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Highly Multiplexed Microbiological/Medical Countermeasure IVD NAT Devices
Considerations on the Draft Guidance

FDA-Industry IVD Roundtable Meeting

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Outline

- Overview/Role of HMMDs
- Background
- General Comments
- Specific Comments
- Looking Forward

Overview/Role of HMMDs

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- Appreciate FDA efforts to support development of HMMD devices, which
  - Serve public health
  - Support overall preparedness
- Represents challenging area for industry and FDA

Background

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- Industry provided a number of recommendations to provide flexibility and support implementation
- Key concerns regarding
  - proposed inclusion of design inputs/outputs
  - requirements for external QCs
  - significant clinical specimens/data
- Additional questions and technical comments

General Comments

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- Appreciate FDA consideration of streamlined approaches to analytical study design
- Would like to better understand rationale for 20 organisms/targets. Will concepts be applicable when <?
- Urge additional consideration of alternative approaches to promote HMMD development
  - e.g., testing of ancillary reagents, clinical specimens, assessment of co-infections

Design Inputs/Outputs

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- Call for inclusion of design inputs and outputs exceeds scope of 510(k) submission info
  - Requirement for QSR, not substantial equivalence
  - Contained in design history file
- *Summary of device risk analysis may be included*

Ancillary Reagent Testing

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- Suggests manufacturers are able to test every reagent
  - *Consider testing of select reagents (specific ancillary reagents)*
- Places manufacturers in untenable position of assessing user compliance with labeling instructions specific to ancillary reagents

External Controls

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- Recommends external quality controls for all validation testing
  - Analytical/clinical
  - Difficult to run external controls for every analyte
  - Internal controls may be sufficient to confirm assay/system performance
- *Consider on case by case technology basis, or a smaller, representative set of positive controls*

Clinical Specimens/Data

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- Recommends substantial clinical specimens/data
- *Need for patient information should be driven by the intended use*
- *Need to provide consistent advice for composite reference methods*

Looking Forward

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- Appreciate FDA efforts to support transparent, efficient approach
- Welcome further discussion with FDA
- Encourage consideration of key comments and other suggestions to improve guidance and facilitate the development of HMMDs

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