

HIV Testing Key Issues, Lessons Learned

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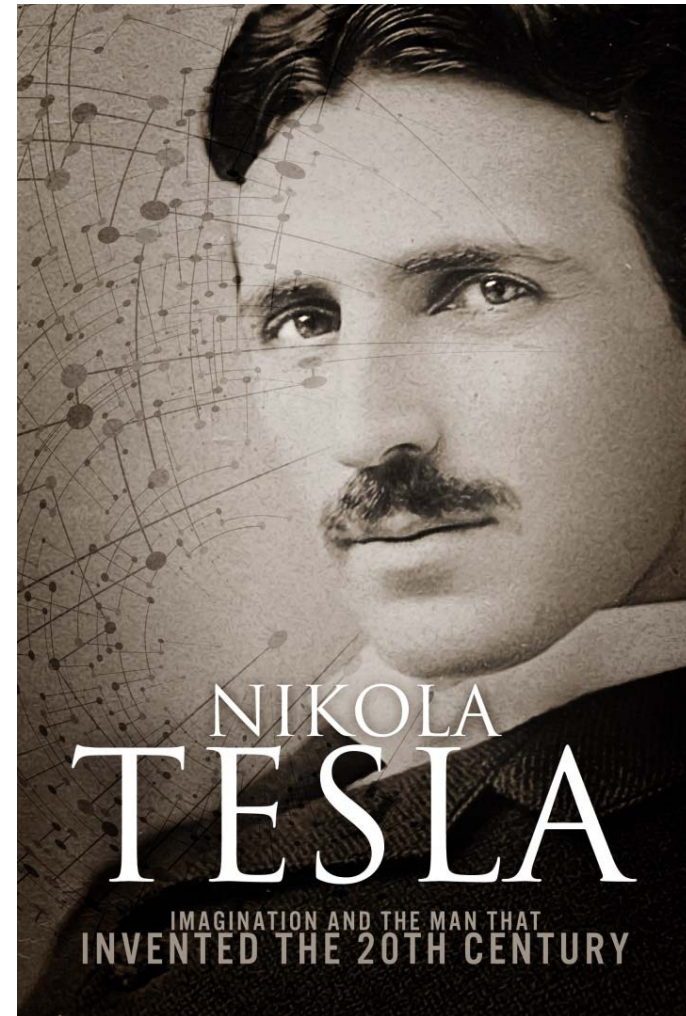
Magee Womens Research Institute

Session Objectives

- Reinforce key points for HIV testing:
 - General issues
 - Shared lessons



ASPIRE Protocol Chairs



ASPIRE Protocol Chairs



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

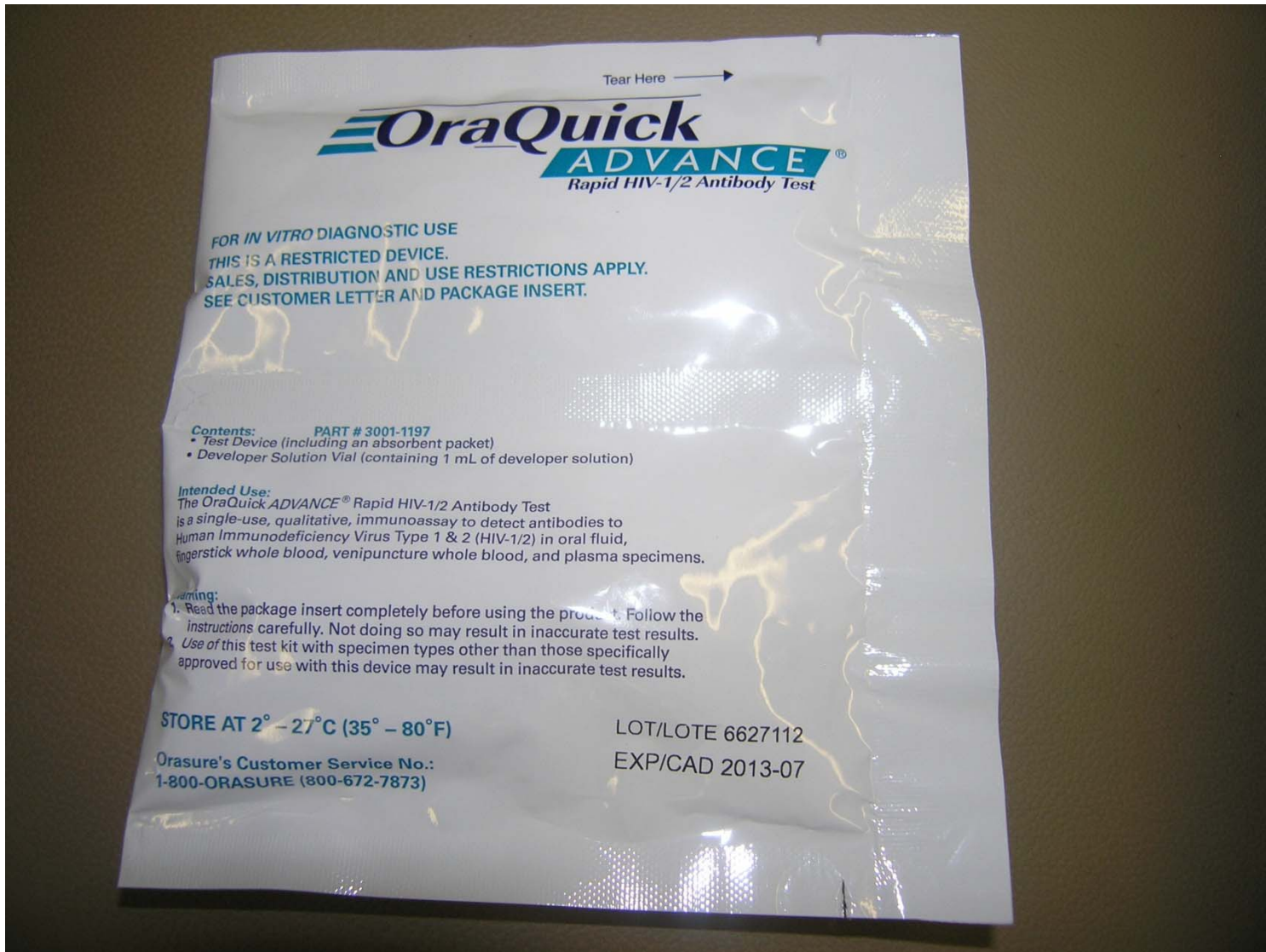




HIV Rapid Testing Physical Environment

- Make sure lighting is adequate
- Make sure space is adequate
- Make sure equipment and supplies are properly arranged
- Make sure waste and SCHARPS 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

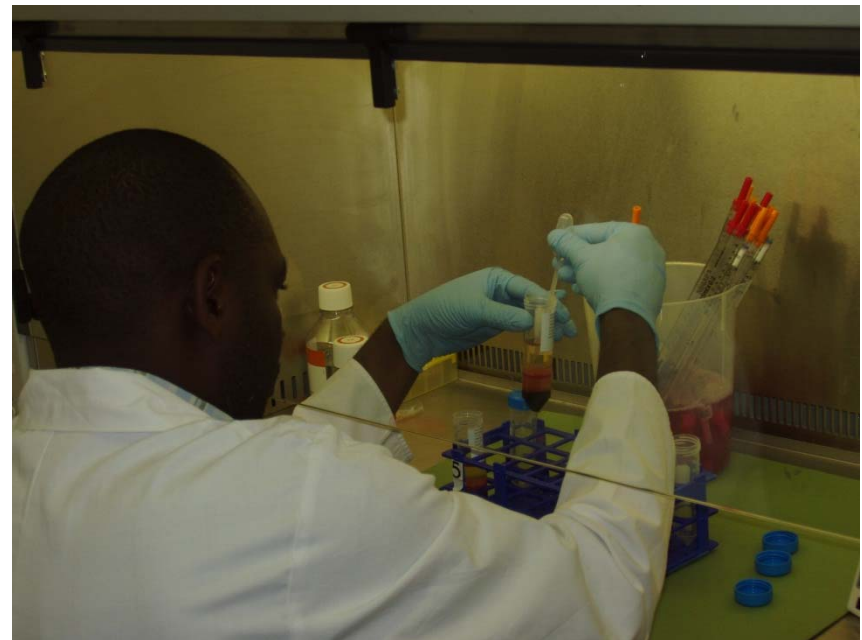


HIV Rapid Testing Procedural Issues

- 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?

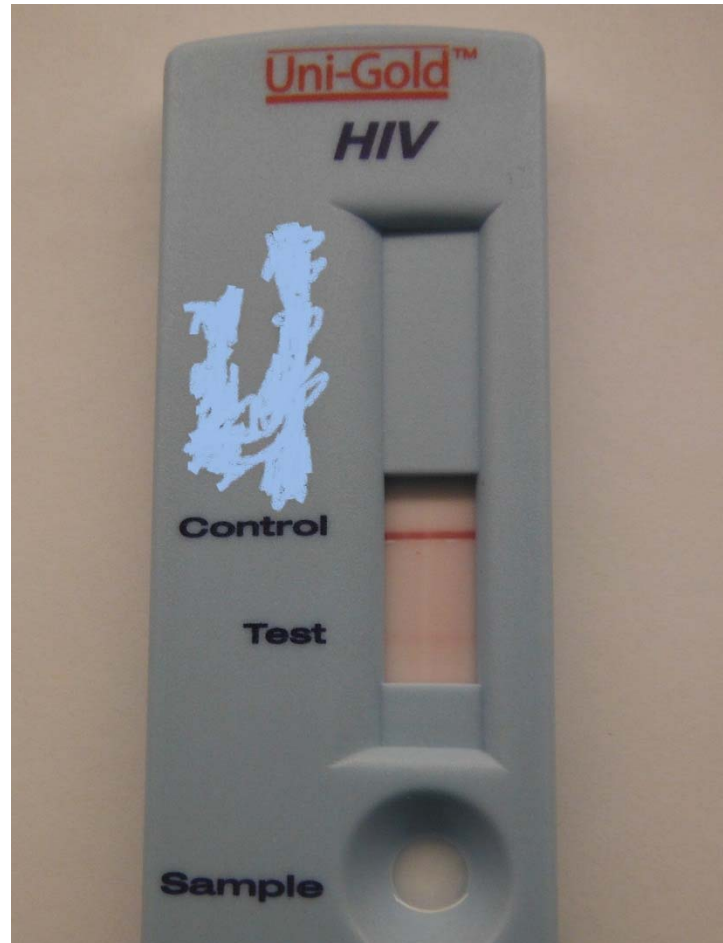
HIV Rapid Testing Clearly Positive



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 i

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.