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NON-DIAGNOSTIC GENERAL HEALTH ASSESSMENT REGISTRATION FORM

This registration form must be completed and received by the San Mateo Count Public Health Laboratory, Department of Health at least 30 days prior to operating a program of non-diagnostic general health assessment.

PART 1: ADMINISTRATION:

A. **Name of Organization or Operator:** _____

Permanent Address: _____

City _____Zip Code_____

Business Phone: ( )_____ Fax: ( ) _____

CLIA Number:_____

B. **Name of Owner**: _____

Address if Different than Above: _____

City _____Zip Code_____

Business Phone: ( ) _____ Fax: ( ) _____

C. **Supervisory Committee Membership:**

Name of **Physician:** _____

Address:_____

City _____Zip Code _____

Business Phone: ( ) _____ Fax: ( ) _____

California Medical License Number: _____Exp Date: _____

Name of L**aboratory Technologist**:

_____

Address:_____

City _____Zip Code _____

Business Phone: ( ) _____ Fax: ( ) _____

California Clinical Laboratory Scientist License Number: _____Exp Date: _____

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D. Record Storage

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 Public Health Laboratory must be notified in writing within 30 days of any change in record storage.

Record Storage Address: _____

City: _____Zip:_____ Business Phone:( ) _____

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PART 2: ASSESSMENT PROGRAM

A. Location Where Assessment are to be Performed (copy off Part 2 for additional sites):
Name of Location:
Address:
City Zip Code
Business Phone: ( ) Fax: ( )

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

Dates	Hours
Dates	Hours
Dates	Hours
Dates	Hours
Dates	Hours
Dates	Hours

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 tests being conducted at this location:

Test and Equipment Name Manufacturer:

__Total Cholesterol

__High-Density Lipoprotein (HDL)

__Low-Density Lipoprotein (LDL)

__Triglycerides

__Blood Glucose

__Hemoglobin

__Dipstick Urinalysis

__Fecal Occult Blood

__Urine Pregnancy

__Other: _____

D. LIST OF EMPLOYEES: Please list all employees who will participate in the non-diagnostic testing at this location.

(f) Authorized to perform Name Title skin puncture

_____ Yes No

_____ Yes No

_____ Yes No

_____ Yes No

(Attach additional sheets if necessary)

NOTE: Please attach documentation of authorization to perform skin puncture for each individual listed above who will perform this procedure.

Complete a separate PART 2A for each additional location where assessments are to be performed.

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PART 3. COMPLIANCE

A. This assessment program must be operated per Section 1224 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 clinical laboratory scientist licensed pursuant to the California Business and Professions Code.

[ ] [ ] 4.The supervisory committee for the program has adopted and signed written protocols which shall be followed in the program. (please include a copy of your written protocols with the 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 part of this program).

[ ] [ ] 6.The written information to individuals includes the potential risks and benefits of assessments 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.

YES NO

[ ] [ ] 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 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, or other medical emergencies.

[ ] [ ] 14. The written protocols contain proper procedures for reporting of assessment results to the individual being assessed (Please attach a copy of your report form).

[ ] [ ] 15. The written protocols contain proper 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

[ ] [l 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 statement signed by a California 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 collections 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.

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PART 4. FEES/REGISTRATION

A. **Non-Refundable Annual Registration Fee**: $100

B. **Licensee**

Name of Person Requesting Registration:_____

Address if Different than Above: _____

City _____Zip Code_____

Business Phone: ( ) _____ Fax: ( ) _____

Make checks payable to: **County of San Mateo**

AND

Return application with check to:

San Mateo County
Public Health Laboratory
Non-Diagnostic Health Assessment Program
225 37th Avenue, Room 113
San Mateo, California 94403

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 and in the County/City in which testing is to be performed.

Signature of Applicant _____

Date of Application _____

San Mateo County
Public Health Laboratory

Reviewed By: _____ Date: _____

Registration Number: _____ Date Issued: _____

Fees Received:_____ Date Expires: _____