The HIV Bridge Algorithm: Linking Point-of-Contact, Laboratory and Patient Care

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Process for Developing New HIV Testing Algorithms

- ✓ APHL/CDC HIV Steering Committee
- ✓ Algorithm Workgroups [Point of contact (POC) and Laboratory]
  *Goal = Develop **multiple** acceptable HIV testing algorithms, i.e., a menu of options*
- ✓ APHL & NASTAD Public Health Surveys
- ✓ 2007 HIV Diagnostics Conference (December 5-7, Atlanta)
- ✓ Preparation of the **Status Report,** released April 2009 at **www.aphl.org/hiv/statusreport**
- ❑ Status Report promotion at national conferences
- ❑ Ongoing data gathering: retrospective and prospective
- ✓ 2010 HIV Diagnostics Conference (March 24-26, Orlando)
- ❑ Recommendations to follow??????

Organizations and Agencies Represented on Workgroups

- Association of Public Health Laboratories
- American Clinical Laboratory Association
- American Society of Microbiology
- Blood Banks
- Commercial Laboratories
- College of American Pathologists
- Health department HIV/AIDS programs
- National Alliance of State and Territorial AIDS Directors
- US Centers for Disease Control and Prevention
- US Department of Defense
- US Food and Drug Administration

Status Report Proposed HIV Testing Algorithms

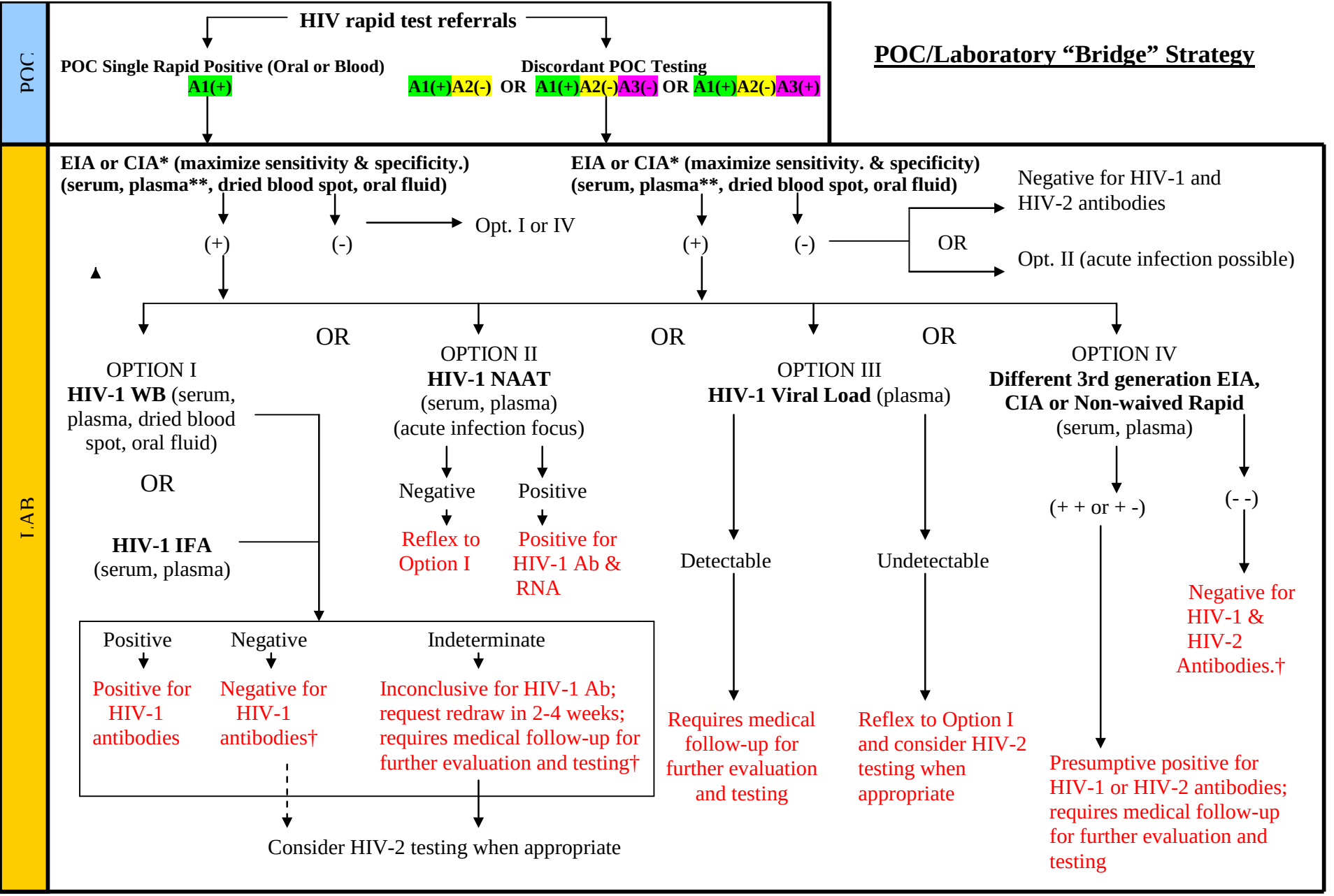
POC Algorithms

1) Single rapid test
2) Two rapid tests performed in serial use on blood
3) Two rapid tests performed in serial use on oral fluid and blood
4) Three rapid tests performed in serial use on blood

Laboratory-based Algorithms

1) HIV-1 only EIA-WB or IFA with option for NAAT and HIV-2 testing
2) HIV-1/2 immunoassay(EIA/CIA)-WB or IFA with option for NAAT and HIV-2 testing
3) Dual HIV-1/2 immunoassays with option for NAAT and HIV-2 testing
4) NAAT for acute HIV infection testing in seronegatives
5) HIV-2 Testing

Question; Can this be simplified? Can we represent POC and laboratory testing in one schematic?



NOTE: Oral fluid and dried blood spot specimens must be validated by user on 3rd generation EIAs or CIAs.

*** This screening stage is recommended for Option II or III and optional for Option I or IV**

**** Promote submission of plasma specimens when appropriate**

† If a window period infection is suspected based on risk assessment or discordant testing, reflex to Option II or III.

Examples of Data Needs for the POC, Laboratory and Bridge Algorithms

- Sensitivity & specificity data
- Population-specific PPV & NPV
- Data for specific serial use of specific assays & rapids
- Impact on reporting TAT
- Cost per test
- Logistics of dual immunoassay platforms or multiple rapid tests on-site
- QA issues
- Reproducibility data over several assay lot numbers.
- Potential use of S/CO threshold values to resolve repeat testing? (lab-based only)
- Validation studies on quantitative NAAT for diagnostic use?

More data needs can be found at **www.aphl.org/hiv/statusreport**

Thank you & Questions

If you are willing to share data or have any questions on the proposed HIV diagnostic algorithms please use

hiv.algorithm@aphl.org