

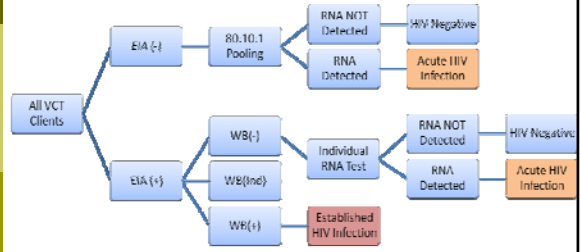
HIV and STD Testing News

NC State Laboratory of Public Health

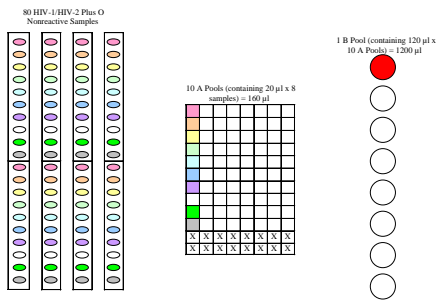
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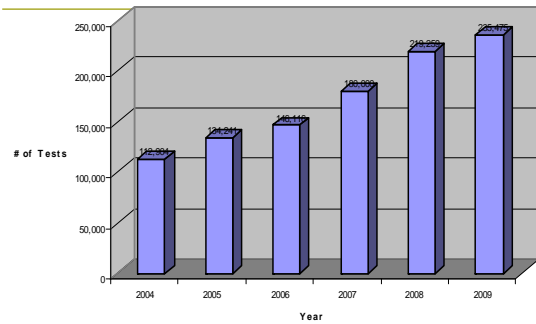
NC HIV Testing Algorithm



SLPH Pooling Strategy



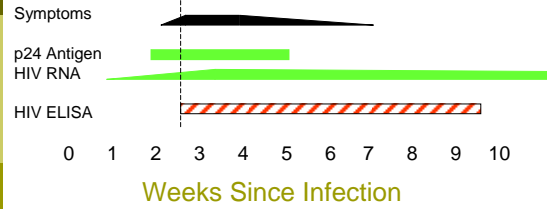
Increase in HIV Antibody Tests 2004-2009



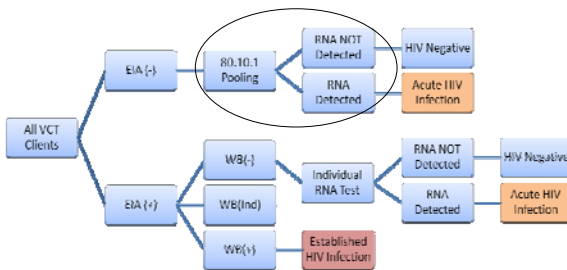
HIV Ag/Ab Assays

- FDA approval of 4th generation HIV p24 Ag/Ab Combination assay from Abbott Diagnostics
- Detects the spectrum from acute to chronic infection (cannot differentiate)
- Narrows the “window period” between infection and detection
- Expected to replace existing test algorithms that use pooled NAAT for detection of acute cases

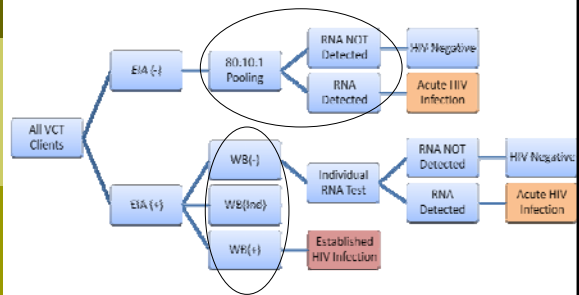
HIV-1 Testing Timeline:



NC HIV Testing Algorithm



NC HIV Testing Algorithm



Implementation of New HIV Assay



- Decreased TAT
 - Negative results in 2-3 days vs. 2-3 weeks
 - Detection of acute cases in 4 days vs. 2 weeks
- Increase testing capacity ???



- Could miss 20% of acute cases – 3/year
- Increased costs
- Must develop and implement new approved test algorithms

Reminders for HIV Submissions

- Pay particular attention to the labeling of tubes
 - Automated equipment at SLPH demands consistency (EIA instruments, capper/uncapper instrument, pooling instrument, Tigris)
- New HIS labels
 - Good for HIV scannable forms (contains all required information)
 - Bad for sample tubes (4" labels are too long)
- Most importantly, make sure patient ID information on test request exactly **matches** information on sample tube label
 - Full first and last name and either SSN or DOB
- Sample volume needed for HIV testing: **3.0 mL**
- Clerical errors
 - Continue to fax requests for corrections to reports
 - Error rate <0.6% (QA study conducted in December 2009)
- Post-test counseling information no longer required

Syphilis

- SLPH uses TRUST for non-treponemal screening; titer if Reactive.
- Switched from Captia IgG EIA to TrepSure EIA for confirmation of non-treponemal results in August 2009
- TrepSure detects both IgM and IgG antibodies
- Fewer “equivocal” confirmatory results:

Captia	2.4% Equivocal Rate (2008)
TrepSure	0.4% Equivocal Rate (2009)
- 2.0% lower = 2,200 patient results/year!

Reminders for Syphilis Submissions

- Provide two matching identifiers on sample and form (full first and last name and either SSN or DOB)
- Use newest downloadable forms from website (no two-part pink carbon forms for TRUST)
- Indicate screening titer on requests for confirmatory testing
- Include submitter information on all test requests
- Use correct mailers:
 - white label/SYPHILIS for TRUST
 - blue label/SPECIAL SEROLOGY for TrepSure
- Don't include Rubella samples with Syphilis samples

Chlamydia/Gonorrhea

Recommendations from Expert Consultation Meeting in January 2009
(expected to comprise 2010 Chlamydia/Gonorrhea Testing Guidelines
- due out this fall)

- NAATs are test of choice for detection of CT/GC infections in men and women with and without symptoms.
 - GenProbe PACE non-amplified probe test will be discontinued 12/31/2012
 - GC culture still important to monitor antibiotic resistance
- Optimal specimen types for NAAT are first catch urine from men and vaginal swabs from women.
 - SLPH will change from endocervical swabs to all vaginal swabs in January 2011
 - Advantages include patient self-collection options
 - Vaginal swabs will replace limited urine testing in Family Planning clinics

Chlamydia/Gonorrhea

- NAATs are recommended for detection of rectal and oropharyngeal infections caused by *C. trachomatis* and *N. gonorrhoeae*.
 - Testing of these specimen types have not been cleared by the FDA for use with NAATs
 - Laboratories must establish performance specifications to satisfy CMS regulations for CLIA compliance prior to reporting results for patient management
 - Testing not available yet at SLPH
- Routine repeat testing of NAAT positive screening specimens is not recommended.
 - SLPH discontinued repeat testing of low positive results in 2009
- NAATs are acceptable for use in adult cases of sexual abuse.
 - SLPH does not offer Chain of Custody for legal cases

Reminders for CT/GC Submissions

- **Adhere to testing criteria to ensure specimen will be tested:**
 - All females < 25 years of age, all pregnant females, all symptomatic females
 - retest for CT/GC at three months post-treatment
 - sex partner referral
 - high risk history (new partner, multiple partners)
 - CT testing prior to IUD insertion
- **Complete all sections of test request form:**
 - Clinic Type
 - Specimen source
 - Signs/symptoms
 - Pregnancy status
 - Reason for visit

Reminders for CT/GC Submissions

- Check expiration dates on collection kits. Sample will be deemed UNSAT if kit expiration date precedes collection date.
- Ensure that the final volume of urine in urine collection kit falls between the two black fill lines on the transport tube.



Herpes

- HSV culture service available only to LHDs and other state operated health care facilities
- Specimens for HSV culture limited to the following:
 - Specimens from prenatal patients who have a suspicious lesion not previously confirmed as herpes. Routine cultures in the absence of lesions are not accepted.
 - Specimens from patients presenting with an atypical lesion where a clinical distinction cannot be made between herpes, chancroid, and syphilis.
 - Cultures done simply to confirm a clinical diagnosis of herpes not available on a routine basis
- Herpes virus culture from urogenital sites limited to one specimen/patient. If more than one site is cultured, both swabs should be submitted in the same transport tube. **DO NOT** place more than two swabs in a single viral transport medium vial.

Lymphogranuloma venereum (LGV)

- Rectal swab specimen should be collected and tested for chlamydia by NAAT first
(rectal NAAT for chlamydia/GC not currently available at SLPH)
- If rectal swab specimen is NAAT positive for chlamydia, sample will then be forwarded to CDC for differential LGV testing
- If initial NAAT cannot be performed at local level, CDC can perform this testing first on suspect samples
- LGV serology is not available at either SLPH or CDC
- If serology is desired, specimen can be sent to a reference lab (Focus Diagnostics)

Chancroid (*Haemophilus ducreyi*)

- No longer recommend culture of organism because it is seldom successful; diagnosis usually made by clinical evidence and exclusion of other STD agents associated with lesions
- PCR: Collect specimens from lesions of inguinal bubo on a **dry swab (not one with semi-solid transport media)**
- Maintain swab at -20° C until time of shipment to SLPH, then ship with cold packs
- Specimen will be forwarded to CDC for PCR testing
- Turn around time for test results is generally 1-2 weeks

Lab Tip #1: Use Correct Tubes & Caps

- Sarstedt tubes and caps
- Order from SLPH website

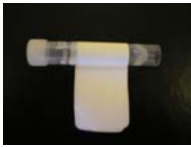


- No Simport tubes/caps
- No glass tubes
- No SST (clot tubes)

Lab Tip #2: Label Tubes Correctly



- No flags
- No tails
- No wrap-arounds



Lab Tip #2: Label Tubes Correctly



- No spiral wraps
- No wrinkles
- No label covering top screw threads



Lab Tip #3: Use Correct Mailers

- Mailers are color-coded for sorting
- Don't mark through label
- Order online



Questions???

