts

FDA Questions to the Panel

November 19, 2026

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

Use Cases for National Preparedness

1. What are the main benefits and risks of using pathogen-agnostic sequencing for emergency response, and how can the risks be mitigated?
2. How can the use of pathogen-agnostic sequencing be incorporated into the clinical workflow in the early stages of an outbreak? Later stages?
    a. What are the practical barriers to implementing these technologies in clinical and public health laboratory settings?
    b. How could the results be used to enhance the emergency response?
    c. What are the most critical factors for inclusion in the PAS results report in an emergency response context?
    d. Under what circumstances would reporting results to public health authorities be helpful for an emergency response?

Pathogen-Agnostic Sequencing Design

3. What are the critical design features for pathogen-agnostic sequencing to function safely and effectively in emergency preparedness/response scenarios?
    a. What are the considerations for establishing cut-offs for organism reporting?
    b. How generalizable is performance for one microbial species to another?

    c. What are the risks and potential mitigations in validating performance using a representative organism approach?
    d. What are the considerations for establishing and monitoring background signals (i.e., low level background contamination) over time?
4. How can bioinformatics systems and databases be designed and validated to remain agile even as pathogen sequences evolve?