

# **CLIA Proficiency Testing Regulations for Microbiology**

**CLIAC Meeting**

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## **General Regulations in Subpart H Apply**

- ❑ Enroll in PT program for each specialty and subspecialty for certification**
- ❑ Test the samples in the same manner as patient's specimens**
- ❑ Don't send PT samples or portions of samples to another laboratory for analysis which a laboratory is certified to perform in its own laboratory**
- ❑ PT required only for the test system/assay used as primary method for patients**



# Current Regulated Analytes

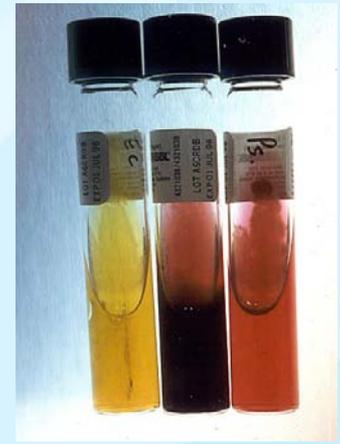
- ❑ **Diagnostic Immunology**
  - Syphilis Serology
  - General Immunology – 15 analytes
- ❑ **Chemistry**
  - Routine Chemistry – 25 analytes
  - Endocrinology – 7 analytes
  - Toxicology – 15 analytes
- ❑ **Hematology – 10 analytes**
- ❑ **Immunochemistry – 5 analytes**
- ❑ **Microbiology – 0 analytes**



# Specialty of Microbiology

## □ 5 Subspecialties:

- Bacteriology
- Mycobacteriology
- Mycology
- Parasitology
- Virology



- ## □ For each subspecialty, unsatisfactory performance = failure to attain an overall testing event score of at least 80%





# Regulations for Subpart I- PT Programs for Bacteriology

- **Five types of laboratories based on types of services offered:**
  1. Gram stain and/or primary inoculation
  2. Direct antigen techniques +/- gram stain and primary inoculation
  3. #2. plus ID to genus level aerobic bacteria from superficial sites (throat, urine, cervical, urethral) and susceptibility testing
  4. #2. plus ID to species level aerobic bacteria from any source plus susceptibility testing
  5. #4. plus ID anaerobic bacteria



# Regulations for Subpart I- PT Programs for Bacteriology

- ❑ 5 samples /testing event; 3 testing events /yr
- ❑ Samples must contain representatives from 6 major groups of bacteria:
  - Anaerobes
  - *Enterobacteriaceae*
  - Gram positive bacilli
  - Gram positive cocci
  - Gram negative cocci
  - Miscellaneous gram negative bacteria
- ❑ 50% of the samples mixture of principal pathogen plus normal flora



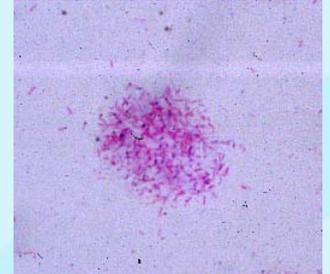
} 1 AST/event



# Regulations for Subpart I- PT Programs for Mycobacteriology

## □ Five types of laboratories based on types of services offered:

1. Acid-fast stain and refer
2. Acid-fast stain, primary inoculation and refer
3. Acid-fast stain, isolate and ID M.tb +/- susceptibility and refer MOTT
4. Acid-fast stain, isolate and ID all mycobacteria and refer susceptibility testing
5. Acid-fast stain, isolate, ID and susceptibility testing on all mycobacteria





## **Regulations for Subpart I- PT Programs for Mycobacteriology**

- ❑ 5 samples / testing event; 2 testing events /yr**
- ❑ Samples must contain representatives from 5 major groups (complexes) of mycobacteria:**
  - TB (TB / *M. bovis*) + 1 AST /event**
  - Group I (*M. kansasii*)**
  - Group II (*M. szulgai*)**
  - Group III (MAI)**
  - Group IV (*M. fortuitum*)**
- ❑ 50% of the samples mixtures of principal mycobacteria and normal flora**



# Regulations for Subpart I-PT Programs for Mycology

- **Four types of laboratories based on types of services offered:**
  1. Isolate and ID yeasts and /or dermatophytes to genus level
  2. Isolate and ID yeasts and /or dermatophytes to species level
  3. Isolate and ID all fungi to genus level
  4. Isolate and ID all fungi to species level





# Regulations for Subpart I-PT Programs for Mycology

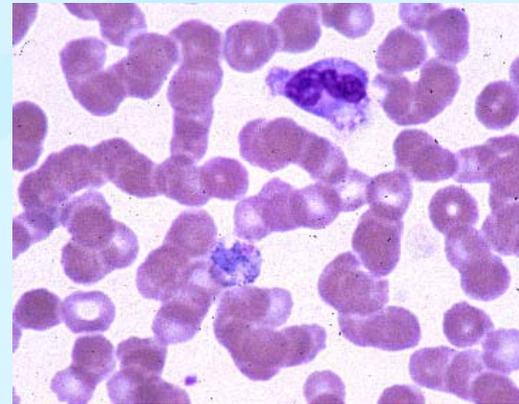
- ❑ 5 samples / testing event; 3 testing events /yr
- ❑ Samples must contain representatives from 5 major groups of fungi:
  - Yeast / yeast-like fungi (*Candida albicans*)
  - Dimorphic fungi (*Blastomyces*)
  - Dematiaceous fungi (*Exophiala*)
  - Dermatophytes (*Trichophyton*)
  - Saprophytes / opportunistic fungi (*Aspergillus*)
- ❑ No susceptibility testing required





# Regulations for Subpart I-PT Programs for Parasitology

- **Two types of laboratories based on types of services offered:**
  1. Direct observation (wet mount) or pinworm prep and refer
  2. Use concentrated prep and permanent stains





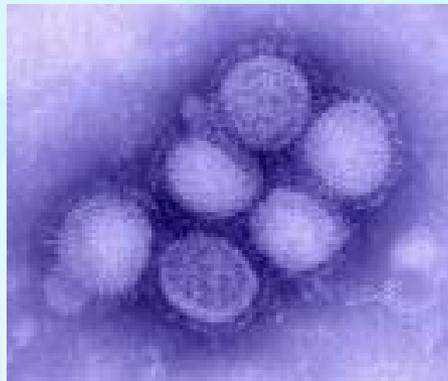
# Regulations for Subpart I- PT Programs for Parasitology

- ❑ **5 samples / testing event; 3 testing events /yr**
- ❑ **Samples must include:**
  - Formalized specimens
  - PVA fixed specimens
  - Blood smears
  - Some samples without parasites
- ❑ **No PT required for direct antigen techniques**



# Regulations for Subpart I-PT Programs for Virology

- ❑ **Two types of laboratories based on types of services offered:**
  1. Direct detection of viral antigen or structure
  2. Isolate and ID viruses and use direct antigen detection
- ❑ **5 samples / testing event; 3 testing events / yr**
- ❑ **No provision for ID viruses by molecular methods**





## Regulations for Subpart I- Scoring for Microbiology

- ❑ Program must compare laboratory's response for each sample with response that reflects agreement with 80% of 10 or more referee labs or 80% of all participating laboratories
- ❑ Deduct credit for reporting additional organisms not in the sample
- ❑ Laboratories evaluated only on the drugs routinely reported on patients
- ❑ Score for testing event is average of scores for each type of testing performed

