

Cytology Update

Centers for Medicare & Medicaid
Division of Laboratory Services
September 20, 2006



2005 National Cytology Proficiency Testing Results

Initial Testing Event

<u>Totals</u>	<u>Scored 90%</u>	<u>Did Not Score 90%</u>
12,831	11,654 (91%)	1,177 (9%)



2005 National Cytology Proficiency Testing Results

Initial Testing Event

<u>Type</u>	<u>Scored 90%</u>	<u>Did Not Score 90%</u>
CT	6,083 (93%)	447 (7%)
Pri MD	312 (67%)	156 (33%)
Sc MD	5,242 (90%)	570 (10%)
LT	17 (80%)	4 (20%)

Cytology Proficiency Testing 2006 Preliminary Data

Initial Testing Event

<u>Totals</u>	<u>Scored 90%</u>	<u>Did Not Score 90%</u>
5,947	5,663 (95%)	284 (5%)

Cytology Proficiency Testing 2006 Preliminary Data

Initial Testing Event

<u>Type</u>	<u>Scored 90%</u>	<u>Did Not Score 90%</u>
CT	2,984 (96%)	134 (4%)
Pri. MD	222 (89%)	27 (11%)
Sec. MD	2,450 (95%)	123 (5%)
LT	7 (100%)	0 (0%)

Specialized Reviews of Cytology Laboratories

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Statutory Authority

“ standards requiring periodic inspection of cytology services by persons capable of evaluating the quality of cytology services.”

Laboratory Selection

- **Complaints**
- **Nominations**
- **Random**

Survey Team Composition

- Project Director/Technical Director
- Survey Team Leader
- Survey Team Members
- On-Call Cytopathologist
- CMS Project Officer

Survey Process

- **Laboratory Selection**
- **Contractor Notification**
- **Survey Team Development**
- **Laboratory Notification**

Survey Process (Continued)

- On-Site Survey
- Statement of Deficiencies (2567)
 - Standard Level
 - Condition Level
 - Immediate Jeopardy
- Plan of Correction (POC)

Enforcement

- **Principal Sanctions**
 - **Suspension**
 - **Limitation**
 - **Revocation**

Enforcement (Continued)

Alternative Sanctions

- Directed Plan of Correction
- On-site Monitoring by State
- Civil Money Penalty

Appeals

- **Administrative Law Judge Hearing (ALJ)**
- **Departmental Appeals Board**

Civil Action

- U.S. District Court
 - Temporary Injunction
 - Restraining Order

Criminal Sanctions

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Laboratory Registry

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Specialized Review of Cytology Laboratory Survey Findings

July 1988-August 2006

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Laboratories Surveyed

Laboratories Surveyed: 616

Independent Laboratories: 520

Hospital Laboratories: 96

Surveys Performed

Surveys Performed: 657

Routine: 346*

Complaint: 158*

Revisit: 30

Focus: 39

* Data not tracked on 84 laboratories
from 7/88 through 9/92

Additional Information

# Laboratories Surveyed	616
# Laboratories With Condition Level Deficiencies	199
# Laboratories Sanctioned by CMS	11
# Laboratories Terminated from CLIA Program	7
# Laboratories Voluntarily Withdrew from CLIA Program	5



Comparison # Laboratories Surveyed

07/88-09/02

10/40-8/06

Labs Surveyed:

533

83

Ind. Labs:

448 (84%)

72 (86%)

Hospital Lab:

85 (16%)

11 (13%)

Comparison # Surveys Performed

7/88-9/02

10/04-8/06

Surveys Performed:	569	88
Routine:	282* (50%)	64 (73%)
Complaint:	139* (24%)	19 (22%)
Revisit:	29 (5%)	1 (1%)
Focus:	35 (6%)	4 (5%)

* Data not tracked on 84 laboratories from 7/88 through 9/92

Comparison of Additional Information

	7/88-9/02	10/04-8/06
# Labs Surveyed	533	83
# Labs With Condition Level Deficiencies	184 (35%)	15 (18%)
# Labs Sanctioned by CMS	11 (2%)	0 (0%)
# Labs Terminated from CLIA Program	6 (1%)	1 (1%)
# Labs Voluntarily Withdrew from CLIA Program	3 (<1%)	2 (2%)



Thank You!

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