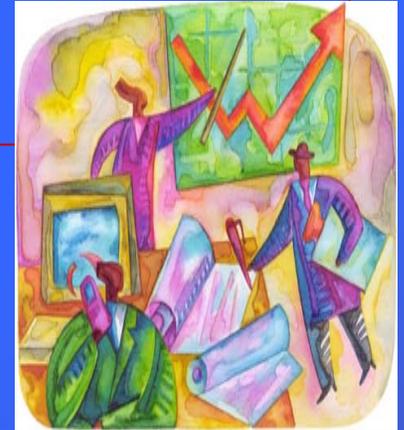


CLIA Update 2008, Part 2

CLIA Update



- **Topics for Discussion:**

- Current Statistics 6/08
- Cytology PT NPRM & Data
- Oversight of Genetic Testing
- PT Regulation Update Plan
- CMS QC Policy Change
- CLSI EP-23: Alternative QC for Laboratories
- PT Referral
- Waived Test Concerns

Current Statistics

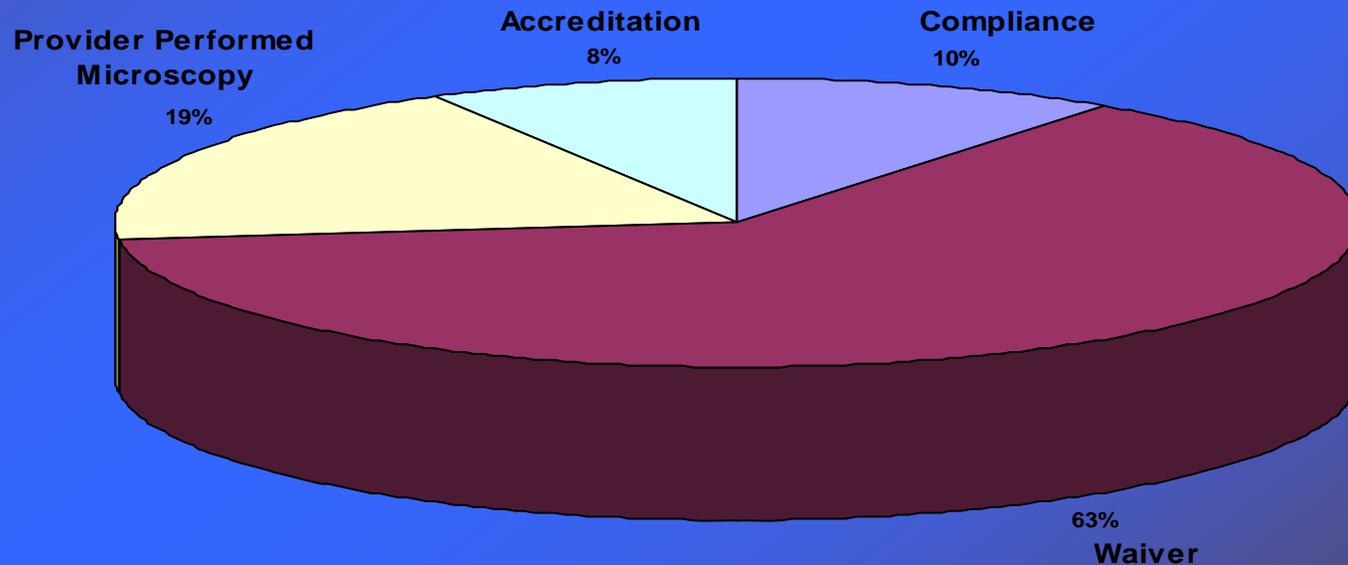
- **Total Number of Laboratories: 206,940**
 - Compliance: 19,412
 - Waived: 126,219
 - Provider Performed Microscopy: 38,783
 - Accredited: 16,261
 - Exempt: 6,265
 - NY: 3,124
 - WA: 3,141



CMS data base 6/2008

Current Statistics

CLIA Labs by Certificate Type (Non-Exempt Only)

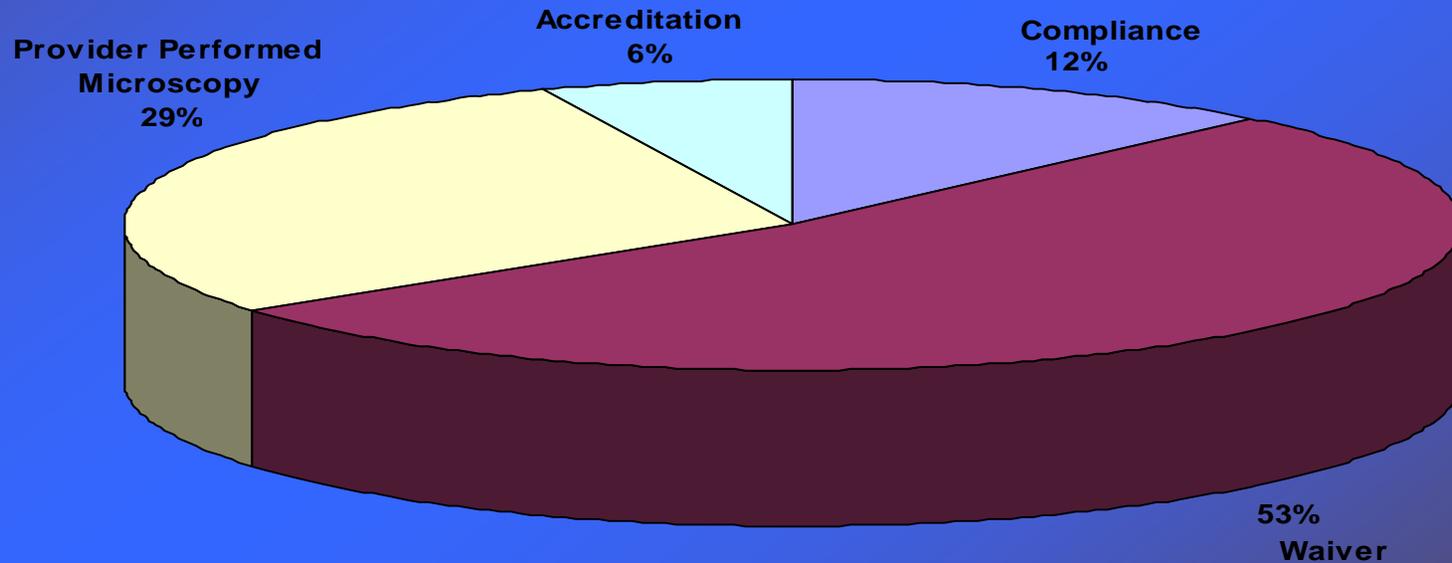


Source: CMS CLIA database 6/10/2008



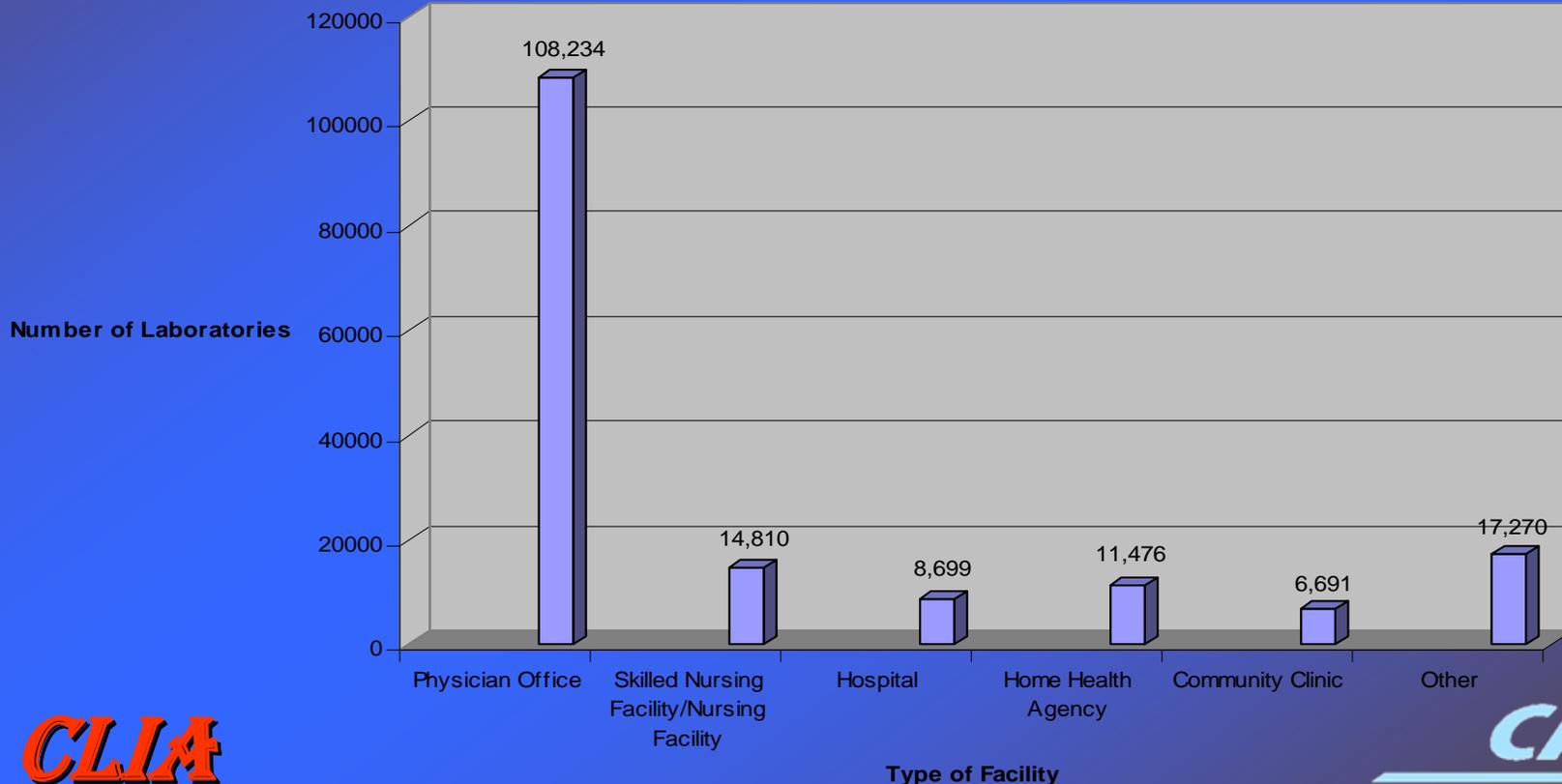
Current Statistics

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



Current Statistics

Total CLIA Laboratories Registered Self-Selected Laboratory Types



Cytology PT

Regulation:

- Proposed rule reflects 17 CLIAC recs.
- In clearance at HHS.
- Contains questions & solicits comments.
- Comments accepted; both pos. & neg.!
- Comments analyzed & final produced.
- Legislation passed House; debated in Senate.
 - Would eliminate PT & require continuing education.

Cytology PT

2005—FINAL Initial Test (10 slides/2 hrs.)

	<u>Pass</u>	<u>%</u>	
CT	6083	93%	
Path w/o CT	312	67%	
Path w/CT	5242	90%	
<u>TOTAL Tested</u>			
	12,831	11,637	91%

Cytology PT

2006 FINAL Initial Test (10 slides/2 hrs.)

	<u>Pass</u>	<u>%</u>
CT	6085	95%
Path w/o CT	372	83%
Path w/ CT	5437	95%
<u>TOTAL Tested</u>		
	12,752	11,894 95%

Cytology PT

2007 Prelim. Initial Test (10 slides/2 hrs.)

	<u>Pass</u>	<u>%</u>
CT	6052	97%
Path w/o CT	387	89%
Path w/ CT	5544	97%
<u>TOTAL tested</u>		
12,435	11,983	96%

Cytology PT

Comparison of PT Performance

2005	91% passed
2006	95% passed
2007	96% passed

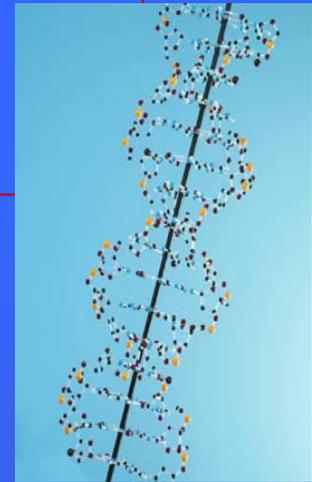


Genetic Testing Oversight

CMS Actions in Lieu of a GT Specialty:

- Provided surveyor education.
- Initiated plan w/ CDC to update PT regulations.
 - Will promote use of formal PT when available.
 - Will evaluate mechanisms for alternative assessment.
- Encouraged public/private partnerships.
- Promoted use/development of prof. standards.
- Hired staff w/ GT expertise.
- Determined existing enforcement is sufficient.

Genetic Testing Oversight



CMS Actions in Lieu of a GT Specialty:

- Seek to enroll more GT labs.
- Monitoring DTC labs ongoing.
- Expanded CLIA web site w/ certification status.
- Collaborate w/ CDC on MMWR to educate labs.
- Work w/ FDA on test valid. reviews.
- Evaluating tests for CLIA coverage.
- Exploring creative survey methods w/ Partners.

PT Regulation Update

- Plan w/ milestones & est. timeline developed
 - Includes target values, grading system, PT providers, labs, PT referral, alternative assessment
 - Will require a proposed rule w/ comment & final
 - No firm ETA
- List of related issues compiled
- CDC/CMS met one full day early '08 to discuss
- Agreed to utilize CLIAC process w/ SME WG

PT Regulation Update

- Ongoing teleconf. betw. CDC/CMS convened
- Medicare data reviewed for test frequency
- PT providers' meeting scheduled in Nov.
- Evaluating possible mechanisms for analyte selection/removal.
- Considering vehicles to publish analytes.
- Soliciting a CLIAC recommendation to proceed

Changes in QC—“Analytic Systems”--2003

- Verification of performance specifications for mod. complexity tests.
- Clarification of calibration verification (checks).
- QC procedures—2 levels of ext.QC or EQC req'd.
- Initially all 3 were “educational”.
- Pertinent CMS “Brochures” on CLIA web site.

Continue Educational QC, w/ Limited Scope



- *Retain QC (493.1256) as educational !*
 - Effective 12/31/2007
 - CMS labs had 2 ‘educational’ surveys;
 - Should understand & comply.
- **Discontinue as educational:**
 - Test method verification (493.1253)
 - Maintenance & Function Checks (493.1254)
 - Calibration & Cal. verif. (493.1255)

CMS QC Survey Policy

- Until new QC policies are in place, labs will continue to receive “educational” surveys for *only* QC procedures at 493.1256.
- Labs not meeting QC stds. receive a **letter** urging them to correct, in lieu of deficiency;
 - *If serious quality issues, QC may be cited.*
- Existing requirements not met continue to be cited on a deficiency statement (CMS-2567).
 - **Calibration, cal ver. , test method verif., & function checks now in this category!!**

CMS QC Survey Policy

- Accredited labs continue to meet their AOs QC standards.
- CMS is working w/ AOs to standardize inconsistent policies.
 - Through Partners in Laboratory Oversight.

Status Alternative QC Development



- 2005 CLSI meeting sponsored by lab prof. orgs., government, industry & AOs, discussed a plan for **“QC for the Future”**.
 - *Labs need more info from manufacturers.*
 - *One-size-fits-all QC not good for diff. test systems/labs.*
- Two CLSI docs under development for QC.
 - *Alternative QC for labs (Jim Nichols) & risk management for manufacturers (Greg Cooper).*
- Interpretive Guidelines will be revised accordingly.
 - CMS hasn't determined if Options 1-3 will remain.

Status Alternative QC Development

- CMS is working w/ CLSI to develop 2 guidance “Evaluation Protocol” documents.
 - Includes reps from labs, industry & gov’t.
 - Utilizes a consensus process.
 - Exciting, groundbreaking efforts!
- *Manufacturers’* - using ISO risk mgt. principles.
- *Laboratories’* - to design custom QC.
- CLSI Subcommittee vote—Fall ’08.



PT Referral WARNING!



STOP

- Review & learn CLIA PT regs, Subpart H.
- Do not send a PT sample or part of a sample to another lab for testing!
 - Be cautious w/ reflex & confirmatory tests.
 - PT is by certificate; don't send to sister lab w/ different certificate number.
- Do not communicate w/ another lab about PT results.
 - Until after PT program deadline & your results ret'd.
 - QA/PT Coordinators---robust policies & procedures avoid perception of cheating.

PT Referral **WARNING!**



STOP

- Report to CMS any PT samples you receive in your lab from another lab during the PT event..
- PT includes analytes **NOT listed** in the regulations.
 - If a CMS approved PT provider is utilized to meet alternative assessment/QA requirements.

PT Referral **WARNING!**



STOP

- PT referral, whether intentional or not, results in the most serious CLIA penalties.
 - Loss of CLIA certificate for one year.
 - Includes cancellation of Medicare/Medicaid payment.
 - Lab dir. (LD) can't direct ANY lab for 2 yrs.
 - Listing on CLIA annual Lab Registry—CMS web site.
- CMS has prevailed in all appeals to date.
- CMS sending letter to LDs.
 - Contains PT FAQs for labs.
- CMS will develop PT Brochure.

Partners In Laboratory Oversight

- AOs, ES, VA, SA & CMS met since '05 twice/yr.
- Established elevated levels of coordination & collaboration; professional respect
- Improved oversight capability & info sharing
- Presented “ Best Practices”
- Developing data-driven performance measures
- Continue to ID discussion issues; e.g., CW labs

CMS Waived Test Concerns

- **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)

PROJECT

Background

- The only standard for CW laboratories is to *follow manufacturer's instructions & register w/ CMS.*
- As part of the CW project, each CW laboratory responds to questions about its waived testing.

CERTIFICATE OF WAIVER (CW)

PROJECT DATA

Background

1999 Pilot Project:

- CO & OH each visited 100 CW & PPMP laboratories; 50% had quality problems!
- As a result of findings in CO & OH, CMS expanded the pilot to the 8 other States.

CERTIFICATE OF WAIVER (CW)

PROJECT DATA

Background to Present

2000-2001 Expanded Pilot:

- Surveyors in MA, NY, PA, MS, NM, IA, AZ, ID visited 436 COW & PPMP laboratories; 32% had quality problems.

Present

- CMS-CLIA initiated CW Project April 2002 to survey 2% of CW labs per year & it's ongoing.

Results of CMS CW Project FY 2006



Initial visits

Of 1947 labs visited, 69% answered “yes” to Question #5; meaning they were following the manufacturer’s instructions.



Follow-up visits

Of 414 labs revisited for not following manufacturer’s instructions, 353 or 85% improved upon revisit.

2004 CDC Findings Include...

- 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%)
- CDC & NY studies correspond to CMS’.

(Presentation CLIAC_Waived testing update_Sept 2004.ppt)



Question? To Consider

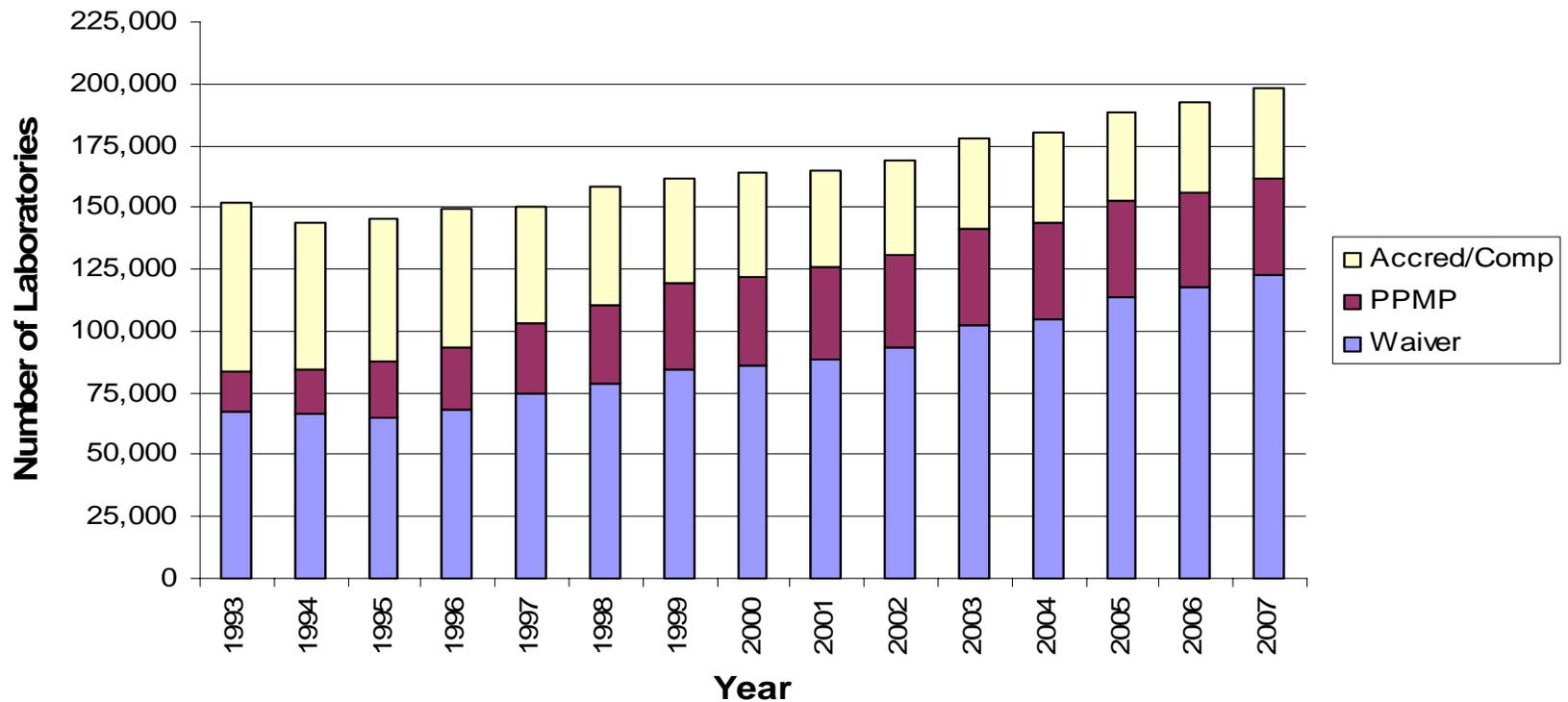
Have CW lab & test device performance improved sufficiently so that approval of a waived CBC test system will not be detrimental to patient care?

Since 1992.....

- CLIA-waived tests have increased from 8 to about 100 tests.
 - This represents 1000's of test systems!
- The number of laboratories issued a CW has grown exponentially from 20% to 60% of the >206,000 laboratories enrolled.

of Non Exempt Labs by Application Type

Non Exempt by Application Type



Waived Testing

- Provides for 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



CMS Concerns with the CBC Waiver

- General issues
- Pre-analytical Issues
 - Analytical Issues
- Post-analytical Issues

General Concerns

- Should an automated differential be categorized as waived? Does it meet definition of “*simple*”?
- How does the device perform under real lab conditions w/ actual testing personnel?
- How are varying hematological clinical conditions & patient populations addressed?
- The level of expertise to operate the device & judgment required to interpret the test results
- Lack of data management capability

Pre-Analytical Instrument

- Patient Identification (entry/storage of)
 - Number one patient safety issue
- Temperature/Humidity requirements
- Safety & Biohazard issues
- Maintenance

Pre-Analytical Operator/Instrument

- Operator training is necessary
- Instrument Setup (level of difficulty)
 - Can operator change setup? Or--
 - Can setup features be locked?
- Reagent Preparation
 - Single or Multiple steps?

Pre-Analytical Specimen Collection

- Detailed instructions for all specimen types (fingertick, venipuncture, heelstick)
- Increase emphasis on.....
 - Collection technique (bubbles, clotting, volume)
 - Specimen interferences – lipemia, hemolysis
 - Errors due to delay in placing cartridge into device
 - Flags/errors when present?

Analytical Instrument Validation

- Broaden studies to demonstrate simplicity & robustness of test system
 - Accuracy
 - Precision
 - Sensitivity
 - Specificity
 - Reportable range

Analytical Instrument Validation

- Clinical validation studies should be expanded to include:
 - Hematological disease states
 - Different patient populations (pediatrics & oncology)
 - Comparison to analyzers w/ different methodologies

Analytical Reagents & Quality Control (QC)

- Test limitations & precautions noted in PI & flagged?
- Are reagents temperature &/or light sensitive?
- Is the test process time-sensitive?
- QC must be required, at a minimum, w/ each new lot/operator.
- State clearly that external QC must comply w/ local, state & other applicable requirements.

Analytical Internal QC/Calibration

- Does device have internal QC?
- Is it factory calibrated?
- How frequently are these performed?
- What do they monitor?
- Does the device store the results for retrieval?
- Does it flag the operator if not acceptable?
Or Not produce a result?

Analytical Patient Testing

- How are blood cells counted (technology)?
- Are all types of WBC's identified?
 - Cell size variability addressed?
 - Interfering substances?
- Abnormal cells correctly identified (NRBC's, Blasts, Sickle cells)? Flagged?

Analytical Patient Testing

- Identify rouleaux, giant platelets, platelet clumps?
- Fail safes for fatal errors?
 - Does the software prevent result reporting?
- Error codes for other unacceptable situations?
 - Can error codes be overridden by operator?

Post Analytical Results Reporting

- Level of result interpretation (normal vs. abnormal)
 - Abnormal results & error codes flagged?
 - Error codes flagged included on test report?
 - Can results be printed, saved, retrieved?
 - Does manufacturer provide reference ranges?
 - For various clinical/patient populations?

Summary of General Concerns

- Should an automated CBC & differential be categorized as waived? Does it meet the definition of “*simple*”?
- Level of expertise to operate the device & judgment required to interpret the test results.
- How does device perform under real lab conditions w/ actual testing personnel?
- How are varying hematological clinical conditions & patient populations addressed?
- Is there no risk of harm if performed incorrectly?
- Issues throughout the entire testing process.
- Lack of data management capability.

Final Comment

Based on the multiple concerns identified w/ this test system, there are still significant potential areas of risk that must be addressed to reduce the likelihood of harm to the patient.

Where to Find Info

- CMS Web site:

- www.cms.hhs.gov/clia/

- “Laboratory Demographic Look- Up”

- Brochures, state/ regional contacts, application

- CMS Central Office, Baltimore

- 410-786-3531

- Judy Yost’s email:

- Judith.yost@cms.hhs.gov



THE END!!

THANK YOU!!
QUESTIONS???

