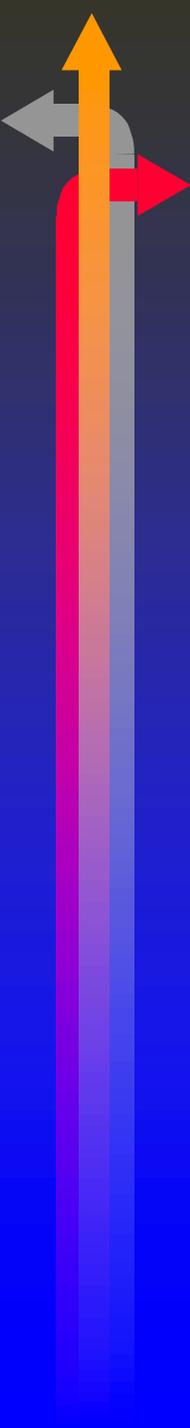
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# HCFA Studies-Waived Laboratories & Moderate Complexity Standards-Myths & Facts

Judith A. Yost, M.A., M.T. (ASCP)

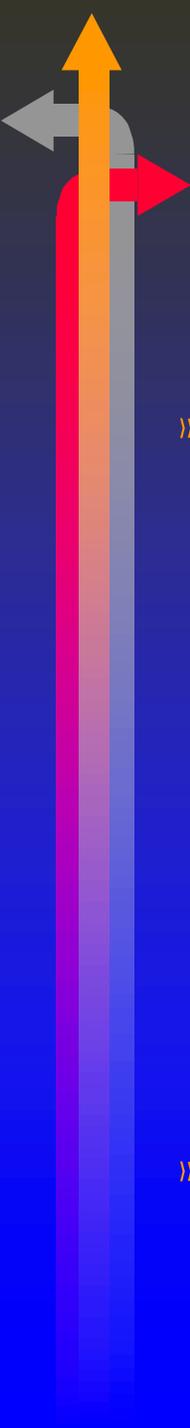
FDA BPAC Meeting

June 14, 2001



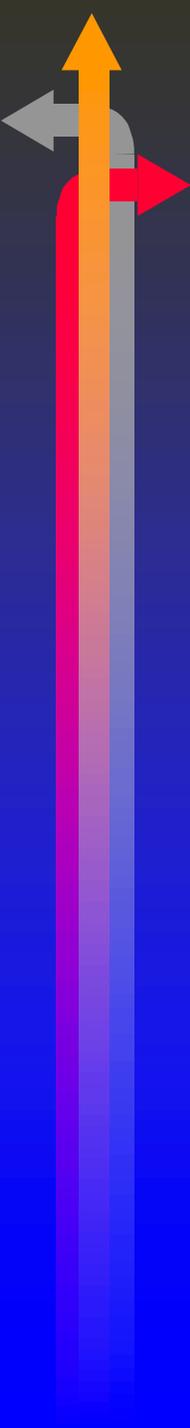
# Background

- »»» CLIA Law - waived tests are simple and have an insignificant risk of an erroneous result
- »»» Waived tests have no standards or routine oversight under CLIA regulations
- »»» 54% (92,000/170,000) of the laboratories in CLIA have a Certificate of Waiver (COW)



# Background Continued

- »»» 42CFR 493.35-CLIA authority to survey COW laboratories
  - »»» If laboratory tests beyond the scope of its certificate
  - »»» If a complaint is alleged
  - »»» If there is serious risk of harm to patients
  - »»» To collect information on waived tests
- »»» 42CFR493.15-waived labs must follow manufacturer's instructions



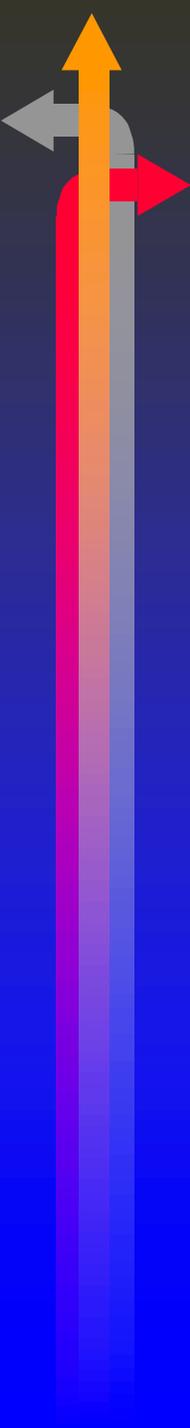
# Background Continued

- »»» CO, OH, NY conducted studies of COW laboratories
- »»» 50% had quality problems
- »»» Office of Inspector General (OIG) study of waived laboratories supports HCFA findings
- »»» CDC studies concur



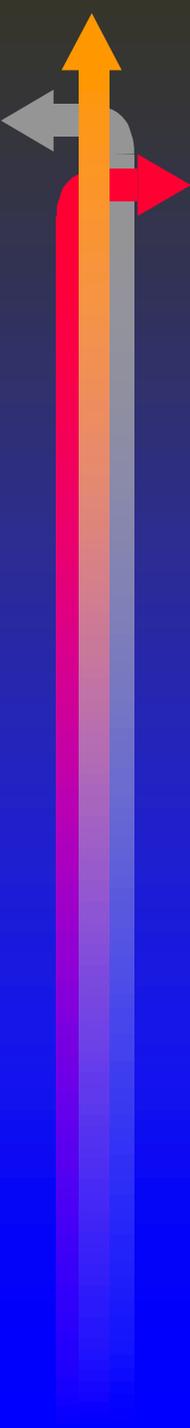
# HCFA Expanded Studies

- »»» 8 additional states-MA, NY, PA, MS, NM, IA, AZ, ID
- »»» 2.5% sample - 270 COW laboratories surveyed
- »»» Announced, educational and information gathering surveys
- »»» Project survey period - Oct 2000 to Jan 2001



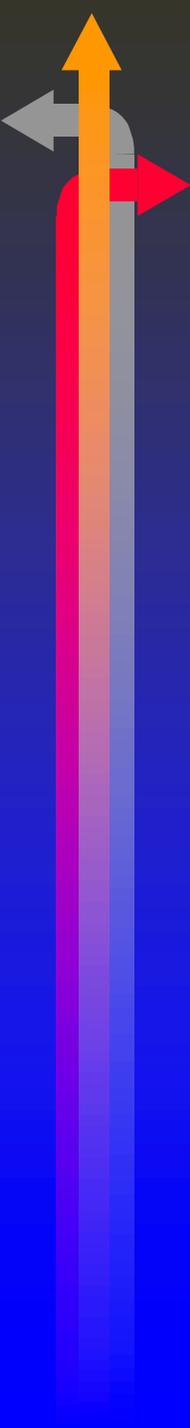
# HCFA Study Findings

- ⇒ Waived Testing Personnel - RN, M.D./D.O., LPN
- ⇒ Quality Problems in COW labs:
  - ⇒ 32% - failed to have current manufacturer's instructions
  - ⇒ 32% - didn't perform QC as required by manufacturer or per CDC's contingency
  - ⇒ 16% - failed to follow current manufacturer's instructions
  - ⇒ 7% - didn't perform calibration as required by manufacturer

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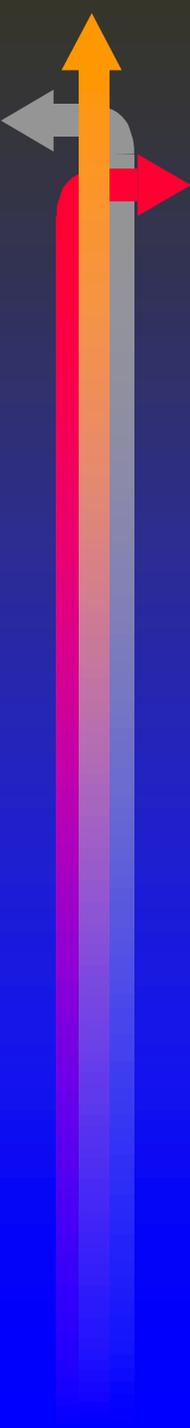
# HCFA Study Findings Continued

- »»» Additional Quality Problems in waived laboratories
  - »»» 20% - cut occult blood cards and urine dipsticks
  - »»» 19% - personnel neither trained nor evaluated
  - »»» 9% - didn't follow manufacturer's storage and handling instructions
  - »»» 6% - using expired reagents/kits



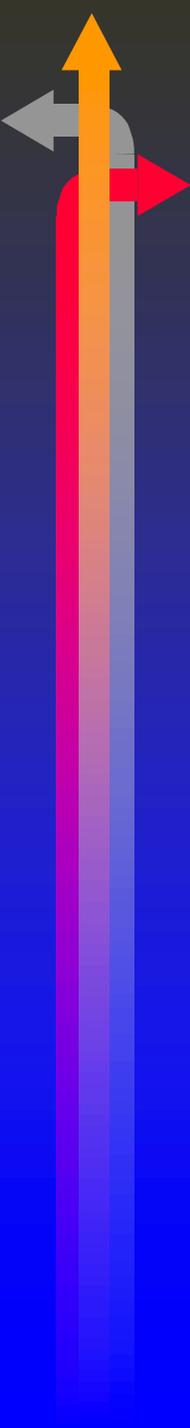
# OIG STUDY FINDINGS

- »»» Laboratories not following manufacturers instructions,
- »»» Failure to identify incorrect results,
- »»» Testing beyond laboratory's CLIA certificate,
- »»» Untrained staff,
- »»» Lack of quality controls,
- »»» Poor equipment,
- »»» Poor storage of reagents,
- »»» Poor record keeping, and
- »»» Misunderstanding of CLIA requirements.



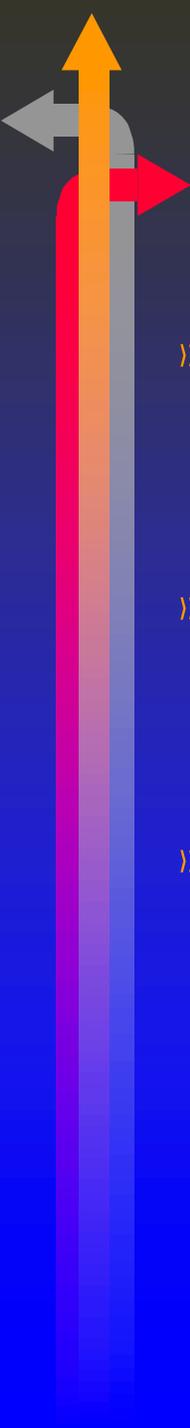
# STATISTICS

- »»» Waived laboratories surveyed -270 (2.5%)
- »»» Facility Types: POL--67%, SNF--11%, ESRD--3%
- »»» Location: Urban--69%, Rural--31%
- »»» States in HCFA study with laboratory licensure programs: ID, MA, PA

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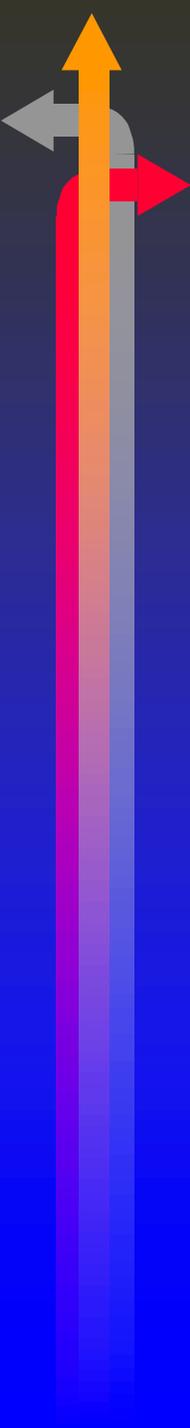
# HCFA RECOMMENDATIONS

- »»» Institute an educational program for COW laboratories
- »»» Validate the effectiveness of the educational program
- »»» Survey a percentage of COW laboratories annually

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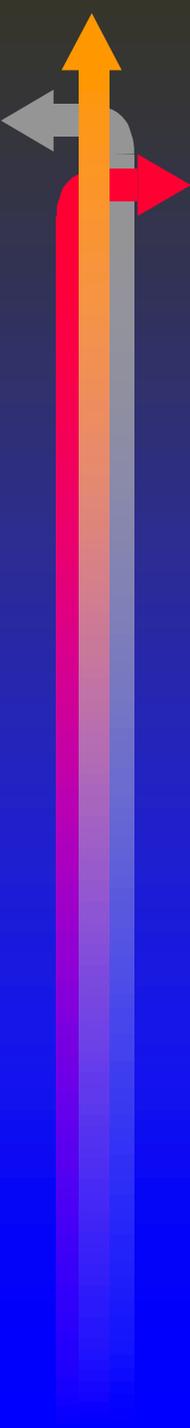
# HCFA RECOMMENDATIONS

- »»» Develop a self-assessment tool for COW labs
- »»» Provide information on CLIA requirements to new COW laboratories
- »»» Have State Agencies randomly telephone a sample of COW laboratories to determine if problems or questions exist



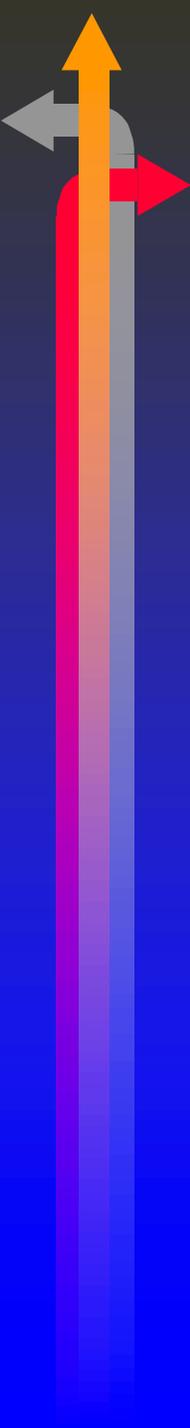
## ADDITIONAL RECOMMENDATIONS BY OIG

- »»» Require labs applying for COW certificates to identify which test systems they will use (checklist on application)
- »»» Establish a mechanism whereby Medicare claim denials can be used to inform State Agencies about labs billing Medicare outside their certificate
- »»» Review waived testing at moderate/high complexity labs during routine surveys



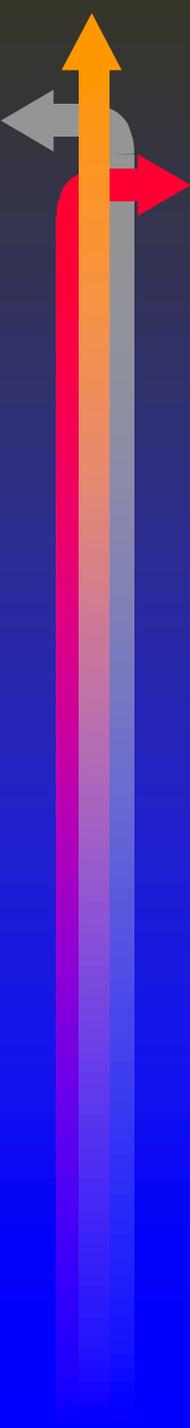
# HCFA Study Summary

- »»» Corroborates findings of the Colorado/Ohio pilots, OIG, CDC & New York studies
- »»» 48% of waived laboratories have quality testing problems
- »»» M.D.'s & R.N.'s not following manufacturer's instructions/CDC QC requirements
- »»» Laboratories located in states with regulations have fewer problems
- »»» All labs visited want to produce quality results



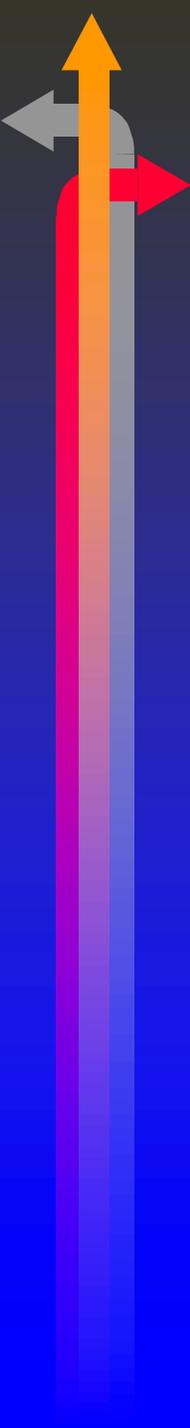
# HCFA Study Summary Continued

- »»» Appreciated by labs; considered educational
- »»» The number of waived laboratories continues to increase due to increase in waived tests
- »»» CLIA-regulated laboratories demonstrate improved performance over time
- »»» Significant findings have serious implications for patients:
  - »»» Not following manufacturer's instructions AND
  - »»» Lack of testing personnel training



# Moderate Complexity vs Waived Myths & Facts

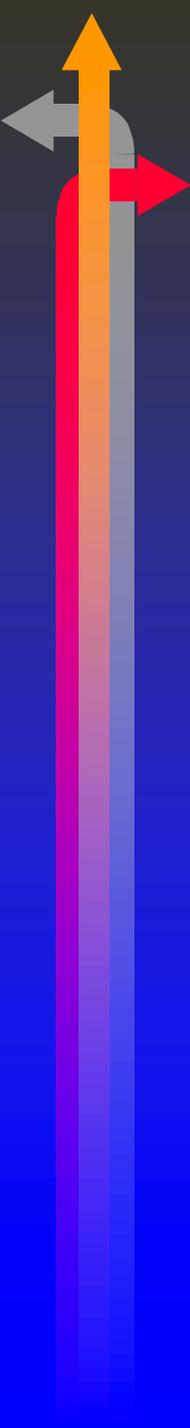
- »»» Application process identical for Moderate & Waived Certificates
  - »»» Application on HCFA web site or state agency
- »»» Waived laboratories
  - »»» Enroll in program
  - »»» Pay certificate fee
  - »»» Follow manufacturer's instructions



# Moderate Complexity vs Waived Myths & Facts

## »»» Moderate Complexity

- »»» One certificate per site or:
  - »»» Limited public health option for multiple sites
    - »»» Federal, state or local public health or not-for-profit
    - »»» Combination of 15 waived and moderate tests
    - »»» One certificate saves survey and certificate costs
  - »»» Biennial onsite survey via accred. org. or HCFA
    - »»» Certificate & survey fees based on annual test volume; low volume bargains available
    - »»» Educational approach with QA focus
    - »»» Good performers rewarded with self-assessment



# Moderate Complexity vs Waived Myths & Facts

»»» Moderate Complexity Quality Standards include:

»»» Personnel

»»» Director qualifications= B.S. degree in science

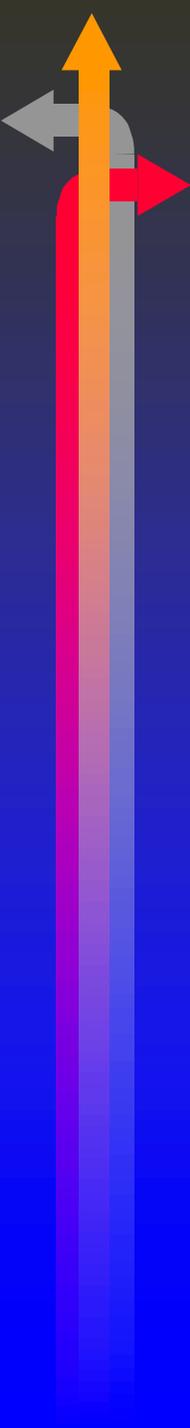
»»» Testing personnel=H.S. with training

»»» Quality Control

»»» Built- in controls acceptable (2 levels/day of testing)

»»» Manufacturers require QC for **BOTH** waived & moderate tests

»»» Use package insert for SOP manual



# Moderate Complexity vs Waived Myths & Facts

## »»» Moderate Complexity Quality Standards

### »»» Proficiency testing (P.T.)

#### »»» Enroll with vendor of choice

»»» 16 providers; modules corresponding to test menu

#### »»» Accuracy twice per year if no P.T.

»»» Example: Split specimens

#### »»» Educational value to laboratory

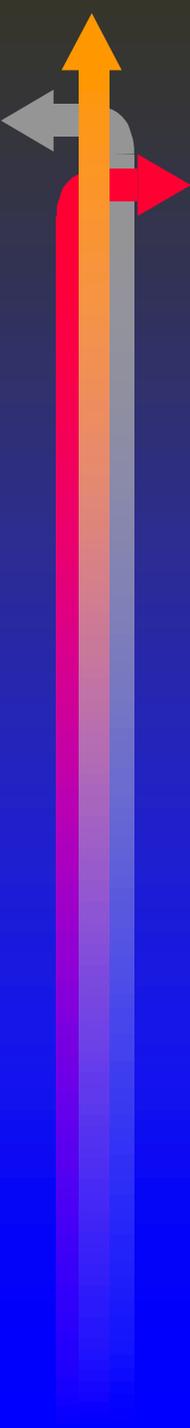
#### »»» One enrollment per certificate (limited public health)

## »»» Patient Test Management

#### »»» Record keeping system/audit trail

#### »»» Use patient chart or unique system

#### »»» No required forms



# Moderate Complexity vs Waived Myths & Facts

## »»» Moderate Complexity Quality Standards

### »»» Quality Assurance

»»» Encompasses quality standards

»»» Effective communication

»»» Problem resolution

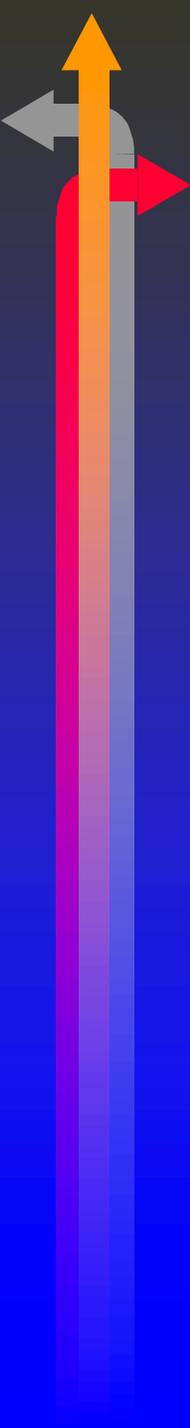
»»» Compare lab data to patient information

»»» Includes things you already do

### »»» Enforcement

»»» Educational approach successful in resolving problem findings

»»» Sanctions imposed only on labs with serious problems



# Summary Moderate vs. Waived

- »»» Minimal basic standards to safeguard quality
- »»» Low cost & burden to labs
- »»» Use existing mechanisms, if applicable
- »»» Technical assistance available from states
- »»» Accredited labs doing waived tests easily meet mod./high standards e.g., ancillary sites
- »»» 9 years of CLIA demonstrate no loss of access
  - »»» Number of POL's enrolled in CLIA increased
  - »»» Lab performance improved