Snapshot of Regulatory Issues of Importance to IVD Industry

April 2021

AdvaMedDx—Who we are

- Division of Advanced Medical Technology Association (AdvaMed)
  - World's largest association representing manufacturers of medical devices, diagnostics, and medical information systems

- AdvaMedDx committed to specifically addressing issues facing manufacturers of diagnostics in the United States and globally

Outline—Issues to be covered

- Diagnostics Regulatory Reform
- EUA Process and Access to Samples
- MDUFA IV and V
- CLIA/POC
- EMC Expectations
- Other

Dx Regulatory Reform

- Need for legislation for modernized, Dx-specific, risk-based approach for all Dx tests
- Single, predictable regulatory framework promotes innovation and patient access
- Bi-cameral, bi-partisan VALID Act introduced March 2020.

Dx Regulatory Reform, cont'd.

- Opportunity for refinements, including Tech Cert, modifications and fully risk-based approach
- Seeking reintroduction of improved VALID Act in Spring 2021
- Will continue work to improve and expedite advancement of VALID Act through the legislative process.

EUA Process and Access to Samples

- Streamlining availability of emergency Dx, drawing on lessons learned
- Working to advance proposals to support emergency Dx development through
  - Access to samples
  - Promoting use of real-world evidence
  - Clarifying CLIA-waiver status
  - Appropriate transition

MDUFA IV & V

- MDUFA IV Implementation
  - OHT7 Workload Challenges due to pandemic, including presubs & submissions
  - AdvaMed and AdvaMedDx closely monitor key metrics and regularly engage with FDA
- MDUFA V formal negotiations launched

CLIA/POC

- Working to ensure appropriate implementation of final CLIA-waiver guidances, which reflected AdvaMedDx recommendations
- Developing proposals to pursue risk-based policies for new or modified POC tests

EMC Instrumentation Expectations

- FDA shifted EMC instrument testing expectations
- Much higher testing levels per standard for therapeutics instead of longstanding standard for Dx
- Manufacturers discovered shift as part of submission review
- Working with FDA to address issue

Questions?