



MONTEREY COUNTY HEALTH DEPARTMENT LABORATORY
1270 Natividad Road
Salinas, CA 93906
(831) 755-4516
Fax (831) 755-4652

NONDIAGNOSTIC GENERAL HEALTH ASSESSMENT PROGRAM
REGISTRATION FORM

This registration form is required pursuant to the California Business and Professions Code §1244, and must be completed and received by the Health Department Laboratory, at least 30 days prior to operating a program of nondiagnostic general health assessment. Please include check for \$100.00 with your registration packet. Checks should be made to Monterey County Health Department.

PART 1: ADMINISTRATION:

A. Name of Organization or Operator: _____
Permanent Address: _____
Zip Code: _____
Business Phone: () _____ Fax: () _____
CLIA Registration Number: _____

B. Name of Owner: _____
Address If Different Than Above: _____
Zip Code: _____
Business Phone: () _____ Fax: () _____

C. Supervisory Committee Membership:

Name of Physician: _____
Address: _____
Zip Code: _____
Telephone: () _____
California Medical License Number _____
Expiration Date: _____

Name of Laboratory Technologist: _____
Address: _____
Zip Code: _____
Telephone: () _____
California Clinical Laboratory Technologist License Number: _____
Expiration Date: _____

PART 2: ASSESSMENT PROGRAM

Site Number: _____
(For Health Department Use)

Please make additional copies of part 2 if necessary; a separate copy of part 2 must be completed for each location where assessments will be performed.

A. Location Where Assessments are to be Performed:

Name of Location: _____

Address: _____

Zip Code: _____

Telephone During Work Hours () _____

After Work Hours () _____

B. Dates and Hours Program will be Operating at this Location:

Dates	Hours	Days of Week
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

(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 Nondiagnostic General Health Assessments being Conducted at this Location.

Total Cholesterol

High-Density Lipoproteins (HDL)

Low-Density Lipoproteins (LDL)

Triglycerides

Blood Glucose

Occult Blood

Other specify: _____

D. Type and Manufacturer of 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 nondiagnostic testing at this location.

NAME and title	Authorized to perform skin puncture	
	YES	NO
_____	[]	[]
_____	[]	[]
_____	[]	[]
_____	[]	[]
_____	[]	[]

(Attach additional sheets if necessary)

NOTE: Please attach documentation of authorization to perform skin puncture for each individual listed above that will perform this procedure. Include name, signature, and California Medical License Number of the physician.

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 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 111245 of the Health and Safety Code.
 - B. Are not adulterated as specified in Article 2 (commencing with Section 111250) of Chapter 6 Division 21 of the Health and Safety Code.
 - C. Are not misbranded as specified in article 3 (commencing with Section 111330) of Chapter 6 of Division 21 of the Health and Safety Code.
 - D. Are not new devices unless they meet the requirements of Section 111550 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 purpose 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 use.
- 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.

NOTE: If you generate regulated medical waste (such as liquid blood or sharps) you must register with the appropriate jurisdiction. For further information contact Monterey County Health Department, Division of Environmental Health Solid Waste Section at (831) 755-4579

- 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.

NOTE: Written protocols and test records must be retained for at least one year after testing has been completed. These records must be readily accessible and are 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 specimen by the finger prick method only 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: _____

Zip Code: _____

Business Phone: () _____ Fax () _____

I certify that the above information is accurate and complete and that I am 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.

Signature of Applicant

Date of Application

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FOR OFFICIAL USE ONLY

Reviewed by: _____ Date: _____

Registration number: _____ Date issued: _____

Expiration Date: _____