Operational Updates
MTN Regional Meetings
Capetown, South Africa
October 19-22, 2009

Edward Livant MT (ASCP), MPH
MTN Network Laboratory
Update 1: Review of GCLP Oversight

DAIDS

MTN ACTG HVTN IMPAACT HPTN

pSMILE

PPD
Update 2: MTN Network Lab

- You can always send any lab questions to Ted and he will answer or refer them to the appropriate people.
- When in doubt on any issue, please contact MTN for clarification.
- Ted is the primary contact for MTN 001, 003, 003B, US sports related questions and 015. (MTN 004-US only).
Update 2: What Questions Might Ted Refer?

- Lorna Rabe: BD Probetec, Rapid BV and TV kits, wet mounts, general microbiology (MTN 005 US only and India MTN 006-US only.)
- Pam Kunjara: MTN 016 (MTN 002, 007, 008-US only)
- Urvi Parikh: HIV resistance, HIV RNA, Virology Questions
- Charlene Dezzutti: Administrative questions, BSWG questions and some study related issues
Update 2: What Questions Might Ted Refer?

- DAIDS/SMILE: GCLP issues
- FHI/SCHARP: Protocol Issues, documentation issues, data questions, CFR-LDMS reconciliations
- FSTRF: LDMS questions
Update 2: Communications

- **mtnnetworklab@mtnstopshiv.org**
  - Will reach Ted, Charlene, Lorna, Pam
  - We see frequent internet problems—if you don’t hear back in a reasonable time, email again.
Update 3

- Frequency of QC for Rapid Tests
Update 4

- Parallel Testing for Rapid Testing
Update 5

- Validation Requirements for CLIA Waived FDA approved tests
Non FDA approved kits and reagents
Update 7

- Precision validation for qualitative tests that involve a numeric calculation
Questions?

Who is this Clown?