Human Immunodeficiency Virus Serology (HIV) Supplemental Information

Serologic assays are available for the detection of antibodies to the human immunodeficiency virus. The SDPHL follows the CDC algorithm and utilizes a Fourth Generation HIV Ag/Ab Combo assay. The Assay tests for a qualitative detection of HIV p24 antigen and antibodies to HIV-1 and HIV-2. All reactive tests are repeated in duplicate to verify the initially reactive test result. All repeatedly reactive tests (two or more reactive) are confirmed by the Geenius HIV 1/2 Supplemental Assay.

Specimen Collection/Labeling/Requisition Form

1. Serum/Plasma Specimen
   Collect approximately three to five milliliters of whole blood (or serum) in a red top tube (no additive), labeled with patient's identifier, date, and name of the submitter. Plasma specimens are acceptable in tubes with the following anticoagulants: EDTA, sodium heparin and lithium heparin.

Requisition Form

Complete the SDPHL requisition form providing:

1. Name or unique patient identifier
2. Test(s) requested
3. Date specimen collected
4. Submitter's name and address
5. Any information submitter needs for patient identification, e.g., chart number, address, physician name, contact person and phone number
6. Race, sex and age/DOB

Reporting and Interpretation of Results

When HIV Ag/Ab Combo results are negative, the test results will be reported as "Nonreactive" and no further testing will be performed on this sample. Repeat sampling at a later date may be necessary in order to detect developing antibodies.

When the Combo test has repeatedly reactive results, the Geenius Supplemental Assay will automatically be run. Both results will be reported to the provider.

When the HIV Ag/Ab Combo test is reactive and the Geenius Supplemental Assay is Negative or Indeterminate, the specimen should be tested for HIV-1 by RNA Nucleic Acid Amplification Testing (NAAT). The RNA Qualitative Assay has very specific specimen guidelines. If the guidelines are met, the specimen will be sent off immediately. If not, a new specimen will be requested before submitting to the CDC.

- Whole Blood, Plasma, or Serum may be run up to 72 hours $\leq$25°C.
- After centrifugation, may be held an additional 5 days at 2-8°C.
- Plasma may be stored $\leq$20°C for longer periods.

The following recommendations are made regarding follow-up specimens:

1. If the result of the HIV Geenius is indeterminate, submit another specimen for testing within a month. If the second specimen is also indeterminate, the patient should be tested again at three and six months.

Unacceptable Specimens

1. Identification on form and specimen do not match
2. No identification on specimen
3. Specimen over 7 days old
4. Specimen transport tube broken in transit
5. Insufficient quantity for testing
6. No sample received with form
7. The specimen did not arrive in appropriate temperature range.