Tiered Networks & Regulation of Diagnostics

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Disclosure

• I have no actual or potential conflict of interest in relation to this program/presentation.
Functional, Tiered National Laboratory Networks

- Provide laboratory confirmation for priority diseases
- Support national integrated disease surveillance
- Provide individual patient care

Universal Health Coverage

Health Security
Core Capabilities – Effective Networks

- Effective Networks
- Supply Chain/Equip Mgt
- Governance/Org
- Workforce
- Policy/Regulation
- Surveillance
- Quality
- Biosafety/Biosecurity
- Sample ref/transport
- National
- Regional
- District
- Health Center
- Community
- Infracts
Required Actions – Regulation of Diagnostics

- National IVD and medical device regulation policy
- Pre-marketing IVD registration
- Post-marketing surveillance and publication of a national authorized reagent list every year
Regulation of Diagnostics in Africa

• Few countries with capacity to review each IVD for quality, safety, and performance in pre-market setting, although many have legal mandate
• Some research labs evaluate IVDs but post-market surveillance is rare
• Control of medical devices and IVDs often confined to national disease control programs (i.e. TB, HIV...)

ASLM
Opportunities

- AFCAD (Africa Collaborative Initiative to Advance Diagnostics)
- Regional harmonisation (i.e. Pan African Harmonisation Working Party)
- WHO EDL and pre-qualification
- International Medical Devices Regulatory Forum
- ASLM Framework – IVD regulation during outbreaks