CLIA UPDATE

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Statistics

Total Enrollment	**192, 533**	
Certificate type	No. Labs	POLs
Compliance	20,607	13,627
Waiver	111,338	51,792
Provider Performed Microscopy	39,088	32,265
Accreditation	15,544	5,835

Exempt States (NY & WA) *5956*

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Accrediting Organization (AO) Enrollment

• COLA	6260
• College of American Pathologists	5246
• Joint Commission on Healthcare Accred.	3153
• American Osteopathic Association	49
• American Association of Blood Banks	214
• American Society for Histocompatibility & Immunogenetics	129

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Labs by Self-Selected Types

Type	Number
POL	104,994
Nursing homes	14,741
Hospitals	8,617
Home Health Agency	9,051
Community Clinics	6,522
Independent Labs	5,239

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CLIA DATA TRIVIA

- 88% of labs perform up to 25,000 tests/ yr.
- 0.3% of labs perform > 1M tests/yr.
- There are 3,874 pharmacies enrolled.
- The most frequently cited deficiencies (labs receiving letters) related to the final CLIA regulations were in QC in the areas of test method verification, calibration & calibration verification & QC procedures.
  - Where the most significant changes were made.

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Topics for Discussion

- **CLIA Statistics**
- **CW Surveys**
- **QC for the Future**
- **Partners in Laboratory Oversight**
- **GAO Audit**

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CW Surveys

- CMS will continue to conduct visits in ‘06.
- Data demonstrates quality issues ongoing.
- MMWR Report and Best Practices.
- CMS Tips for Waived Labs Brochure.
- Data utilized to define effectiveness of CLIA—GPRA measure.
  - Follow up visits reflect sustained improvement.

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CW Immediate Jeopardy (IJ) Defined

Date	Test	Lab	Reason	Outcome
4/02	gluc.	nsg.home	Result reported >rept. range	trng.
6/02	gluc.	ESRD clinic	arterial sample	POC
3/03	CBC	POL	cert./QC, etc.	stop test
3/03	Rh/HCG	ASC	cert./QC, etc.	stop test
6/03	gluc./PPM	POL	cert./QC, etc.	stop test

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QC for the Future

- Why QC is Important:
  - Lab tests contribute to 70% medical decisions.
  - 7 Billion tests performed/yr.
  - 40,000 labs subject to QC
  - QC demonstrates test performed correctly.
- QC is & has been most frequently cited deficiency since 1992.

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QC for the Future

- CMS added flexibility in ’03 regs for labs to decrease external QC under certain conditions using Interpretive Guidelines instead of regulations.
- Thus, the infamous Equivalent QC (EQC) was conceived.

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QC for the Future

- Prior to the ’03 regulations, both CDC & CMS convened meetings with experts, including CLIAC.
- We learned that one size doesn’t fit all.
- Did not receive any other viable solutions for QC.

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QC for the Future

- In 2003, CMS requested CLSI to convene a meeting to discuss QC alternatives.
  - Alternatives would be developed under the consensus process.
- CMS chaired an organizing committee with representatives from AACC, AdvaMed, ASCLS, FDA,CDC & CLSI.
- Meeting was sponsored by laboratory professional orgs. & AOs.

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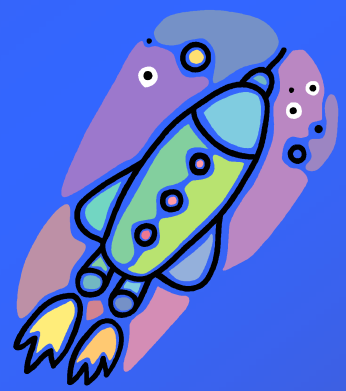

QC for the Future

- Meeting held Mar. 18, 2005.
- Plenary speakers included:

James Westgard	Elissa Passiment
LuAnn Ochs	Joe Boone
Fred Laskey	Valerie Ng
Tom Hearn	Don Powers
Judy Yost	

Moderator: Robert Habig---Pres.-Elect CLSI

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QC for the Future

- Afternoon Breakouts had lively discussions, but no concrete results for CMS.
  - Manufacturers must provide labs more info.
  - Risk management information from manufacturers could facilitate the lab's ability to design QC protocols.
  - Each device/method needs diff. types & levels of QC.
  - You need to consider the unique aspects of each lab personnel, environment, etc.)
  - CMS & AO QC policies inconsistent.

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QC for the Future

- The initial product from the meeting is a CLSI project proposal to develop Risk Management guidance for mfgrs.
- Mfgrs. would validate an alternative QC procedure for their test system & include this info & risk info for the lab in the labeling.
- This project, EP-22, is underway.

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QC for the Future

- EP-22: Principles of manufacturer's validation of risk mitigation using quality controls.
- Objectives are:
  - Assess definitive risk;
  - Prove one's QC mitigates risk;
  - Determine which data is required.

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QC for the Future

- Critical Factors in QC Decisions
  - QC must detect immediate errors & over time.
  - Risks & costs must be balanced.
  - All labs are unique.
  - Science & logic must converge.
  - QC is one part of lab's quality system.

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QC for the Future

- RISKS:
  - Manufacturers—device failures
  - Labs-failure to detect mistakes
  - Patients—Potential adverse health consequences

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QC for the Future

- In discussions with QC experts from labs, industry & government, it was decided that an additional CLSI document should be created to provide guidance to labs in developing their QC protocols using the manufacturer's risk management information & considering the environmental factors unique to the lab.

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QC for the Future

- The final QC decision remains with the lab director.
- CMS would accept this QC, if both CLSI docs are followed, as meeting CLIA QC.
- Report of QC for the Future on CLSI web site.
- Presentations will be published in Laboratory Medicine.

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QC for the Future

Come join us and participate in the development of the new document for laboratories!

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Partners for Laboratory Oversight

- Partnership of lab oversight orgs.: AOs, CMS, CDC, Exempt states, States w/ licensure programs, VA.
- Three successful meetings thus far.
- Next mtg. Is 2006 w/ interim projects.
- Positive feedback rec'd. from all attendees & CMS management.

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Partners in Laboratory Oversight

- **Meeting results**:
  - **Identified essential elements of the survey process;**
  - **Improved information-sharing protocols;**
  - **Updated complaint protocol;**
  - **Developed rapid response alert-major situations.**
  - **Shared best practices.**
- **Future projects:**
  - **Ensure consistent policies; diminish lab confusion.**
  - **Implement performance measures for AOs.**
    - **Similar to those used by CMS for States.**

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GAO INVESTIGATION

- Audit of laboratory Quality Assurance.
- Initiated in Jan. 2005 by Rep. Elijah Cummings of Baltimore due to MGH issues is ongoing.
- Focus on CMS oversight & performance of AOs and State agencies under CLIA.

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THE END!

THANK YOU!!

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