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”
Accrediting Agencies Differ:

- Each agency has their own auditing process depending upon the situation.
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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
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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

<table>
<thead>
<tr>
<th></th>
<th>Reference Negative</th>
<th>Reference Positive</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strip Negative</td>
<td>$113/125 = 90%$</td>
<td>$7/150 = 5%$</td>
</tr>
<tr>
<td>Strip Positive</td>
<td>$12/125 = 10%$</td>
<td>$143/150 = 95%$</td>
</tr>
</tbody>
</table>
Analytes & Possible Disease States

- Leukocytes
- Nitrite
- Urobilinogen
- Protein
- pH
- Blood
- Specific Gravity
- Ketone
- Bilirubin
- Glucose

Leukocytes and Nitrite → Urinary Tract Infection
Analytes & Possible Disease States

Leukocytes
Nitrite
pH
Occult Blood

Urinary Tract Infection
Kidney Cancer
Kidney Stones
Bladder Cancer

Glucose
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Analytes & Possible Disease States

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- **pH**
- **Occult Blood**
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**Urinary Tract Infection**

- **Kidney Cancer**
- **Kidney Stones**
- **Bladder Cancer**

**Chronic Kidney Disease**

- **Specific Gravity**
- **Ketone**
- **Bilirubin**
- **Glucose**
Analytes & Possible Disease States

- **Leukocytes** → Urinary Tract Infection
- **Nitrite** → Kidney Cancer
- **pH** → Kidney Stones
- **Occult Blood** → Bladder Cancer
- **Protein** → Chronic Kidney Disease
- **Blood** → Diabetes
- **Glucose** → Gestational Diabetes
- **Ketone** → Eating Disorders
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Leukocytes Nitrite → Urinary Tract Infection

pH Occult Blood → Kidney Cancer

Protein Blood → Kidney Stones

Glucose Ketone → Bladder Cancer

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Liver Function
Analytes & Possible Disease States

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Urinary Tract Infection
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**Eating Disorders**
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- Occult Blood

**Liver Function**
- Bilirubin
- Urobilinogen
- Specific Gravity

**Kidney Function**
- Glucose
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…
Compliance Affects all Testing Steps

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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
Operator Training and Control
Operator Training and Control

- Operators trained to run each type of diagnostic test
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- Documentation of operator certification is key
  - Should include recertification date
Operator Training and Control

- Operators trained to run each type of diagnostic test
- 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:

- Be able to review and improve upon a laboratory plan for compliance including:
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- Understand elements of compliance specific to urinalysis testing
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