

# Today's Featured Speaker

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Judy is currently the Director of the Division of Laboratory Services, the division that is responsible for the oversight and administration of the CLIA program.

# Everything You Always Wanted to Know About Waived Testing & CLIA!

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DIVISION OF LABORATORY SERVICES

**CLIA**

**CMS**  
CENTERS for MEDICARE & MEDICAID SERVICES

# Topics for Discussion



- CLIA Statistics
- Growth of Waived Tests & Laboratories
- CMS' Position on POC/Waived Testing
- CMS' Certificate of Waiver Project Data
- CMS' Next Steps for Waived Laboratories
- Questions???

# Current CLIA Statistics

Total Number of Laboratories 221,793

Total Non-Exempt 215,057

– Compliance 19,404

– Accredited 15,864

– Waived 141,994

– Provider Performed Microscopy 37,795

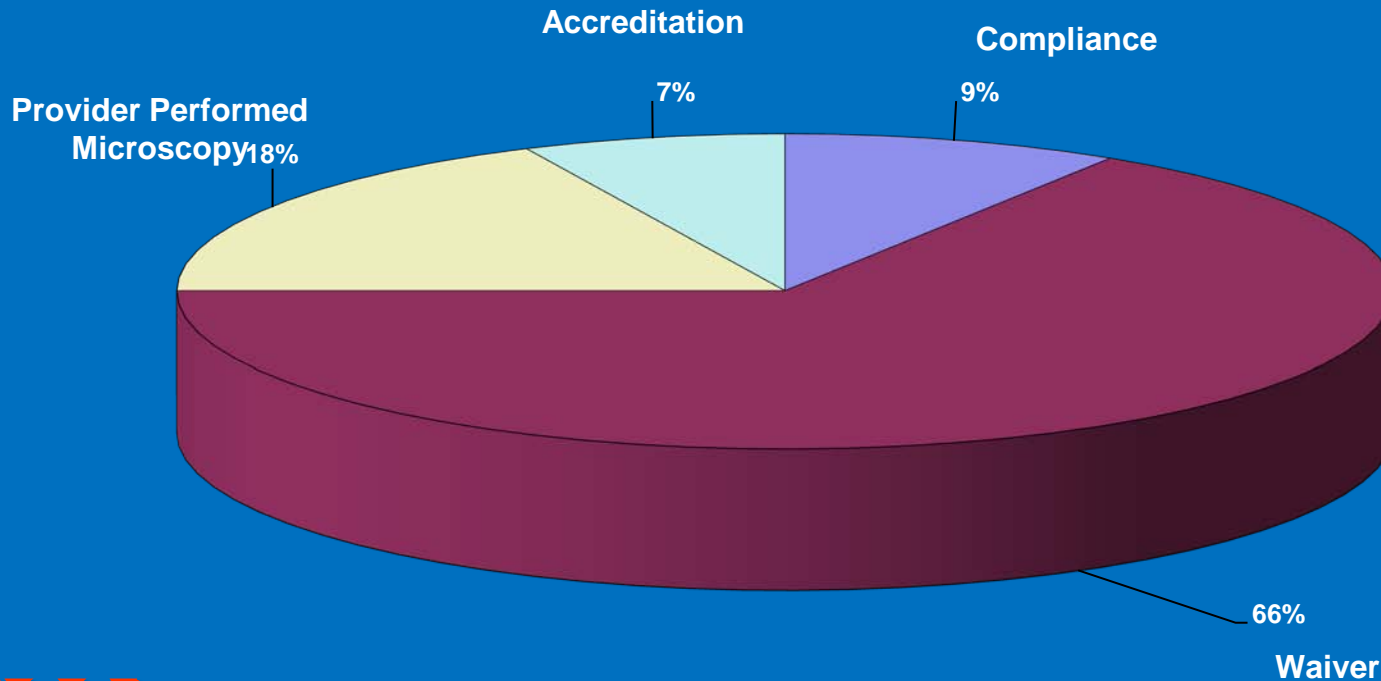
– Exempt 6,736

• NY 3,264

• WA 3,472

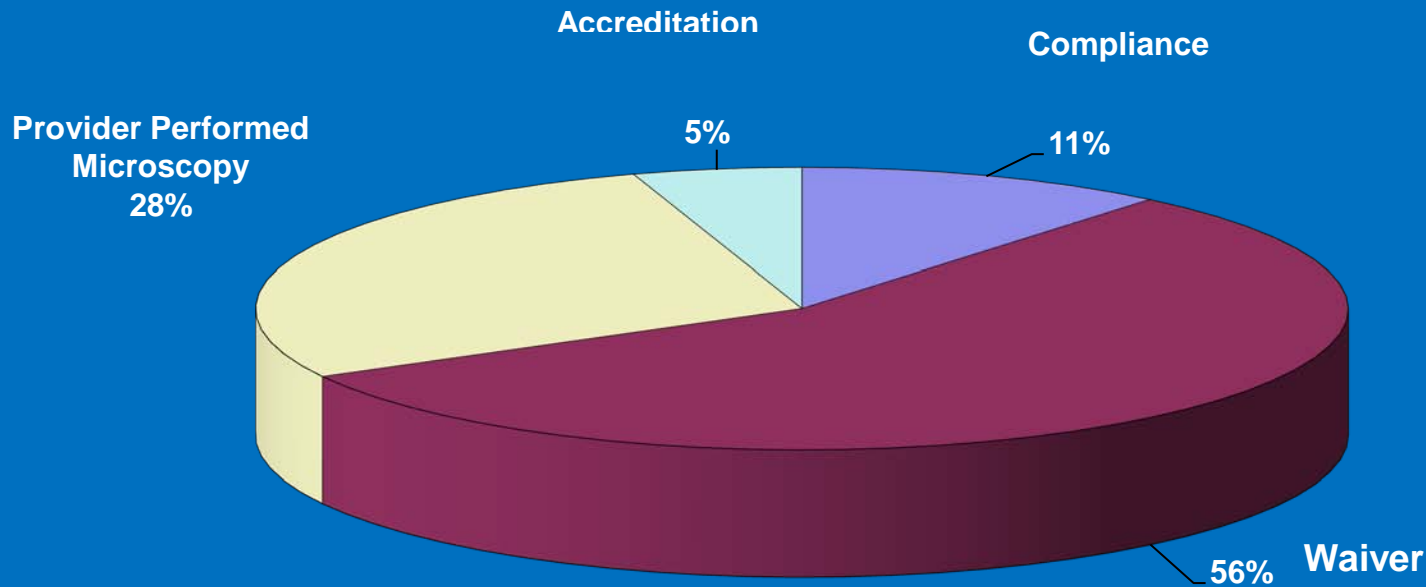
# Current CLIA Statistics

## CLIA Labs by Certificate Type (Non-Exempt Only)



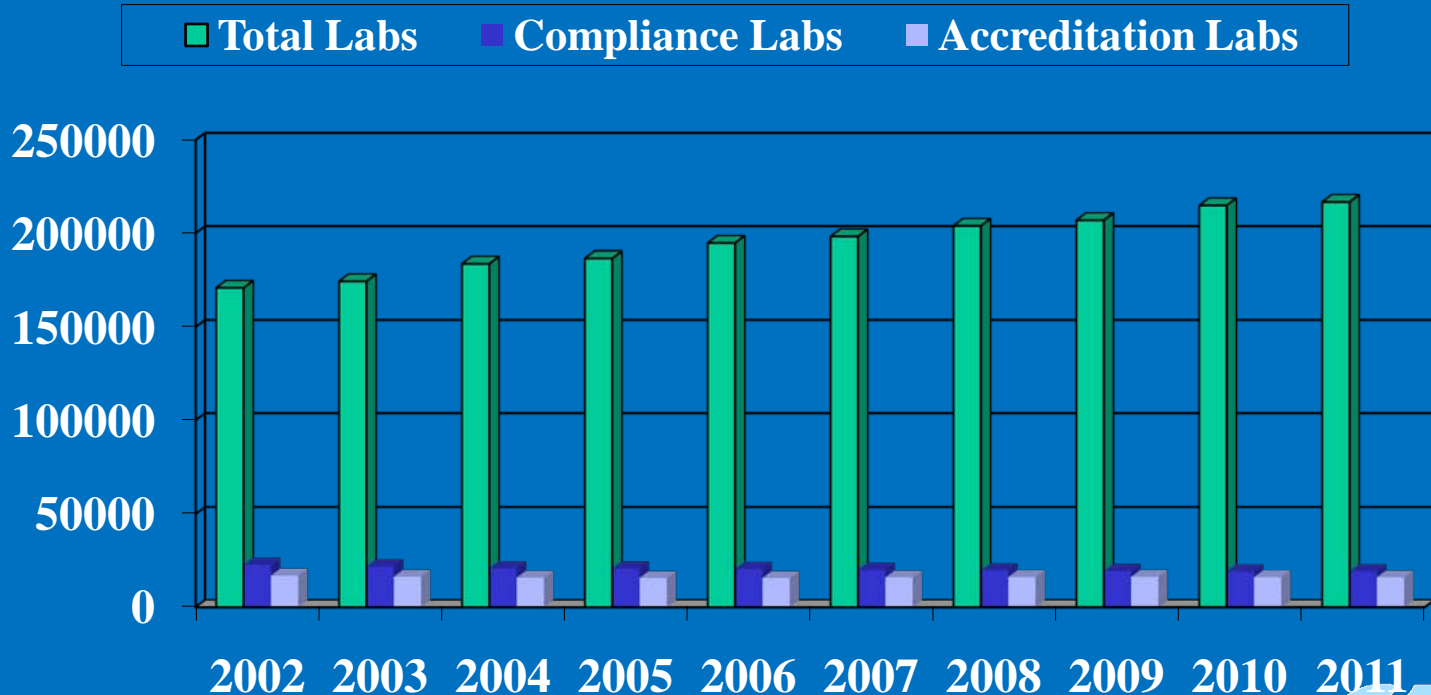
# Current CLIA Statistics

## Physician Office Laboratories by CLIA Certificate Type (Non-Exempt Only)



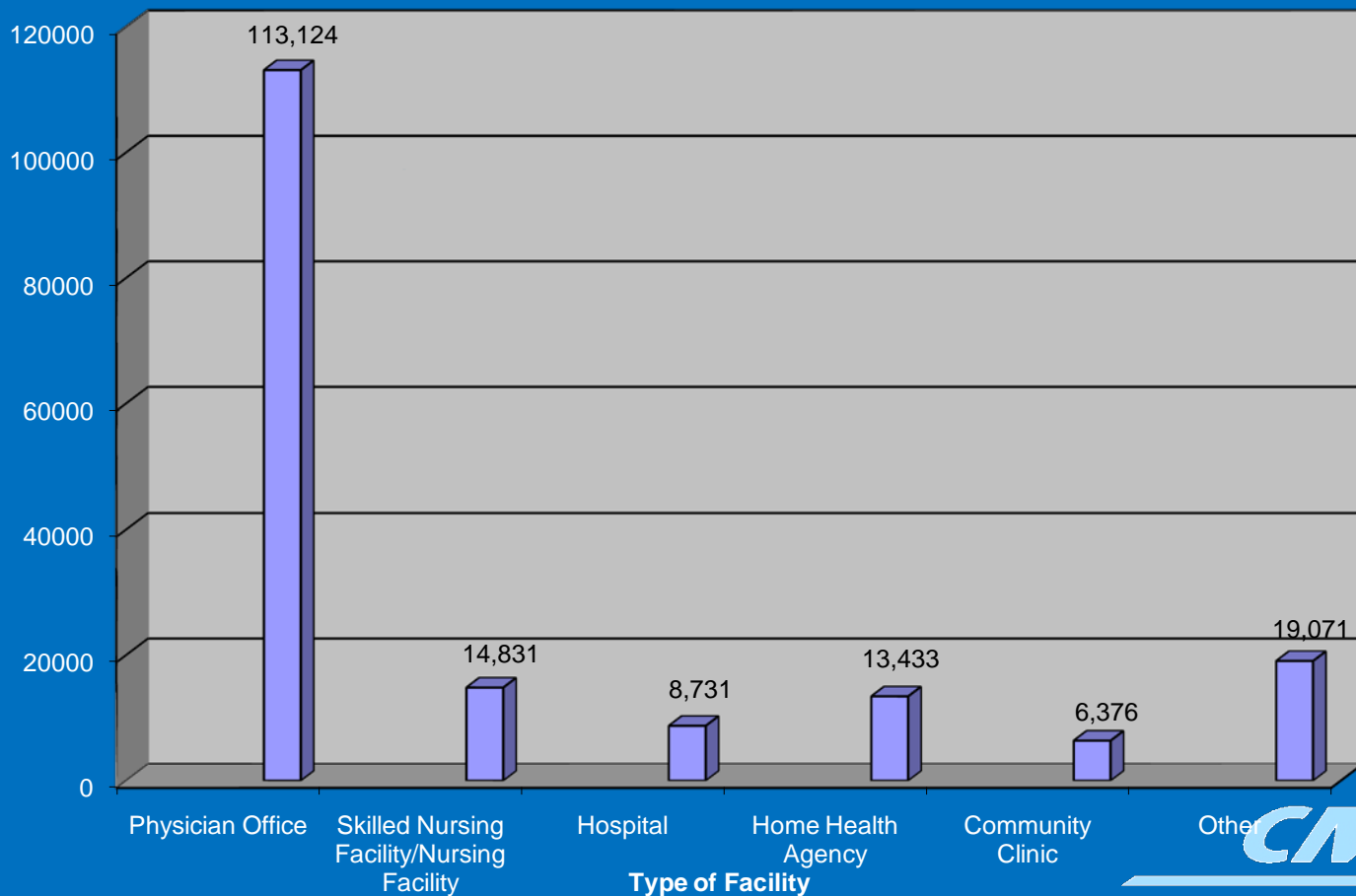
# Current CLIA Statistics

## Decade Trend



# Current CLIA Statistics

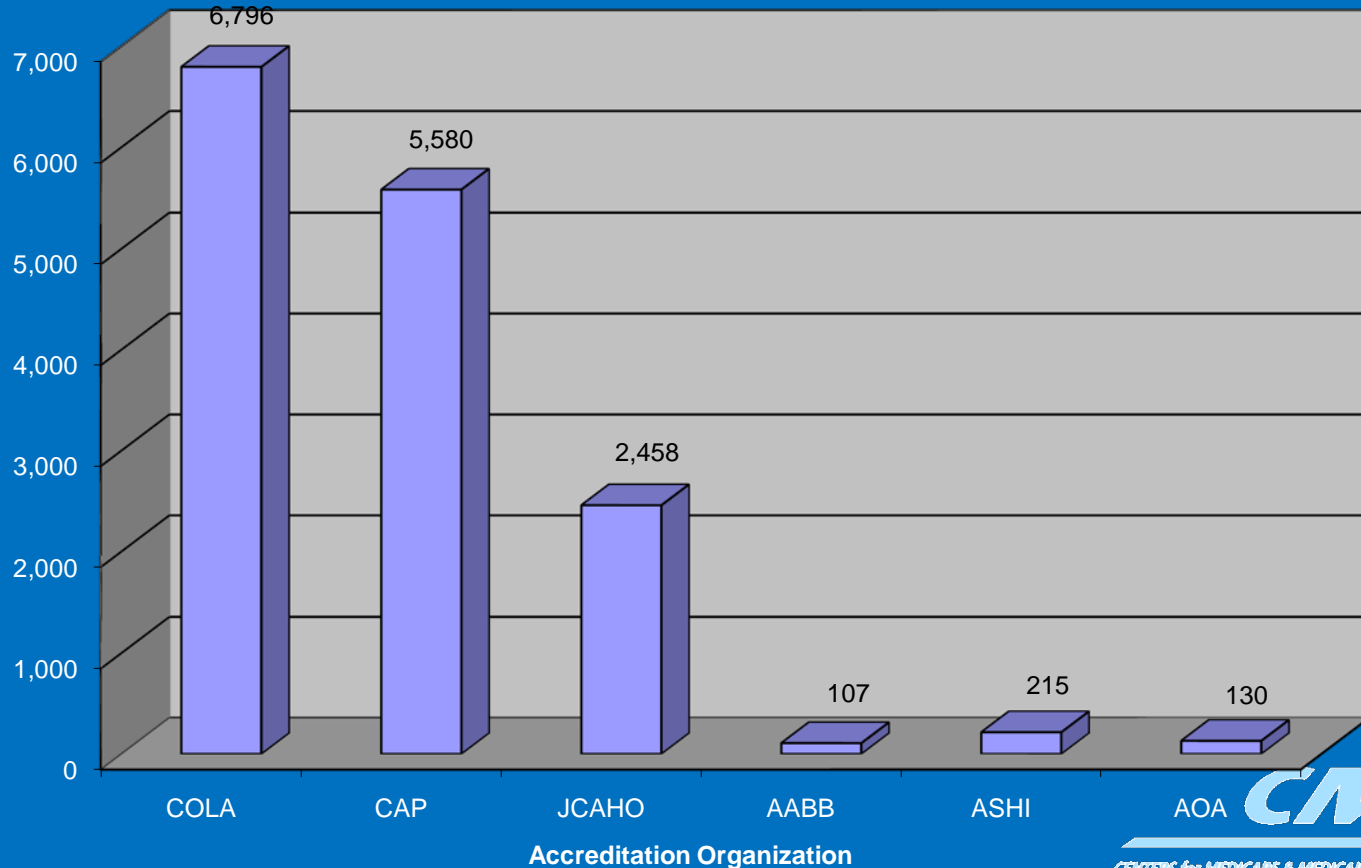
Total CLIA Laboratories Registered  
Self-Selected Laboratory Types





# Current CLIA Statistics

Number of CLIA Certificate of Accreditation Laboratories  
by Accreditation Organization



# Growth of Waived Tests & Laboratories

## By CLIA definition.....

Waived tests are;

“.....simple laboratory examinations & procedures which –

Employ methodologies that are so simple & accurate as to render the likelihood of erroneous results negligible;

Pose no reasonable risk of harm to the patient if the test is performed incorrectly”.

# Certificate of Waiver (CW) Laboratory Requirements

## The only standards for CW laboratories:

- *Follow manufacturer's instructions*
- Register with CMS
- Pay small certificate fee every 2 years

NOTE: Some CW labs are part of accredited facilities & are subject to their quality standards.

# CMS Position on Waived/POC Testing

- Offers timely, efficient, convenient patient care
- Continues to increase
- Increased testing comes w/ issues:
  - ✓ Testing personnel less-trained; may not ID problems
  - ✓ No routine oversight w/ no funding/resources
  - ✓ Minimal manufacturer recommended QC
  - ✓ Pre & post analytical issues

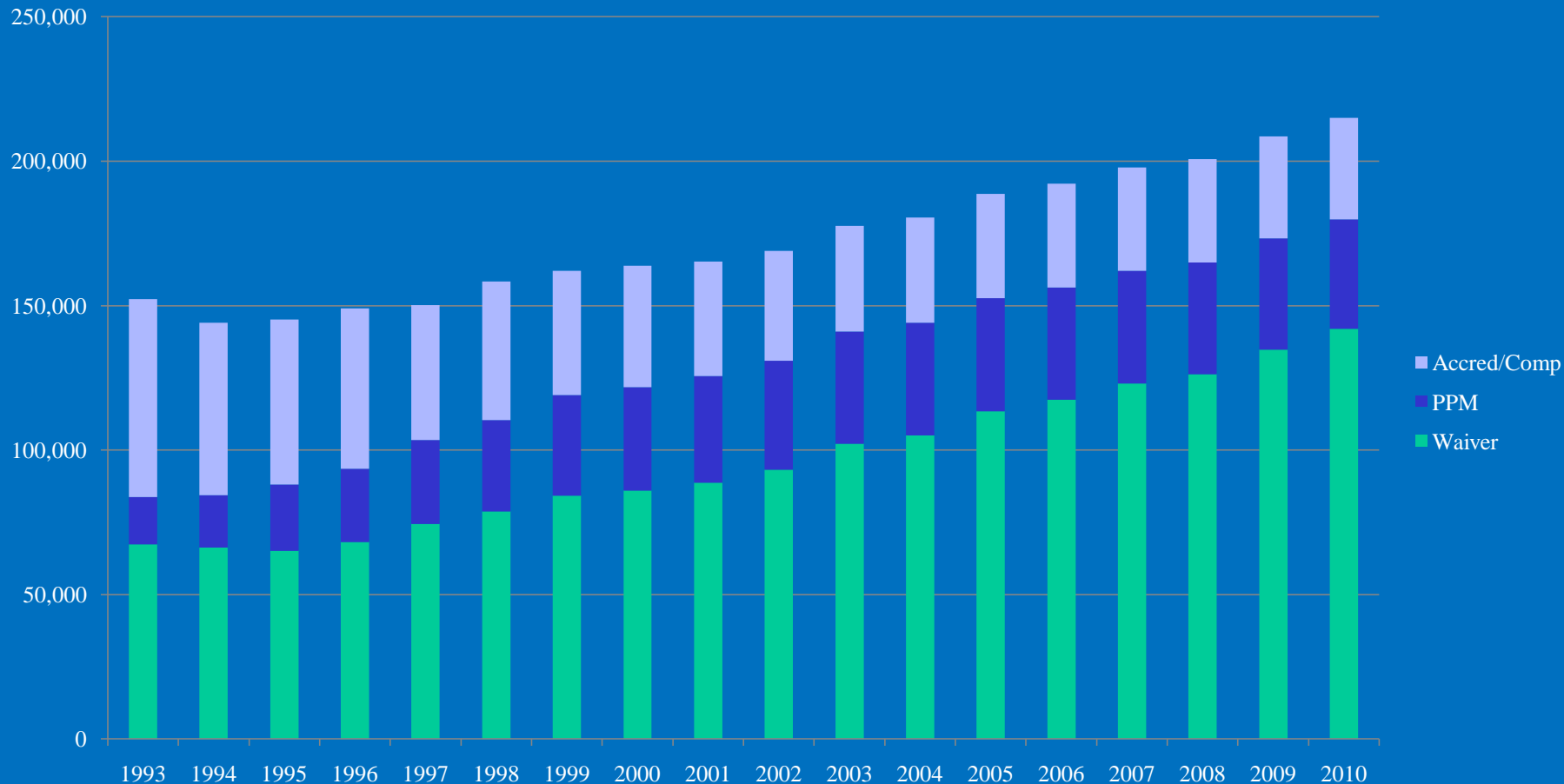


# Growth of Waived Tests & CW Laboratories

Since 1992.....

- CLIA-waived tests have increased from 8 to > 100 tests.
  - **This represents 1000's of test systems!**
- The number of laboratories issued a CW has grown exponentially from 20% to 66% of the >220,000 laboratories enrolled. And it is growing.....

# Growth of Waived Tests & CW Laboratories



# Growth of Waived Tests & CW Laboratories

- Waived tests increased due to new, accurate & robust technologies designed by manufacturers
  - Meet FDA criteria for waiver
  - Tested under ideal conditions
  - Performed by individuals w/ some lab background



# Growth of Waived Tests & CW Laboratories

- Huge growth in numbers & types of waived tests.
  - Most frequently performed tests in small labs
  - Tests typically done in POC settings
- Waived certificate is an incentive due to no government oversight & Medicare payment rec'd.
  - Creates less burden to the lab
  - Decreases costs to the lab
    - No PT/little QC
    - No routine survey
  - Lab makes \$\$\$



# Certificate of Waiver (CW) Project

Due to concerns about complaints & growth of CW labs, in 1999 CMS:

- Began visits to 100 CW & PPM labs in CO & OH; **50% had quality problems!**
- As a result, CMS expanded this pilot to 8 more States--

# Certificate of Waiver (CW) Project

## 2000- Present-- Expanded Pilot:

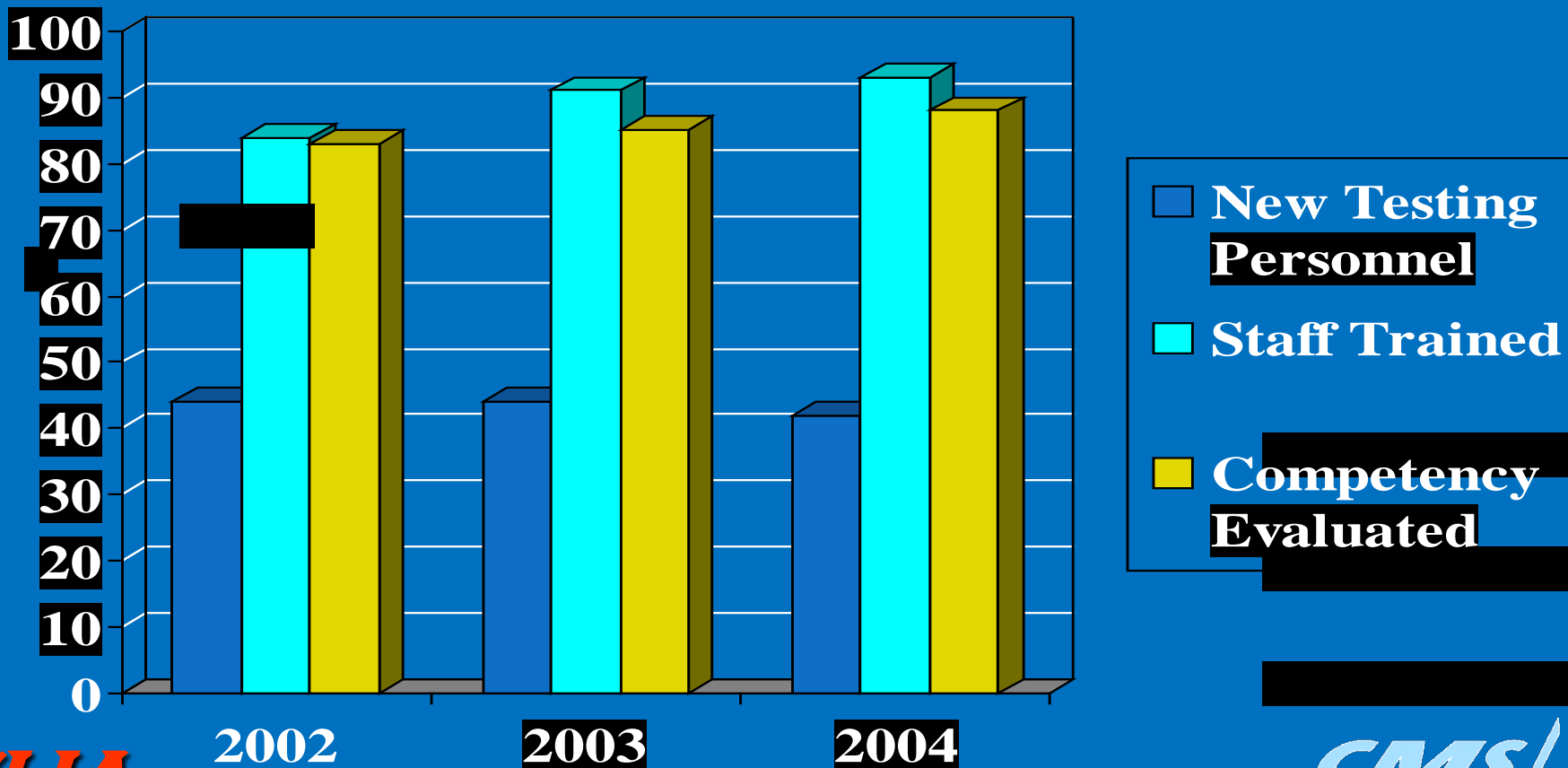
- Surveyors in MA, NY, PA, MS, NM, IA, AZ, ID visited 436 COW & PPMP laboratories; **32% had quality problems!**
- CMS-CLIA initiated an ongoing national project in 2002 to conduct educational visits for 2% of CW labs to collect data.
- Ea. lab responds to questions about its waived testing & rec. gd. lab practice info.

# Certificate of Waiver (CW) Project

## In 2002-2003:

- Change in testing personnel=43-44% of labs
- Provide timely results=95-99% of labs
- Chose to enroll in PT=8-10% of labs

# Certificate of Waiver (CW) Project—Personnel & Training



# Certificate of Waiver (CW) Project—Reports at CLIAC '04

The CDC reported issues found in CMS CW surveys correlate w/ CDC's studies.

New York State DOH reported similar findings from their visits.

Office of Inspector General also did a study with the same findings as CMS.

They all found the following:

# Certificate of Waiver (CW) Project-CDC Report at CLIAC'04

- High staff turnover in waived testing sites
- Lack of formal laboratory education
- Limited training in test performance & QA
- Lack of awareness concerning “good laboratory practice”
- Partial compliance with manufacturers’ QC instructions ( ~55-60%)

# Certificate of Waiver (CW) Project--2006



## Initial visits

- Of 1947 labs visited, 69% were following the manufacturer's instructions.



## Follow-up visits

- **85%** of labs not following manufacturers' instructions initially showed improvement after intervention.

# Certificate of Waiver (CW) Project-- Serious Risk to Patient Health!!

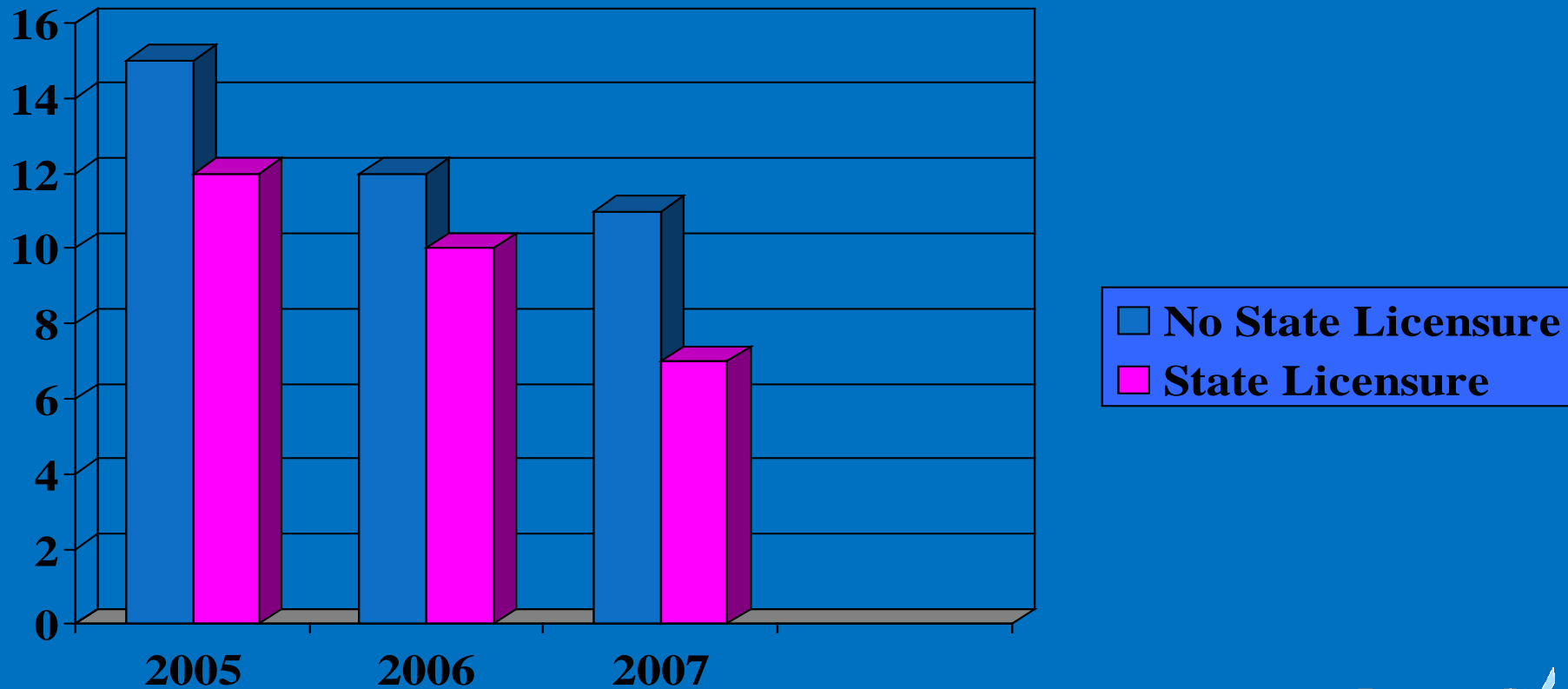
- FY 2005: 6/1678 surveys or <1% labs
- FY 2006: 6/1938 surveys or <0.5% labs
- FY 2007: 2/1737 surveys or <0.20% labs
- FY 2008: 3 out of 1902 surveys or <0.16% labs
  
- Consider if this is extrapolated to total CW lab population!



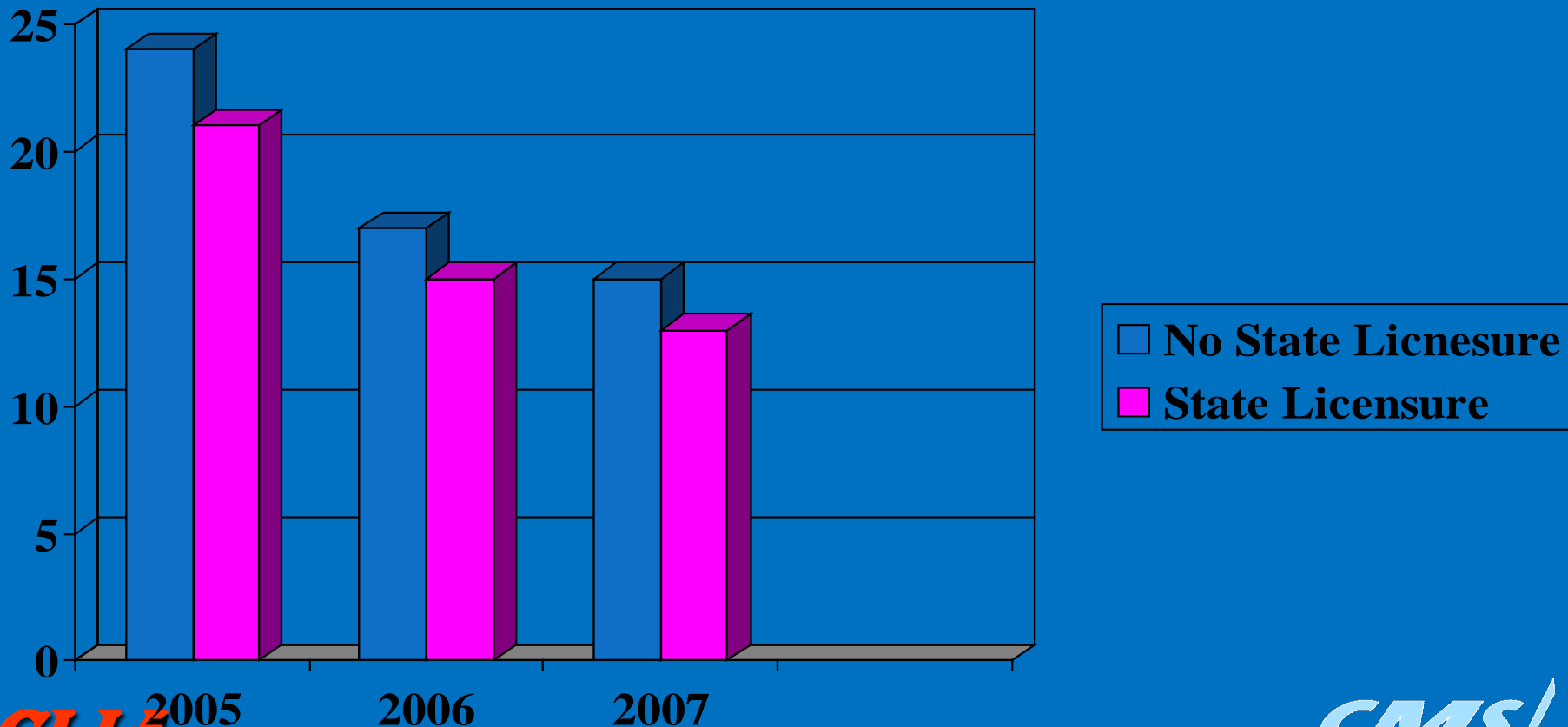
# Certificate of Waiver (CW) Project -Labs Performing Non-Waived Tests



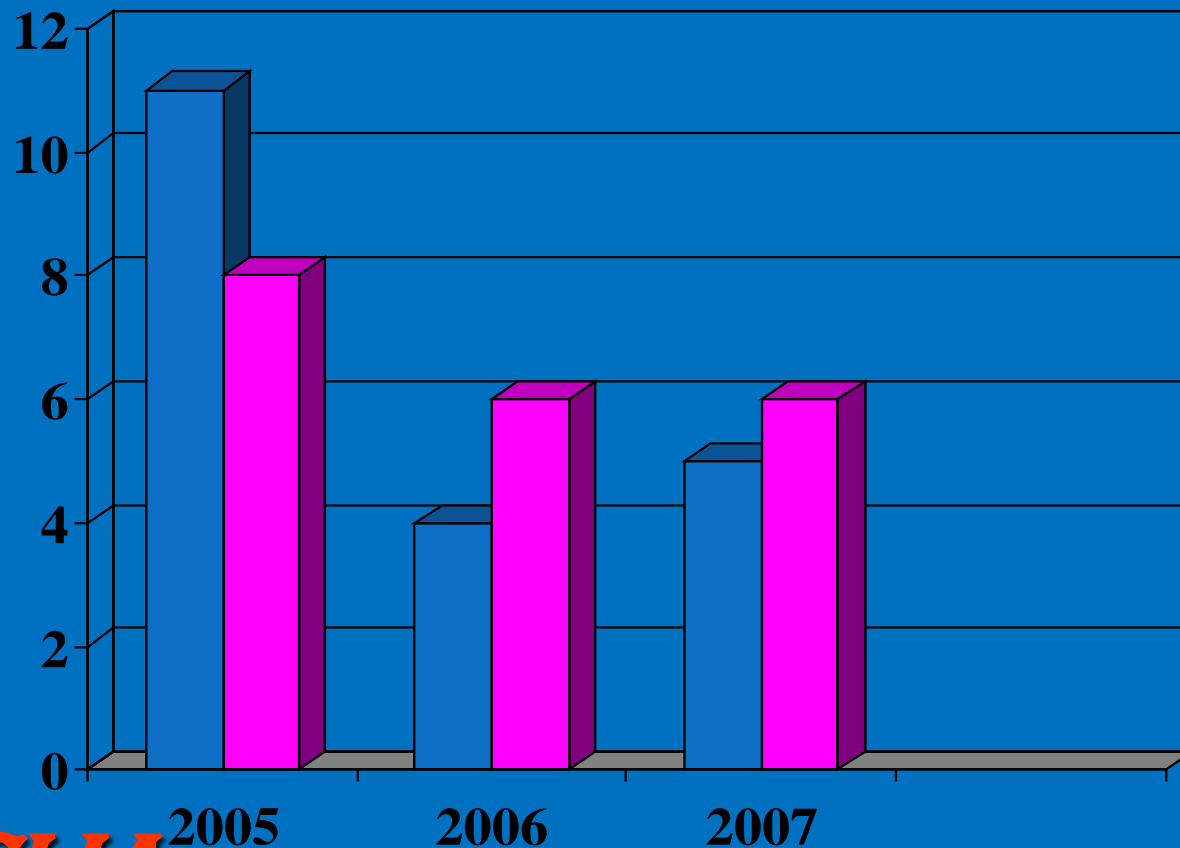
# Certificate of Waiver (CW) Project- Labs w/o the Manufacturer's Instructions



# Certificate of Waiver (CW) Project- Labs Not Performing QC Initial Visit

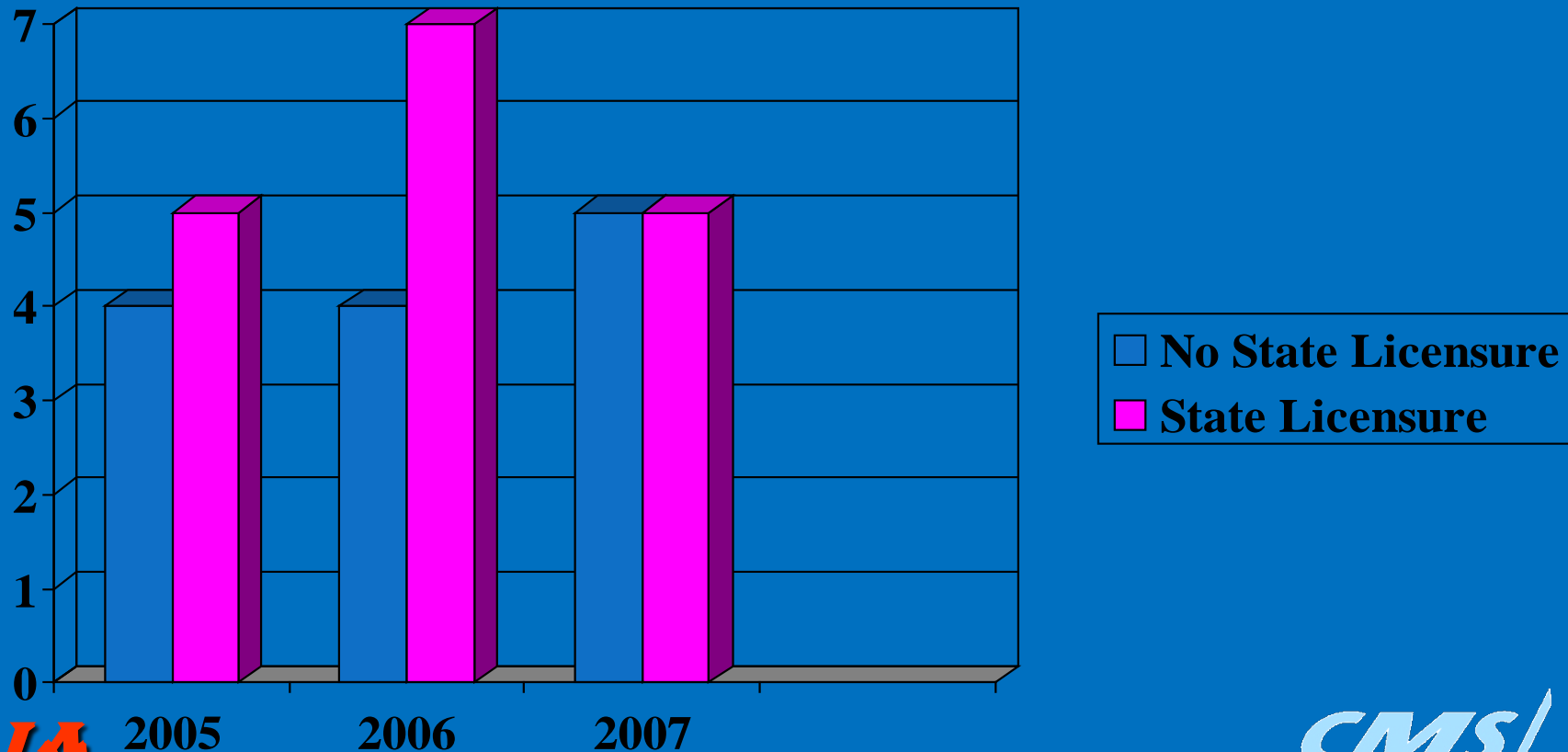


# Certificate of Waiver (CW) Project- Labs Not Performing QC Follow Up Visit



□ No State Licensure  
■ State Licensure

# Certificate of Waiver (CW) Project- Labs Participate in Voluntary PT

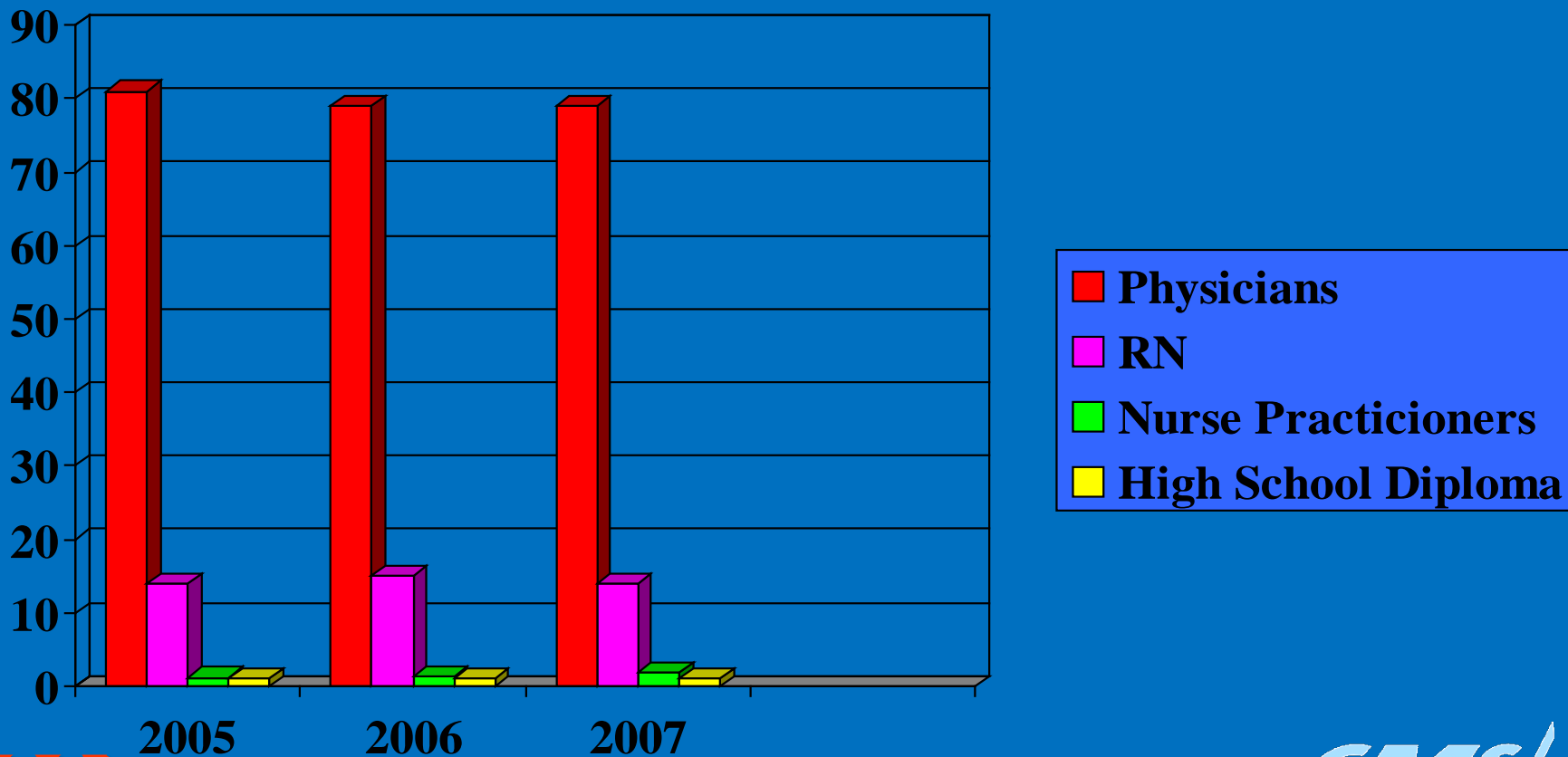


# Certificate of Waiver (CW) Project- Performance w/ Voluntary PT Enrollment

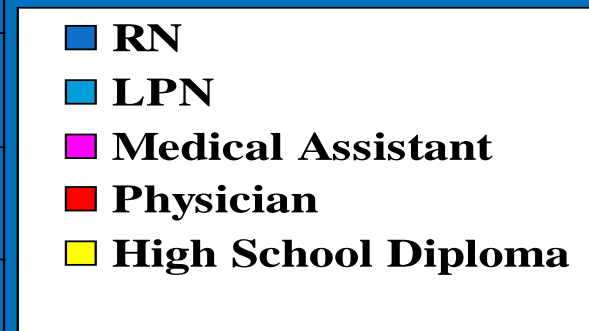
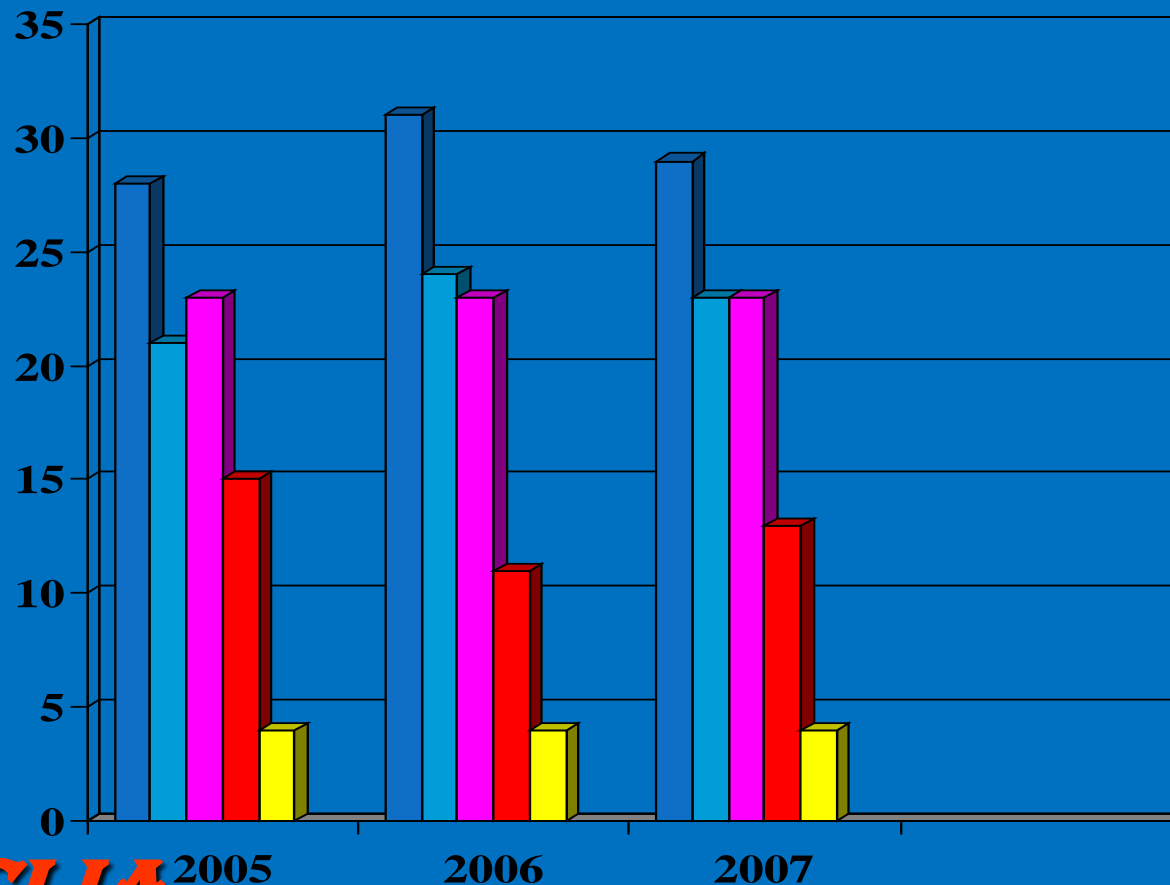
<u>CMS Survey Response</u>	<u>PT</u>	<u>No PT</u>
• Lab has current PI*	98%	88%
• Performs required QC	95%	75%
• Performs function checks/ Calibration	75%	62%
• Performs confirmatory test	25%	15%

\*package insert

# Certificate of Waiver (CW) Project- Lab Directors



# Certificate of Waiver (CW) Project- Testing Personnel





# Certificate of Waiver (CW) Project--Summary

## The CW Project has:

- Raised the awareness of the need to follow manufacturer's instructions for testing
- Identified labs testing beyond the scope of the lab's waived certificate
- Provided education about CLIA, laboratory testing & Good Lab Practices
- Confirmed that labs w/ routine oversight perform significantly better & improve over time.



# Next Steps for Waived Testing..



- Number of CW labs increasing exponentially
- Education is effective, but resources are lacking
- CMS developed an “Issue” paper w/ multi-faceted recommendations for agency mgt.
- CMS to convene w/ Partners to develop long & short term plans.

# Next Steps for Waived Testing.....

## Short term

- Continue CW project indefinitely
- Provide edu. materials w/ ea. new ap, on web site, w/ on-site visits; update CE clearinghouse
- Initiate test menu collection w/ apps
- Collaborate w/ Partners/CDC to ID add'l. efforts
- Enlist support of med., mfgr. & patient advocacy orgs.
- Evaluate data from AO/ES w/ CW standards
- Coordinate w/ FDA on overlapping issues
- Publish comprehensive report

Long term-Change the CLIA law to improve oversight

# Where to Find Info:

- CMS CLIA Web site:
  - [www.cms.hhs.gov/clia/](http://www.cms.hhs.gov/clia/)
  - NEW FEATURE: “Lab Demographic Look- Up”
  - Brochures, state contacts, application, guidelines
- CMS Central Office, Baltimore
  - 410-786-3531
- Judy Yost’s email:
  - [Judith.yost@cms.hhs.gov](mailto:Judith.yost@cms.hhs.gov)



# Questions??

## THANK YOU!!

