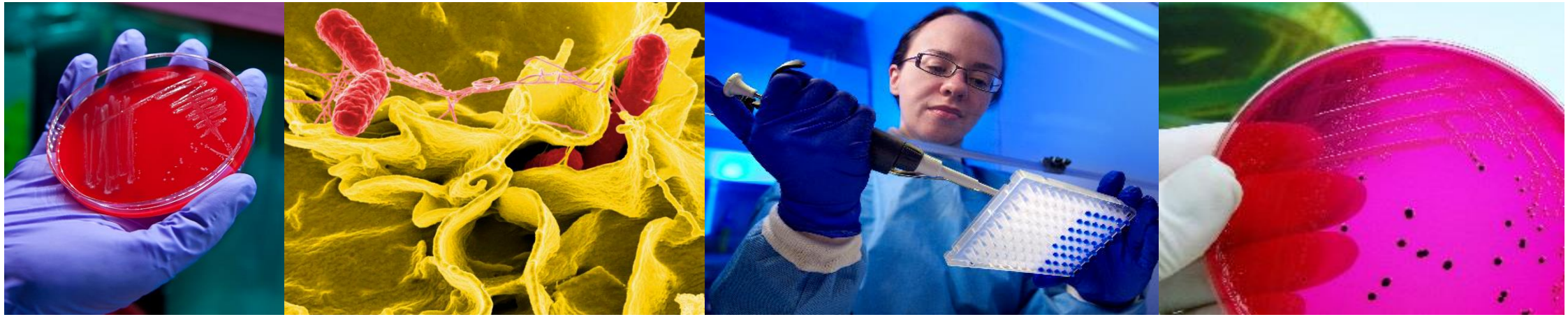
FDA – Industry IVD Roundtable Meeting

Culture Independent Diagnostic Initiative & Molecular Multi-Analyte Gastrointestinal Detection Panels – Public Health and Industry Efforts



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Advantages and Challenges

- New multiplexed diagnostic tests offer great benefit to physicians, patients, and laboratories
- High sensitivity and more rapid results as compared to conventional culture
- However, these new tests may hinder the ability to preserve viable organisms needed for public health related activities

We support continuing partnerships to ensure the availability of organisms for surveillance and susceptibility testing

Product Development – A Company Perspective

- **Customer requirements from "voice of customer" activities are gathered during Concept and Definition Phases**
  - Customer "must haves" and other requirements are documented through interviews with lab personnel, clinicians, administrators and other key stakeholders
  - Requirements are translated into specification
  - Technology solutions are chosen to meet specifications
  - Conflicting requirements can create challenges
    - e.g., cell lysis required for testing while preserving a viable organism

Opportunities for Improvement in Product Development

- **Ensure engagement with public health laboratories in "voice of customer" activities**
  - Understand and incorporate public health needs into the product development process
- **Encourage incorporation of future public health needs for access to needed specimens in the event that a notifiable pathogen is detected**
- **Manage conflicting product requirements**

Opportunities to Improve Collection and Preservation of Isolates

- **Laboratories are required to follow manufacturers instructions according to the Clinical Laboratory Improvement Amendments (CLIA)**
  - AdvaMedDx members support providing public health recommendations to clinical labs
  - Information should reinforce the need to preserve isolates or clinical materials for submission to the appropriate public health laboratory
    - <u>Precaution related to Public Health Reporting</u>:
      Laboratories must follow state and/or local rules pertaining to reportable pathogens and should consult their local and/or state public health laboratories for isolate and/or clinical sample submission guidelines

Opportunities to Better Understand the CIDT Landscape

Provide informational resources for labs

- FDA could, for example, post a list of approved or cleared molecular diagnostics on the FDA website
  - This will serve as a helpful resource on new molecular multi-analyte gastrointestinal (GI) disease agent detection panel devices that are cleared or approved with a one-stop shop for understanding how specimens are processed

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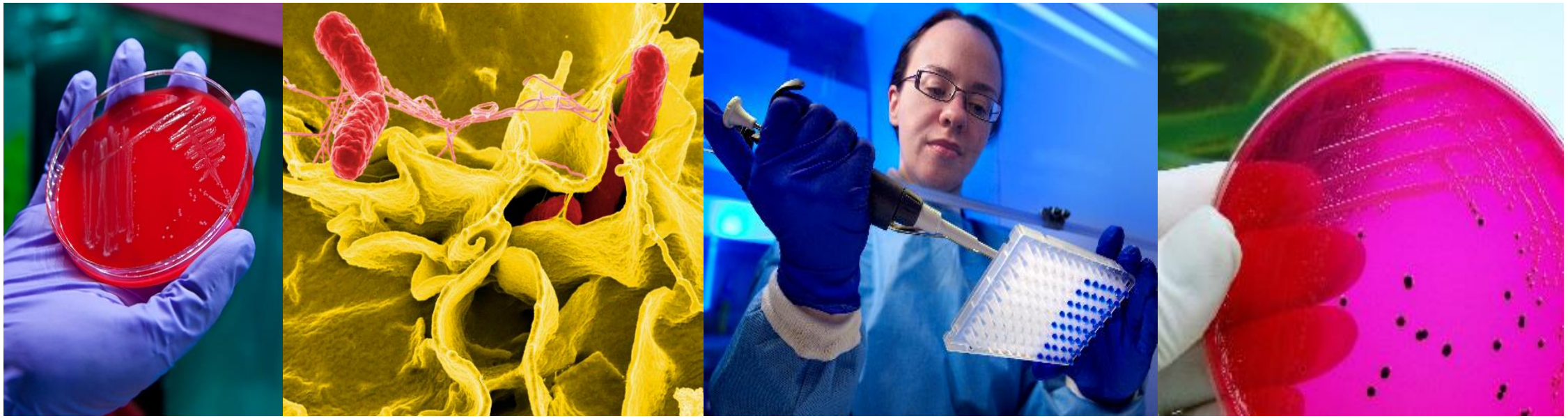

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