

# CMS Certificate of Waiver Project Data Review

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CLIAC Presentation

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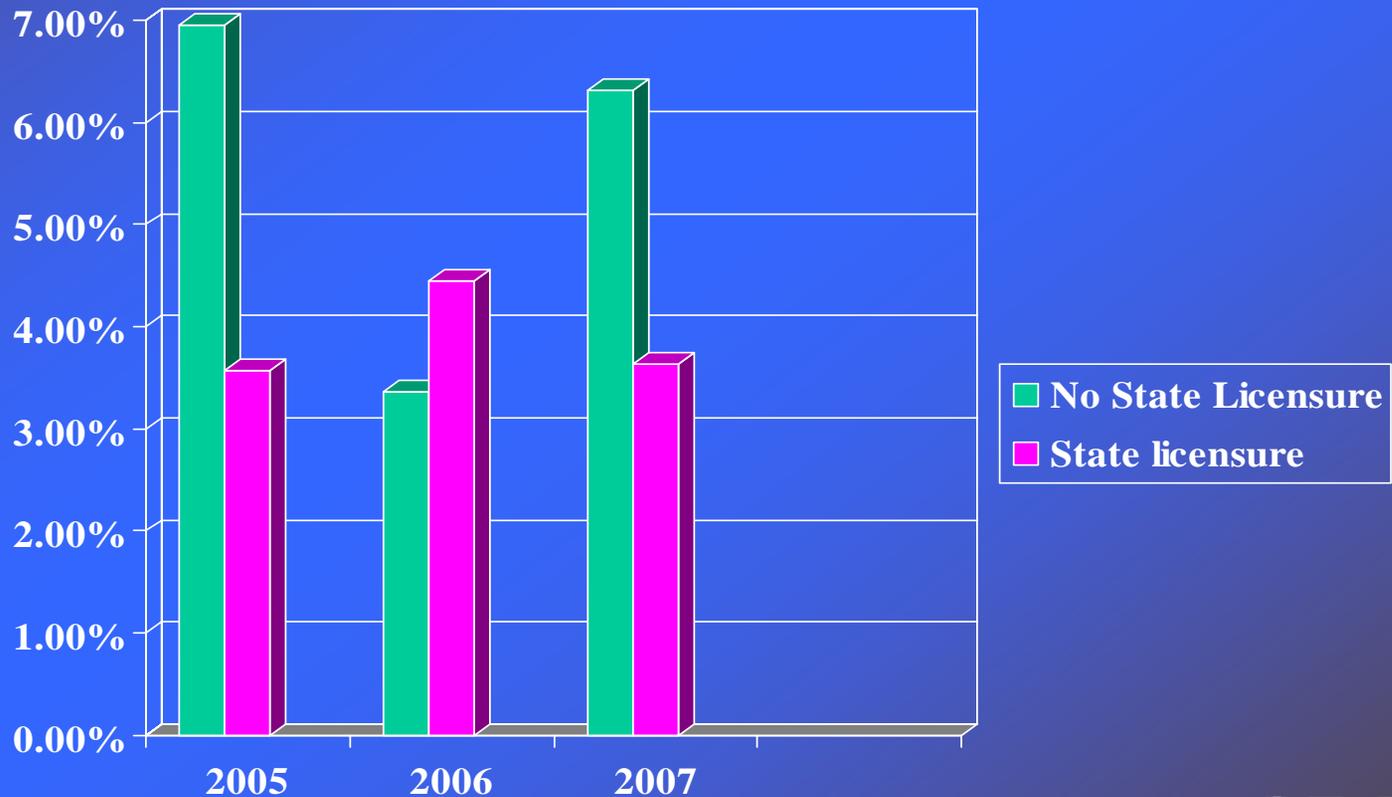
# Regulatory Requirements

Laboratories with a Certificate of Waiver (CW) are required to:

- Enroll in CLIA
- Pay the appropriate fees
- Follow the manufacturers instructions

# Percentage of CW Labs Performing Non-waived Tests

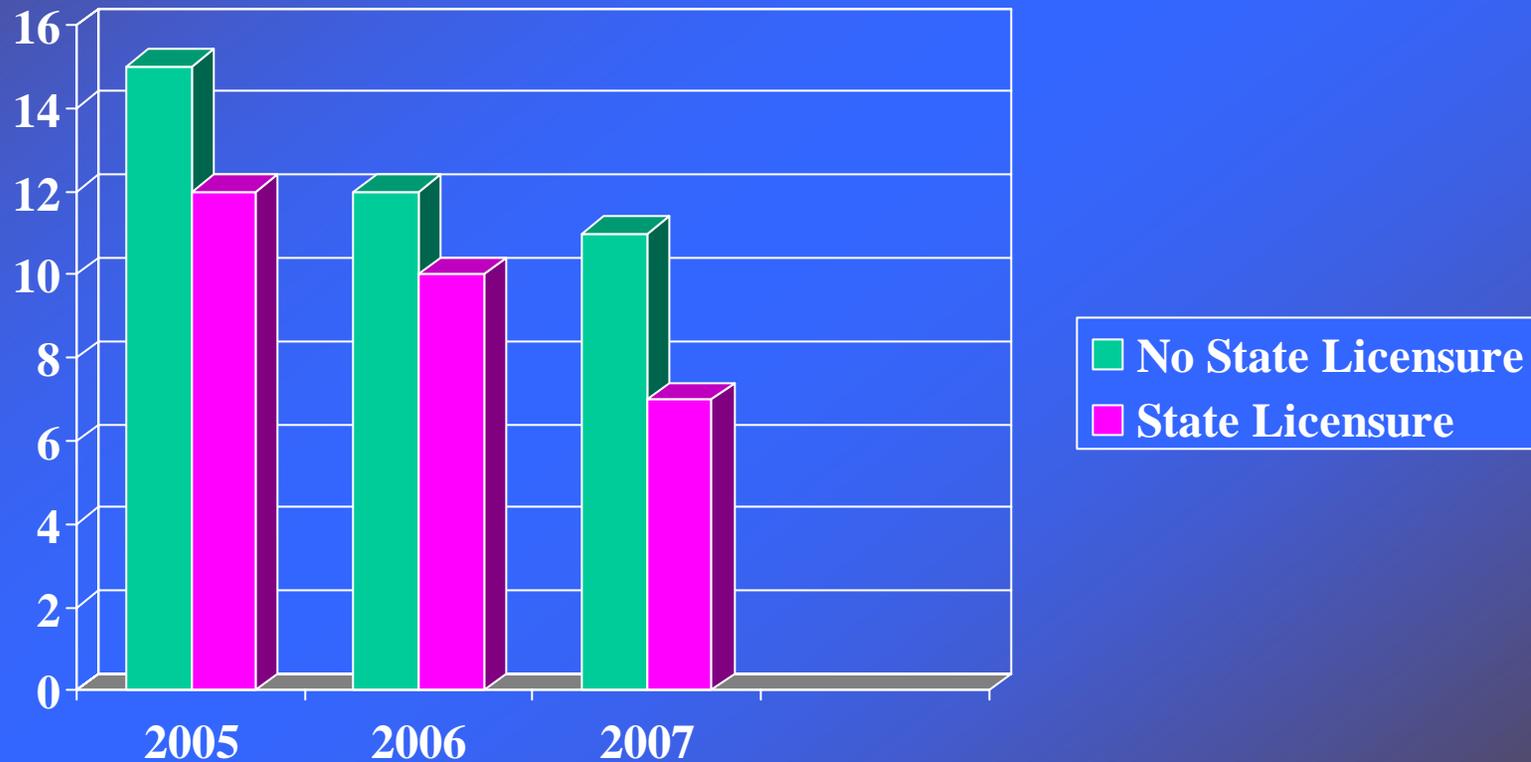
Source: CMS Database



# CW Labs Considered to Pose Imminent and Serious Risk to Public Health

- FY 2005: 6 out of 1678 surveys or <1%
- FY 2006: 6 out of 1938 surveys or <0.5%
- FY 2007: 2 out of 1737 surveys or <0.20%

# CW Labs that Did Not Have the Manufacturer's Instructions



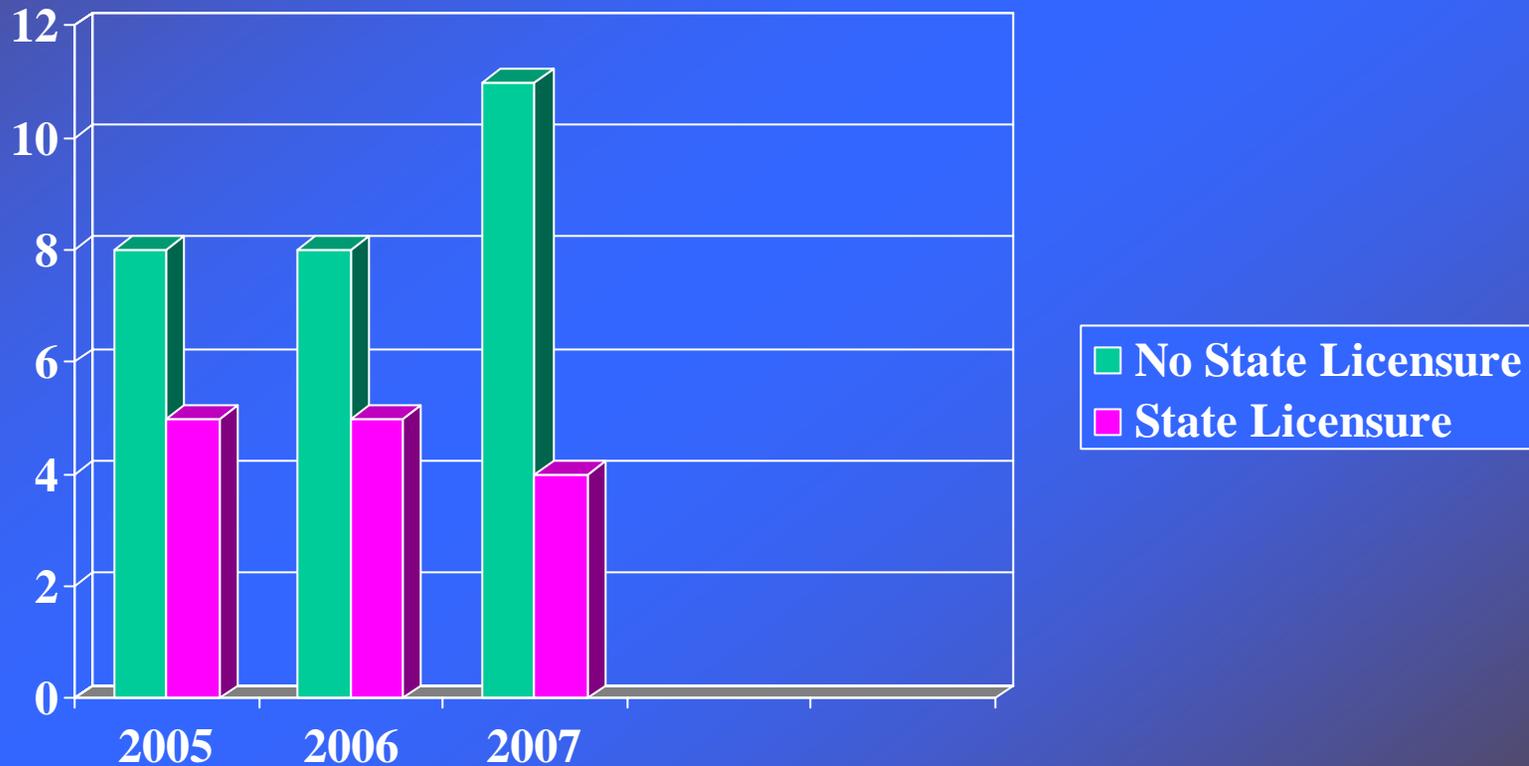
# CW Labs that Did Not Follow Manufacturer's Instructions for Use of Appropriate Specimen

- FY 2005: No State Licensure: 2%  
State Licensure: Less than 1%
- FY 2006: No State Licensure: 2%  
State Licensure: Less than 1%
- FY 2007: No State Licensure: 3%  
State Licensure: Less than 1%

# CW Labs that Did Not Adhere to Manufacturer's Storage and Handling Instructions

- FY 2005: No State Licensure: 5%  
State Licensure: <1%
- FY 2006: No State Licensure: 3%  
State Licensure: <1%
- FY 2007: No State Licensure: 5%  
State Licensure: 2%

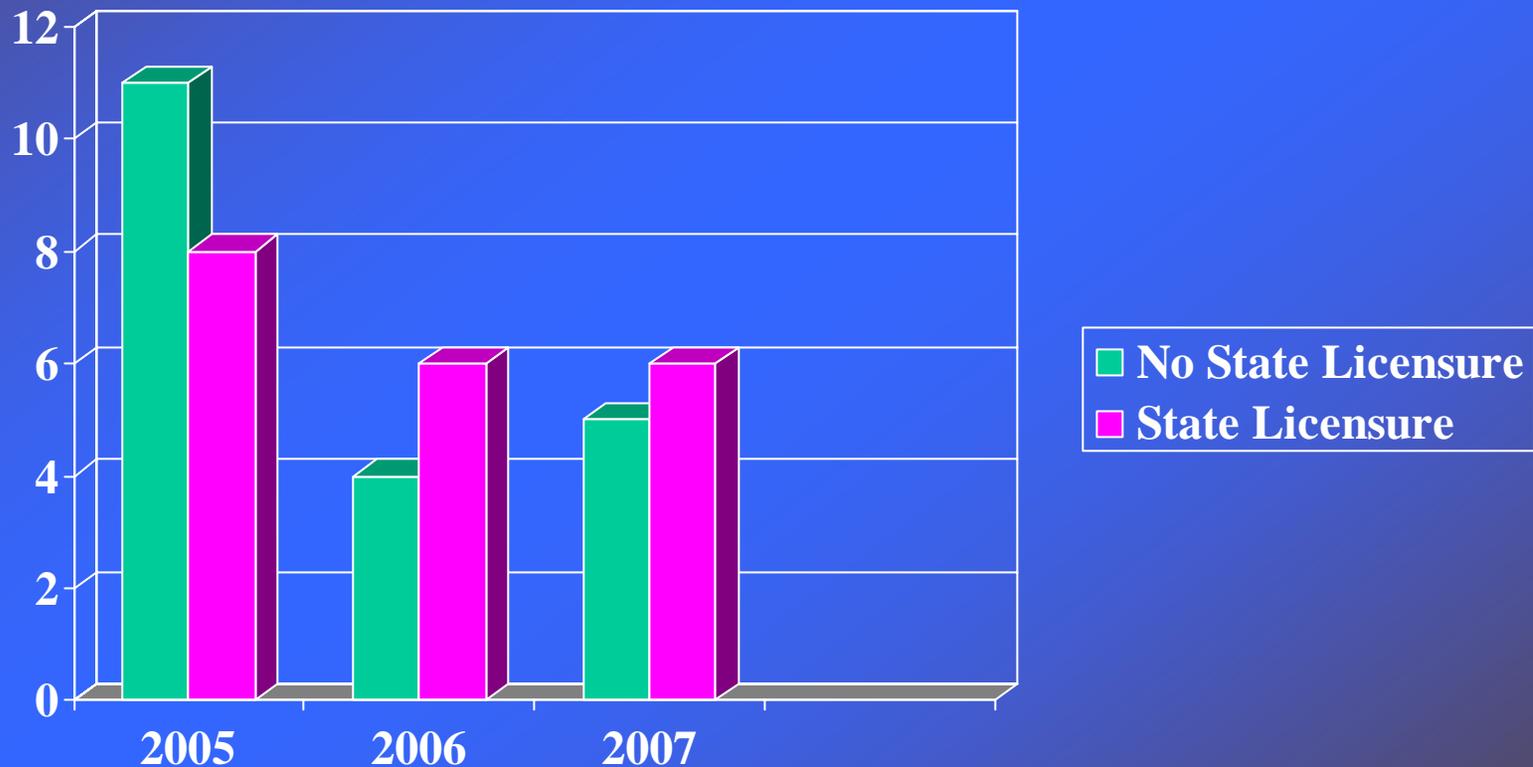
# CW Labs that Did Not use Proper Expiration Date for Storage Method



# CW Labs that Were Not Performing Required Quality Control on Initial Visit



# Labs that Were Not Performing Required Quality Control After Follow Up Visit



# Labs that Were Not Performing Required Calibration or Function Checks

- FY 2005: No State Licensure: 3%  
State Licensure: 4%
- FY 2006: No State Licensure: 2%  
State Licensure: 3%
- FY 2007: No State Licensure: 1%  
State Licensure: 3%

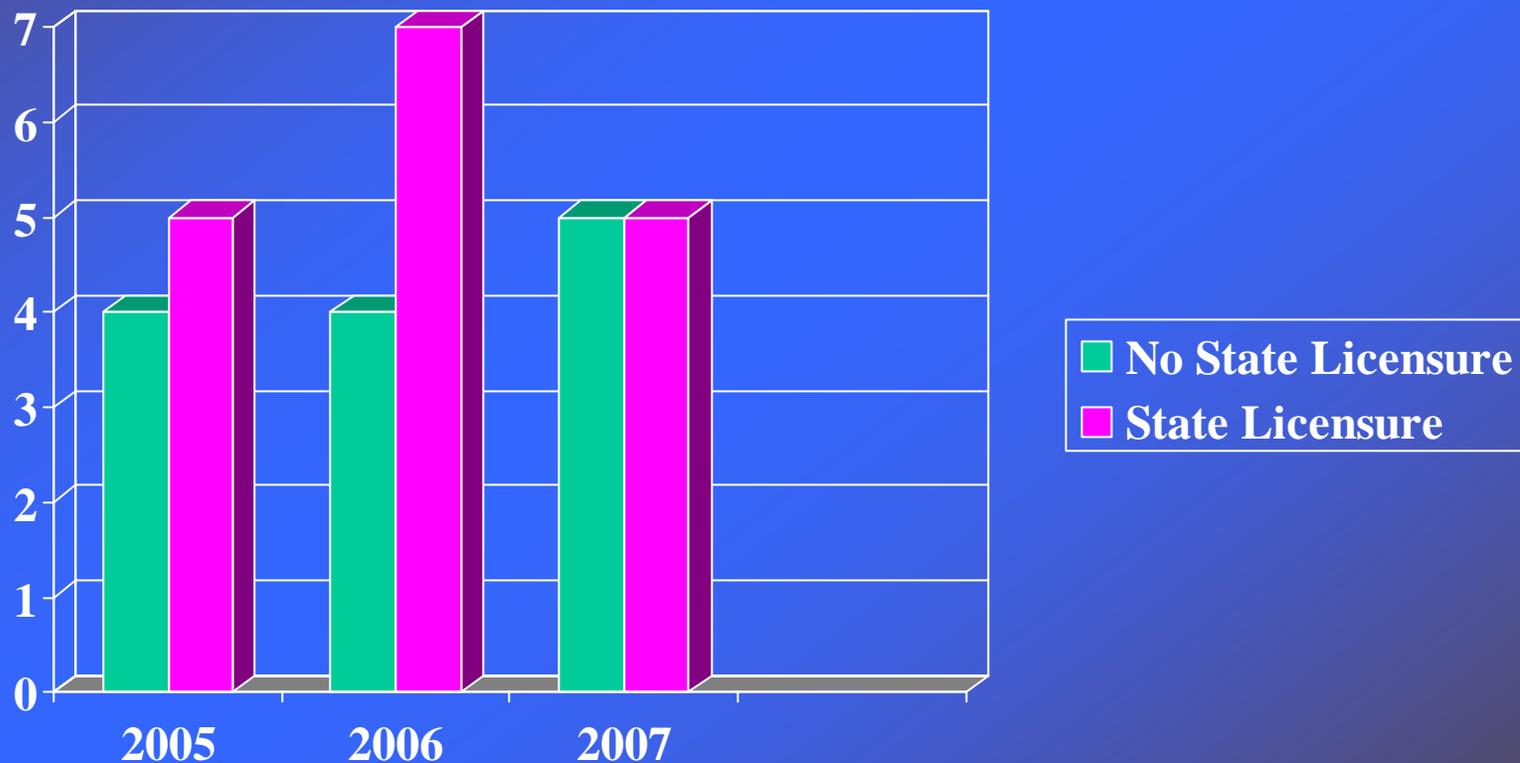
# CW Labs that Were Not Reporting Patients' Test Results as Recommended by Manufacturer



## CW Labs that Were Not Performing Required Instrument Maintenance

- FY 2005: No State Licensure: 2%  
State Licensure: 2%
- FY 2006: No State Licensure: 1%  
State Licensure: <1%
- FY 2007: No State Licensure: 1%  
State Licensure: 1%

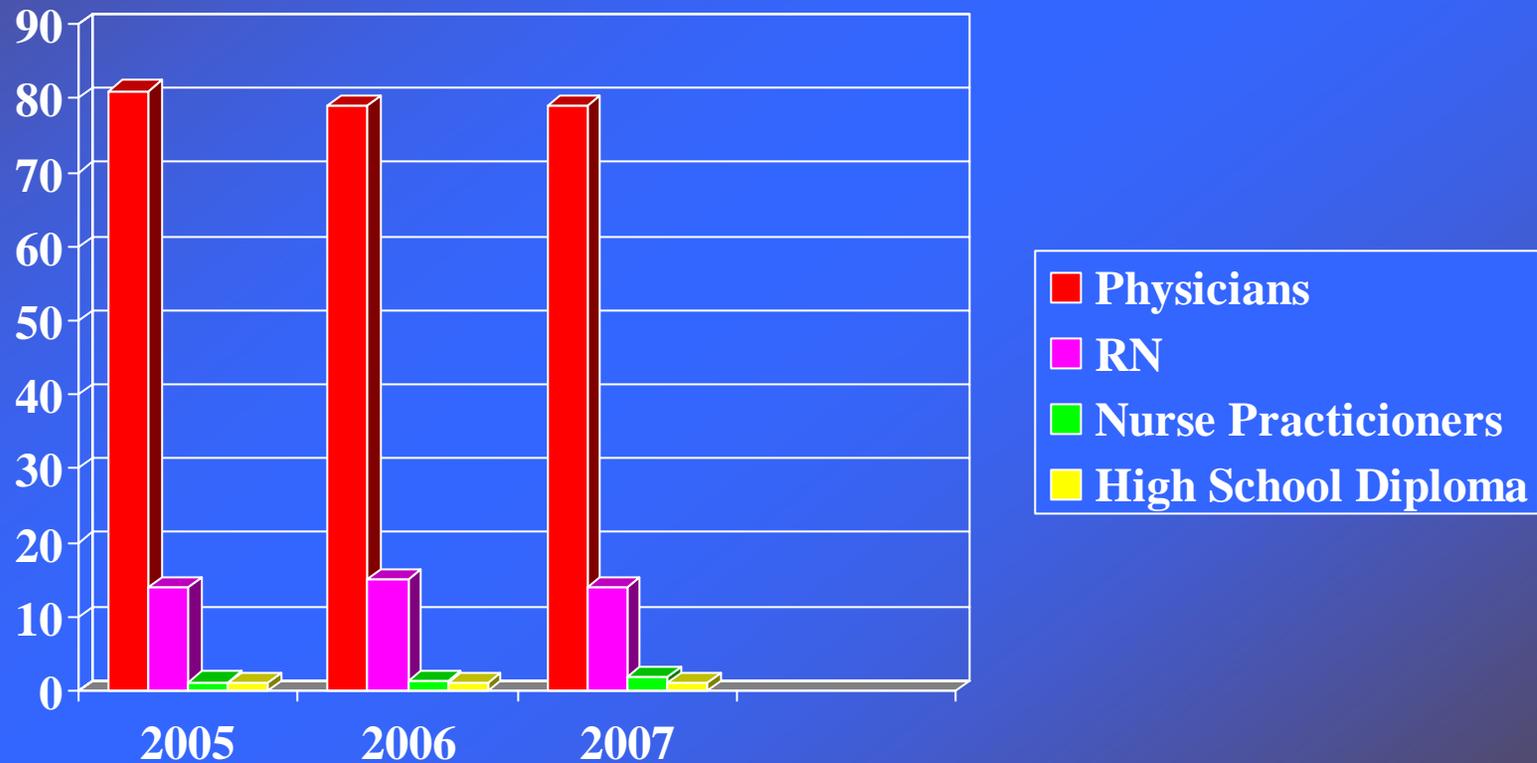
# CW Labs that Participate in Voluntary Proficiency Testing



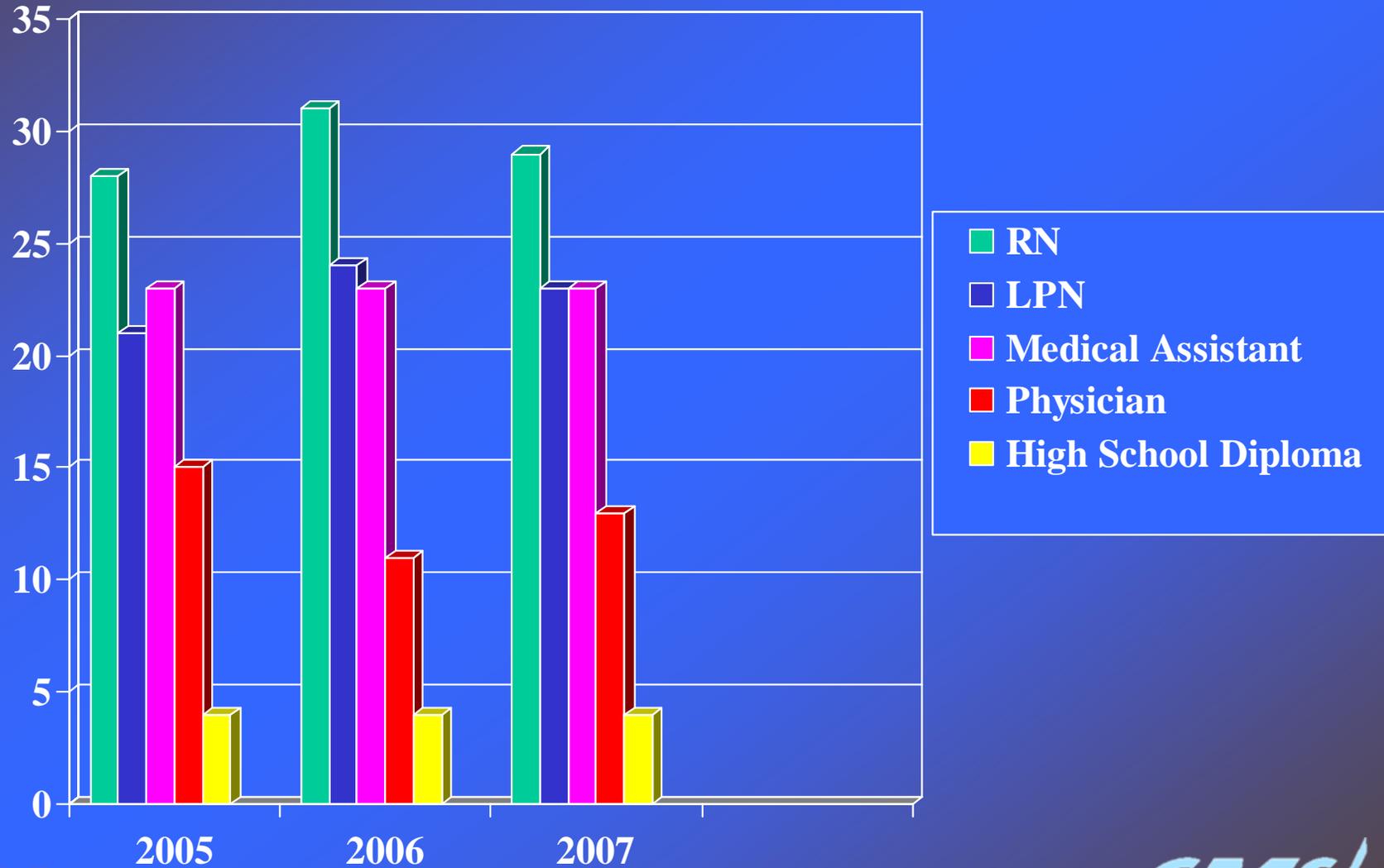
# Interesting Facts about CW Labs



# Who Are the CW Lab Directors??



# Who are the CW Testing Personnel?



# CMS Visits Are Definitely Worthwhile!

In summary, the CW Project has:

- Raised the awareness of following the manufacturer's instructions for testing
- Identified labs testing beyond the scope of their waived certificate
- Provided labs education about CLIA, laboratory testing and Good Lab Practices

# Any Questions??

