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

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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 hand held 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
7. Strip technology
   a. Device detects strip specimen QNS and displays ‘QNS’; serum/plasma specimens are detected and displays ‘invalid specimen’;
   b. Strip contained in a sealed individual foil pouch; room temperature storage
   c. Pouches scanned for lot# and expiration (lock outs)
   d. No calibration required with new lot#
8. 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
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 barcoded, 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 barcoded armbands 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 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’
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**Legend:**

- **Action steps**
- **Risk Area**
- **Decisions**
- **Checks Barriers**
- **End of Process**
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
# 11 Steps to Focus & Simplify Policies and Procedures

1. Map the process

2. Identify any applicable regulatory and/or accreditation requirements
   a. CAP, AABB, TJC, DNV, CMS, State, OSHA, DEQ, EPA

3. Evaluate process for Improvement Opportunities
   a. Look for high risk, error-prone areas
   b. Assess using Lean principles
   c. Look for mistake-proofing opportunities
   d. Compliance to regulatory and accreditation standards

4. Re-design the process based on identified improvement opportunities and update the process map

5. Assess document needs based on the revised process map
   a. Policy (defines the overarching rule)
   b. Process (treated as a job aid)
   c. Procedure (supports the policy)
   d. Job Aids (supports the procedure)

6. Create needed documents
   a. Use company guidelines and templates
   b. Perform draft and validation reviews

7. Gain approval for documents

8. Maintain document control

9. Communicate, educate/train staff
   a. Read & Sign acknowledgements

10. Implement the new/revised documents

11. Develop methods to monitor the process for compliance
### Patient Test Procedure:

<table>
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<tr>
<th>Required Action Steps</th>
<th>Performed by</th>
<th>Supplemental Guidance</th>
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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

- Lecture: 5% retention after 24 hours
- Reading: 10% retention after 24 hours
- Audio Visual: 20% retention after 24 hours
- Demonstration: 30% retention after 24 hours
- Discussion Group: 50% retention after 24 hours
- Practice by Doing: 75% retention after 24 hours
- Teach Others: 90% retention after 24 hours

Source: National Training Laboratories, Bethel Maine
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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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.
Required Training:

- 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
- reagent stability and storage;
- implement quality control policies

钒 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.
Boots on the Ground Breakout: Policies, Procedures, Training, Competency

Q&A