Appendix E

Testing for Human Immunodeficiency Virus (HIV) Infection

I. Criteria for selection of a laboratory for HIV antibody testing:

A. Biosafety level (BSL) 2 practices should be employed. BSL 2 is suitable for work involving agents of moderate potential hazard and closely approximates the level of biosafety that a competent hospital laboratory should have. This includes (1) laboratory personnel trained in handling pathogenic agents and directed by a competent scientist; (2) limited access to the laboratory when work is being conducted; (3) avoidance of generation of aerosols, splashes, and spills; (4) gloves worn by all laboratory personnel; (5) proper disposal of all disposable equipment and wastes, (i.e., autoclave, disinfection, incineration); and (6) decontamination of work surfaces at the end of the workday or when overtly contaminated.

B. The laboratory is able to obtain HIV test kits from an acceptable manufacturer, such as those that are approved by the United States Food and Drug Administration or the equivalent of other nations and the product instructions are followed explicitly; and

C. the laboratory conducts proficiency testing as an integral part of the laboratory program with, at the minimum, blinded in-house samples that are run on a regular basis with review by the supervisor.

II. Obtaining and Processing Blood Specimens

A. Blood specimens for testing in a local laboratory should be stored in a test tube or vial, placed in a refrigerator (DO NOT FREEZE), and delivered to the laboratory as soon as possible. Blood should be drawn from a large firm vein in an area free from skin lesions.

B. If specimens must be transported to a laboratory at a distant location, the following procedures should be followed:

1. Select blood container tube/syringe of desired size. Since serum is needed, no anticoagulants should be used.

2. Collect at least 5 ml of blood.

3. Centrifuge (2000rpm/15 minutes) to separate serum.

4. Transfer serum into suitable watertight container, (e.g., test tube, vial).

5. Dry ice should be used when shipping sera; however, if dry ice is not available, ambient temperature is satisfactory, PROVIDED the total elapsed time between collection of specimen and testing does not exceed two weeks.

(NOTE: If dry ice is not available, sodium azide vials may be used. If sodium azide vials are used, it is important that the laboratory be advised.)

6. Serum specimen should be placed in a securely closed, watertight container (primary container (test tube, vial, etc.)) which shall be enclosed in a second, durable watertight container (secondary container). Several primary containers may be enclosed in a single secondary container, if the total volume of all the primary containers so enclosed does not exceed 50 ml. The space at the top, bottom, and sides between the primary and secondary containers should contain sufficient nonparticulate absorbent material (e.g., paper towel) to absorb the entire contents of the primary container(s) in case of breakage or leakage. Each set of primary and secondary containers should then be enclosed in an outer shipping container constructed of corrugated fiberboard, cardboard, wood, or other material of equivalent strength.

7. Dry ice. If dry ice is used as a refrigerant, it must be placed outside the secondary container(s). If dry ice is used between the secondary container and the outer shipping container, the shock absorbent material should be placed so that the secondary container does not become loose inside the outer shipping container as the dry ice sublimates.

8. Label. The outer shipping container should

bear a label as required by local law/regulations for intra-country shipments and in accordance with the International Air Transport Association's regulations for international shipments.