# [ DOH ADMINISTRATIVE ORDER NO. 2005-0027, August 15, 2005 ]

## RULES AND REGULATIONS GOVERNING THE REGULATION OF HIV TESTING LABORATORIES

I. Background/Rationale:

In 1989, the Department of Health issued Administrative Order No. 55-A, s. 1989 otherwise known as "Rules and Regulations Governing the Accreditation of Laboratories Performing HIV Testing" in accordance with Republic Act 4688: "Clinical Laboratory Law" and Republic Act 1517: "Blood Bank/Center Law". Since then, a number of testing centers have secured accreditation.

In order to promote a truly safe, effective and efficient blood transfusion services, Republic Act 7719: "National Blood Services Act of 1994" and its Implementing Rules and Regulations were passed. Further, to strengthen the fight against the spread of HIV/AIDS infection, Republic Act 8504: "Philippine AIDS Prevention and Control Act of 1998" was enacted. As mandated under Section 19 of such law, all testing centers, hospitals, clinics and laboratories offering HIV testing services shall seek accreditation of the DOH, which shall set and maintain reasonable accreditation standards.

With the ratification of the above-mentioned laws, the advances in health technology and the need to streamline the current procedure in securing accreditation, review and subsequent amendment of Administrative Order No. 55-A s. 1989 is believed to be indispensable.

II. Objective:

These rules and regulations are promulgated to ensure utmost safety and quality in the performance of HIV testing by laboratories.

III. Scope:

Performance of any of the following laboratory procedures shall be covered by these rules and regulations:

1. Screening tests for HIV antibody

    1.1 Enzyme Immunoassay (EIA)
    1.2 Particle Agglutination (PA)
    1.3 Other screening tests for HIV antibody

2. Confirmatory tests for HIV antibody

    2.1 Western Blot (WB)
    2.2 Immunofluorescence (IF)

2.3 Radio Immuno-Precipitation Assay (RIPA)
2.4 Other supplemental tests for HIV antibody

## IV. Definition of Terms:

A. Applicant refers to the owner or head of a clinical laboratory or blood center securing permission to operate an HIV testing laboratory.

B. BFAD refers to the Bureau of Food and Drugs

C. BHFS refers to the Bureau of Health Facilities and Services of the DOH. It shall exercise the regulatory function provided in this Order.

D. Blood Center refers to a blood service facility duly authorized by the DOH-BHFS pursuant to A.O. No. 2005-0002 with the following service capabilities:

1. Donor recruitment/retention and care of voluntary blood donors,

2. Collection of blood (mobile or facility based) from qualified voluntary blood donors,

3. Processing and provision of blood components

4. Storage, issuance, transport and distribution of units of whole blood and/or blood products to hospitals and other health facilities.

5. For National and Sub national and selected Regional Blood Centers only: testing units of blood for five (5) infectious disease markers (Anti-HIV 1/2., Anti-HCV, HbsAg, Syphillis, Malaria)

The Blood Centers shall be classified into Regional, Sub national and National whose service capabilities will be determined by the National Council for Blood Services.

E. Confirmatory/Supplemental Test refers to the test performed on samples reactive to the screening test to ensure that the results were true positive. This test includes but is not limited to Western Blot (WB), Line immunoassay (LIA), Immunofluorescence Assay(IF) and Polymerase Chain Reaction (PCR).

F. DOH refers to the Department of Health.

G. EQAS refers to the External Quality Assessment Scheme. It is an external evaluation of a laboratory's performance using proficiency panels. It shall evaluate the effectiveness of the quality assurance program.

H. HIV refers to the Human Immunodeficiency Virus that causes Acquired Immune Deficiency Syndrome

I. HIV Test Kit refers to the reagent used for the determination of the presence of antibody, antigen, viral genome and viral particles in a clinical specimen indicating infection by HIV types 1 and 2.

J. HIV Testing shall include the determination for the presence of antibody, viral genome antigen/protein, viral particles in a clinical specimen indicating infection by the Human Immunodeficiency Virus (HIV) types 1 and 2.

K. NRL refers to the National Reference Laboratories for HIV/AIDS, Hepatitis and Sexually Transmitted Diseases or "National Reference Laboratories for Confirmatory Testing of Blood Donors and Blood Units" designated by the Secretary of Health as stipulated in Department Order 393-E s. 2000. It is a laboratory capable of doing screening and confirmatory laboratory services, training, and surveillance and external quality assurance program for laboratory tests. Whenever conflicting results occur, the NRL shall make the final decision.

L. NRL/RITM NVBSP refers to the Research Institute for Tropical Medicine. It is the designated National Reference Laboratory for the Confirmatory Testing of Blood Donors and Blood Units as stipulated in Department Order No. 393-E s 2000.

M. NRL-SACCL/SLH refers to the STD/AIDS Cooperative Central Laboratory of the San Lazaro Hospital. It is the designated National Reference Laboratory for HIV AIDS, Hepatitis and Sexually Transmitted Infections.

N. NVBSP refers to the National Voluntary Blood Services Program.

O. Screening Test refers to initial serological test performed to determine the presence of antibody and/or antigen against HIV 1 and HIV 2. This test includes but is not limited to Enzyme Immunoassay (EIA) and Particle Agglutination Test (PA) and Rapid Assay.

P. Specimen refers to the body fluid that is collected from a person and submitted for analysis.

## V. Policies and Guidelines:

### A. General

1. Only licensed clinical laboratory and/or blood center designated by the NVBSP are allowed to operate an HIV testing laboratory provided that requirements set forth in these regulations are met. Permission to operate an HIV testing laboratory shall be included in the License to Operate a clinical laboratory or blood center.

2. The BHFS or the CHD may conduct unannounced on site monitoring visits and shall document the overall quality of the laboratory setting.

3. The HIV testing laboratory shall be a section/unit/division of a clinical laboratory or blood center.

4. The number of HIV testing laboratory an HIV Proficient Medical Technologist can handle shall be based on the Guidlines on Quality Assurance Program for HIV Testing Laboratories set forth by the NRL-SACCL/SLH.

### B. Specific

1. Physical Plant - There shall be a designated area within the clinical laboratory or blood center adequate enough for the conduct of HIV testing. The designated area shall be well-lighted and ventilated, dust free with adequate water supply and provision of an area for decontamination of