



## NONDIAGNOSTIC GENERAL HEALTH ASSESSMENT REGISTRATION FORM

This registration form must be completed and received by the San Diego County Public Health Laboratory at least 30 days prior to operating a program of Non-diagnostic general health assessment.

### **PART I: ADMINISTRATION**

A. Name of Organization or Operator: \_\_\_\_\_  
Permanent Address with ZIP Code:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Billing Address if different than above:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

B. Name of Supervisor or Manager: \_\_\_\_\_  
Business Phone: \_\_\_\_\_

Email address: \_\_\_\_\_

Name of Contact Person: \_\_\_\_\_

Business Address with ZIP Code if different than above:

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Business Phone: \_\_\_\_\_

Fax Number: \_\_\_\_\_

E-mail Address: \_\_\_\_\_

C. Supervisory Committee Membership:

Name of Physician: \_\_\_\_\_

Business Address with ZIP Code:

\_\_\_\_\_  
\_\_\_\_\_

Business Phone: \_\_\_\_\_

Email Address: \_\_\_\_\_

California Medical License Number: \_\_\_\_\_

Expiration Date: \_\_\_\_\_

Name of Clinical Laboratory Scientist: \_\_\_\_\_

Business Address with ZIP Code:

\_\_\_\_\_

Business Phone: \_\_\_\_\_

Email Address: \_\_\_\_\_

California Clinical Laboratory Scientist License No. \_\_\_\_\_

Expiration Date: \_\_\_\_\_

**NOTE: All operators must have a permanent address where records of testing and protocols shall be stored for the purpose of review for at least one year after testing has been completed. The San Diego County Public Health Laboratory must be notified in writing within 30 days of any change in record storage location.**

## **PART 2: COMPLIANCE**

A. This assessment program must be operated per Section 1244 of the California Business and Professions Code. Please answer each of the following questions.

**YES NO**

1. This program will be a Nondiagnostic health assessment program, whose purpose will be to refer individuals to licensed sources of care as indicated.

2. This program will utilize only those devices which comply with all of the following:

A. Meet applicable state and federal performance standards pursuant to Section 26605 of the Health and Safety Code.

B. Are not adulterated as specified in Article 2 (commencing with Section 26610) of Chapter 6 of Division 21 of the Health and Safety Code.

C. Are not misbranded as specified in Article 3 (commencing with Section 26630) of Chapter 6 of Division 21 of the Health and Safety Code.

D. Are not new devices unless they meet the requirements of Section 26670 of the Health and Safety Code.

3. This program maintains a supervisory committee consisting of at a minimum, a California licensed physician and surgeon and a laboratory

technologist licensed pursuant to the California Business and Professions Code.

- 4. The supervisory committee for the program has adopted **written protocols which shall be followed in the program**. (Please include a copy of your written protocols with this application).
- 5. The protocols contain provision of written information to individuals to be assessed. (Please include a copy of any written information that you will provide individuals as a part of this program).
- 6. The written information to individuals includes the potential risks and benefits of assessment procedures to be performed in the program.
- 7. The written information includes the limitations, including the Nondiagnostic nature, of assessment examinations of biological specimens performed in the program.
- 8. The written information includes information regarding the risk factors or markers targeted by the program.
- 9. The written information includes the need for follow up with licensed sources of care for confirmation, diagnosis, and treatment as appropriate.
- 10. The written protocols contain the proper use of each device utilized in the program including operation of analyzers, maintenance of equipment and supplies, and performance of quality control procedures including the determination of both accuracy and reproducibility of measurements in accordance with instructions provided by the manufacturer of the assessment device used.
- 11. The written protocols contain the proper procedures to be employed when collecting blood by skin puncture, if blood specimens are to be obtained.
- 12. The written protocols contain proper procedures to be employed in handling and disposing of all biological specimens to be obtained and material contaminated by those biological specimens.
- 13. The written protocols contain proper procedures to be employed in response to fainting, excessive bleeding, or other medical emergencies.
- 14. The written protocols contain procedures for reporting of assessment results to the individual being assessed (please attach a copy of your report form).
- 15. The written protocols contain procedures for referral and follow up to licensed sources of care as indicated.

16. The written protocols contain the procedures for transport and/or dispose of regulated medical waste. Please indicate which system is currently being used.

[ ] Mail-Back System, Please specify \_\_\_\_\_

[ ] UFPF

[ ] Other, please specify \_\_\_\_\_

**NOTE:** The written protocols adopted by the supervisory committee shall be maintained for at least one year following completion of the assessment program during which period they shall be subject to review by state health department personnel and the local health officer or his or her designee, including the public health laboratory director.

B. If skin puncture to obtain a blood specimen is to be performed, please complete the following:

**YES NO**

All individuals performing the skin puncture are authorized to do so under the California Business and Profession Code.

Effective April 9, 2003, all persons performing phlebotomy (including finger stick for obtaining blood samples) whose education does not include phlebotomy must possess a phlebotomy certificate issued by the State of California Department of Health Services.

**NOTE: Skin puncture means the collection of a blood specimen by the finger prick method only and does not include venipuncture, arterial puncture, or any other procedure for obtaining a blood specimen.**

C. The individual submitting this form certifies that the information provided is accurate and complete and that he/she is aware of the laws and regulations that apply to Nondiagnostic testing in the State of California and in the County in which testing is to be performed.

Name of Person Requesting Registration: \_\_\_\_\_

Signature of Applicant: \_\_\_\_\_

Date of Application: \_\_\_\_\_

Business Phone: \_\_\_\_\_

**FOR OFFICIAL USE ONLY**

**Reviewed By:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Registration number:** \_\_\_\_\_

**Expiration Date:** \_\_\_\_\_