CLIA Update 2014

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Topics For Discussion

- CMS/CLIA Laboratory Enrollment Data
- Top 10 CMS Survey Deficiencies
- CLIA Regulations Update
  - PT Revisions
  - Patient Access
  - Burden PT Referral
- Test Act Next Steps
- IQCP Implementation Plan & Status
- GPRA Goal—Waived Labs
- Resources

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Current Statistics--Enrollment

Total Number of Laboratories	**244,564**
Total Non-Exempt	**236,882**
Compliance	18,959
Accredited	16,081
Waived	165,058
Provider Performed Microscopy	36,784
Exempt	**7,682**
NY	3,810
WA	3,872

CMS data base 1/2014

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Current Statistics

Physician Office Laboratories by CLIA Certificate Type

(Non-Exempt Only)

- Waiver: 59.3%
- Provider Performed Microscopy: 24.3%
- Compliance: 10.3%
- Accreditation: 4.9%

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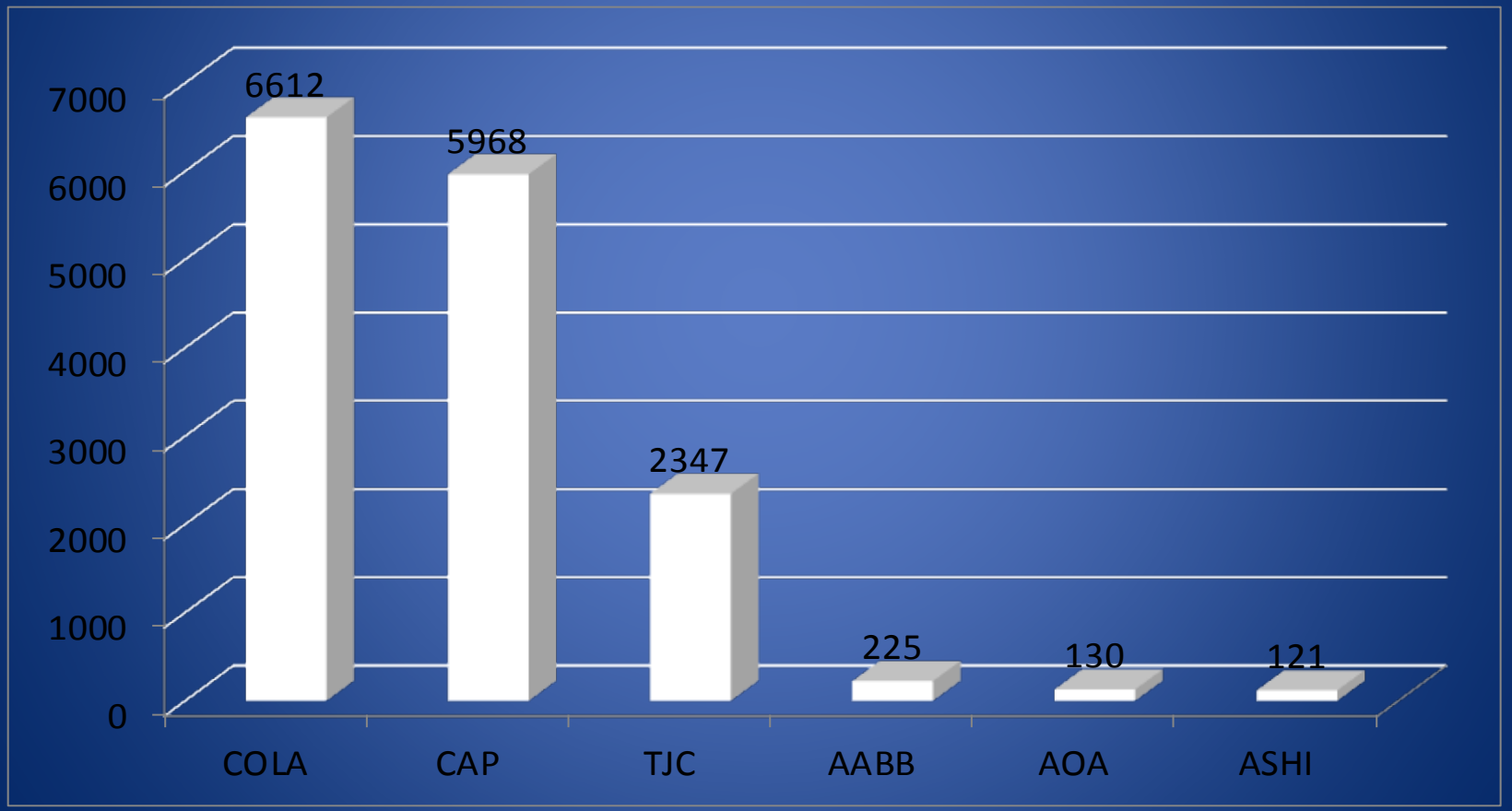
Number of CLIA Certificate of Accreditation Laboratories by Accreditation Organization



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CMS Top Ten Deficiencies (Conditions)

- Mod Complexity LD qualifications 3.7%
- Successful PT participation 3.3%
- High Complexity LD qualifications 1.5%
- PT enrollment 1.4%
- Analytic System (QC) 1.0%

*Data from 17,873 surveys

CLIA data system 12/13

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CMS Top Ten Deficiencies (Conditions) Cont'd.

- Mod Complexity test personnel 1.0%
- TC qualifications 0.8%
- Hematology 0.6%
- High Complexity test personnel 0.4%
- TS qualifications 0.3%

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CMS Top Ten Deficiencies (All)

- Proper storage of reagents & specimens 5.4%
- Analytic systems QA 4.7%
- Alternative PT if no PT available 2X/yr. 4.6%
- Procedure manual 4.1%
- Test reports –patient ID 4.0%

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CMS Top Ten Deficiencies (All) Cont'd.

- Manufacturer's instructions 3.9%
- Mod Complexity LD qualifications 3.7%
- Expired reagents 3.5%
- Calibration verification 3.4%
- Successful PT participation 3.3%

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CMS 2319-F: Patient Access Rule

- Final rule published 2/6/14.
- Centers for Disease Control and Prevention (CDC), Office of Civil Rights (OCR-administers HIPAA) & CMS collaborative effort.
- Revises CLIA regulations at 493.1291(f) and
- Adds new regulation at 493.1291(l)
- Removes exceptions for CLIA and CLIA exempt labs under Privacy rule.

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CMS 2319-F: Patient Access Rule

- Requires all labs that are HIPAA covered entities to provide patients access to their test reports.
- Note: Except as provided in 493.1291(l), test results must only be released to authorized persons, the persons responsible for using them, and the lab that initially requested the test.
- CLIA Interpretive Guidelines will be revisited to ensure laboratories & stakeholders have clear guidance on best practices/resources to implement Health Information Technology.

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CMS 3271-P Fecal Occult Blood (FOB) Testing

- Proposed rule to amend CLIA regulations by
  - Specifying waived test categorization applies only to non-automated FOB tests
  - Removing copper sulfate method from waived list if comments confirm test no longer in use
- FDA rec'd. apps for automated FOB tests which use more complex, automated technology that doesn't meet waived criteria.

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CMS 3271-P Fecal Occult Blood (FOB) Testing

- This regulatory adjustment will permit FDA to categorize FOB tests appropriately.
- Project is a CDC/CMS/FDA collaborative effort.
- Proposed rule is in clearance; no ETA yet.

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Updating PT Regulations

- CMS collaborating w/ CDC
- Received CLIAC recommendations, based on expert input
- Requires significant levels of data compilation & analysis
- CDC working w/ data from PT programs & statistician to determine better target values
- Reviewing current analyte list, grading criteria & target values, etc.
- Proposed rule in early development & will solicit comments on changes
- Final standards will be phased in to allow time for implementation

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PT Referral in Burden Rule #2
CMS 3267-P

- NPRM published 2/7/13
- Proposes one-time exception carve- out for intentional PT referral regarding confirmatory & reflex testing; i.e., if PT sample goes to another lab for testing
- Comments received generally in support
- Final in clearance; 2014 publication planned
- Guidance will be provided to surveyors & labs

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Taking Essential Steps for Testing Act of 2012 (TEST Act – HR 6118)

- Amendment to the CLIA statute signed by the President on 12/4/12.
- Clarifies that PT samples are to be tested in the same manner as patient specimens, EXCEPT that no PT samples shall be sent to another laboratory for analysis.

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Taking Essential Steps for Testing Act of 2012 (TEST Act – HR 6118)

- Allows the Secretary enforcement discretion for:
  - Revocation of the CLIA certificate for PT referral; and
  - Imposition of the 2 year owner/operator ban when sanctioned for PT referral

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Taking Essential Steps for Testing Act of 2012 (TEST Act – HR 6118)

- Proposed rule is a rider included w/ FQHC rule (CMS 1443-P) details 3 hierarchical adverse actions for PT referrals by seriousness (defines when discretion will be applied & when revocation will be imposed).
- Public comments rec'd. &final rule in clearance
- ETA for rule is 2014

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Individualized Quality Control Plan (IQCP) Topics

- Background & History of CLIA QC
  - In the beginning (1992)…
  - 2003 Quality System Regulations
  - Inception of EQC--2004
- 2005 ‘QC for the Future’ Meeting
  - Partnership w/ CLSI & development of EP-23
  - Publication of EP-23 in 2011
- CMS’ Development of & Plan for Individualized Quality Control Plan (IQCP)
  - Education & Transition Period
  - Implementation Status

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IQCP Background & History

- CLIA Law passed—1988
- Final CLIA Regulations published—1992
  - 5 basic QC requirements—mod. complexity phase-in
    - Follow manufacturer's instructions
    - All QC actions acceptable during phase- in
  - All QC requirements apply to high complexity
- Many expert meetings convened by CDC/CMS to find better QC, but to no avail
- Quality System (QS) Regulations pub.—2003
  - Updated all QC requirements

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IQCP Background & History

- 2003 QS regulation--new provision for alternative QC in CMS' Interpretive Guidelines (IG) in lieu of changing regulations w/ new technology, as long as "equivalent quality testing" is provided--*42 CFR 493.1250*.
- Default: 2 levels external QC/day of testing

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Inception of EQC

- Equivalent QC or ‘EQC’ developed in IG as a voluntary alternative QC--2004
  - Option employed depends on the extent internal QC monitors total testing process
  - Minimizes frequency of external QC required
  - Helps save costs/resources for labs
  - Acknowledges technological advances
  - Director responsible for choice of QC plan
  - Remaining quality systems must be acceptable

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Inception of EQC

- Concerns expressed by industry, laboratories, experts, etc.
- Many laboratories adopted EQC successfully & have no quality issues; but no flexibility
  - EQC limited in scope
- CMS reached out to CLSI to facilitate development of an scientific, objective consensus QC guideline

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CMS-CLSI Partnership

- CLSI convened the well-attended ‘QC for the Future’ meeting in 2005
- Sponsored by accrediting orgs., industry, professional orgs. & gov’t. agencies
- Outcome:
  - Stakeholder concern that manufacturers don’t provide labs sufficient information
  - ‘One-size-fits-all’ QC doesn’t work w/ new technology

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EP-23 Becomes IQCP

- CLSI meeting directed the development of Evaluation Protocol (EP)-*23—Laboratory Quality Control Based on Risk Management*
  - Chaired by James Nichols, PhD
  - Assembled expert group
  - Published October, 2011
- CMS incorporated key EP-23 concepts into CLIA IG as QC policy, called **Individualized Quality Control Plan -- IQCP**

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IQCP Policies

- CMS S & C letter-link on CMS/CLIA website
- Applies to CMS-certified non-waived labs
- Covers all phases of the testing process
- May or may not reduce QC amt. or frequency
- IQCP is optional; default is regulation - 493.1256(d)
- Lab must define a QC number, type & frequency in its QCP
- Includes existing & new analytes/test systems & specialties, except cytology/histopathology

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IQCP Pro's

- Can be customized based on patient pop., environment, test system, personnel, test uses
- Offers flexibility & framework to achieve QC compliance for each test; broad in scope
- Adaptable to future technology advancements
- Permits labs to develop a QCP using their existing quality practices/information
  - E.g., test verification data is a start
- Considers known risks mitigated by mfgr. &
- Formalizes laboratories' risk mgt. decisions

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IQCP Facts

- Once effective, IQCP will supersede current EQC policy
- Includes Risk Assessment (RA), Quality Control Plan (QCP) & Quality Assessment (QA)
- Existing CLIA QC & QS concepts won't change
- No regulations will change!
- CMS' outcome oriented survey won't change
- Minimally, labs must follow mfr's. instructions
- Lab director has overall responsibility for QCP

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IQCP Facts

- There is an education & transition period starting Jan. 1, 2014 to Jan. 1, 2016 for labs before IQCP is fully effective
  - Surveys will be educational
- At the end, labs must be in compliance w/ their QC choice
- Or deficiencies will be cited
  - Surveyors will provide educational materials to labs
- National Surveyor Training on IQCP was conducted in Nov. 2013
- Ongoing educational info & guidance will be provided to labs

www.cms.hhs.gov/clia/

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IQCP

In the interim, CMS certified labs should:

- Continue to follow existing QC protocols
- Learn about EP-23 concepts & IQCP
- Plan & complete their transition accordingly
  - Phase out EQC (if using it)
  - Decide to implement default QC or IQCP

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IQCP & Accredited Labs

- CMS has solicited accrediting orgs (AO) to determine their interest in IQCP
- Accredited labs should continue to meet their accrediting org.'s current QC standards until they receive notice from their AO about any QC changes
- AOs need to:
  - select option
  - Revise standards accordingly
  - Obtain CMS approval
  - Educate their labs

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IQCP Educational Period

- No control procedure regulatory citations will be issued during the education & transition (E/T) period, unless serious test quality problems are found
- All questions regarding IQCP may be directed to the CMS electronic mailbox

IQCP@cms.hhs.gov

- Please stay tuned for more information…..

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IQCP Surveyor Training Modules

- History & Rationale for IQCP
- CLIA IQCP Policies
- Overview of Risk Assessment
- Scope of IQCP
- Citations (D-tags) for IQCP
- Surveying for Compliance
- Sample Quality Control Plan (QCP) Evaluations
- Education & Transition Period

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IQCP Educational Outreach

- **CLIA BROCHURES**
  - First in a series of IQCP brochures had its debut
  - Focus is introductory level Q&A addressing:
    - What is IQCP
    - Application
    - Participation
    - Manufacturer Instructions
    - Director Responsibility
  - Distribution
    - CLIA website
    - On-site survey of Certificate of Compliance (COC) labs
    - Booths, public venues, Partners
  - Anticipate the 2nd brochure release by early 2014

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IQCP Educational Outreach

- **COLLABORATION with CDC**
  - CMS is collaborating w/ CDC on further educational material
  - Focus geared towards Physician Office Laboratories (POLs) & other smaller labs,
  - But can be used by all.

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IQCP Communications

- CLIA website: two S&C letters w/ FAQs
  - Will be updated periodically
- Mailbox for inquiries: IQCP@cms.hhs.gov
- Educational Brochures: posted on CLIA website: www.cms.hhs.gov/clia/
- CMS media venues for IQCP press release
- IQCP information/materials will be shared w/ Partners & stakeholders

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IQCP Planning

- IQCP Education & Transition (E/T) Period
  - Two years long—1/14 to 1/16
  - Learn about IQCP & ask questions
  - Determine QC option
  - Make transition plans
  - Begin to implement choice
- IQCP is optional for AO/ES Standards

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IQCP AO/ES Planning

- During Education & Transition (E/T) Period
  - AO/ESs evaluate their standards
  - Ensure AO/ES standards contain acceptable QC options:
    1. CLIA QC regulations as written or
    2. IQCP
- End of E/T Period
  - EQC no longer acceptable
- Changes in AO/ES standards
  - Submit to CMS prior to implementation
  - CMS evaluation: must be equal to or more stringent than the CMS IQCP procedure

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IQCP AO/ES Planning-- Validation

- Validation Surveys for IQCP
  - Surveyors to be trained to follow the standard process of surveying w/ the CLIA requirements
- Validation Surveys: Education & Transition Period
  - Labs will be cited for not following CLIA QC requirements, only if a surveyor identifies **quality testing problems; e.g.,**
    - doing no QC at all
    - serious test quality concerns
    - immediate jeopardy (real or potential harm to patients)

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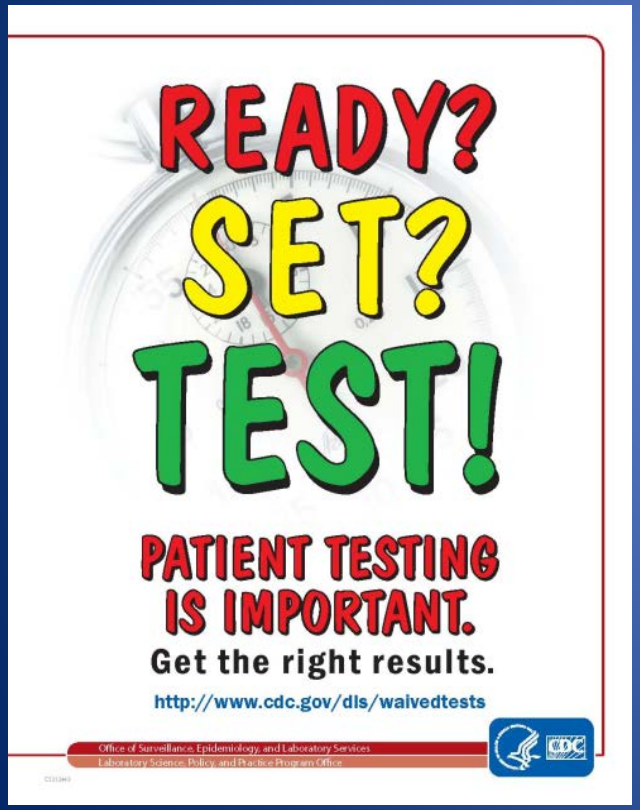
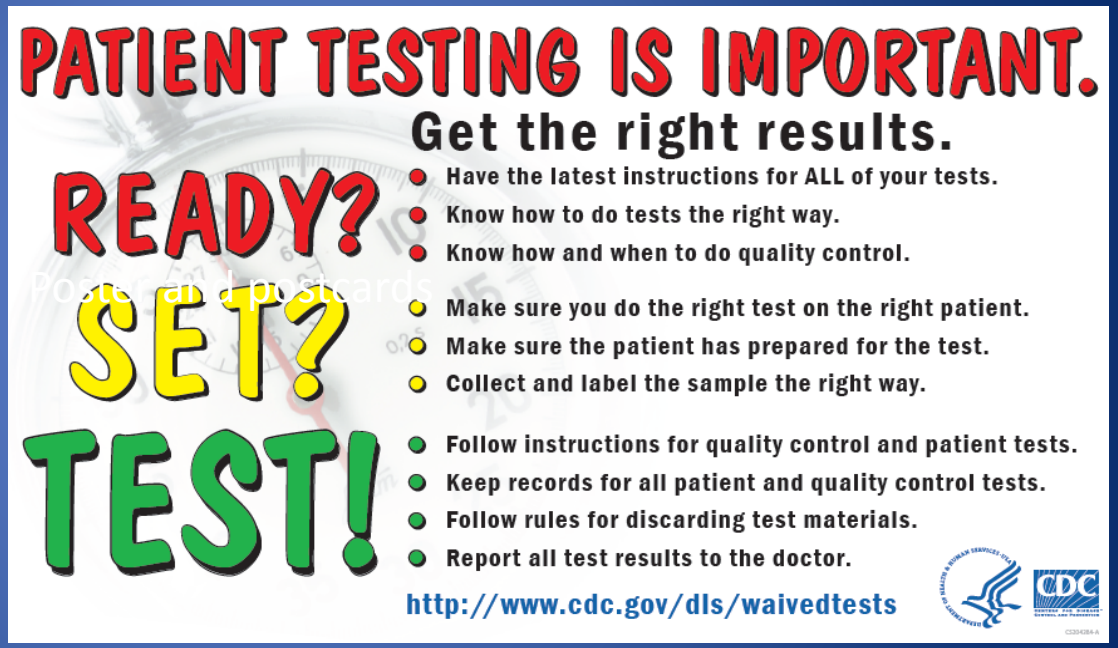
Good Laboratory Practices for Waived Testing Sites

- Educational booklet with job aids





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GPRA 'Ready, Set, Test!' Waived Project

Government Performance Review Act

- Goal – Improved compliance with CLIA standards as measured by increased percentage of Letters of Congratulations (no problems found) sent to waived (CW) laboratories based on onsite educational visits.

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GPRA 'Ready, Set, Test!' Waived Project

- Pilot Study – 2 states in each CMS Region
  - Selected CW labs received copy of 'Ready, Set, Test' booklet prior to their CW survey
  - Post survey information collected regarding lab use of booklet to improve lab practices

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GPRA 'Ready, Set, Test!' Waived Project

- 2010 Baseline – 18% received Letters of Congratulations
  - Results from 2011 – 32%
  - Results from 2012 – 44%
  - Results from 2013 – 45% (386/861 labs)

Conclusion – Educational materials like 'Ready, Set, Test' booklet are well-rec'd.; serve as excellent means to improve lab test quality.

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GPRA 'Ready, Set, Test' Waived Project

- 97% - rec'd. the booklet
- 84% - reviewed the booklet
- 95% - found the booklet helpful
- 50% - changed current practices as a result of reading the booklet
- Helpful sections of booklet:
  - QC log instructions
  - Record keeping
  - QC testing

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Where to Obtain Information

CMS/CLIA Web site:

http://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index.html?redirect=/clia/

CMS CLIA Central Office:

410-786-3531

Judy Yost's Email: **Judith.yost@cms.hhs.gov**

IQCP Mailbox: IQCP@cms.hhs.gov

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THE END!

THANK YOU!!

QUESTIONS??

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