

Regulatory Issues: Everything You Need to Know but Didn't Know You Should Ask

Beverly Metchock, DrPH, D(ABMM)

Mycobacteriology Laboratory Branch/Division of TB Elimination

June 21, 2010

Background and Format

Currently many TB laboratories are using or are planning to use:

Laboratory developed tests (LDTs);

FDA-approved tests “off-label;”

Commercially-available “Research Use Only” tests.

- ❑ Food and Drug Administration (FDA) regulates manufacturers
- ❑ Centers for Medicare and Medical Services (CMS) regulates laboratories (CLIA)

- ❑ This session is NOT the place to put FDA/CMS/CDC on the “hot seat”
- ❑ This session is an open forum for respectful discussion - learn the rules so we can do our jobs effectively, ethically, and in compliance with regulations

FDA/CDC/NIAID Public Workshop: Advancing the Development of Diagnostic Tests and Biomarkers for Tuberculosis

- ❑ June 7-8,2010
- ❑ Participants from USG, NGOs, WHO, industry, academia
- ❑ Workshop materials posted:
 - www.regulations.gov
Docket No.FDA-2010-N-0156

Upcoming FDA Public Meetings

- June 24 – Public Workshop: Identifying Unmet Public Health Needs and Facilitating Innovation in Medical Device Development:
<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212831.htm>
- July 19-20, 2010 - FDA/CDRH Public Meeting: Oversight of Laboratory Developed Tests (LDTs):
<http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm212830.htm>

Format for this morning:

FDA perspective: Steve Gitterman, MD, PhD

CMS perspective: Kathleen Todd, MT (ASCP)

Panel – Case studies with polling questions

Denise Dunbar, MT(ASCP) – TX Dept. of State Health Services

Devery Howerton, PhD – CDC

Ray Kaplan, PhD – Quest Diagnostics

Susan Mylar, MT(ASCP) – CMS

Mark Pandori, PhD – San Francisco Dept. of Public Health

Questions/comments from audience at the end