GUIDELINES FOR POLICY AND PROCEDURE MANUAL PREPARATION FOR NONDIAGNOSTIC GENERAL HEALTH ASSESSMENT

Each operator of a nondiagnostic general health assessment program (NGHA) must meet all the criteria listed under **Part 3, Compliance**, of the enclosed application. A manual containing all the required procedures and protocols should be submitted along with the application at least 30 days prior to the first scheduled event. Literature from the equipment manufacturer can be used for the procedure manual, but it must be supplemented with procedures that are not covered, i.e. OSHA procedures for bloodborne pathogens (employee training, disposal, protective equipment, etc.), emergency procedures for bleeding, fainting, or medical emergencies. The items required are outlined below.

A. Test Procedure.

1. **Heading** – Name of the organization and test
2. **Principle** – Summary of the test reaction taking place, clinic application
3. **Specimen Requirements** – Type of specimen, patient prep, collection method, amount, collection container, special additives i.e. anticoagulants, timing, sample stability, storage, criteria for unacceptable specimen action to be taken
4. **Reagents** – Store temperatures, warning for hazardous substances
5. **Equipment** – Supplies and Instrumentation (include calibration, calibration frequency, and schedules for both routine and scheduled maintenance)
6. **Procedure** – Safety precautions, step-by-step testing directions, and result reporting
7. **Calculations**
8. **Quality Control** – Identify materials to be used, directions for preparing, labeling, expiration dates, acceptable ranges, corrective action, documentation log
9. **Interpretation** – Include expected patient values, notification procedures for values outside expected range, possible sources of error
10. **Limitations of Method** – Include ranges of linearity, interfering substances, precautions
11. **References** – Texts, package inserts, instrument manual
12. **Signatures** – Dated approval by both members of supervisory committee (review performed annually)

Recommendation: Utilize the supervisory committee Clinical Laboratory Scientist for formulation of the laboratory testing procedures. Their knowledge of CLIA requirements will facilitate the process.

B. Procedure for drawing blood, if blood specimens are to be obtained. (Finger stick method is the only acceptable method for drawing blood under NGHA program regulations.)

C. Procedure for handling and disposal of biological material, (bloodborne pathogen training, containers for biohazardous waste, waste management carrier, etc.)

D. Procedure to be employed in handling excessive bleeding, fainting, or other medical emergency

E. Procedure for reporting assessment results to the individual being assessed and referral of those with possible risk factors or markers

F. Documentation showing authorization of screening staff to perform skin punctures

G. Documentation showing staff have been trained according to manufacturer's directives

H. Supervisory Committee members consisting of a California licensed physician/surgeon and clinical laboratory technologist (CLT)

I. Documentation of a valid **CLIA Laboratory Certificate of Waiver**

J. If transporting waste from one location to another, documentation of a **Limited Quantity Hauling Exemption** for transport of regulated medical waste