### ADDENDUM XVI

## SPECIFICATIONS FOR PERFORMANCE OF HIV ANTIBODY ANTIGEN COMBO

The Serology/Immunology and Chemistry Laboratories will coordinate performance of initial or screening testing for Human Immunodeficiency Virus (HIV) upon completion of the following:

- 1) Electronic or Written order by an Attending Physician or other person authorized to order an HIV-related test; and
- 2) Fulfillment of New York State requirements for HIV education and advisement of HIV-related testing.

## Patient HIV Education/Counseling and Advisement of HIV-related testing

- 1. New York State law requires that all patients or the patient's legal guardian or proxy be counseled both pre- and post-test regarding antibody testing for HIV.
- 2. Pre-Test Counseling is simplified and must include the following:
  - HIV causes AIDS and can be transmitted through sexual activities and needle-sharing, by pregnant women to their fetuses and through breastfeeding infants;
  - there is treatment for HIV that can help an individual to stay healthy;
  - individuals with HIV or AIDS can adopt safe practices to protect others from becoming infected or multiply infected;
  - testing is voluntary and can be done anonymously at a public testing center;
  - the confidentiality of HIV related test results is protected by law; and
  - the law prohibits discrimination based on an individual's HIV status and services are available to help with such consequences
- 3. For routine and expedited testing on women in labor, patients must be advised that an HIV-related test is going to be performed. No such test will be performed if the patient objects, and the advisement and any objection will be noted in the patient's chart.
- 4. Advising that an HIV-related test is being performed on a source patient is not required if each of the following limited circumstances of occupational exposure exists:
  - a. The source is deceased, comatose or is determined by his/her attending practitioner to lack mental capacity to consent to HIV testing and is not reasonably expected to recover in time for the exposed person to receive appropriate medical treatment **and**
  - b. There is no person reasonably available or likely to become available with the legal authority to consent to the HIV test on behalf of the source patient in time for the exposed person to receive medically appropriate treatment; **and**
  - c. The exposed person will benefit medically by knowing the source patient's HIV test results, as determined by the exposed person's health care professional and documented in the exposed person's medical record.
- 5. The AMC AIDS Treatment Center can assist with the provision of counseling services. Assistance is available Monday through Friday from 8:00 am to 4:00 pm by calling Ext. 26864. On weekends or holidays or after 4:00 pm weekdays, calls should be placed to 264-2953 to obtain specific instructions for the provision of counseling for patients who will be discharged during off-hours.
- 6. All other AMC patients seen in Clinic, Departments or specialized areas are considered outpatients and must be counseled by authorized individuals in these areas.

- 7. In cases of rape, occupational exposure or any other situation that may necessitate the release of HIV-related information to another party, an additional consent form must be obtained from the patient or the patient's legal guardian or proxy on either AMC's "Authorization for Use of Disclosure of Protected Health Information" form (available in the Health Information Services Department) or on the NYSDOH "HIPAA Compliant Authorization for Release of Medical Information and Confidential HIV Related information" form [DOH-2557 (2/11)]. A general authorization for the release of information is not sufficient and any disclosure of HIV-related information without proper consent is a violation of State law.
- 8. Once advised consent has been obtained, the Physician must submit an electronic order, written order, or the HIV Rapid Test Requisition. a. For OB/Newborns and Occupational Exposures, expedited HIV Antibody/Antigen Combo will be available within 2 hours.

#### **Patient Billing**

- 1. Patients, including inpatients, may request to either prepay for services or to have the bill for this service sent directly to their home instead of to their insurance carrier. Upon such a request by a patient, it is imperative that their request be communicated to Serology/Immunology at ext. 23508.
- 2. Unless special arrangements are indicated or prepayment is made, billing will be performed in accordance with the insurance information provided in the electronic record or written order.
- 3. To protect the patient's privacy, the bill generated by the hospital for this service will not contain any verbiage that suggests that an HIV test was performed.

#### **Specimen Collection**

- 1. The Phlebotomist/Nurse is responsible for obtaining the biohazard bag, verifying the patient's identity and collecting 5 ml blood (red/gold top tube) for HIV Antibody Antigen Combo Testing.
- 2. If an expedited HIV test is requested, the specimen should be brought immediately to the Lab Service Center.
- 3. For outpatients, HIV Antibody Antigen specimens can either be collected at the physician's office or the patient can be instructed to report to any of AMC's collection sites.
- 4. The specimen should be refrigerated if delivery to the laboratory will be delayed.
- 5. For outpatients, a completed HIV signed order must accompany the specimen to the laboratory.

### Specimen Processing

- 1. All HIV specimens should be delivered to the Laboratory Service Center, C-126.
- a. Expedited HIV test specimens should be brought immediately to the Laboratory Service Center, C-126.
- 2. Specimen processing will not begin until the laboratory receives the completed required requisition/order.
- 3. All repeatedly reactive results are confirmed by supplemental testing via the CDC and NYSDOH approved algorithm.
  - a. HIV antibody differentiation is performed by Serology using the Biorad Geenius HIV1/2 supplemental assay.
  - b. If the result of the HIV antibody differentiation assay is negative or indeterminate, the specimen is sent to NYSDOH for RNA testing.

# **Results Reporting**

- 1. For AMC Hospital and Faculty Practice, negative, reactive and positive results will be available electronically.
- 2. It is the responsibility of the Program Counselor to perform post-test counseling.

For a negative result, the patient (or if the patient lacks capacity to consent, their health care agent, guardian or surrogate) must be provided with information regarding the risks of participating in high risk sexual or needle-sharing behavior.

For a Reactive or Positive Result, the patient must be provided information regarding the risks of participating in high risk sexual or needle sharing behavior. In addition, the physician or designee should indicate the preliminary nature of the result and the need for supplemental/confirmatory testing. With appropriate consent, the physician or designee shall arrange an appointment for follow-up medical care for the patient. Based on the patient's age, the Division of HIV Medicine or Pediatric Infectious Disease can assist in follow-up of a positive or indeterminate supplemental test result.

- 3. All outpatient reports will be sent to the ordering Physician. It is the responsibility of the ordering Physician or other person authorized to ensure provision of post-test counseling as well as placement of the report in the patient's medical record.
- 4. All reactive expedited HIV OB/newborn results will be called to the senior OB Resident. Occupational exposure source patient results will be faxed to EHS for employee follow-up. Positive results will be called to the person identified on the HIV rapid test requisition.
- 5. NYS law, Public Health Law section 2130, effective 1/3/99, requires patient identified cases of HIV infection to be reported by medical providers and laboratories to the NYS Commissioner of Health.
- 6. As of June 1, 2000, NYS Public Health Law (PHL 2131) requires that the identity of persons with confirmed positive HIV Test results be reported confidentially to the New York State Department of Health.

## **Needlestick Incidents**

- 1. Employees are to report immediately following the incident to Employee Health or to the Emergency Department (if off-hours), to have a base line specimen drawn.
- 2. In accordance with the stipulations set forth in the Albany Medical Center Infection Control needle-stick policy, the Serology/Immunology or Chemistry Laboratory will perform expedited HIV screening for source patients provided advised consent is obtained.
- 3. It is the responsibility of the Albany Medical Center Employee Health Test Counselors or the Administrative Nursing Supervisor to perform pre-test counseling and to obtain a Release of Information from the source patient.
- 4. Advising that an HIV-related test is being performed on a source patient is not required if each of the following limited circumstances of occupational exposure exists:
  - a. The source is deceased, comatose or is determined by his/her attending practitioner to lack mental capacity to consent to HIV testing and is not reasonably expected to recover in time for the exposed person to receive appropriate medical treatment **and**
  - b. There is no person reasonably available or likely to become available with the legal authority to consent to the HIV test on behalf of the source patient in time for the exposed person to receive medically appropriate treatment; **and**
  - c. The exposed person will benefit medically by knowing the source patient's HIV test results, as determined by the exposed person's health care professional and documented in the exposed person's medical record.

If source patient advised consent is not obtained due to the above, the exposed person's Physician or other authorized practitioner shall order an ANONYMOUS test of the source patient and attest on the requisition that the above criteria for anonymous HIV testing have been met. If the exposed person is an ordering practitioner; the exposed person cannot order follow-up testing on the source patient. The results of the test but **not** the identity of the source patient may be disclosed to the exposed person's Physician or other authorized practitioner. **The results of the test may not be disclosed to the source patient or placed in the source patient's medical record**.

- 5. If the source patient will be discharged after 5:00 pm, on weekends or holidays, calls should be placed to the hospital page operator, who will page the on-site Administrative Nursing Supervisor for HIV counseling.
- 6. Expedited HIV test results on the source patient will be faxed to EHS. Positive results will be called to the person identified on the HIV test requisition.
- 7. The Employee Health Test Counselor or the Administrative Nursing Supervisor is responsible for post-test counseling.

## Additional Information

- 1. For further information on HIV screening including other procedures and test results, the Serology/Immunology Section Director or Supervisor should be contacted at 262-3501 or 262-3527 respectively.
- 2. Additional information is available through HIV Education at 262-6864.

Associated Reference: AMCH Policy & Procedure Manual File Number 7.000.05.