[DOH ADMINISTRATIVE ORDER NO. 134, S. 2004, January 09, 2004]

GUIDELINES GOVERNING THE REGISTRATION AND PERFORMANCE EVALUATION OF DRUG SCREENING TEST KITS AND REAGENTS

I. RATIONALE

The detection of drugs has an important role in many areas of society such as sports, suspicious deaths, violent crimes, travel and work safety. Results of analysis should be accurate, reliable and defensible. Reporting of a positive drug finding in a biological specimen should be based upon a positive result by a drug screening analysis as well as by confirmatory test. Today, drug screening test like kits are used almost universally for both clinical and medico-legal preliminary examinations of abused drugs. As intended for human use, the drug screening test kits should be subjected to regulations to protect and promote the health of the people by preventing the distribution of substandard drug screening test kits. For this purpose, it is essential that the government promulgate certain rules and regulations governing the registration of drug test kits sold and used in the country.

II. LEGAL MANDATE

Pursuant to Article III Section 39 of RA 9165 also known as the Comprehensive Dangerous Drugs Act of 2002, the Department of Health is tasked to license and accredit drug testing centers in each province and city in order to assure their capacity, competency, integrity and stability to conduct laboratory examinations. As part of improving the quality of the results of drug testing laboratories, the Department of Health through the Bureau of Food and Drugs and National Reference Laboratory - East Avenue Medical Center is tasked to establish an effective regulatory system for drug screening test kits in which the primary goal is to ensure safety, quality and effectiveness of the drug screening test kits as a condition to commercial marketing.

The Bureau of Food and Drugs pursuant to its function as the regulatory agency for diagnostic reagents/kits in the Philippines, has the responsibility of assuring the quality, safety and efficacy of drug screening test kits and reagents sold to the public in accordance with the mandate of R.A. 3720.

BFAD in discharging this responsibility evaluates the following:

a. all drug screening test kits/reagents submitted for registration (initial/renewal)

b. drug screening test kits/reagents submitted to BFAD for

investigation by concerned citizens; and

c. drug screening test kits/reagents collected from licensed distributors for monitoring purposes.

The East Avenue Medical Center (EAMC) is the designated National Reference Laboratory (NRL) and Occupational Health, Toxicology and Micronutrient Assay pursuant to D.O. 393-E s. 2000. As an NRL, it is mandated to evaluate the performance of drug screening test kits/reagents.

III. SCOPE

These guidelines shall apply to all drug test manufacturers and traders/distributors (importers/exporters/wholesalers) of drug screening test kits/reagents.

IV. DEFINITION OF TERMS

1. **Applicant -** refers to an establishment or a natural or juridical person that seeks to register drug screening test kits/reagents.

2. **Conformance -** refers to the fulfillment of the requirements of the standard.

3. **Cut-off value of the drug testing kit -** the concentration used to establish and report a specimen as negative or positive.

4. **Distributor/Exporter -** refers to any establishment that exports raw materials, active ingredients and/or finished drug screening test kits/reagents to another country.

5. **Distributor/Importer -** refers to any establishment that imports raw materials, active ingredients and/or finished drug screening test kits/reagents for its own use or for wholesale distribution to other establishment or outlets.

6. **Distributor/Wholesaler -** refers to any establishment that procures raw materials, active ingredients and/or finished drug screening test kits/reagents from local establishment for local distribution on wholesale basis.

7. **Drug Screening Test Kits/Reagents -** refers to testing device/reagents which is used alone or in combination intended for use in the examination of specific type of specimen for the purpose of preliminary identification of drug metabolite.

8. **Drug Trader -** refers to any establishment which is the registered owner of the drug screening test kits/reagents, procures the raw materials and packing components, and provides the production monographs, quality control standards and procedures, but sub-contract the manufacture of such product to a licensed

manufacturer.

9. **Gas Chromatograph-Mass Spectrometry -** refers to the combined technique extensively used for qualitative and quantitative analysis. GC separates a sample into its components and MS operating as the detector of GC clarifies the structure. It is the established confirmatory method when a preliminary positive test results for drugs/metabolites is obtained.

10. **Manufacturer -** refers to any establishment engaged in operations involved in the production of devices, including propagation, processing, compounding, finishing, filling, packing, re-packing, altering, ornamenting and labeling with the end in view of storage, distribution or sale of the drug screening test kits/reagents provided that for the purpose of this regulation the compounding and filling of prescriptions in drug testing laboratories and hospital shall not be considered as production operations.

11. **Negative control specimen -** refers to synthetic or human urine specimen found below the cut-off value or absence of substance for drugs/metabolites.

12. **Performance Evaluation -** refers to the procedures to verify the data submitted by the applicant.

13. **Positive control specimen -** refers to synthetic or human urine specimen found positive or spiked with known concentrations of specific drugs/metabolites.

14. **Registration -** means the process of approval to manufacture, import, export, sell, distribute or transfer any drug screening test kits/reagents that is determined to be safe, effective and in conformance to quality and safety standards.

15. **Samples -** refer to the drug screening test kits/reagents subject for performance evaluation.

16. **Sensitivity -** the ability of a test to detect all positive specimen for drug/metabolite. The smallest concentration of drugs/metabolite that can be detected.

17. **Specificity -** the ability to discriminate between various similar drugs and identify all negative specimen for drugs/metabolites correctly.

18. **Standard -** reference material of known purity or a solution containing a metabolite of known concentration.

19. **Test Efficiency -** the over-all liability of a test to correctly identify positives and negatives. The combination of the sensitivity and the specificity of an assay to give an idea of the total effectiveness of the test.

V. REQUIREMENTS

A. Application for Registration of Drug Screening Test Kits by BFAD

1. Notarized Letter of Application from manufacturer/trader/distributor.
2. Valid License to Operate (LTO) as drug manufacturer/trader/distributor issued by BFAD.
3. Government Certificate of Clearance and Free Sale/Registration Approval of the Product from country of origin and duly authenticated by territorial Philippine Consulate.
4. Good Manufacturing Practice (GMP) Certificate attesting to the status of the manufacturer, competency and reliability of the personnel and facilities and duly authenticated by territorial Philippine Consulate.
5. Certificate of Agreement between the manufacturer and trader/distributor regarding the product involved. If importer, it must be authenticated by the Philippine Consulate.
6. Specific Use and Directions for Use. (Product insert)
7. Copy of latest Certificate of Product Registration. (renewal)
8. List of all raw materials used as components of the reagents/test kits.
9. Technical specifications/physical description of the drug screening test kits/reagents.
10. Process-control procedure and expected performance specifications.
11. Flowchart of the manufacturing procedure.
12. Stability studies of the product to justify claimed shelf-life. Signed by the authorized company representative.
13. Immediate label, box label, package insert, brochure.
14. Representative samples (2) in the market or commercial presentation
15. Evidence of registration fee/payment (charge slip/official receipt)

B. For Performance Evaluation by NRL: