

# Cytology Update

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

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# 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%)

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# 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%)

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# 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

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# 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

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# 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

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# Comparison of Additional Information

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

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Thank You!

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