

Laboratory Breakout Session

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Objectives for Lab Breakout

- To gain an understanding of pSMILE, a new Network Lab “Partner”.
- To clarify standard NL testing strategies.
- To read and understand the NL MOP, lab manual, and training software.
- Lessons learned from Site presentations and Group Discussions.

Gain an Understanding of pSMILE

- pSMILE – patient Safety Monitoring International Laboratory Evaluation
- pSMILE will supply CAP panels and evaluate results monthly.
- NL representative will evaluate results weekly and help the Site with any corrective issues.
- The sites will report back directly to pSMILE.

pSMILE Action Items

- NL will be proactive in evaluating proficiency results.
- Sites will work with the NL to perform and write-up corrective actions.

Clarify Network Lab Testing Protocols

- Review of Probetec operations
- Validation of coagulation
- HIV Rapid testing review
- HIV WB proficiency testing online

Laboratory Testing Action Items

- Review all testing runs and assure accurate results.
- Query clinician or laboratory if results are inconsistent.
- Contact the lab manager or the MTN NL if questions remain.
- Make sure all online proficiency testing is completed on time.

Overview of MTN MOP, Lab manual, and training software

- The MTN MOP is under review and will be online next month.
- HPTN/MTN laboratory manual is online and available.
- New Excel Templates for Laboratory Assays.

MOP, Lab manual, and software Action Items

- Review MOP and laboratory manual and contact the NL if there are questions or errors found.
- Utilize the Excel Templates but validate them first with Site data.

Lessons learned from Lab presentations

- ProbeTec: Pipetting technique is critical to prevent carryover contamination.
- Coagulation: Make sure ISI value stays the same. If not re-evaluate the normal range and mean. Comparison of old and new lot.
- Hematology: If using multiple instruments comparisons are required.

Lessons learned from Lab presentations

- Chain of custody: QC of results from contract lab is critical. Transcriptional errors can occur. Signatures from each person handling the specimen should be documented.
- HIV Rapid Tests and Western Blot: Indeterminate results for WB should be clarified by the NL.

Group Discussion Example 1

- How would you handle expired reagents or close-to-expire reagents?
 - Notify Lab manager
 - Contact Back-up laboratory to run specimen.
 - If it is a chronic problem, identify new vendors.

Group Discussion Example 2

- What would you do if your LDMS computer crashed and your hard-drive is destroyed?
 - Contact FSTRF for data recovery.
 - Make sure you provide regular back-up of your data to ensure recovery.
 - Manually enter PTIDs, date, visit number until computer is up and running then print out labels.