Santa Barbara County PUBLIC Health DEPARTMENT

**Public Health Laboratory**
315 Camino Del Remedio, Santa Barbara, CA 93110
Phone: 805-681-5256 Fax: 805-681-4753

# NON-DIAGNOSTIC GENERAL HEALTH ASSESSMENT REGISTRATION FORM

This registration form must be completed and submitted to the Santa Barbara County Public Health Laboratory at least thirty days prior to beginning a Non-Diagnostic General Health Assessment (NGHA) Program.

DATE OF APPLICATION: _____

## PART 1: ADMINISTRATION

1. Organization/Operator Name: _____
   Permanent Business Address: _____
   City: _____
   State: _____
   Zip Code: _____
   Business Phone: _____
   Fax Number: _____
   CLIA License Number: _____
2. Name of Business Owner: _____
   Address (if different from above): _____
   City: _____
   State: _____
   Zip Code: _____
   Business Phone: _____
   Fax Number: _____
3. Name/title of Clinical Consultant/Supervising Physician:_____
   Business Address: _____
   City: _____
   State: _____
   Zip Code: _____
   Business Phone: _____
   Fax Number: _____
   California Medical License Number: _____
   Expiration Date: _____
4. Name of Laboratory Technologist:_____

Business Address: _____
City: _____
State: _____
Zip Code: _____
Business Phone: _____
Fax Number: _____
California Clinical Laboratory Scientist (CLS)/Certified Phlebotomy Technician (CPT) License Number: _____
Expiration Date: _____

5. Name of Individual Requesting Registration (Licensee):_____
   Business Address: _____
   City: _____
   State: _____
   Zip Code: _____
   Business Phone: _____
   Fax Number: _____
6. Record Storage:
   *For the purpose of compliance and review, all organizations and/or operators of NGHA programs must have a permanent address where testing records and protocols are stored for at least one year after testing has been completed.*
   Record Storage Address: _____
   City: _____
   State: _____
   Zip Code: _____
   Business Phone: _____

**PART 2: ASSESSMENT PROGRAM**

***Complete a separate "Part 2: Assessment Program" for each assessment site. If you are registering or planning to register an additional site, only complete this portion of the application form***

1. Name of location where assessments are to be performed:_____
   Business Address: _____
   City: _____
   State: _____
   Zip Code: _____
   Business Phone: _____
   Fax Number: _____
2. Dates and hours program will be operating at this location:

| Date | Hours of Operation | Days of the Week |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

***NOTE:*** *Any alterations to date(s), time(s), and/or location(s) must be reported via written correspondence to the Santa Barbara County Public Health Laboratory at least 24 hours prior to the start of the program.*

3. Type of NGHA test(s) to be conducted at the proposed location:

| Designation (x) | Test | Equipment Name | Manufacturer |
|---|---|---|---|
| ☐ | Blood Glucose | | |
| ☐ | Fecal Occult Blood | | |
| ☐ | Hemoglobin | | |
| ☐ | High-density lipoprotein (HDL) | | |
| ☐ | Low-density lipoprotein (LDL) | | |
| ☐ | Total Cholesterol | | |
| ☐ | Triglycerides | | |
| ☐ | Urinalysis (Dipstick UA) | | |
| ☐ | Urine Pregnancy (Qualitative) | | |
| ☐ | Other | | |
| ☐ | Other | | |

4. List of employees: please list all employees who will participate in the testing portion of the program. Attach additional sheets if necessary.

| Name and Title | Performing Skin Puncture (Yes/No) |
|---|---|
| | Yes ○ No ○ |
| | ○ ○ |
| | ○ ○ |
| | ○ ○ |
| | ○ ○ |

**PART 3: COMPLIANCE**

*This assessment program must be operated according to Section 1224 of the California Business and Professions Code (CA Bus & Prof Code § 1224 (2016)).*

Please answer each of the following questions:

**[YES] [NO]**

[ ☐ ] [ ☐ ] 1. This program will be a non-diagnostic 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 California 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 California 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 California Health and Safety Code.

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

[ ☐ ] [ ☐ ] 3. This program maintains a supervisory committee consisting of, at minimum, a California licensed physician and/or surgeon and a Clinical Laboratory Scientist (CLS) licensed pursuant to the California Business and Professions Code.

[ ☐ ] [ ☐ ] 4. The program's supervisory committee has adopted and signed written protocols, which shall be followed for the duration of the program.

***<u>Documents required:</u> Please include a copy of the written protocols with this application.***

[ ☐ ] [ ☐ ] 5. The protocol(s) contain copies of written information which will be provided to individuals at assessment.

***<u>Documents required</u>: Please include a copy of any written information that will be provided to individuals as 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 non-diagnostic 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 assessment test(s).

[ ☐ ] [ ☐ ] 9. The written information informs the individuals of the need for follow up with licensed care providers for confirmation, diagnosis/diagnoses, and treatment as appropriate.

[ ☐ ] [ ☐ ] 10. The written protocol(s) contain proper procedure(s) for referral and follow up to licensed care providers as indicated.

[ ☐ ] [ ☐ ] 11. 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.

[ ☐ ] [ ☐ ] 12. The written protocols contain the 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, and/or other medical emergencies.

[ ☐ ] [ ☐ ] 14. The written protocols contain proper procedures for reporting of assessment results to the individual being assessed.

***<u>Documents required:</u> Please attach a copy of the result report that will be provided to patrons of the program.***

**NOTE:** *The written protocols adopted by the supervisory committee shall be maintained for at least one year following completion of the assessment program. The written protocols 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.*

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

**[YES] [NO]**

[ ☐ ] [ ☐ ] 1. All individuals performing the skin puncture are authorized to do so under the California Business and Professions Code (CA Bus & Prof Code § 1224 (2016)).

[ ☐ ] [ ☐ ] 2. All individuals performing the skin puncture procedure possess a statement signed by a California licensed physician and/or surgeon which attests that the named individual has received adequate training in the proper procedure to be employed in skin puncture.

***<u>Documents required:</u> Please include documentation of certification to perform skin puncture for each individual listed above who will perform this procedure.***

[ ☐ ] [ ☐ ] 3. Written protocols contain the proper procedures to be employed when obtaining blood specimens.

***<u>Documents required:</u> Please include a copy of the written protocols with this application.***

**NOTE:** "*Skin puncture" is defined as a method for the collection of blood samples via finger prick and* ***does not include*** *venipuncture, arterial puncture, and/or any other procedure for obtaining a blood specimen.*

**PART 4: FEES/REGISTRATION**

- Non-Refundable Annual Registration Fee: $100.00
- Make checks payable to: County of Santa Barbara
- Return application(s) with check(s) to:

  Santa Barbara County Public Health Laboratory
  Non-Diagnostic Health Assessment Program
  315 Camino del Remedio, Room 262
  Santa Barbara, California 93110
- If you have any further questions, please contact:

  Debra Palacio
  Laboratory Director
  Santa Barbara County Public Health Laboratory
  315 Camino del Remedio, Room 262
  Santa Barbara, California 93110
  805-681-5255
  Debra.Palacio@sbcphd.org

**CERTIFICATION**

I certify that the above information is accurate and complete and that I am aware of the laws and Regulations that apply to NGHA programs in the State of California and in the County in which testing is to be performed.

Name of Applicant: _____

Signature of Applicant: _____

Date signed: _____

Click here to submit completed form to Public Health Lab **Submit**

**FOR OFFICIAL USE ONLY**

Reviewed by: _____

Date: _____

Registration Number: _____

Date Issued: _____

Expiration Date: _____

Fee Received: _____

**Santa Barbara County Department of Public Health**

*A copy of this page will be returned to the Applicant upon receipt, review, and approval of the application, all required documents, and program fee.*