

# Clinical Laboratory Improvement Amendments of 1988 (CLIA)

## NATIONAL CYTOLOGY PROFICIENCY TESTING 5 Year Review

Centers for Medicaid and Medicare Services  
Survey and Certification Group  
Division of Laboratory Services

June 2010



## *Importance*

- Pap Tests detect changes in the cervix before they develop into cancer.
- Approximately 55 million Pap smears were performed annually (2009) \* 6% expected to be abnormal (3.5 million)
- 74% decrease in cervical cancer deaths due to implementation of the Pap Test.
- Cervical cancer in 2007 ranked # 14 in frequency.

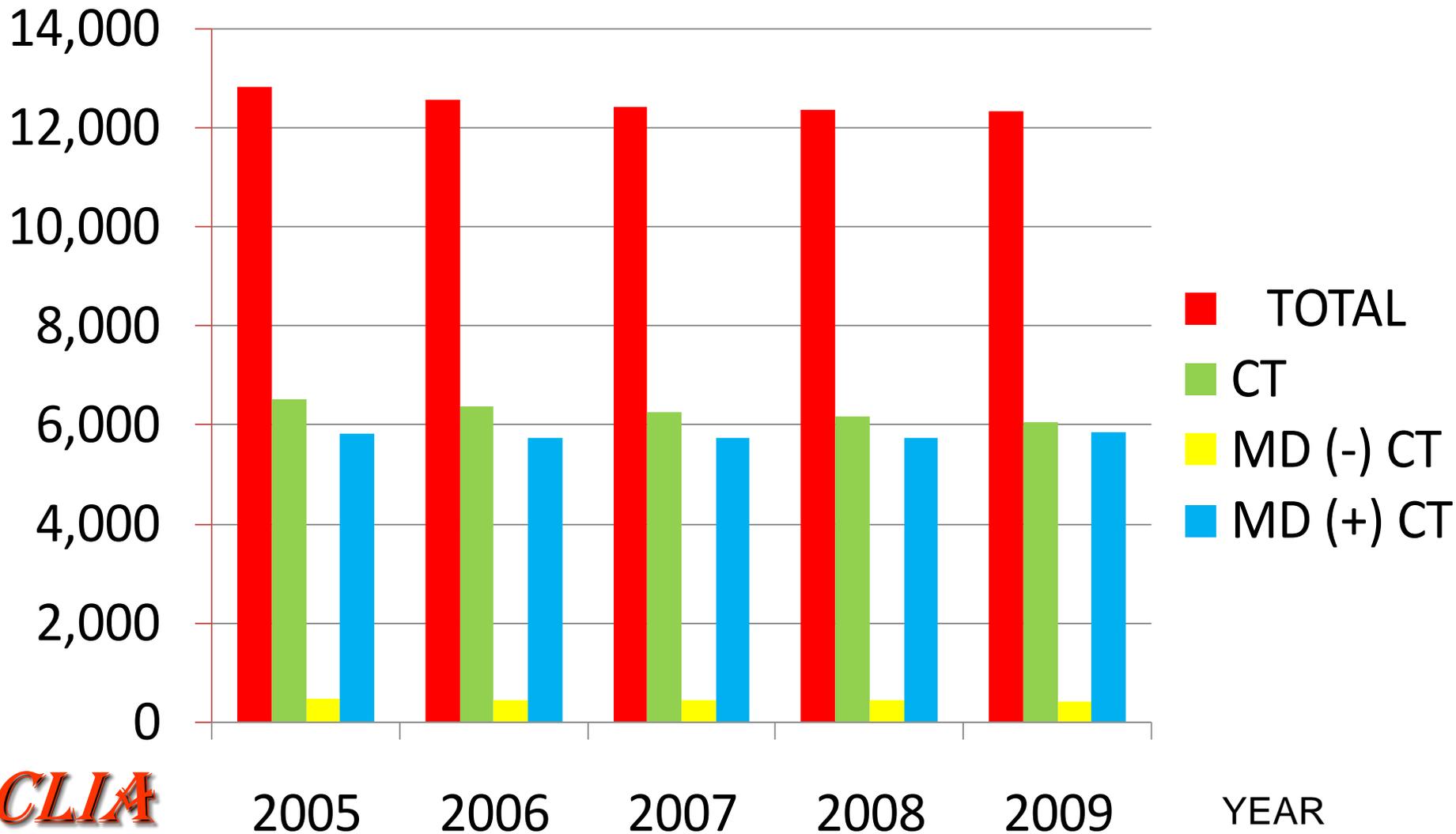
\* **CLIA**

\*data available at NIH/NCI

# Test Sequence

- Initial Test - 10 slide test-2 hours
  - If unsuccessful, schedule re-test within 45 days
- First Retest - 10 slide test-2 hours
  - If unsuccessful, may continue to screen, but slides must be reviewed. Obtain additional education & then re-test
- Second retest – 20 slide test- 4 hours
  - If unsuccessful, cease gyn cytology screening, obtain further education (but may continue to perform other duties)
- Third retest – 4<sup>th</sup> attempt-20 slide test-4 hours

# Cytology PT Participation (2005-2009)



# National 2009

INITIAL TEST (10 slides/2hours)								
			Total Tested		PASS	%	Unsuccessful	%
<b>Participant</b>			<b>12346</b>		11989	97%	357	3%
<b>CT</b>			6064		5911	97%	153	3%
<b>Path with cytotechnologist</b>			5861		5709	97%	152	3%
<b>Path without cytotechnologist</b>			421		369	88%	52	<b>12%</b>

# 2009 Results

Initial Testing Event (10 Slides in 2 Hours)

<u>participant</u>	<u>Successful</u>	<u>Unsuccessful</u>
CT	5911 (97%)	153 (3%)
MD (-) CT	369 (88%)	52 (12%)
MD (+) CT	5709 (97%)	152 (3%)
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12346	11989 (97%)	357 (3%)

*Final Results for 2005  
Maryland & American Society for Clinical  
Pathologist( ASCP)  
originally MIME*

Initial test (10 slides in 2 hours)

Total

12,831

Passed

11,654 (91%)

Unsuccessful

1,177 (9%)

**CLIA**

**CMS**  
CENTERS for MEDICARE & MEDICAID SERVICES

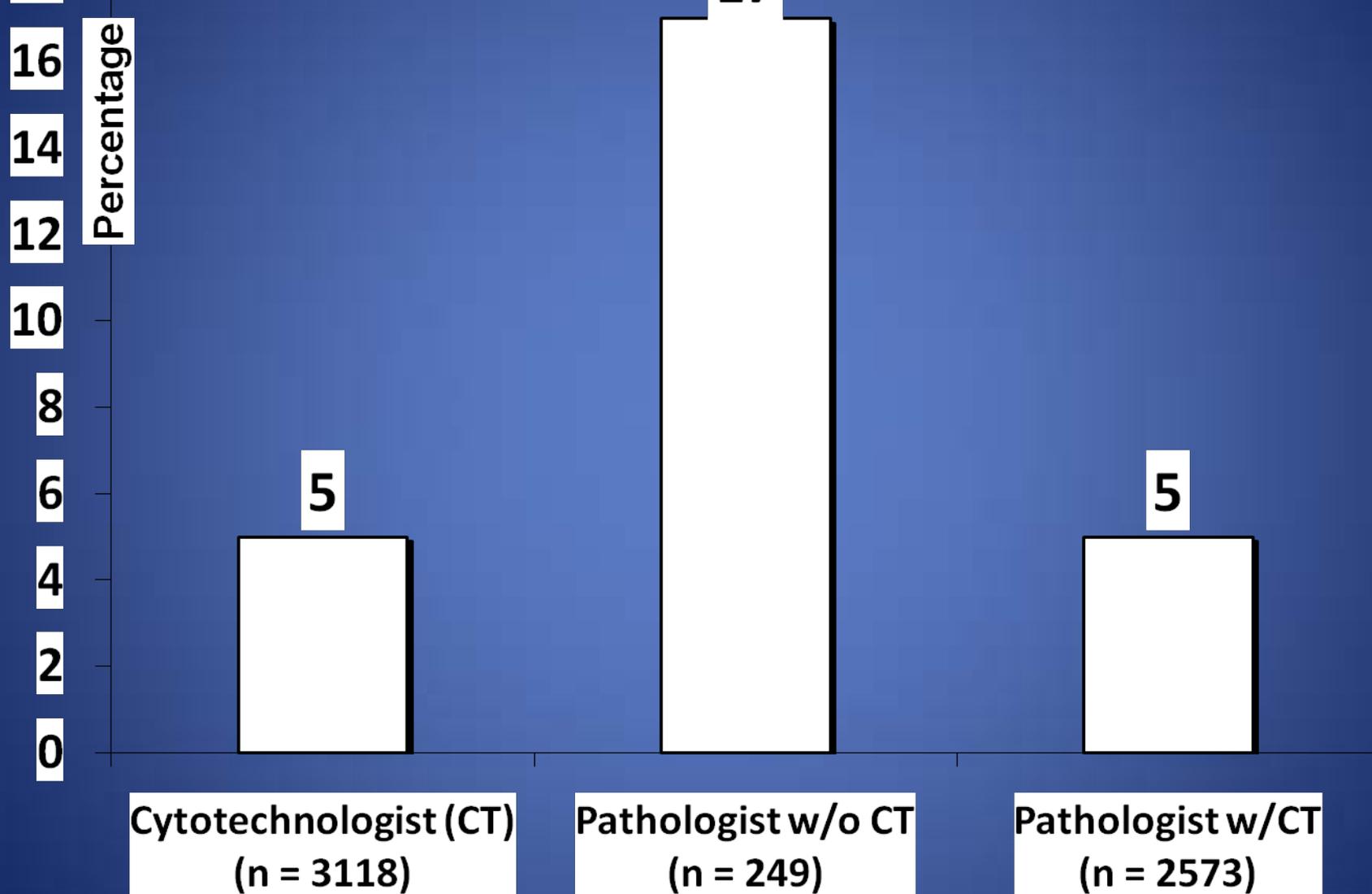
# 2005 Results

Initial Testing Event (10 Slides in 2 hours)

<u>participant</u>	<u>Pass</u>	<u>Unsuccessful</u>
CT 6530	93%	7%
<b>MD (-) CT 468</b>	<b>67%</b>	<b>33%</b>
MD (+) CT 5812	90%	10%
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Total 12, 831		

# Initial Test Scores for UNSUCCESSFUL

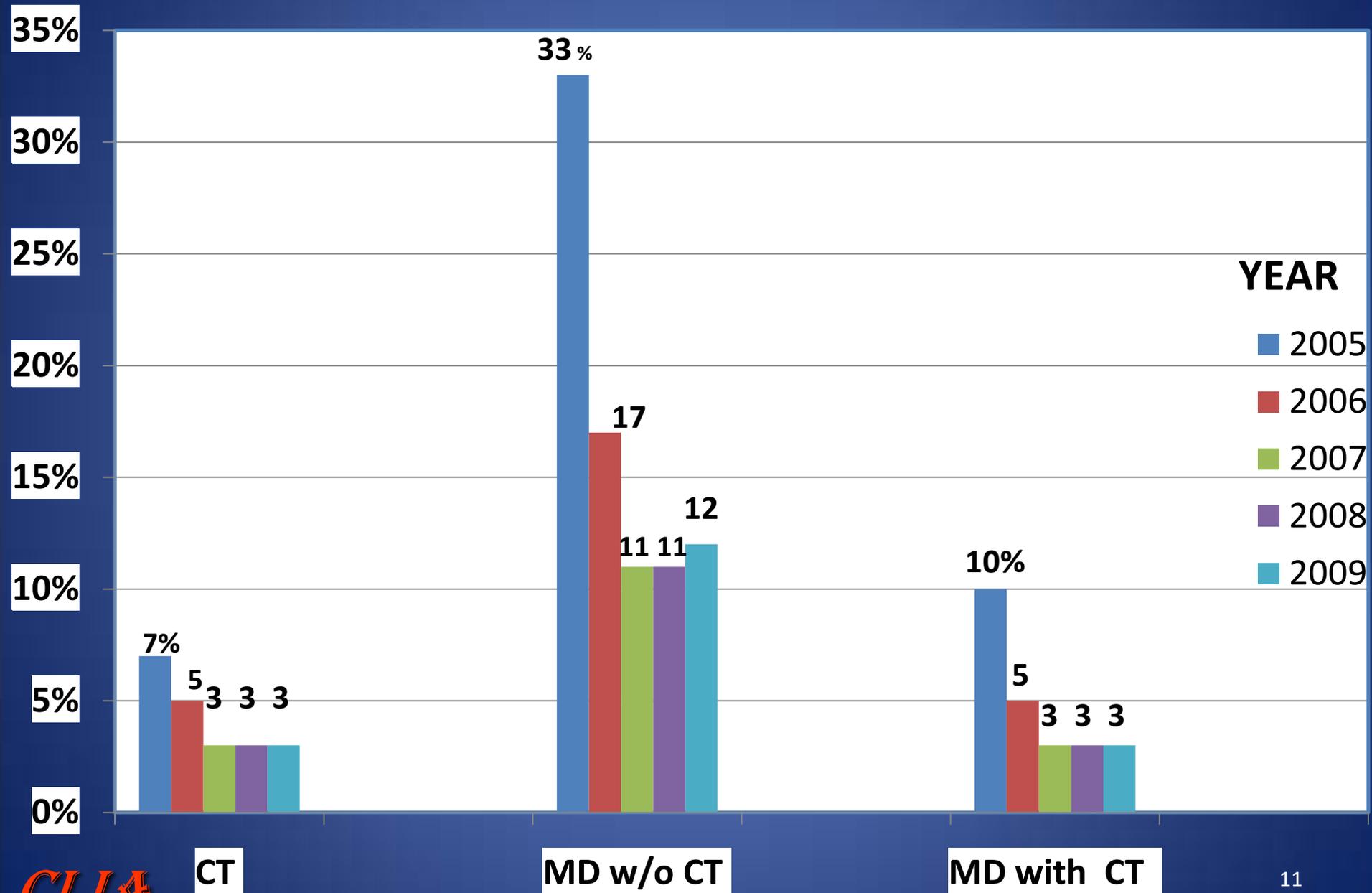
participation in Cytology PT 2006



# National 2008

INITIAL TEST (10 slides/2hours)								
			Total Tested		PASS	%	Unsuccessful	%
Participant			12368		11988	97%	380	3%
CT			6184		6016	97%	168	3%
Path with cytotechnologist			5742		5577	97%	165	3%
Path without cytotechnologist			442		395	89%	47	11%

# 5 YEAR SUCCESS RATE BY PARTICIPANT TYPE



# 5 YEAR REVIEW OF CYTOLOGY PROFICIENCY BY PARTICIPANT

CT	MD w/o CT	MD with CT	YEAR
7%	33%	10%	2005
5%	17%	5%	2006
3%	11%	3%	2007
3%	11%	3%	2008
3%	12%	3%	2009

