Urinalysis Compliance Tools

POCC Webinar

January 19, 2011

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Learning Objectives

- Be able to review and improve upon a laboratory plan for compliance including:
  - Competency
  - Documentation
  - Proficiency
- Understand elements of compliance specific to urinalysis testing
- Gain ability to find resources to help with compliance

Compliance Basics

- Create your site plan
  - ❑ Diagnostic testing
  - ❑ Quality control
  - ❑ Operator training

- Follow Through!
  - ❑ You must actually do what you said you would do!

- Document the implementation
  - ❑ To provide evidence that you followed your site's written plan

Clinical Laboratory Improvement Act (CLIA)

- The Center for Medicare and Medicaid Services (CMS) regulates all laboratory tests in the US

- Regulate through Clinical Laboratory Improvement Amendments (CLIA)

- CLIA Waived labs
  - Perform simple tests
  - Operator might not be a trained laboratory technician
  - No legally required audits although audits can occur randomly

- CLIA Moderate Complexity labs
  - Permitted to run more complex tests
  - Requires a higher level of operator training / education
  - Audits legally required; more frequent

Question for you: CLIA Certification

CLIA Certification

- Waived tests can be performed under a Moderate Complexity certificate

- Moderate Complexity tests cannot be performed under a Waived certificate

- Hospital may hold the CLIA certificate - responsible for the testing at offsite facilities
    - outpatient clinics
    - urgent care centers
    - nursing homes
    - physician's office groups

CLIA Waived Tests

- Visual urinalysis testing is waived

- Tests run on instruments can be waived

- Assay menu can include waived and moderately complex tests

POC Testing Accreditation and Audits

- College of American Pathologists (CAP)

- Commission on Office Laboratory Accreditation (COLA)

- Food and Drug Administration (FDA)
  - CLIA Waived
  - Clinical Laboratory Improvement Act (CLIA) Moderate / High Complexity
    - Moderate Complexity includes Provider Performed Microscopy Procedures (PPMP)

- The Joint Commission accredits non-waived labs; does not recognize waived status

- Survey (audit) every two years to accredit and check compliance

Question for you: Accrediting Agencies

Accreditation Tools

- Example from The Joint Commission is Periodic Performance Review (PPR) software
  - Web-enabled tool via secure extranet
  - Self Assessment Process
  - Submitted annually
  - Plans of Action and Measures of Success
- "Most commonly found deficiencies in laboratory inspections"
  - *W. Foubister in CAP Today, March 2001 at www.CAP.org*

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- Usually the checklist used by your accrediting agency is available to you -- it is helpful for setting up your site's testing process, quality control and operator training procedures
- Tips for survey:
  - Know how to access needed records
  - Inform surveyor of your staff's schedule
  - Inform staff that they will be asked questions during the survey
  - Encourage open participation

Now about Urinalysis…

- Standard dip and read urinalysis testing uses strips containing several tests.

- The strips can be read visually against a color chart on the bottle label

- Some urinalysis strip products are good until the expiration date printed on the bottle label and/or carton (so, there is no shorter opened bottle use life)

Now about Urinalysis…

- The strips can be read instrumentally, providing more standardization of the reading and documentation of results.

- When urinalysis strips are read instrumentally, the results can be sent into a Hospital or Laboratory Information System (HIS/LIS)
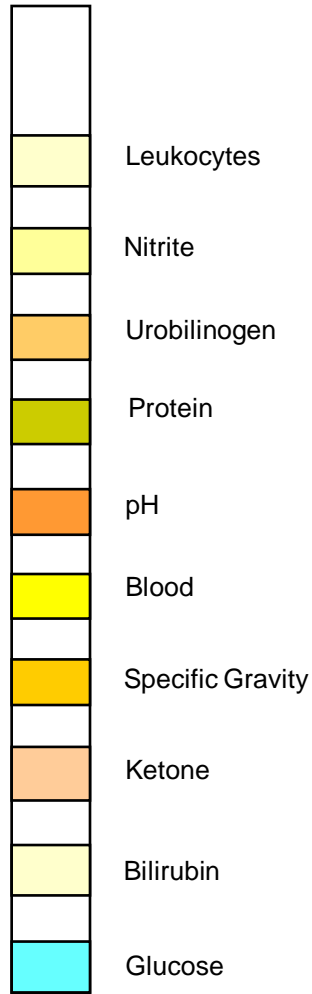
Urinalysis Results are Semi-Quantitative

- Urinalysis strip results are not quantitative

- Statistical measures usually not appropriate include:
    - Linearity
    - Precision
    - Standard Deviation (SD)
    - Coefficient of Variation (CV)

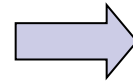- Statistical treatment of semi-quantitative data is unique

Truth Table Example

	Reference Negative	Reference Positive
Strip Negative	113/125 = 90%	7/150 = 5%
Strip Positive	12/125 = 10%	143/150 = 95%

Analytes & Possible Disease States

Leukocytes

Nitrite

Urobilinogen

Protein

pH

Blood

Specific Gravity

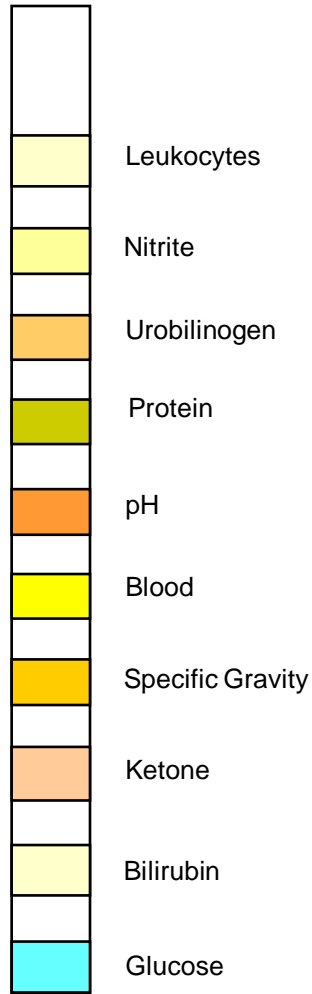Ketone

Bilirubin

Glucose

**Leukocytes
Nitrite**   →   **Urinary Tract Infection**

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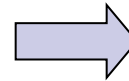
**pH
Occult Blood** → **Kidney Cancer
Kidney Stones
Bladder Cancer**

Analytes & Possible Disease States

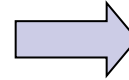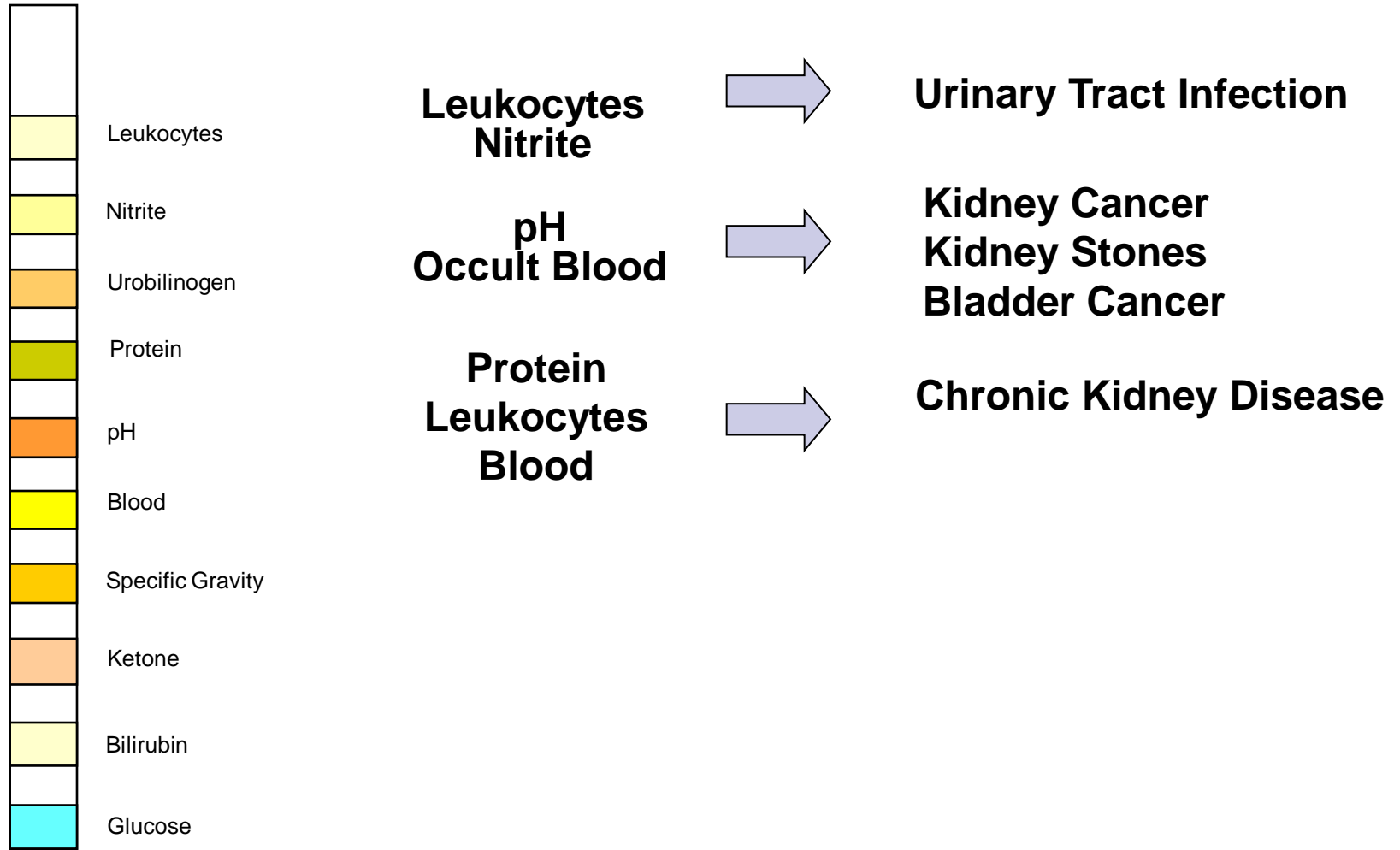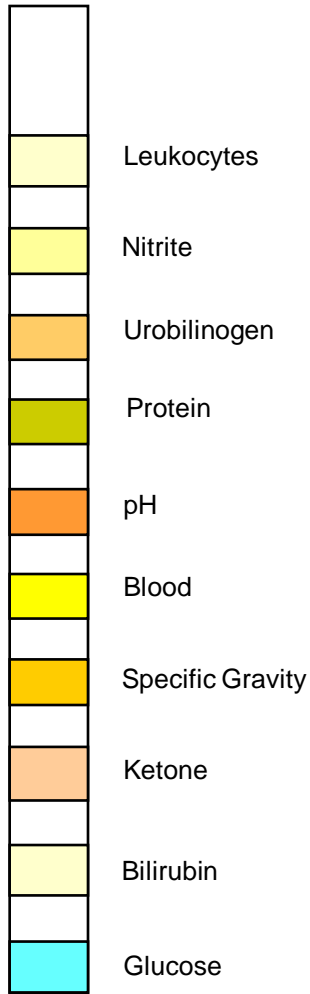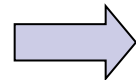|	
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**Leukocytes
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Glucose
Ketone → **Diabetes**
Gestational Diabetes
Eating Disorders

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Color strip	
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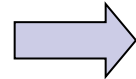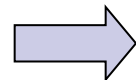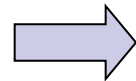Occult Blood** → **Kidney Cancer
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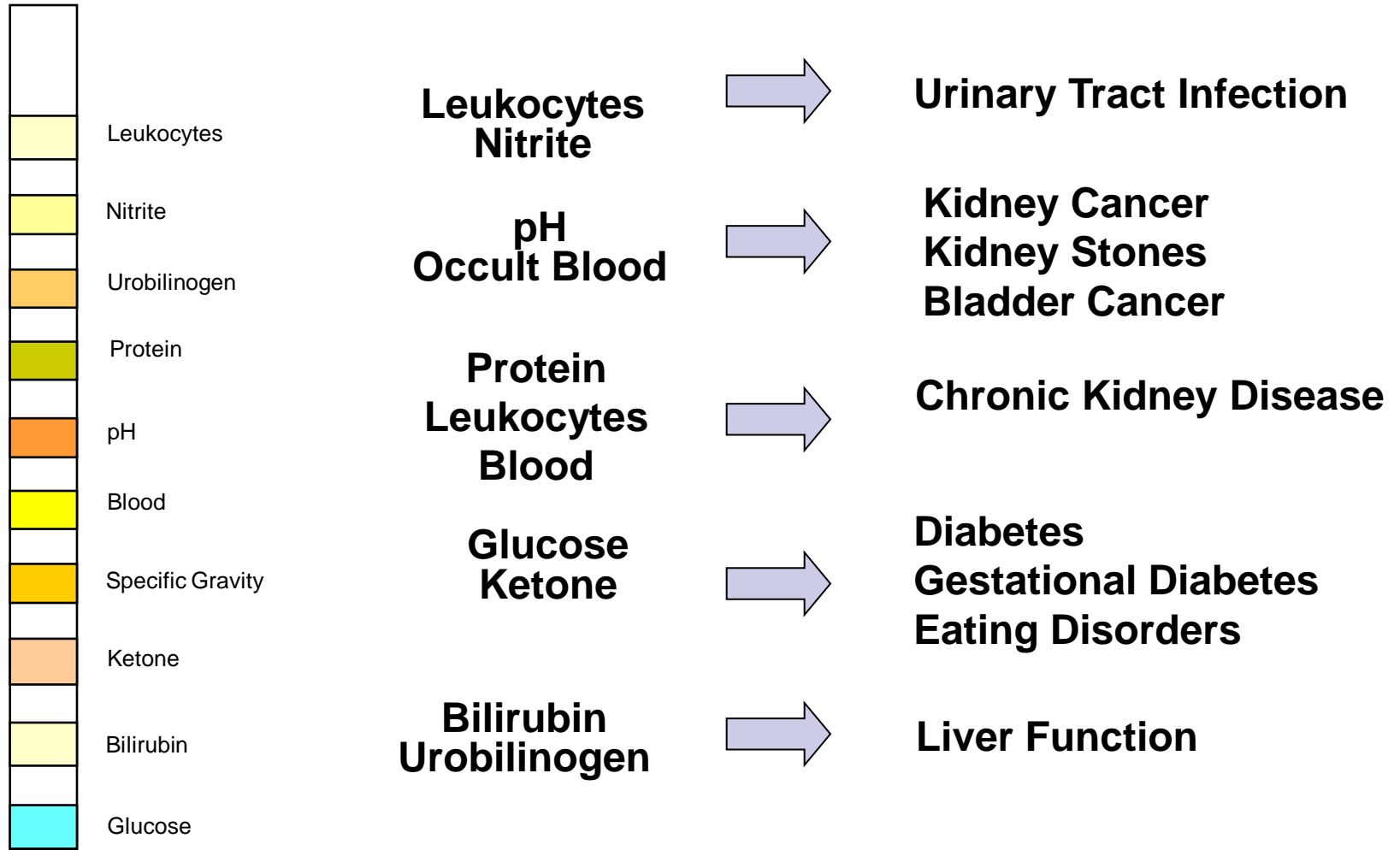
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Leukocytes
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**Bilirubin
Urobilinogen** → **Liver Function**

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Urinalysis Results Utility

- Urinalysis results are used to detect:
  - ☐ Urinary Tract Infections (UTIs)
  - ☐ Early chronic kidney disease
  - ☐ Metabolic dysfunction (Diabetes)
  - ☐ Liver dysfunction

- Additional popular urine tests include:
  - ☐ hCG
  - ☐ Tablet tests (to detect reducing sugars, bilirubin, and ketone),
  - ☐ Microscopic analysis
  - ☐ Visual determination of color and clarity

Urinalysis Compliance Challenges

- Assuring quality of test results and documentation

- Keeping procedures up to date

- Maintaining competency for large number of operators spread out

- Performing and documenting quality control tests at the required frequencies

Urinalysis Compliance Challenges

- Recording reference ranges in the patient record
  - According to The Joint Commission, only quantitative results require this

- Maintaining audit documentation including:
  - Lot numbers
  - Operators
  - Instrument serial numbers

- Knowing what urinalysis testing is being done where, including visual reading

- The operator is often a nurse
  - Nurses are not laboratorians

Compliance Affects all Testing Steps

Pre-analytics

Sample quality & volume, sample & patient identification …

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Inspection Readiness	Policies & procedures, safety of testing environment, reagent labeling

Quality Control

- Each laboratory establishes their own quality control process, following manufacturer's instructions.

- Urinalysis strip quality control required for both visual and instrumental testing

- Testing of both normal and abnormal control solutions:
    - Once per day
    - Each time a new lot is used
    - And if a new operator is being trained

- Complete quality control records include:
    - Results
    - Date and time
    - Operator
    - Test lot number
    - Quality control lot number
    - Instrument serial number

Centralized QC management

Quality Control Made Easier

- **Instrument reading of urinalysis strips provides:**

  - Documentation of quality control results on a printout
  - Quality control results transmission to the HIS / LIS
  - Ability to recall QC data for auditor
  - Scheduling of quality control testing
 - Quality control lockout function

Automated Instrument Quality Checks

- Humidity exposure
- Identify and assure that the correct strip is being used
- Barcode reading of urinalysis strip and quality control material lot numbers
- Automatic calibration on-board
- Combined record of Urinalysis strip and Quality Control lot numbers and expiration dates

Urinalysis Operators (Users) include:

- Nurses
- Physicians
- Emergency Department (ED) staff
- Physician Assistants
- Nursing Techs
- Nurse Practitioners
- Lab Techs
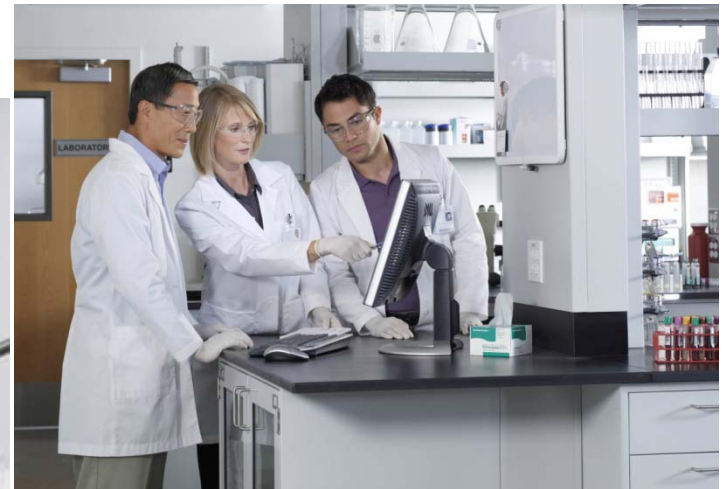
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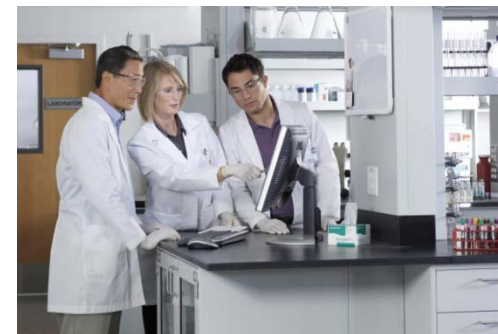- Operators trained to run each type of diagnostic test

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- Documentation of operator certification is key
  - Should include recertification date

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- Operators review training material and take a quiz to show competency
- Supervisor observe testing to assure proper technique
- Documentation of operator certification is key
  - Should include recertification date
- Instrument can include an operator lockout function

Proficiency and Peer Group Testing

- Proficiency testing allows a lab to test unknown solutions and have the results graded

- Proficiency testing programs must be run by a group other than the test manufacturer in order to count for accreditation

- Peer Group testing allows comparison of results from all peer labs

- Programs from diagnostic test manufacturers can help laboratories prepare for accreditation

Goals of Competency Assessment

- Ensure proficient users
  - Knowledge and ability to perform a test
  - Can perform appropriately without supervision
  - Determine validity of test results
  - Take appropriate action when required

- Minimize testing errors

- Ensure regulatory compliance (reduce inspection / survey citations or deficiencies)

- Improve patient safety

- Resource: Some diagnostic test manufacturers offer product education and operator training programs via internet

How to Organize?

- POCT Coordinators should consider whether to:
  - Manage all POC testing under one complexity category (for example, Moderate) to simplify oversight
  - Manage POC testing according to the FDA CLIA category that is appropriate

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- Resource: Clinical Laboratory Standards Institute (CLSI) POCT08-A Quality Practices in Non-Instrumented Near Patient Testing

Compliance Tips

- Create a program that fits your site's testing and staff resource situation.

- Continuously check on what works, what doesn't.

- Change the program as needed to optimize.

- Keep lines open between Point of Care Coordinators and Nursing Education group.

Compliance Tips

- Leverage Point of Care testing checklists (CAP and CLIA).

- Watch operators in real time to see who needs training.

- Document competency of staff and audit trail.

- Encourage operators to openly participate in surveys / audits.

- Understand and reduce pre-analytical and data entry error sources.

- Follow manufacturer's instructions for quality control testing and product storage (temperature and humidity).

Resources

- The Joint Commission
  - www.jointcommission.org
- Commission on Office Laboratory Accreditation (COLA)
  - www.cola.org
- Centers for Medicare and Medicaid Services (CMS)
  - CLIA: www.cms.hhs.gov/clia/
  - CoPs: www.cms.hhs.gov/CFCsandCoPs/
- Centers for Disease Control and Prevention (CDC)
  - www.phppo.cdc.gov/clia/
- Food and Drug Administration CLIA database
  - www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCLIA/Search.cfm
- College of American Pathology (CAP)
  - www.cap.org
- Clinical Laboratory and Standards Institute (CLSI)
  - www.clsi.org

These were today's objectives:

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