



OIVD Update

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Organizational Change - Center

- Dan Schultz, MD - retired
- Jeff Shuren, MD, JD – acting
- Nation wide search in progress for
 - New Director
 - New Deputy for Science
 - New Deputy for Policy



Agency Initiatives

- Protecting Public Health
 - Quick compliance actions
 - Pro-actively manage public health issues
 - Glucose Meters
 - Personalized Medicine



Agency Initiatives

- Transparency
 - Twitter
 - Public Meetings
 - Youtube



Agency Initiatives

- Program review – 510(k)
 - Internal Review
 - IOM Review



Organizational Change – OIVD+

- Office Musical Chairs

- Aldon St.Pierrez
- Mary Pastel – Associate Director
- Zivana Tezak - Associate Director for Science and Technology
- Marina Kondratovich– Associate Director for Clinical Studies

- Radiology Branch



OIVD+ - getting our day job done

- Meeting MDUFMA timelines
- Hiring and training new reviewers



Guidances

- Antimicrobial Susceptibility Test
- Detection or Detection and Differentiation of HPV
- Registration and Listing
- eMDR - Electronic Medical Device Reporting
- H1N1 EUA



Guidances – Special Controls

- Respiratory Panel
 - Influenza A Virus Subtypes
 - Human Metapneumovirus (hMPV)
 - Respiratory Viral Panel Multiplex
- Cardiac Allograft Gene Expression Profiling Test



Notable New Approvals/Clearances

- Clearances
 - OVA1



Emergency Use Authorizations

- 12 EUAs
- CDC, Manufacturers, and CLIA laboratories



Notable Meetings

- Advisory panel meeting on HemoCue's White Blood Cell Analyzer waiver application
- Advisory panel meeting on Digital Pathology
- FDA-IDSA Respiratory Track Infections workshop