U.S. FOOD & DRUG ADMINISTRATION

Public Workshop: Antimicrobial Susceptibility and Resistance: Addressing Challenges of Diagnostic Devices

Welcome back!

Progress

- **Rome wasn't built in a day, but they were laying bricks every hour...**

Progress

Cleared Devices –Direct from Specimen

- **Cepheid MRSA**: nasal, wound, blood culture
- **Cepheid van-R**: *van*A/*van*B – rectal swabs
- **Cepheid Carba-R** – bacterial isolates, rectal swabs (five carbapenemase RMs, *kpc*, *ndm*, *vim*, *imp*, *oxa*-48, CTX-M)

- **Biofire BCID (multiplex)** – positive blood cultures (*mec*A, *van*A, *van*B, *kpc)*
- **Nanosphere BC-GP and BC-GN (multiplex)** – positive blood cultures (BC-GP: multiple organisms plus *mec*A, *van*A, *van*B) (BC-GN: multiple organisms plus *kpc*, *ndm*, *vim*, *imp*, *oxa*-48, CTX-M)
- **Icubate and Great Basin:** Positive blood cultures: Staph. Enterococcus, *mec*A, *van*A, *van*B
- **Cepheid MTB-RIF:** sputum, TB and rifampin resistance marker

Challenges

- Exceptional progress has been made yet challenges exist; it is because of these new challenges that we are here today
  - More complex use cases and more complex devices which detect greater than 10 analytes and with the capability of detecting common and “newer” resistance genes
  - Non-sterile specimen analysis (e.g., when is it appropriate to report commensal organisms)
  - AMR gene detection by PCR is a little more nuanced than organism ID (small gene targets, expression, alt AMR mechs.)
  - Develop labeling which fulfills our transparency requirements and also helps clinicians and users understand the value and limitations of the IVD device.
  - Dual goal to improve patient management and stewardship

Immediate Goals

- Better understand the issue and gather input from you on the scope of the challenges.
  - What information do comparator(s) methods confer about the patient status? Direct from specimen vs. from cultured isolate; Molecular vs. phenotypic
  - How to analyze and present data from multiple comparator methods?
  - What information will help physicians make better decisions?
- How to present data when there are multiple organisms and/or markers detected in one specimen?
  - Particularly difficult for “non-sterile” sources where marker can be from one of multiple organisms

Agenda

Afternoon Session - New Technologies for Detection of Resistance

Time	Topics	Presenter(s)
1:00-1:05PM	Introduction to Afternoon Session	Kristian Roth FDA, CDRH
1:05-1:25PM	Recent Industry Experience and Perspective on the Advantages and Challenges of Methods for the Detection of Resistance Markers	Mike Dunne bioMérieux
1:25-1:40PM	Public Health Implications of Antimicrobial Resistance Surveillance	Daniel Sahm IHMA
1:40-2:00PM	Clinical and Laboratory Experience with Interpretation and Reporting Resistance Markers	Patricia Simner Johns Hopkins Hospital
2:00-2:15PM	FDA Perspective on Scientific Review of Novel Technologies for Detection of Resistance	Kimberly Anderson FDA, CDRH
2:15-2:40PM	Challenges of the Clinical Use and Interpretation of Genotypic vs. Phenotypic Drug Resistance Testing	Robert Bonomo Cleveland VA MC Scott Evans Harvard University
2:40-2:55PM	Efforts and Resources for Addressing Antimicrobial Resistance	Jean Patel CDC
2:55-3:15PM	Public Comments	Patricia Conville FDA, CDRH
3:15-3:30PM	Break	
3:30-5:00PM	Panel Discussion	
5:00-5:10PM	Closing Remarks	Uwe Scherf FDA, CDRH

Your Role

- Think about the questions!
- Network
- DOCKET!