County of San Luis Obispo Health Agency

Department of Public Health

2191 Johnson Avenue ▪ P.O. Box 1489
San Luis Obispo, California 93406
(805) 781-5500 ▪ FAX (805) 781-1023

Non-Diagnostic General Health Assessment
Registration Form

THIS REGISTRATION FORM MUST BE COMPLETED AND RECEIVED BY THE SAN LUIS OBISPO COUNTY PUBLIC HEALTH DEPARTMENT AT LEAST 30 DAYS PRIOR TO OPERATING A PROGRAM OF NON-DIAGNOSTIC GENERAL HEALTH ASSESSMENT.

Part 1: Administration

A.

Organization or Operator: _____

Permanent Address: _____

_____

CITY _____ STATE _____ ZIP _____

Business Telephone: ( ) _____

Email Address: _____

B.

Name of Owner: _____

Address if Different: _____

_____

CITY _____ STATE _____ ZIP _____

Business Telephone: ( ) _____

Email Address: _____

C. Supervisory Committee Membership:

Name of Physician: _____

Address: _____

_____

CITY _____ STATE _____ ZIP _____

Telephone: ( ) _____

California Medical License Number: _____ Expiration Date: _____

Name of Laboratory Technologist: _____

Address: _____

_____

CITY _____ STATE _____ ZIP _____

Telephone: ( ) _____

Cal. Clin. Lab Technologist License # : _____ 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 Luis Obispo County Health Department must be notified in writing within 30 days of any change in record storage location.

Part 2: Assessment Program

A. LOCATION WHERE ASSESSMENTS ARE TO BE PERFORMED

Name of Location: _____

Address: _____

_____

CITY _____ STATE _____ ZIP _____

Telephone During Work Hours: ( )

After Work Hours: ( )

B. DATES & HOURS PROGRAM WILL BE OPERATING AT THIS LOCATION (Example)

DATES	HOURS	DAYS OF WEEKS	
ongoing	*8 to 5*	*M, Th*	**example**
	or		
ongoing	*various*	*First Tuesday*	**example**

(Attach additional sheets if necessary)

NOTE: ANY CHANGES IN TIMES, DATES, OR LOCATION MUST BE REPORTED IN WRITING TO THE HEALTH DEPARTMENT AT LEAST 24 HOURS PRIOR TO THE OPERATION OF THE PROGRAM.

C. TYPE OR KIND OF NON-DIAGNOSTIC GENERAL HEALTH ASSESSMENTS BEING CONDUCTED AT THIS LOCATION

- ☐ Total Cholesterol
- ☐ High-Density Lipoproteins (HDL)
- ☐ Low-Density Lipoproteins (LDL)
- ☐ Triglycerides
- ☐ Blood Glucose
- ☐ Occult Blood

Other: _____

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 Luis Obispo County Health Department must be notified in writing within 30 days of any change in record storage location.

Part 2: Assessment Program

A. LOCATION WHERE ASSESSMENTS ARE TO BE PERFORMED

Name of Location: _____

Address: _____

_____

CITY _____ STATE _____ ZIP _____

Telephone During Work Hours: ( )

After Work Hours: ( )

B. DATES & HOURS PROGRAM WILL BE OPERATING AT THIS LOCATION

DATES	HOURS	DAYS OF WEEKS

(Attach additional sheets if necessary)

NOTE: ANY CHANGES IN TIMES, DATES, OR LOCATION MUST BE REPORTED IN WRITING TO THE HEALTH DEPARTMENT AT LEAST 24 HOURS PRIOR TO THE OPERATION OF THE PROGRAM.

C. TYPE OR KIND OF NON-DIAGNOSTIC GENERAL HEALTH ASSESSMENTS BEING CONDUCTED AT THIS LOCATION

- ☐ Total Cholesterol
- ☐ High-Density Lipoproteins (HDL)
- ☐ Low-Density Lipoproteins (LDL)
- ☐ Triglycerides
- ☐ Blood Glucose
- ☐ Occult Blood

Other: _____

D. TESTING EQUIPMENT TO BE USED AT THIS LOCATION

NAME OF EQUIPMENT	MANUFACTURER

(Attach additional sheets if necessary)

E. LIST OF EMPLOYEES

PLEASE LIST ALL EMPLOYEES WHO WILL PARTICIPATE IN THE NON-DIAGNOSTIC TESTING AT THIS LOCATION

NAME & TITLE —– AUTHORIZED TO PERFORM SKIN PUNCTURE	YES	NO

(Attach additional sheets if necessary)

Part 3: 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 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 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 pursuant to the California Business and Professional Code.
☐	☐	4. The supervisory committee for the program has adopted written protocols, which shall be followed in the program.
☐	☐	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 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 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 drawing blood, 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 referral and follow-up to licensed sources of care as indicated.

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		
☐	☐	1.	All individuals performing the skin puncture are authorized to do so under the Business and Professions Code.
☐	☐	2.	All individuals performing the skin puncture possess a signed statement signed by a licensed physician and surgeon which attests that the named person has received adequate training in the proper procedure to be employed in skin puncture.

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

Name of Person Requesting Registration: _____

Address if different than above: _____

_____

CITY STATE ZIP CODE

Business Telephone: ( ) _____

Fax : ( ) _____

Email Address: _____

I certify that the above information is accurate and complete and that I am aware of the laws and regulations that apply to non-diagnostic testing in the State of California, County of San Luis Obispo.

_____ _____

Signature of Applicant Date of Application

FEES: Single Event = **$85.00** Multiple Event = **$125.00**

Please submit your payment with this application. We accept Check, Credit Card or Money Order

☐ Check #_____ ☐ M.O. **Make Checks & MO's = Payable to: SLO Public Health Laboratory**

☐ C.C. (Master Card/Visa Accepted Only)_____ Exp. D ate: _____

FOR OFFICIAL USE ONLY

Received By: _____ Date:_____

Registration #: _____ Issue Date:_____

Expiration Date:_____