

OIVD Update

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Organizational Change

- Uwe Scherf
 - Deputy Director Microbiology
- Reena Philip
 - Deputy Director Immunology Hematology
- Carol Benson
 - Deputy Director Chemistry Toxicology

Guidances

- Detection of *Helicobacter pylori*
- Class II Special Controls Guidance
Document: Herpes Simplex Virus Types
1 and 2 Serological Assays
- Detection of *Clostridium difficile*

- Detection of Antibodies to *Borrelia burgdorferi*
- Nucleic Acid-Based In vitro Diagnostic Devices for the Detection and Differentiation of Methicillin-Resistant *Staphylococcus aureus* (MRSA) and *Staphylococcus aureus* (SA)
- Ovarian Adnexal Mass Assessment Score Test System

- Screening and Diagnostic testing for *Chlamydia trachomatis* and/or *Neisseria gonorrhoea*
- Detection and identification of *Bacillus spp.*

- 30-Day Notices, 135-Day Premarket Approval (PMA) Supplements and 75-Day Humanitarian Device Exemption (HDE) Supplements for Manufacturing Method or Process Changes
- Electronic Source Documentation in Clinical Investigations

- RUO/IUO

- As a result of the publication of the final 2007 ASR rule we have seen an increase in the number of previously labeled “ASRs” being market as RUO
- This draft guidance document is intended to clarify the types of in vitro diagnostic (IVD) products that are properly labeled “for research use only” (“RUO”) or “for investigational use only” (“IUO”)

Notable Approvals

- Dako's Her2 for Gastric Cancer
- OraQuick HCV Rapid Antibody Test
- Roche's cobas HPV Test
- Ortho's VITROS® Immunodiagnostic Products HBeAg
- Abbott's RealTime HCV

Notable De novo's

- **Norovirus Assay**

Notable clearances

- Leishmaniasis
- Q fever
- toxoplasmosis parasite
- Diagnose and distinguish MRSA and MSSA
- Everolimus Immunoassay

Significant Recalls

- Beckman Coulter, Inc., Synchron LX Clinical Systems Ion Selective Electrolyte (ISE) Flow Cell
- bioMérieux, Inc., VITEK® 2 Gram Negative Susceptibility Cards Containing Piperacillin/Tazobactam (TZP2) – Expanded Recall
- Gen-Probe Inc., AccuProbe Group B Streptococcus Culture Identification Test, AccuProbe Mycobacterium Tuberculosis Complex Culture Identification Test, and AccuProbe Mycobacterium Avium Complex Culture Identification Test
- Abbott Glucose Test Strips

DTC genetic testing

- Letters to manufactures advising them they were marketing IVDs.
- Congressional Hearing
- GAO report
- Manufacturers and FDA are working on bringing the manufacturers into compliance
- Public Panel Meeting March 8th and 9th

LDTs

- Public Meeting – July 19th and 20th on strengthening Oversight.
- Docket open until September 15th
- FDA plans to publish a guidance on the overall regulatory framework, a guidance on collecting information on what tests are offered, and a guidance describing the synergies between CLIA regulations and QSr.

June Meetings

- Ultra High Throughput Sequencing for Clinical Diagnostic Applications - Approaches to Assess Analytical Validity, June 23, 2011
- TB and HIV Diagnostics in Adult and Pediatric Populations scheduled for June 28-30

Other Happenings

- Continuing to integrate radiology
- Oversight of 3rd Party review program now within OIVD
- Impact of proposed reorg on OIVD
- Unclassified products – may be some upcoming classification panels