POINT OF CARE TESTING
MED Laboratory Branch
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Learning Objectives

- Define Point of Care Testing
- Discuss advantages & disadvantages of POCT
- Review regulatory requirements
- Identify basic requirements for performing waived and PPM test procedures.
- Describe the phases of testing and factors to be considered
- Identify how to improve performance and in so doing prevent errors
What is POCT?

Definition:

“Point of Care Testing are tests designed to be used at or near the site where the patient is located that do not require permanent dedicated space and tests are performed outside the physical facilities of clinical laboratories.”

(College of American Pathologists)
Where is POCT Performed?

- Home and community environments
- Primary Care Clinics
- Disaster and pandemic scenarios
- Ambulances or paramedical vehicles
- Hospitals – ED, ICU and operating rooms
## Advantages & Disadvantages

<table>
<thead>
<tr>
<th>POCT Advantages</th>
<th>POCT Disadvantages</th>
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</thead>
<tbody>
<tr>
<td>• Easier sample collection</td>
<td>• Increased workload</td>
</tr>
<tr>
<td>• Simpler pre-analytical process</td>
<td>• Potential errors due to lack of expertise and QC</td>
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<tr>
<td>• Faster test results available leading to more timely treatment</td>
<td>• Potentially incompatible to local lab methodology</td>
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<tr>
<td>• Removes testing access barriers</td>
<td>• Increased cost</td>
</tr>
<tr>
<td>• Increased patient satisfaction</td>
<td>• Inadequate storage of results</td>
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Regulatory Requirements

Clinical Laboratory Improvement Act (CLIA)

- Center for Medicare and Medicaid Services (CMS) regulates all clinical laboratory tests in the US
- Regulate through Clinical Laboratory Improvement Amendments (CLIA)
- CLIA quality standards ensure the accuracy, reliability, and timeliness of the patient’s test results.
- Use of FDA approved kits
- Clinical laboratory testing in MED Laboratory as well as in HU laboratories and clinics in embassies and consulates worldwide are subject to CLIA regulations.
POCT Categories

Waived Testing

• Simple tests with an insignificant risk of erroneous results
• Originally consisted of 8 tests – now over 1,800 tests
• Majority of testing performed in physician offices with little supervision or adequate personnel
• Errors can still occur and seriously affect patient care
• Examples: urine dipstick, glucose, rapid strep, pregnancy test, stool occult blood, influenza, biochemistry studies, *H. pylori*, prothrombin time/INR, etc.

Other testing categories include:

• Non-Waived – Moderate and High Complexity Testing
• Provider performed microscopy (PPM)
POCT Categories

- **Provider-Performed Microscopy (PPM)**
  - Performed by a physician, NP, PA, or nurse midwife
  - Criteria for classification:
    - Procedures are Moderate Complex
    - Primary instrument – microscope
    - Specimen is labile; delay in testing could compromise accuracy
    - QC controls are not available to monitor entire testing process
    - Limited specimen handling is required
  - *Examples*
    - Wet mounts - vaginal, cervical or skin specimens
    - Pinworm examinations
    - Fern Test
    - Urinalysis – microscopic
    - Fecal leukocyte examination
    - Semen analysis presence / absence
    - Nasal smears for eosinophils
MED POCT Testing Program

Issues to consider before deciding to perform testing or to introduce a new test in your HU:

- Local or off shore testing resources
- Oversight of testing – Someone will need to be responsible
- Testing personnel – Personnel who perform testing will need to be trained and competent
- Regulatory requirements – per CLIA
- Safety issues - Must implement OSHA BBP Standards with universal precautions, staff training, ECP, hepatitis B vaccination, etc.
- Location for testing – Testing will need to be performed in a location with adequate space, appropriate environment, and proper disposal of biohazardous waste.
- Record keeping system – System required for the documentation and storage of records, procedure manual, package inserts, training and CT records.
- Selecting tests – Consider the test characteristics, sample requirements, patient population, patient follow-up, and costs when choosing a test.
- Quality Assurance – Evaluate and look for ways to improve the quality of the testing.
MED POCT Testing Program
Recommendations

- Limit POCT program to waived testing and PPM
- Standardize kits / comparability
- Limit the types of test kits used
- Ensure proper training / CT of staff performing testing
- Perform QC per SOP with proper documentation
- Monitor performance of staff performing testing
Data Management and Oversight

*Regional Medical Laboratory Scientists* (RMLS) will assist in providing:

- Recommendations for testing
- Provide training and competency assessments
- Review QC testing and documentation
- Review performance
- Review reporting and record keeping systems
- Monitor process control
HU POCT Procedures

Glucose screening  QuickVue Strep
QuickVue HCG
Urine Dipsticks
Stool occult blood
QuickVue Influenza
QuickVue RSV
QuickVue Mono
QuickVue Chlamydia
Alere-Binax NOW Malaria*

Other
QuickVue RSV
QuickVue Mono
QuickVue Chlamydia
SD Dengue*
SD Chikungunya *
QBC* hematology analyzer
Piccolo* biochemistry
Cobas* - d-dimer & troponin
coliert – water testing

* Not waived
The Quality Assurance Cycle

Pre-Analytic
- Patient/Client Prep
- Sample Collection
- Personnel
- Competency Test
- Evaluations

Analytic
- Data and Lab Management
- Safety
- Customer Service
- Sample Receipt and Accessioning
- Sample Transport

Post-Analytic
- Reporting
- Record Keeping
- Quality Control Testing
Pre-analytic Phase

- Occurs before testing begins
- Up to 75% of test errors occur in the pre-analytic phase
- Random errors undetectable by QC testing
- May lead to a serious patient misdiagnosis
- Errors can be prevented with the proper performance of QC, continuing education, effective specimen collection systems, and quality products

- These good lab practices should be followed:
  - Confirmation of test orders
  - Patient identification
  - Patient preparation and pretest information.
  - Procedures for specimen collection, handling, including labeling
  - Preparation of test area and materials
Analytic Phase

- Occurs during the testing process
- Estimates of up to 20% of test errors occur
- There is no way to know if the results are biased up or down because of methodology or instrument problems
- These good lab practices should be followed:
  - Quality control
  - Test performance
  - Reading the results
  - Interpretation
  - Problem resolution
  - Recording results
Post-analytic Phase

- Occurs after the testing
- Estimates of up to 40% of test errors
- These good lab practices should be followed:
  - Reporting test results
  - Confirmatory testing
  - Informing patient of test results
  - Record keeping
  - Quality assessment
It Starts and Ends with the Patient

- Remember that the laboratory testing process begins and ends with patient care
- All laboratory tests MUST be interpreted in light of the clinical picture
- Although testing may yield unexpected results that are critical in guiding patient evaluation and management, be vigilant for spurious results from improper specimen collection, mislabeled specimens, clerical errors and other pre-analytic, analytic and post-analytic errors
It's a WAIVED test, NOT a WAVE test!!
MED POCT Testing Program

Areas of Concern

- Consistent errors in HU testing
  - Failure to read and follow instructions
  - Lack of QC to monitor kit performance
  - Lack of documentation and record keeping
  - Use of expired reagent and test kits
  - Misinterpretation of results
  - Use of non approved test kits
  - Uncertainty on how to act on results
  - Poor maintenance of equipment
  - Safety – lack of gloves, disposal of medical waste
Wear your PPE
Break Out Demonstrations

- PPM procedures
- Rapid test kits
- One Touch Glucometer
- Collection of nasal pharyngeal specimen
- Preparation of malaria smears - thick and thin
- Alere BinaxNOW Malaria kit
Resource Information

“To Test or Not to Test, Considerations for Waived Testing”, CDC. 
Https://wwwn.cdc.gov/clia/Resources/WaivedTests/

Ready ? Set? Test!  Patient Testing is Important. Get the right results. CDC.

Ready? Set ? Test Online Course. CDC.
Laboratory Contacts

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- Christine Deigni, RMLS - Beijing Region
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- Joanna Morrison, RMLS - Moscow Region
- Kim DeGroat, RMLS - Frankfurt Region
- James Adams, RMLS - Cairo and Addis Ababa Regions
- Carolyn Mermon, RMLS - Mexico City Region
- Marilyn Kennedy, Director Laboratory Programs and Services
On To The Laboratory Practicum

Questions?
PPM Training Module
Vaginal Wet Prep

- After donning a lab coat, perform hand hygiene and put on gloves
- Perform microscope maintenance, if required. Clean the objectives and eyepieces with lens cleaning solution and lint-free lens paper.
- Check expiration dates of reagents and supplies
- Label two microscope slides with patient identifiers
Obtain Specimen

- Collect vaginal specimen using 2 swabs
- Place swabs in a small tube with 2-3 drops saline
- Deliver to lab
- Optional:

*Have patient collect their own specimen*
Prepare Slides

Saline Slide:
- Place 1 drop saline on a slide
- Mix 1st specimen swab sample in the saline
- Coverslip
- Discard swab in bio-waste

KOH Slide:
- Place 1 drop KOH on a slide
- Mix 2nd specimen swab in the KOH
- Perform “Whiff test”
- Coverslip
- Discard swab in bio-waste
Microscopic Exam

- Start with low power (10x) and switch to high (40x)
- Focus up and down through the plane of cells
- Adjust light to better visualize cellular matter
Microscopic Exam – Saline Slide

- Examine saline prep slide on low power (10x) and high power (40x) for:
  - Bacteria
  - Fungal elements (yeast, budding yeast, mycelia)
  - Motile *Trichomonas* and human cellular elements
  - Presence or absence of Clue Cells, WBC, or RBC

- After the microscopic examination, discard slide into a Sharps container
Microscopic Exam – KOH Slide

- Examine KOH prep slide on low power (10x) and high power (40x)
  - Look for yeast or mycelia elements
  - KOH dissolves (or digests) cellular elements (RBC, WBC, epi cells) enhancing fungal elements
  - Report as yeast and/or mycelia present or absent

- “Whiff Test”
  - KOH changes the pH to alkaline resulting in a distinct foul-smelling fishy odor
  - Test used in diagnosis of BV
  - Report as “Whiff Test” positive or negative

- After the microscopic examination, discard slide in a Sharps container
Blood Cells

- Blood Cells
  - Red Blood Cells
    - Normally not present
    - May be present due to contamination during menstruation
  - White Blood Cells
    - Increased during ovulation and menses
    - A few to several seen in healthy women
Squamous Epithelial Cells

- Predominant cell found in vaginal mucosa
- Large, flat cells (30 to 50 μm) with a small, single nucleus (size of RBC) and a large area of cytoplasm
- May appear as single cells with well defined edges or grouped in clusters or sheets, folded, or rolled
- With degeneration they may be misdiagnosed as Clue Cells
- Normal findings
Yeast and/or Mycelia

- *Candida albicans* associated with vaginal infections
  - Two forms seen - yeast phase and mycelia
    - Single yeast cell - 5-7 microns in diameter, w/out a bud
    - Mycelia - up to 50 microns long, thick-walled tube-like structures, appear branched, and may have terminal buds

- **Presence**
  - Normal: none, occasional (< 1 seen in 10 hpfs)
  - Abnormal: > 1 seen per hpf (increased)
  - Increased numbers indicate candidiasis

- Often confused with RBC - KOH lyses RBC, WBC and epithelial cells

- **Diagnosis:**
  - Saline prep slide may have budding yeast and/or mycelia and the KOH slide will show those fungal elements more clearly
  - “Whiff test” is negative
  - Combination of organisms
Bacterial Vaginosis

- Bacterial Vaginosis (BV)
  - Clue cells
    - Vaginal squamous epithelial cells
    - Smudged granular appearance
    - Indistinct borders
    - Seen in saline prep
  - "Whiff test" – Positive
  - Lack of inflammatory cells & absence in normal flora
**Trichomonas vaginalis**

- **Trichomonas vaginalis**
  - Protozoan parasite w/ 3-5 anterior and 1 posterior flagella
  - Common STD
  - Smaller than epithelial cell
  - Have rapid, jerky motility that can be seen under low power microscopy
  - Examine the specimen within 15 minutes of collection
  - Can resemble WBCs or epithelial cells
  - Report positive only if seen moving
  - Diagnosis:
    - Seen on the saline prep only
    - And, the whiff test may be positive
Bacterial Flora

- Lactobacilli
  - Accounts for 50-90% of bacteria present in healthy vagina
  - Large, non motile, rods (gram positive rods)
  - Acid pH maintains bacterial flora in balance by preventing proliferation of ‘other bacteria’

- Other bacteria
  - *Gardnerella vaginalis* (small, non motile, coco bacilli)
  - *Mobiluncus sp* (thin, curved, motile rods) and others

- Artifacts
  - Fibers, pollen, mucus, starch granules, and sperm
Wet Prep Limitations

- Limitations
  - Failure to vigorously swirl the swab in the saline to dislodge the specimen may lead to erroneous results.
  - Non-motile *Trichomonas* could be mistaken for WBC or epithelial cells.
  - Oil droplets from vaginal medications may be mistaken for yeast, however, they vary greatly in size and are highly refractile.
  - Cotton fibers from the swab may resemble fungi.
  - Microscope lighting is critical for the KOH prep examination.
  - Failure to examine the entire cover slip area may result in false negatives.
Wet Prep - Reporting

- Clue cells, *Trichomonas* and yeast/mycelia – reported individually
  - Negative (or Absent)
  - Positive (or Present)

- White Blood Cells
  - Negative: < 10 WBCs per hpf
  - Positive: > 10 WBCs per hpf

- Positive results are not quantified
## Vaginitis Differentiation

<table>
<thead>
<tr>
<th></th>
<th>Normal</th>
<th>Bacterial Vaginosis</th>
<th>Candidiasis</th>
<th>Trichomoniasis</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Symptom presentation</strong></td>
<td>Odor, discharge, itch</td>
<td>Itch, discomfort, dysuria, thick discharge</td>
<td>Itch, discharge, ~70% asymptomatic</td>
<td></td>
</tr>
<tr>
<td><strong>Vaginal discharge</strong></td>
<td>Clear to white</td>
<td>Homogenous, adherent, thin, milky white; malodorous “foul fishy”</td>
<td>Thick, clumpy, white “cottage cheese”</td>
<td>Frothy, gray or yellow-green; malodorous</td>
</tr>
<tr>
<td><strong>Clinical findings</strong></td>
<td></td>
<td>Inflammation and erythema</td>
<td>Cervical petechiae “strawberry cervix”</td>
<td></td>
</tr>
<tr>
<td><strong>Vaginal pH</strong></td>
<td>3.8 - 4.2</td>
<td>&gt; 4.5</td>
<td>Usually ≤ 4.5</td>
<td>&gt; 4.5</td>
</tr>
<tr>
<td><strong>KOH “whiff” test</strong></td>
<td>Negative</td>
<td>Positive</td>
<td>Negative</td>
<td>Often positive</td>
</tr>
<tr>
<td><strong>NaCl wet mount</strong></td>
<td>Lacto-bacilli</td>
<td>Clue cells (≥ 20%), no/few WBCs</td>
<td>Few to many WBCs</td>
<td>Motile flagellated protozoa, many WBCs</td>
</tr>
<tr>
<td><strong>KOH wet mount</strong></td>
<td></td>
<td>Pseudohyphae or spores if non-<em>albicans</em> species</td>
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</tbody>
</table>
Trichomonas vaginalis
WBC’s
Mycelia
Candida - Budding Yeast Cells
Clue cells

Saline: 40X objective
RBC’s
Lactobacilli and Squamous Epithelial Cell

Saline: 40X objective

Source: Seattle STD/HIV Prevention Training Center at the University of Washington
Can you name the cells?

Saline: 40X objective

Source: Seattle STD/HIV Prevention Training Center at the University of Washington
Thank you!