



# Implementation of Cytology PT

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# Presentation Topics

- Law, Regulations
- Approved PT Programs - 2005
- Cytology PT Implementation
- Diagnostic Categories
- Data Collection, Reporting
- Cytology PT After 2005
- Additional Information



# CLIA Law---October 31, 1988

“Periodic confirmation and evaluation of the proficiency of individuals involved in screening or interpreting cytological preparations, including announced and unannounced on-site proficiency testing of such individuals, with such testing to take place, to the extent practicable, under normal working conditions.”



# CLIA Regulations---February 28, 1992

- Contain specific requirements for Cytology

Proficiency testing – Subpart H and Subpart I

- o Subpart H – Laboratories

- o Subpart I – Proficiency Testing (PT) Program

<http://www.phppo.cdc.gov/clia/regs/toc.aspx>



# Subpart H---Laboratory Requirements

The laboratory must ensure:

- Each individual performing gynecologic cytology examinations is enrolled in a program
- Each individual obtains a passing score (90%)
- Required remedial actions are taken following any failure of a testing event



# Subpart I---PT Program Requirements

The PT program must:

- Submit application by July 1 for approval to begin regulatory testing the next calendar year
- Be private, non-profit
- Provide annual testing and retesting (for failures)
- Provide announced and unannounced testing



# Subpart I---PT Program Requirements (Continued)

- Compile 10 and 20 glass slide test sets
  - ❖ Reference slides with consensus of a minimum of 3 pathologists
  - ❖ Include one slide from each diagnostic category
- Score tests using CLIA scoring for pathologists (TS) and cytotechnologists (CT)
- Provide test reports to participants, laboratories, CMS
- Maintain documentation of testing



# Reapproval of PT Programs

PT program must:

- Submit reapproval application by July 1 for next calendar year
- Provide information on testing experience for previous testing cycle
  - ❖ Number of CT and TS Enrolled and Tested
  - ❖ Pass/Fail Data
  - ❖ Retest Data
  - ❖ Changes to Program
  - ❖ Additional Information



# CLIA Approved PT Programs 2005

- State of Maryland Cytology Proficiency Testing Program (1994)
- Midwest Institute for Medical Education, Inc. (2004)

\*Enrollment in one of these programs is required.



# Implementation Timeline



Ensure each person:

Laboratory Dates

CMS Dates

Is enrolled

June 30, 2005

June 30, 2005

Has been tested

December 31, 2005

April 2, 2006

Has passed

December 31, 2006

December 31, 2006



# What does this mean?

The laboratory must ensure each CT and TS examining gynecologic preparations:

- June 30, 2005 is enrolled in a CLIA approved PT program
- December 31, 2005 has been tested at least once
- December 31, 2006 has achieved a passing score
- December 31, 2006 has taken remedial actions, for any testing event failure

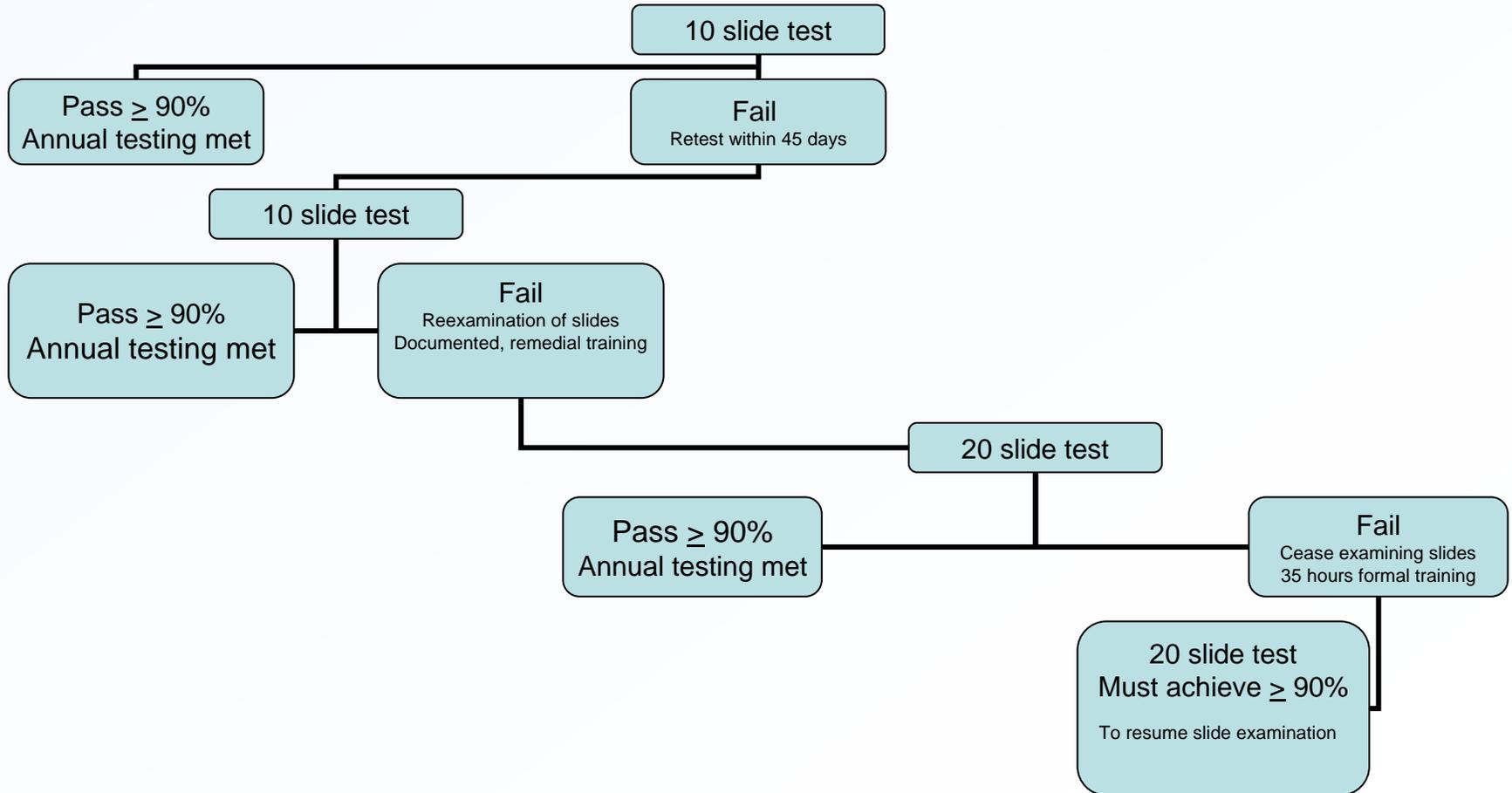


# Testing Sequence

- Initial - 10 slide test
- Retest - 10 slide test
- Second retest – 20 slide test
- Third retest – 20 slide test



# Testing Sequence





# PT Diagnostic Categories

- A **Unsatisfactory** for diagnosis due to:
  - ❖ Scant cellularity
  - ❖ Air drying
  - ❖ Obscuring material (blood, inflammatory cells, or lubricant)
- B **Normal or Benign Changes**--includes:
  - ❖ Normal, negative or within normal limits
  - ❖ Infection other than Human Papillomavirus (HPV) (e.g., Trichomonas vaginalis, changes or morphology consistent with Candida spp., Actinomyces spp. or Herpes simplex virus)
  - ❖ Reactive and reparative changes (e.g., inflammation, effects of chemotherapy or radiation)
- C **Low Grade Squamous Intraepithelial Lesion**--includes:
  - ❖ Cellular changes associated with HPV
  - ❖ Mild dysplasia/CIN-1
- D **High Grade Lesion and Carcinoma**-- includes:
  - ❖ High grade squamous intraepithelial lesions which include moderate dysplasia/CIN-2 and severe dysplasia/carcinoma in- situ/CIN-3
  - ❖ Squamous cell carcinoma
  - ❖ Adenocarcinoma and other malignant neoplasms.



# Remediation for 2005

If remedial action is required:

- Laboratories must ensure individuals receive appropriate training
- Laboratories must document training and submit information to PT provider
- PT provider will submit this information to CMS
- Individual must be retested
- CMS is giving wide discretion the first year



# Reportable Information

Within 15 days, the PT Provider must report results to CMS and the following:

- To the Individual – score, pass/fail, and if appropriate, area of failure
- To the Laboratory Director – summary of results for all participants in the laboratory – score, pass/fail, and if appropriate area of failure
- In the event the individual works at multiple laboratories, results will go to the Laboratory Director at each laboratory



# CYPERS

- Cytology Personnel Record System
- Monitor enrollment and participation
- Record of individual scores
- Ensure compliance with CLIA requirements



# Testing in 2006 and Future

- Individuals must be enrolled and tested annually
- Laboratories must ensure enrollment, annual testing and remedial actions (if needed)
- Laboratories must stay in a program for one year before switching to another program



# Approval of Other Programs

The program must:

- Submit application by July 1, 2005 for approval and testing beginning January 1, 2006
- Meet requirements in subpart I
  - ❖ Be non-profit
  - ❖ Provide annual testing and retesting (for failures)
  - ❖ Provide announced and unannounced testing
  - ❖ Compile 10 and 20 glass slide test sets
    - o Reference slides with consensus of 3 pathologists
    - o Include one slide from each category
  - ❖ Score tests using CLIA scoring for pathologists (TS) and cytotechnologists
- Provide test reports to participants, laboratories, and CMS
- Maintain documentation of testing



# Summary of Requirements for 2005

The laboratory must ensure each CT and TS:

- June 30, 2005 is enrolled in a CLIA approved PT program
- December 31, 2005 has been tested at least once
- December 31, 2006 has achieved a passing score
- December 31, 2006 has taken remedial actions, for any testing event failure



# Questions and Concerns

**CDC CLIA hotline 770-488-8155**

**<http://www.phppo.cdc.gov/clia/default.aspx>**

**CMS 410-786-3531**

**<http://www.cms.hhs.gov/clia/default.asp>**