HIV Testing Key Issues, Lessons Learned

Edward Livant BSMT MPH
MTN Laboratory Center
University of Pittsburgh Medical Center
Magee Womens Research Institute
Session Objectives

- Reinforce key points for HIV testing:
  - General issues
  - Shared lessons
ASPIRE Protocol Chairs
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HIV Testing-Sample Integrity
HIV Testing-Sample Integrity

- Positive Identification of Participants
  - Must be positively identified each time a participant comes to the clinic
  - Finger printing systems may help but do not appear to be fool proof.
  - Must be re-established each time a sample is collected
HIV Testing-Sample Integrity

- Specimen Labelling-how to avoid errors
  - Do not pre-label specimen containers and tubes (Exceptions for surgical collections…)
  - Label immediately after collection.
  - Collect from one participant at a time.
HIV Rapid Testing
Physical Environment
HIV Rapid Testing
Physical Environment

- Make sure lighting is adequate
- Make sure space is adequate
- Make sure equipment and supplies are properly arranged
- Make sure waste and SHARPS containers are easily accessible
- Reference charts on walls may be helpful.
HIV Rapid Testing
Procedural Issues
HIV Rapid Testing
Procedural Issues

- Kit supplies
  - Verify FDA approved catalog numbers with each shipment.

- Quality Control
  - Each shipment
  - Each lot
  - Weekly when testing done
  - Trouble shooting
HIV Rapid Testing
Procedural Issues

- **Staff Competency**
  - Training and competency assessment must occur before any staff performs HIV testing.
  - Competency should be assessed at a minimum after 6 months and annually thereafter.
  - May do more frequent/unannounced assessments.
HIV Rapid Testing
Procedural Issues

- Staff Competency
  - Extra attention needed for staff who may be required to do testing infrequently
  - How do you assess competence….?
HIV Rapid Testing
Procedural Issues

- Staff Competency-External Quality Assurance
  - EQA panels assess test methods and staff competence
  - All staff involved in HIV rapid testing must be rotating through performing panels.
  - Don’t always pick the All-Star to do the panels.
  - Sites can create their own QA panels
HIV Rapid Testing
Procedural Issues

- Second Checker
  - Must have all qualifications, training, and competency assessments of primary tester.
  - Must read test kit within allowable time in kit insert.
  - All must be documented for each test.
HIV Rapid Testing
Procedural Issues

- Weak test bands
  - Any test band on a valid test is considered positive
  - An HIV rapid test can never be “indeterminate”
    - Two rapid tests can be “discordant”
  - What are possible results for a single HIV rapid test?
HIV Rapid Testing
Clearly Positive
HIV Rapid Testing
Clearly Negative
HIV Rapid Testing
Clearly....not sure
HIV Rapid Testing
Clearly….not sure

- There have been cases where the primary tester and second checker don’t agree if a band is present.
- How would you handle this situation?
HIV Rapid Testing Documentation

- All corrections must be done to GCP standards.
- Changes to results should be rare and must be done in real time.
- You can not change a result between positive and negative results after the fact. If a past result is in doubt, contact the management team for guidance.
Oversight

SPICY AND VEGETARIAN

LAMB BIRYANI
tender lamb cubes in tomato sauce in masala sauce with chutney

THAI RED CURRY CHICKEN
boneless chicken, red curry, lemon

PEAS AND POTATO
in masala sauce with chutney

MUSHROOMS AND COUGETTES
grilled and finished in star anise
Oversight

- The Laboratory is ultimately responsible for any testing done by non-lab staff
- There must be good cooperation between clinic and lab for this to succeed.
Oversight

- Testing log review frequency may vary by need
- Contact the laboratory in case of questions
- Discuss issues with staff who are doing testing
- Systems must be set up to accommodate hectic busy situations.