OIVD s Role in FDA Medical Countermeasure Initiatives

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CBRN Detection Devices

- Issues:
  - Few FDA cleared diagnostic devices
    - All are biothreat ,no chemthreat or biodosimetry tests
  - Most have been developed by CDC and DoD
    Some are available as lab developed tests
  - Clinical specimens hard to find or non-existent

CBRN Detection Devices

- Successes:
  - Collaboration
    - 4 DoD tests cleared on robust JBAIDS field lab. instrument
    - Pre-EUA review of 73 DoD tests has begun
    - FDA/DoD MOU agreement signed
    - DoD diagnostic expert 1 year detail program in place
  - Transparency
    - Clearance reviews posted on OIVD website
    - Two guidance docs. in draft form for anthrax and plague
  - CDRH CBRN Team formed 2 y ago
  - Pre-& Post-Market Tracking/Shortage
    - Processes in place

Cleared CBRN Devices

- Assay #
  - B.anthracis 5
  - Y.pestis 1
  - F.tularensis 3
  - Brucella sps. 6
  - Q fever 3
  - Alphavirus 1
  - Equine encephalitis 1

In the Pipeline-1

- Pre-IDE reviews in progress for 2 additional tests for the detection of biothreat agents
- Meeting held with BARDA to ensure ongoing collaboration for biodosimetry devices that they are funding and that FDA will review for clearance
- OIVD data base under development with general information about each CBRN and potential availability of reagents for diagnostic /surveillance use

In the Pipeline- 2

- For commercial multiplex devices. Recommendation to mix non-CBRT and CBRT tests in same panel (CBRT assays may be masked under non-emergency conditions)
- Pre-EUA submission review track considered a viable option by FDA for MCMs

Questions:

- Any questions concerning MCMs contact:
- the Division of Microbiology Devices for Biothreat diagnostic tests
- the Division of Radiology for Biodosimetry devices
- the Division of Hematology for Rad/Nuc diagnostic tests