Laboratory Regulations Update

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Objectives

- Describe the use of glucose meters in critically ill patients
- Identify changes to CLIA Interpretive Guidelines for Individualized Quality Control Plans (IQCP)
- Review the top AACC government affairs committee priorities for Capitol Hill Visits this year

POCT Glucose

A glucose test is not necessarily a glucose test

This fact has been known for many years

Glucose Testing Methods

- Core Laboratory – glucose hexokinase
- POCT – glucose oxidase, glucose dehydrogenase
- Critical Care – glucose oxidase

- Method differences
- Calibration differences
- Whole blood to plasma considerations

Blood Glucose Meter Precision

- 95% of results fall within ± 2SD
- Core Lab

  93.7 ± 0.9 mg/dL (1.0% CV)

  282.7 ± 1.9 mg/dL (0.7% CV)
- POCT

  49.0 ± 9.2 mg/dL (18.6% CV)

  283.0 ± 15.0 mg/dL (5.3% CV)
- Clinically the ADA has recommended glucose meters to have CV's of <5% at all levels and accuracy to within 5% of a lab result. (1987)

Blood Glucose Meter

- 95% of results within ± 20% if >100 mg/dL
- 95% of results within ± 20 mg/dL if <100 mg/dL
- Most recent evaluation by FDA on patient samples:

	<100 mg/dL		>100 mg/dL	
	<20mg/dL	>20mg/dL	<20%	>20%
Meter A	0%	22%	0%	24%
Meter B	0%	14%	0%	0%
Meter C	2%	6%	0%	0%
Meter D	4%	10%	4%	0%

- Currently marketed glucose meters fail to meet consensus criteria in the hypoglycemic range.

Chen ET, Nichols JH, Duh SH, Hortin G. Performance evaluation of blood glucose monitoring devices. *Diabetes Technol Ther* 2003;5:749-68.

Glucose Meter Potential Interferences

- Environmental
  - Air, exposure of strips
  - Altitude
  - Humidity
  - Temperature
- Operational
  - Hemolysis
  - Anticoagulants
  - Generic test strips
  - Amniotic fluid/Animal
  - Arterial and catheter
  - Volume of sample
  - Reuse of strips
- Physiologic
  - Hematocrit (neonates)
  - Prandial state
  - Hyperlipidemia
  - Oxygenation
  - pH
- Drugs
  - Maltose
  - Acetaminophen
  - Ascorbate
  - Mannitol
  - Dopamine

Table 1—*Confounding variables in glucose measurement*

Variable	Methodology affected* GO	GD
Hematocrit		
Anemia	↑	↑
Polycythemia	↓	↓
Oxygen concentration		
Hypoxia	↑	—
Oxygen therapy	↓	—
pH (6.8–7.55)	—	—
Low pH	−/↓	—
High pH	−/↑	—
Hypothermia	↑	↓/↑
Hypotension	↑	↑/↓
Drugs		
Ascorbic acid	↓	↑/−
Acetaminophen	↓	↑
Dopamine	—	↓
Icodextrin	—	↑
Mannitol	↑	—

*Change relative to venous plasma measured at central laboratory. GO, glucose oxidase.

Glucose Measurement: Confounding Issues in Setting Targets for Inpatient Management

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SUSAN S. BRAITHWAITE, MD[3]
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source of the sample, and specimen matrix (i.e., plasma versus whole blood). This study will review assay principles

DIABETES CARE, VOLUME 30, NUMBER 2, FEBRUARY 2007

The Hospital Issue

- The critical nature of hospitalized patients presents extreme conditions to bedside glucose meters in terms of PO2 and hematocrit, and increasing the potential for interferences from drugs and hospital therapies like intralipid nutrition. Because of these circumstances, the same meters utilized for home self-testing do not always perform well when applied to hospitalized patients.

Table 1. COMPARISON OF HOME AND HOSPITAL POINT-OF-CARE GLUCOSE TESTING

Home POCT Glucose	Hospital POCT Glucose
Single operator	Multiple operators
Single meter	Multiple meters
Serial monitoring on one meter	Single samples on multiple meters
Ambulant patient	Bedridden patient
Relatively healthy patient	Acute and chronic illnesses
Capillary samples only	Noncapillary samples possible

Clarke W, Nichols JH. Bedside Glucose Testing : Applications in the Home and Hospital. *Clinics in Laboratory Medicine: Point-of-Care Testing.* Lewandrowski K editor. June 2001.

Glucose Meters

- FDA clears glucose meters for the following intended uses:
  - For quantitative measurement of glucose in whole blood (e.g., capillary, venous, arterial)
  - For use by healthcare professionals or lay users
  - A few are cleared for use on neonates

  For the following indications:
  - As aid in monitoring the effectiveness of diabetes control program
  - Not intended for the diagnosis of or screening for diabetes

Other ways they are also used (off-label):

- Glycemic control protocols in hospitals (diabetics and non-diabetics)
- Critically ill patients
- Anything they are needed for in the hospital

Glucose Meters

- Manufacturers submit the meters to FDA with home use claims even when they intend to sell them as hospital use meters

- They submit validation data suitable for home use capillary self testing, and minimal validation in arterial and venous blood (if claimed)

- This submission strategy allows the hospital meters to be waived (due to OTC status) without the need for CLIA waiver studies

Glucose Meters

- In recent years concerns have been raised citing the inability of currently cleared glucose meters, if not adequately validated and controlled by the hospital, to perform effectively in critical care settings, given that these devices were not originally designed or evaluated for this type of use.

- Patients in critical care settings can be more acutely ill and medically fragile, and are more likely to present physiological, pathological and pre-analytical factors that could interfere with glucose measurements as compared to other types of users.

- For critically ill patients who by their very nature tend to be more seriously ill, any inaccuracies in the meters could further increase the risk to these patients.

Glucose Meters

- For many years, FDA has requested that all labeling for glucose meters include a statement in their device labeling indicating that the system is not intended to be used in the critically ill patient population.

- FDA requested this statement because the device has not been designed for use in, or studied in this population.

- By including the statement in the Limitation section, FDA hoped to clarify that use in the critically ill population is an off label use and hospitals need to validate that use and place appropriate controls to assure the accurate and appropriate use of the device.

Off Label Use

- Hospitals are recently becoming more aware of these limitation statements

- FDA has been receiving more questions about these limitations, including whether use of meters in the ICU would be off label use

- Because off-label use would void the waived status, facilities would technically need CLIA high complexity certification to use these meters:
  - In critically ill patients
  - In people without diabetes
  - Health fairs and screening the general public for diabetes

- **Challenge –** abrupt disruption of glucose meter use in hospital settings may adversely affect patient safety

Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
Document issued on: January 7, 2014

You should submit comments and suggestions regarding this draft document within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. Identify all comments with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this document, contact Patricia Bernhardt at patricia.bernhardt@fda.hhs.gov, or at 301-796-6136.

NEW YORK
state department of
HEALTH

Nirav R. Shah, M.D., M.P.H.
Commissioner

Sue Kelly
Executive Deputy Commissioner

January 13, 2014

Re: Off-label Use of Glucose Meters

Dear Laboratory Director:

As laboratory director, you are jointly and severally responsible with the owner for the maintenance and operation of the clinical laboratory (Article 5, Title V of New York State Public Health Law). This includes testing that is performed at the point-of-care (POCT) or as part of a health fair or other community screening event.

The US Food and Drug Administration (FDA) is responsible for approving medical devices, including glucose meters, based upon the performance characteristics established by the manufacturers (validation data) and submitted by the manufacturers to the FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 15-11-CLIA

DATE: **November 21, 2014**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Directions on the Off-Label/Modified Use of Waived Blood Glucose Monitoring Systems (BGMS)

Memorandum Summary

- **"Off-Label Use" of BGMS:** Using a test outside of its Food and Drug Administration (FDA)-approved/-cleared intended use, limitations or precautions, as indicated in the manufacturer's instructions, is considered "off-label use." "Off-label use" applies whether the test is waived or non-waived and it means that the test is considered modified and therefore defaults to a high-complexity test under the Clinical Laboratory Improvement Amendments (CLIA) regulations. This will require all laboratories using the device for an "off label use" to meet all applicable CLIA high-complexity requirements.
- **Surveyors Will Document Off-Label Use:** If any non-compliance is identified, a written statement of deficiencies (Form CMS-2567) will be issued and followed up using standard operating procedures and timeframes found in the applicable regulations and guidance documents.

Laboratory Test Limitations

- Lab tests are not fool-proof!
- There is no “perfect” device, otherwise we would all be using it!
- Any device can and will fail under the right conditions
- Those conditions are listed in the limitations section of the package insert, policy and training materials

ACCU-CHEK® Inform II

Test Strips and 1 Code Key

PROFESSIONAL USE

Cat. No. 05942861001

Limitations

- The ACCU-CHEK Inform II test strips are for testing fresh capillary, venous, arterial, or neonatal whole blood. Cord blood samples cannot be used.
- Hematocrit should be between 10–65 %.
- Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
- Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
- Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause overestimation of blood glucose results.
- If peripheral circulation is impaired, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. This may apply in the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
- This system has been tested at altitudes up to 10,000 feet.

Current Vanderbilt Glucose Procedure

12.0 **PROCEDURE LIMITATIONS**

12.1 Patient hematocrit should be between 10–65 %. Samples outside this hematocrit range will yield inaccurate results.
12.2 Lipemic samples (triglycerides) in excess of 1800 mg/dL may produce elevated results.
12.3 Blood concentrations of galactose >15 mg/dL will cause overestimation of blood glucose results.
12.4 Intravenous administration of ascorbic acid which results in blood concentrations of ascorbic acid >3 mg/dL will cause inaccurate glucose results.
12.5 If peripheral circulation is impaired, collection of capillary blood from the approved sample sites is not advised as the results might not be a true reflection of the physiological blood glucose level. This may apply in the following circumstances: severe dehydration as a result of diabetic ketoacidosis or due to hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.
12.6 This system has been tested at altitudes up to 10,000 feet.
12.7 Refer to Accu-Chek Inform II strip package insert for complete listing of limitations and interfering substances

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- This system has been tested at altitudes up to 10,000 feet.
- The performance of this system has not been evaluated in the critically ill.

This limitation is new as of December 2012 for all glucose meters!

Definition of Critically Ill

- No universal definition of critically ill exists
- Critical illness is any disease process which causes physiological instability leading to disability or death within minutes or hours.(1)
- All inpatients, by virtue of their hospitalization, may be considered “critically ill”. So, critically ill patients are not just those patients in the ICU
  - Consider the OR, ED, Trauma, Sepsis, and others
- CMS and FDA indicate that the definition of what constitutes “critically ill” must be defined by each institution.

British Journal of Hospital Medicine, October 2007, Vol 68, No 10

The BGMS that have been cleared by the FDA as waived for home use were originally designed as consumer devices, intended for use in monitoring glucose levels in an individual patient diagnosed with diabetes. However, over time, the use of BGMS has expanded to include use in healthcare facilities and, in turn, use in patient populations that the manufacturer's studies and performance standards, which were used to evaluate these BGMS for home use, did not address.

Manufacturers' Instructions

The CLIA-certified laboratories must read and follow all of the manufacturer's instructions for waived test systems, including BGMS. This includes any instructions that the manufacturer may include regarding the system's intended use, limitations and precautions. Note that manufacturers' instructions vary in format, and some information may be found in different sections. Moreover, manufacturers' instructions may be updated or changed, and instructions

This means that, when the manufacturer's instructions contain limitations indicating that the BGMS has not been evaluated or cleared for use in critically ill patients, the use of BGMS on critically ill patients will be considered "off-label" use, and, for purposes of the CLIA regulations, will automatically default to high-complexity testing. Facilities may continue to use their waived BGMS on patients as long as they are following the manufacturer's instructions.

Revised Vanderbilt Glucose Procedure

12.0 PROCEDURE LIMITATIONS

12.1 The manufacturer, Roche Diagnostics, has indicated that the performance of the Inform II meter has not been evaluated in critically ill patients. For the purpose of point-of-care glucose testing, Vanderbilt has defined and interprets this "critically ill" testing limitation such that use of the Inform II meter is prohibited for testing in patients with any of the following conditions:

12.1.1. Hematocrits less than 10% or greater than 65%.

12.1.2. Triglyceride levels greater than 1800 mg/dL.

12.1.3. Blood concentrations of galactose >15 mg/dL.

12.1.4. Intravenous administration of ascorbic acid resulting in blood concentrations of ascorbic acid >3 mg/dL.

12.1.5. Use of capillary blood collected by fingerstick in patients with peripheral circulation impairment to include severe dehydration resulting from diabetic ketoacidosis, hyperglycemic hyperosmolar non-ketotic syndrome, hypotension, shock, decompensated heart failure NYHA Class IV, or peripheral arterial occlusive disease.

12.1.6. Cord blood samples

Do not use the ACCU-CHEK Inform II for testing patients exhibiting any of these conditions. Instead, collect venous or arterial blood and send to the clinical laboratory for testing with STAT orders as indicated

12.2 This system has been tested at altitudes up to 10,000 feet.

12.3 Refer to Accu-Chek Inform II strip package insert for complete listing of limitations and interfering substances

DEPARTMENT OF HEALTH & HUMAN SERVICES
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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

DATE: **March 13, 2015**

Ref: Temporary Withdrawal-S&C: 15-11-CLIA and Reissuance as Draft, with Draft Clarifications

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Reissuance of S&C 15-11 As DRAFT ONLY – FOR COMMENT
Off-Label/Modified Use of Waived Blood Glucose Monitoring Systems (BGMS)

We are temporarily withdrawing S&C Memorandum 15-11, which was previously issued on November 21, 2014, and reissuing it in draft-only form in order to:

- Obtain more feedback regarding the use of waived BGMS, the environments in which BGMS are currently used, and any issues that hospitals and other providers have identified with such use;
- Promote added education regarding the current CLIA requirements.

Use of Glucose Meters for Critically Ill Patients

This white paper includes an overview of glucose meter limitations with practical advice for use of glucose meters in critically ill patients

CLINICAL AND LABORATORY STANDARDS INSTITUTE®

Options to Address CMS Changes

- Proposed Policy Change
  - Least disruptive
  - No change in practice, staff already trained and doing this
  - Meets letter of the regulatory change by defining what “critically ill” means for this device – the pkg insert limitations – so not testing under “off-label” uses
- Change to a meter cleared for “critically ill” use
  - Caution, no meter is cleared for use of capillary samples in critically ill patients!
- Stop using glucose meters for “critically ill” patients – use an “alternative” method
  - Require more costly Blood Gas testing
  - Core lab testing with delays in results that could impact care
- Use glucose meters “off-label”
  - CLIA high-complexity testing with required validation in critically ill patients
  - Consequences for staff educational background, licensure (med director), and ongoing documentation.

Blood Glucose Monitoring Test Systems for Prescription Point-of-Care Use

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Guidance for Industry and Food and Drug Administration Staff

Document issued on: October 11, 2016.

The draft of this document was issued on January 7, 2014.

For questions regarding this document, contact Leslie Landree at leslie.landree@fda.hhs.gov, or at 301-796-6147.

U.S. FOOD & DRUG ADMINISTRATION
CENTER FOR DEVICES & RADIOLOGICAL HEALTH

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Office of In Vitro Diagnostics and Radiological Health
Division of Chemistry and Toxicology Devices

Final FDA BGMS Guidance

- Concerns raised regarding performance in some populations
- Patients in healthcare settings more acutely ill, medically fragile and present with physiologic/pathologic factors that could interfere with glucose measurements
- Errors in BGMS accuracy can lead to incorrect insulin dosing, increased episodes hypoglycemia, and further risk to health
- For professional use, identify sub-populations where BGMS may function differently
- All cases, performance should account for factors; disease state, patient condition, physiologic state, and medications where device performance might be affected.

FDA BGMS Guidance Method Correlation

- 350 patients for each sample type (art, venous, cap, heel, etc.)
- Different samples can be from same patient
- Fresh and measured on both device and comparator method
- May not be specifically collected for study, but test must be done per labeling instructions (untrained users) for CLIA waiver
- Patient information should be available to identify interferences
- More than 1 measurement may be averaged for comparator, but no measurements must be excluded
- Must have 10 unaltered specimens <80 mg/dL and >300 mg/dL
- Specimens must reflect intended use population – 9 operators
- Define sub-populations vulnerable to interference (50 samples)
- Evaluate 10 test strip vials covering 3 strip lots (minimum)

FDA BGMS Accuracy Performance Criteria

- To demonstrate BGMS is sufficiently accurate for use by healthcare professionals:
  - 95% values +/- 12% of comparator for glucose ≥ 75 mg/dL, and within +/- 12 mg/dL for glucose < 75 mg/dL
  - 98% values +/- 15% of comparator for glucose ≥ 75 mg/dL, and within +/- 15 mg/dL at glucose < 75 mg/dL
- For instances where BGMS is unable to meet criteria, provide clinical justification for all test results and describe why potential for error would not affect pt safety when extrapolated to intended use setting with great volume tests
- Should measure Hct, Na, pO2 to help identify interference

What is Risk?

CLSI Document EP23

- *Laboratory Quality Control Based on Risk Management; Approved Guideline (EP23-A™)*

- James H. Nichols, PhD, DABCC, FACB, Chairholder of the document development committee

- EP23 describes good laboratory practice for developing a QCP based on the manufacturer's risk mitigation information, applicable regulatory and accreditation requirements, and the individual health care and laboratory setting.

IQCP History

- CLIA 88 requires 2 levels of QC each day of testing!
- Newer lab devices offer internal and engineered control processes that make daily liquid QC duplicative and redundant.
- IQCP allows laboratories to develop a plan that optimizes the use of engineered, internal control processes on a device and balances the performance of external liquid QC without impacting safety!
- CLSI EP23 introduces industrial and ISO risk management principles to the clinical laboratory
- CMS adopted key risk management concepts to develop the IQCP option for quality control
- IQCP replaces 2003 EQC options currently in place.

New IQCP

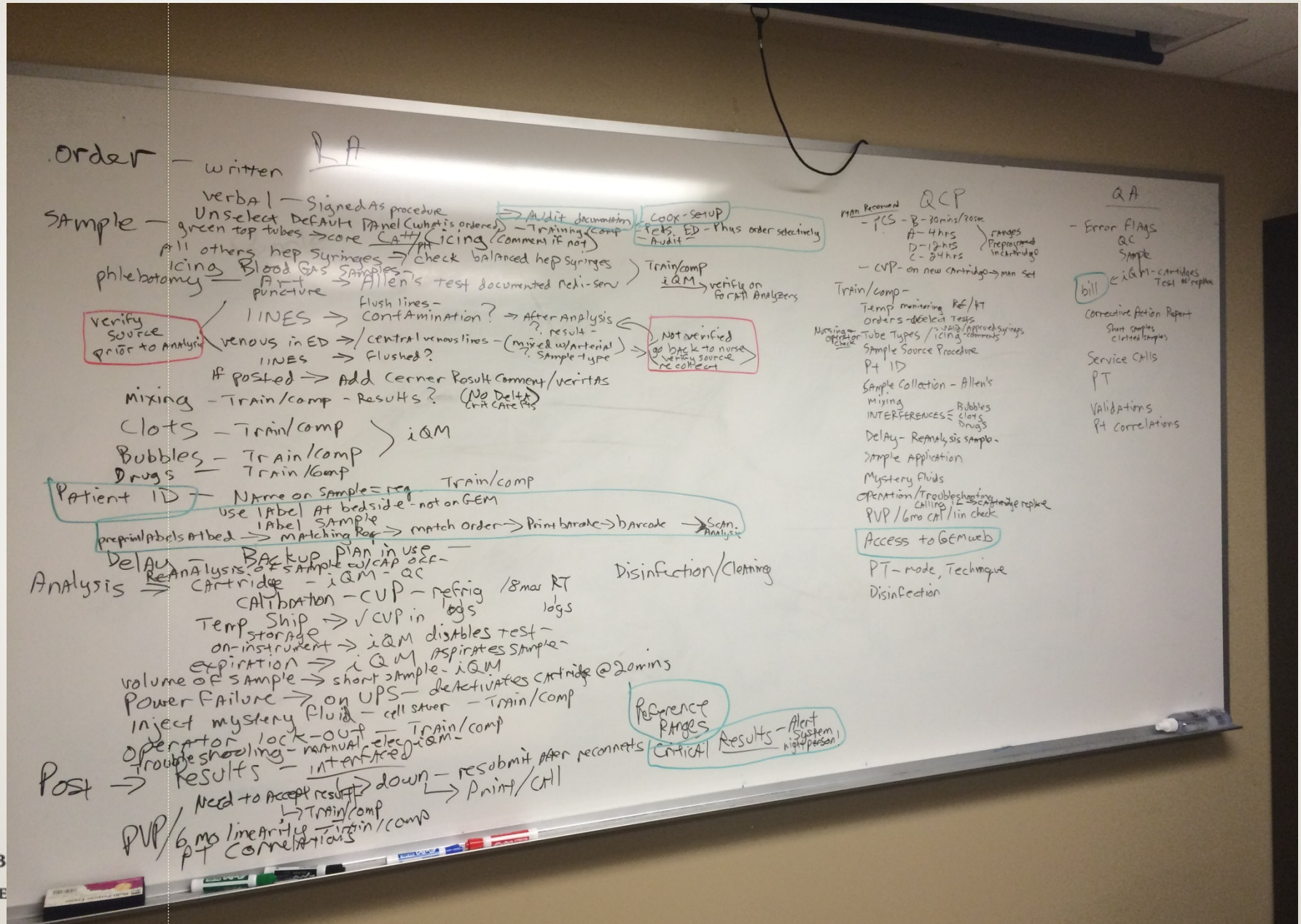
- Two levels of liquid QC required each day of testing

OR

- Laboratory develops an IQCP:
  - Balance internal control processes with external controls
  - Reduce frequency of liquid QC to minimum recommended by manufacturer
  - Maximize clinical outcome, available staff resources and cost effectiveness in the lab

Individualized Quality Control Plan

What Have We Learned From Our IQCPs?



What Have We Learned From Our IQCPs?

- Processes on different units were not uniform
  - Some units had operator lock-out, others did not
- IQCP supports QC rationale and resources
  - Each action is linked to a specific hazard
  - Gives meaning for why we do what we do rather than simply meeting a regulation
- Opportunity for improving efficiency
  - QC the device versus QC the reagent (i-stat)
  - Multi-site validations of reagent shipments
  - Monthly 3 level QC versus 6 month cal verifications

What Have We Learned From Our IQCPs?

- Before: (QC the device)
  - Shipments = 10 shipments/yr x 2 QC x 7 sites = 140 tests
  - Lot validations = 5 x/yr x 2 levels x 8 meters = 80 tests
  - QC monthly = 2 QC x 8 i-stats x 12 mos = 192 tests
  - 6 mo cal-ver = 8 i-stats x 3 levels x 3 reps x 2x/yr = 144 tests
  - 6 mo correlations = 10 patients x 8 i-stats x 2x/yr = 160 tests

  TOTAL = 716 tests

- After: (QC the reagent)
  - Shipments = 4 shipments/yr x 3 QC x 1 site = 12 tests
  - Lot validations = QC shipment, max 4x/yr x 5 pts x 2(old/new) 40 tests
  - QC monthly = 3 QC x 7 sites x 12 mos = 252 tests
  - If additional lot: 3 QC x 7 sites x 4 mos 84 tests
  - 6 mo cal ver and pt correl already done monthly QC/lot val = 0 tests

  TOTAL = 304/(388) tests

VANDERBILT UNIVERSITY MEDICAL CENTER

Savings of nearly half each year!

Proficiency Testing Referral

- Section 353(d)(1)(E) of the Public Health Service Act requires the laboratory to "treat proficiency testing samples in the same manner as it treats materials derived from the human body referred to it for laboratory examinations or other procedures in the ordinary course of business, except that no proficiency testing sample shall be referred to another laboratory for analysis as prohibited under subsection (i)(4)". Additionally, this requirement is emphasized in the CLIA regulations at § 493.801(b).
- A laboratory is not to test PT samples on more than one instrument/method unless that is how they test patient specimens.
- Repeated analysis of PT samples is not appropriate unless patient specimens are similarly tested.

PT Referral

- In cases of repeat PT referral offenses or deliberate cheating (reporting another lab results as its own), CMS has authority to revoke the lab's CLIA certificate for at least 1 year, ban the owner or operator from operating a lab for at least 1 year, and impose civil monetary penalties.
- When a lab refers PT samples to a second lab, defined as a lab with a different CLIA number, but still reports it's own PT results, CMS can suspend or limit the CLIA certificate for less than 1 year, rather than revoke a license, and can include sanctions, such as staff training
- When a lab unintentionally refers PT to another lab, but catches the problem, reports own PT results, CMS can use only alternative sanctions, civil monetary penalties and CMS directed staff training.

Examples of PT Referral

- Unintentional PT referral may include sending sample as part of reflex, distributive or confirmatory testing because patient's handled this way.
  - Abnormal POCT drugs-of-abuse screen reflexing to confirm MS test
  - TSH POCT that would reflex to a free T4 conducted in another lab
- Best to accession PT sample as a mock patient in LIS system. Will travel lab testing like a patient sample, but can setup IT rules to hold send-out or reflex tests
- For POCT, can't share PT among different sites, each site must order separate PT challenge and return individual results
- For float staff – at multiple clinics, may see same PT sample. Recommend have different staff do PT at each location!

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CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: S&C: 16-18- CLIA
REVISED 05.03.16

DATE: **April 1, 2016**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Personnel Policies for Individuals Directing or Performing Non-waived Tests
Revised due to typographical error under citation of §493.1443(b)(3)

CMS Personnel Policies Update

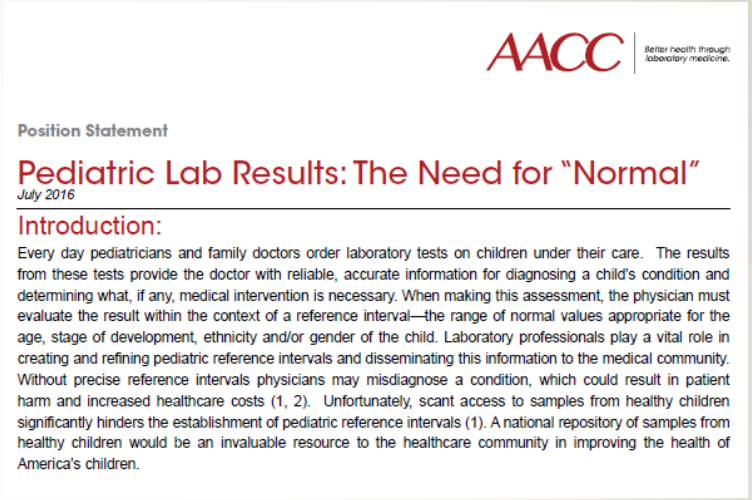
- CLIA surveyors will now accept Primary Source Verification company evidence of personnel qualification compliance
- PSV confirms applicant's credentials by verifying degree, certificate, or diploma received, licenses granted and confirming work history and positions held
- Bachelor's and Associate's degrees in nursing meet the requirement for earning a degree in a biological science for CLIA high and moderate complexity testing personnel
- This draft guidance would allow nurses to both direct and perform same testing as Medical Director or Technologist without additional education!

AACC Policy & External Affairs Core Committee

- To monitor and make recommendations on legislation, regulations, and legal actions pertaining to the clinical laboratory
- To ensure that the interests of AACC members are served.
- To promote member involvement in government relations issues.
- New AACC Policy & External Affairs Core Committee (PEACC) used to be the AACC Government Affairs Cmte
- Dr. James H. Nichols, Past Chair –
  Dr. David D. Koch – current Chair

AACC Position Statements

- Pediatric Lab Results: The Need for “Normal”
- Modernization of CLIA
- Direct-to-Consumer Laboratory Testing
- Advancing Personalized/Precision Medicine
- Oversight of Laboratory Developed Tests
- Newborn Screening and Improving Children’s Health
- Harmonization of Clinical Laboratory Test Results



AACC Better health through laboratory medicine.

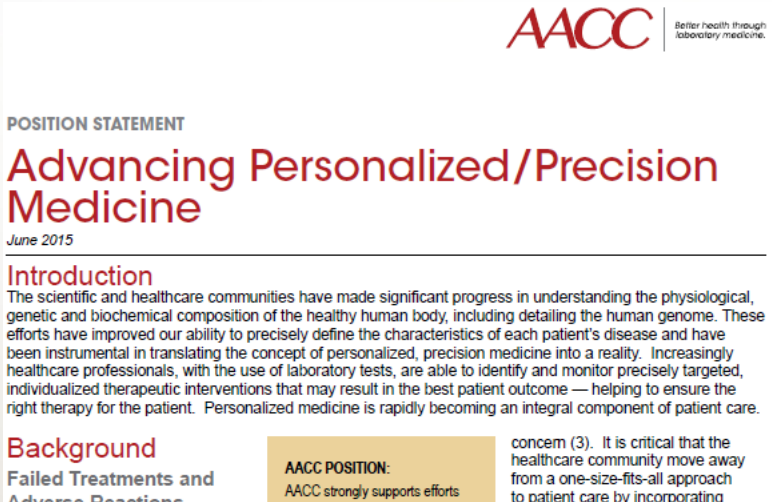
Position Statement

Pediatric Lab Results: The Need for “Normal”

July 2016

Introduction:

Every day pediatricians and family doctors order laboratory tests on children under their care. The results from these tests provide the doctor with reliable, accurate information for diagnosing a child’s condition and determining what, if any, medical intervention is necessary. When making this assessment, the physician must evaluate the result within the context of a reference interval—the range of normal values appropriate for the age, stage of development, ethnicity and/or gender of the child. Laboratory professionals play a vital role in creating and refining pediatric reference intervals and disseminating this information to the medical community. Without precise reference intervals physicians may misdiagnose a condition, which could result in patient harm and increased healthcare costs (1, 2). Unfortunately, scant access to samples from healthy children significantly hinders the establishment of pediatric reference intervals (1). A national repository of samples from healthy children would be an invaluable resource to the healthcare community in improving the health of America’s children.



AACC Better health through laboratory medicine.

POSITION STATEMENT

Advancing Personalized/Precision Medicine

June 2015

Introduction

The scientific and healthcare communities have made significant progress in understanding the physiological, genetic and biochemical composition of the healthy human body, including detailing the human genome. These efforts have improved our ability to precisely define the characteristics of each patient’s disease and have been instrumental in translating the concept of personalized, precision medicine into a reality. Increasingly healthcare professionals, with the use of laboratory tests, are able to identify and monitor precisely targeted, individualized therapeutic interventions that may result in the best patient outcome — helping to ensure the right therapy for the patient. Personalized medicine is rapidly becoming an integral component of patient care.

Background

Failed Treatments and

AACC POSITION:

AACC strongly supports efforts

concern (3). It is critical that the healthcare community move away from a one-size-fits-all approach to patient care by incorporating

AACC Better health through laboratory medicine.

POSITION STATEMENT

Oversight of Laboratory Developed Tests

November 2014

Introduction

Laboratory developed tests (LDTs) are “diagnostic tests that are developed, validated and performed by individual laboratories…These assays are developed for in-house use and are not commercially distributed to other laboratories.”(1) Clinical laboratories develop LDTs to assist in patient care, particularly for patients with medical conditions for which a commercial test does not exist or when an existing test does not meet changing clinical needs. LDTs are currently regulated by the Centers for Medicare and Medicaid (CMS) as high complexity tests—the most stringent standards—under the Clinical Laboratory Improvement Amendments of 1988 (CLIA’88).

In recent years, the Food and Drug Administration (FDA) has asserted that LDTs are medical devices subject to agency review, but that it has deferred oversight to CMS since many of the tests are well-established and the lack of LDTs for ‘rare’ diseases. However, with the dramatic increase in the number and complexity of LDTs, particularly in the field of genetic testing, the FDA is now considering that some LDTs need to be cleared or approved by the agency to ensure their safe and effective use in patient care.

Background

FDA Involvement and Concerns

Since the 1990s, there has been an ongoing discussion between the FDA and stakeholders

AACC POSITION:

Laboratory developed tests (LDTs)

oversight as well. For example, New York State requires laboratories document

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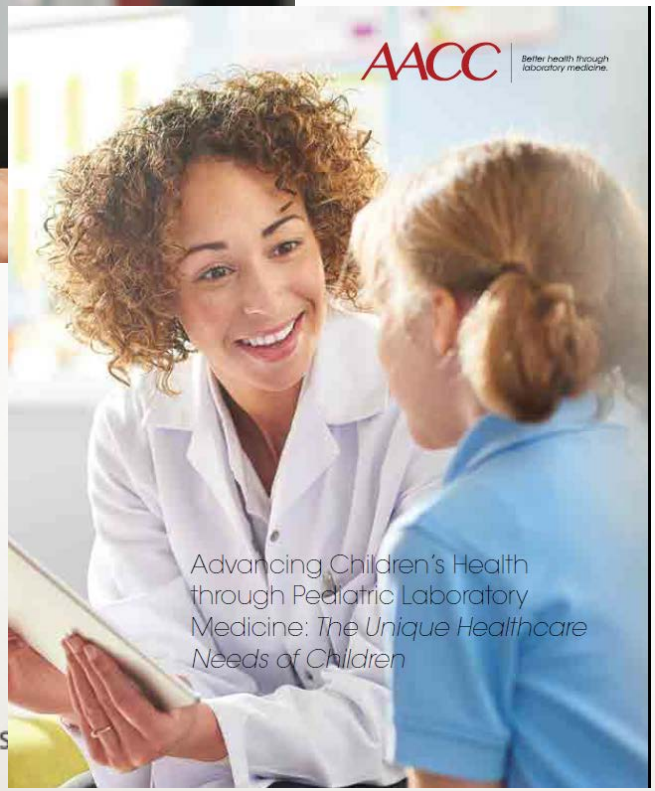
AACC Policy Reports



- Advancing Children's Health through Pediatric Laboratory Medicine: The Unique Healthcare Needs of Children (17 pgs)
- Laboratory Medicine: Advancing Quality in Patient Care (18 pgs)

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AACC Artery Updates

Update from AACC Artery

AACC Urges CMS to Revisit Nurse Equivalency Decision

James Nichols

On April 1, 2016, the Centers for Medicare and Medicaid Services (CMS) issued **Memorandum S&C: 16-18-CLIA**, which states that bachelor's and associate's degrees in nursing meet the CLIA requirements for high and moderate complexity testing personnel. **AACC responded** urging CMS to suspend its decision and utilize the rulemaking process to gather public input. In addition to raising concerns about the decision, the Association stated CMS' action "sets a dangerous precedent for altering personnel requirements without public consultation."

Update from AACC Artery

Laboratory Community Seeks Federal Funding for Harmonization

James Nichols

AACC, joined by other associations, manufacturers and clinical laboratories are **seeking congressional support** to increase funding for the Centers for Disease Control and Prevention (CDC), so that the agency can harmonize clinical laboratory test results. In 2014, the Association succeeded in getting report language included in the end-of-the-year congressional spending bill urging the agency to work with the private sector in accomplishing this task. AACC and its allies are working to translate this legislative directive into reality.

Update from AACC Artery

AACC Urges CLIA Modernization

James Nichols

AACC released a new position statement, "**Modernization of CLIA**," that recommends policymakers update the CLIA regulations to address concerns regarding oversight of laboratory developed tests. The Association makes a number of key suggestions for improving the laboratory standards, such as requiring that laboratories demonstrate the clinical validity of LDTs and broaden inspection teams to include individuals with the expertise to evaluate LDTs. In addition, AACC advises policymakers to narrow the definition of LDTs and update the proficiency testing requirements. The Association will use this position statement to advocate for pragmatic and meaningful ways to enhance CLIA's oversight of LDTs.

Update from AACC Artery

AACC Details Views on DTC Testing

James Nichols

AACC released a new position statement, "Direct-to-Consumer Laboratory Testing," which recommends that consumers have greater access to laboratory testing services and that qualified healthcare professionals be available to assist individuals when ordering or interpreting a test. In addition, the Association urges the federal government to establish guidelines that require DTC facilities to provide sufficient information about their products and services so that consumers can make fully informed health decisions. AACC will use this statement to educate policymakers about DTC testing and suggest policy changes.

Laboratory Voice

Actions

1 advocacy campaign

Find Officials

Look up and contact your officials.

ZIP Code

Comment Letters

AACC continually tracks legislative and regulatory issues of importance to clinical laboratories and the clinical laboratory profession. Recently we commented on a wide range of topics to federal and state authorities. For more information, contact AACC Government Affairs.

2016 LEGISLATIVE AND REGULATORY ISSUES

AACC Provides Input to Senate HELP Committee on LDT Regulatory Oversight
SEPT.19.2016

AACC and healthcare partners continue to pursue CDC harmonization funding
SEPT.12.2016

AACC Opposes VA Proposal to Extend Nurses Scope of Practice to Labs
JULY.22.2016

AACC urges CMS to use rulemaking process regarding CLIA equivalency for nursing degrees
JUNE.17.2016

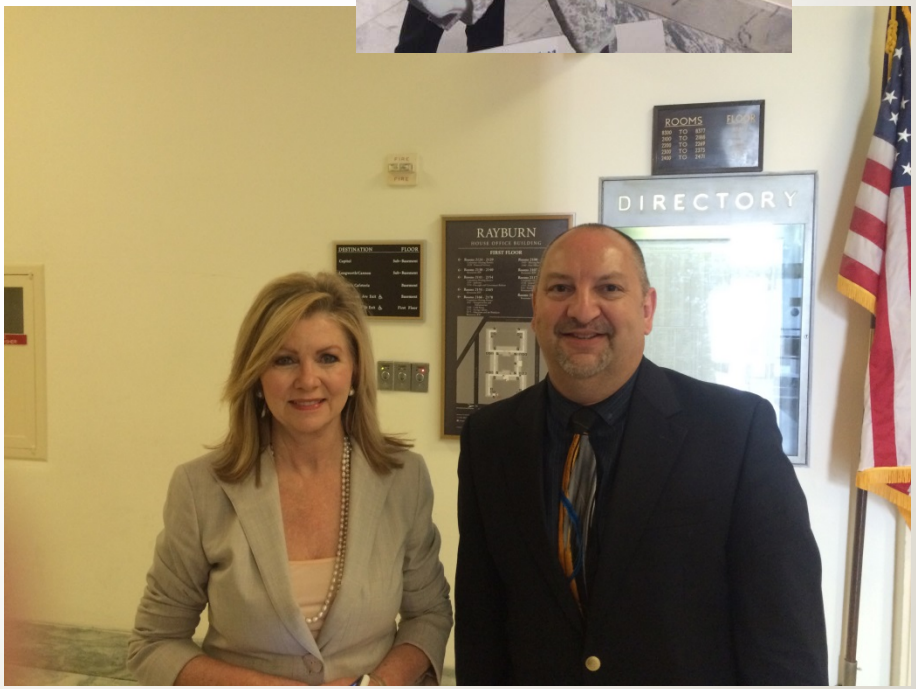
Healthcare groups join AACC in support of federal funding for harmonization
MAY.27.2016

AACC urges the Senate to require FDA justification of guidance documents
MAY.19.2016

AACC urges Senate delay of LDT guidance

AACC Government Affairs Committee Capital Hill Visits

- The value of laboratory testing
  - Role in patient care
  - Who are laboratory specialists?
- Test harmonization
- 21st Century Cures – LDT position statement
- Newborn screening and children's health



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AACC Capital Hill Briefings

- Precision Medicine vs Personalized Medicine
- Direct to Consumer Testing
- Test Harmonization
- Impact of LDT legislation

Summary

- Many hot topics in lab regulations are current concern
- Glucose meters in critically ill patients. Use glucose meters within the package insert limitations, otherwise must perform studies to prove validity and reliability of results in those patients (off-label use)
- Developing an IQCP provides many benefits!
- AACC is a resource for government advocacy!
- I want to thank and acknowledge Courtney Lias and Alberto Guitierrez (FDA) and Karen Dyer (CMS) for borrowing several slides