Boots on the Ground Breakout: Policies & Procedures Training & Competency

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Part 1 Breakout Session Goals (Lou Ann)
Upon completion of this Breakout Session, the participant will be able to:

1) Create a basic process map for this new POC test;
2) Draft a basic SOP to be used for initial training;

Biomarker (BM) Testing MIFU (Package Insert)

1. CLIA category: Non-waived, Moderately Complex
2. CLIA Certificate: Certificate of Accreditation; inspected by CAP
3. Device is an unbreakable handheld with a large display screen; barcode scanner
4. Specimen Requirement: Fingerstick whole blood
5. Testing Requirement: Test immediately at bedside
6. Read quantitative results at 5 minutes from display screen
7. Strip technology:
   a. Device detects strip specimen QNS and displays ‘QNS’; serum/plasma specimens are detected and display ‘invalid specimen’
   b. Strip contained in a sealed, individual foil pouch; room temperature storage
   c. Pouches scanned for lot # and expiration (lock out)
   d. No calibration required with new lot #
8. Linear range: 5-20 mg/dl
   a. Results < 5 mg/dl display ‘Low’; EMR results read: ‘Less than measurable limits’
   b. Results > 20 mg/dl display ‘High’; EMR results read: ‘Exceeds measurable limits’
   c. Critical: > 15 mg/dl
9. Quality control:
   a. Internal runs electronically q 8 hrs if device turned ‘on’ or on charger
   b. External/liquid q 30 days and with each new lot of reagents. Two levels of controls are supplied as bar-coded, single use ampules, stored at room temperature.
   c. Lock out functionality
10. Approved operators scan ID badge to start operating device (operator lock out)
11. Patients have bar-coded arm bands compatible with BM device scanner
12. Results are interfaced via BM Middleware to LIS and then to EMR
13. Hospital Medical unit of 50 operators (RNs and MAs) working 24/7; 12-hr shifts; BSRN each shift as charge nurse
14. Limitations/reason for specimen rejection: do not use clotted specimens
15. All IC, PPE and safety requirements to apply
16. Cleaning & disinfection: 1 minute bleach wipes (one wipe to surface clean; 2nd wipe to disinfect using contact ‘wet’ time of 1 minute; MIFU state ‘clean and disinfect after each patient test’
Process Mapping: Tips to Remember

1. Map out steps in exact order as they should be done per designated role
2. Assess for risk, bottlenecks, duplications and excessive handoffs
3. Ensure compliance with regulatory/accreditation requirements
3 Column Procedure Template:

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Writing</th>
<th>Tips to Remember</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Procedure Writing: Tips to Remember

1. Sequential action steps written as concise phrases starting with an action word
2. Caution statements, notes and limitations placed before the step to which they apply
3. Job aids referenced with related action steps in Supplemental Guidance
4. Ensure compliance with regulatory/accreditation requirements

Part 2 Breakout Session Goals (Peggy)

Upon completion of this Breakout Session, the participants at each table, working as a POC Management Team, will be able to:

1) Discuss possible challenges to successful training of POC Operators & share potential solutions;
2) Draft a ‘check-off’ tool for the new ‘BM’ POCT, which lists elements of training to be completed for successful initial competency assessment.
Training adults – retention is a challenge
The Learning Pyramid

- Ladder: 5%
- Reading: 30%
- Audio Visual: 10%
- Demonstration: 20%
- Discussion Group: 40%
- Practice by Doing: 50%
- Teach Others: 90%

Source: Kaplan Large (January 1974).

11/4/2019

Table Exercise - Small Groups
Lightening Round:
Discuss your biggest challenge in providing effective training

Discuss challenges/barriers with tablemates
Share potential solutions

Challenges in training
For example...

- No training budget – who is paying for reagents & controls & labor?
- How much time to allot for the training?
- Is there sufficient # of trainers/assessors CLIA qualified to fulfill the role of observer?
- Is there a suitable matrix ‘fake patient specimen’ to use for demo and practice of testing during training?
- Location & means of training – onsite clinic or unit with face-to-face trainer? Central classroom with trainer? Remote/distant/online module/videos?
Breakout Task #2:

Draft a ‘check-off’ tool for the new Biomarker (‘BM’) POCT

Does this satisfy initial competency assessment requirements (nonwaived)?

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**Biomarker (BM) Testing MIFU (Package Insert)**

1. **CLIA category:** Non-waived, Moderately Complex
2. **CLIA Certificate:** Certificate of Accreditation; inspected by CAP
3. **Device:** An unbreakable handheld with large display screen, barcode scanner
4. **Specimen Requirement:** Fingerstick whole blood
5. **Testing Requirement:** Test immediately at bedside
6. **Read quantitative results at 5 minutes from display screen**
   a. Strip technology
      - Device detects strip specimen (500iu and displays ‘500iu’); Hemoplasma specimen displays ‘invalid specimen’
      - Strip contained in a sealed individual foil pouch; room temperature storage
      - Pouches scanned for lot# and expiration (lock outs)
      - No calibration required with new lot#
7. **Linear range:** 5-20 mg/dl
   a. Result of < 5 mg/dl displays ‘Low’; EMR results read: ‘Less than measureable limits’
   b. Result of > 20 mg/dl displays ‘High’; EMR results read: ‘Exceeds measureable limits’
   c. Critical: > 15 mg/dl
8. **Quality control:**
   a. Internal runs electronically q 8 hrs if device turned ‘on’ or on charger
   b. External/liquid q 30 days and with each new lot of reagents. Two levels of controls are supplied as barcoded, single use ampules, stored at room temperature.
   c. Lock out functionality
9. **Approved operators scan ID badge to start operating device (operator lock out)**
10. **Patients have barcoded armbands compatible with BM device scanner**
11. **Results are interfaced via BM Middleware to LIS and then to EMR**
12. **Hospital Medical unit of 50 operators (RNs and MAs) working 24/7; 12-hr shifts; BSRN each shift as charge nurse**
13. **Limitations/reason for specimen rejection:** do not use clotted specimens
14. **All IC, PPE and safety requirements apply**
15. **Cleaning & disinfection:** 1 minute bleach wipes (one wipe to surface clean; 2nd wipe to disinfect using contact (‘wet’) time of 1 minute; MIFU state ‘clean and disinfect after each patient test’

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**Competency Assessment, CAP Con’t.**

**CAP GEN.55500 Competency Assessment - Nonwaived Testing Phase II**

Elements of competency assessment include but are not limited to:

1. Direct observations of routine patient test performance
2. Monitoring the recording and reporting of test results, including, as applicable, reporting critical results
3. Review of intermediate test results or worksheets, QC records, PT results, and PM records
4. Direct observation of performance of instrument maintenance and function checks
5. Assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples, and
6. Evaluation of problem-solving skills

A test system may encompass multiple identical analyzers or devices. Different test systems may be used for the same analyte.
Moderate testing training & comp assessment

Content for training - Moderate

Required Training: American Academy of Family Physicians

- proper specimen collection, patient preparation, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens;
- implementing all standard laboratory procedures for performing each test method, for proper instrument use, performing preventive maintenance, troubleshooting, and calibration procedures, maintaining stability and storage;
- implement quality control policies

- An awareness of the factors that influence test results, and the skills required to assess and verify the validity of patient test results through the evaluation of quality control sample values prior to reporting patient test results.

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Q&A