COUNTY OF SAN DIEGO

HEALTH AND HUMAN SERVICES AGENCY
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LIVE WELL SAN DIEGO

Guidelines for Policy and Procedure Manual Preparation for Non-Diagnostic General Health Assessment

NDGHA Operator(s) must meet all the criteria listed under Part II, Compliance, of the Non-Diagnostic General Health Assessment Program Registration Form. A manual containing all the required protocols and procedures should be submitted along with the registration form 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 blood borne pathogens (employee training, disposal, protective equipment, etc.), emergency procedures for bleeding, fainting, or medical emergencies.

A. Test Procedure (SOP):

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 preparation, collection method, amount, collection container, special additives (i.e. anticoagulants), timing, sample stability, storage, criteria for action taken with unacceptable specimens
4. **Reagents**: Storage temperatures, warning for hazardous substances
5. **Equipment**: Supplies and instrumentation (including calibration, calibration frequency, and schedules for both routine and scheduled maintenance)
6. **Procedure**: Safety Precaution, step-by-step testing directions, and result reporting
7. **Calculations**
8. **Quality Control (QC)**: Identify QC 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 ranges, 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 procedures annually)

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

B. Procedure for collecting Blood: If blood specimens are to be obtained, the finger-stick method is the only acceptable method for blood drawing under NDGHA program regulations.

C. Procedure(s) for handling and disposal of biological material: blood borne 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 (CLS)/ Clinical Chemist Scientist (Approved per Kathy Williams at CDPH).

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

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