San Francisco Department of Public Health
Grant Colfax, MD
Director of Health

City and County of San Francisco
London N. Breed
Mayor

NONDIAGNOSTIC GENERAL HEALTH ASSESSMENT APPLICATION (NGHA)

This registration form must be completed and received by the City and County of Santa Francisco Public Health Laboratory ***at least 30 days*** prior to operation of a program of nondiagnostic general health assessment (NGHA).

Applications that are incomplete and/or failure to submit all required documents may result in delays in the processing of your application.

PART 1: ADMINISTRATION

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

Permanent Address: _____

_____
City Zip Code

Business Phone: ( ) _____ Fax: ( ) _____

CLIA #: _____ Exp.: _____

B. **Name of Owner:** _____

Address (if different than above): _____

_____
City Zip Code

Business Phone: ( ) _____ Fax: ( ) _____

C. **Supervisory Committee Members:**

Name of Physician: _____

Address: _____

_____
City Zip Code

Business Phone: ( ) _____ Fax: ( ) _____

CA Medical License #: _____ Exp.: _____

Name of Clinical Laboratory Scientist: _____

Address: _____

_____
City Zip Code

Business Phone: ( ) _____ Fax: ( ) _____

CA Clinical Laboratory Scientist License #: _____ Exp.: _____

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 Code

Business Phone: ( ) _____ Fax: ( ) _____

PART 2: ASSESSMENT PROGRAM

A. Location where assessment is to be performed (complete a separate Supplemental Form 2A for each additional location):

Name of Location: _____

Permanent Address: _____

_____
City Zip Code

Business Phone: ( ) _____ Fax: ( ) _____

B. Dates and hours program will be in operation at this location (attach additional sheets if necessary):

Dates	Hours	Dates	Hours

Note: Any changes in times, dates or location must be reported in writing to the NGHA program office at least 24 hours prior to the operation of the program.

C. Nondiagnostic test being conducted at this location:

(✓)	Test	Equipment Name	Manufacturer
☐	Total Cholesterol		
☐	High-Density Lipoprotein (HDL)		
☐	Low-Density Lipoprotein (LDL)		
☐	Triglycerides		
☐	Blood Glucose		
☐	Hemoglobin		
☐	Dipstick Urinalysis		
☐	Fecal Occult Blood		
☐	Urine Pregnancy		
☐			
☐			

D. List all employees for this location (attach additional sheets if necessary):

Name	Title	(✓) Authorized to perform skin puncture *	
		Yes	No
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐
		☐	☐

* Note: Submit documentation of authorization to perform skin puncture for each individual checked "Yes" above. Include name, signature and California Medical License number of the physician attesting. For licensed individuals submit copy of valid license.

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

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. To comply with current California law, you must be able to answer yes to all questions and supportive documentation must be submitted with this application.

YES	NO	
[ ]	[ ]	This program will be a nondiagnostic health assessment program (NGHA), whose purpose will be to refer individuals to licensed sources of care as indicated.
[ ]	[ ]	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.
[ ]	[ ]	This program maintains a supervisory committee consisting of at a minimum, a California licensed physician and surgeon and a Laboratory Clinical Scientist licensed pursuant to the California Business and Professions Code.
[ ]	[ ]	The supervisory committee for the program has adopted written protocols, which shall be followed in the program. (Include a copy of your written protocols with this application.)
[ ]	[ ]	The protocols contain provisions of written information to individuals to be assessed. (Include a copy of all written information that will be provided to individuals as part of this program.)
[ ]	[ ]	Written information to individuals includes the potential risks and benefits of assessment procedures to be performed in the program.
[ ]	[ ]	Written information includes the limitations, including the nondiagnostic nature, of assessment examinations of biological specimens performed in the program.
[ ]	[ ]	Written information includes information regarding the risk factors or markers targeted by the program.
[ ]	[ ]	Written information includes the need for follow up with licensed sources of care for confirmation, diagnosis, and treatment as appropriate.
[ ]	[ ]	Written protocols contain the proper use of each devices utilized in the program. Protocols must include the 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.
[ ]	[ ]	Written protocols contain the proper procedures to be employed when drawing blood, if blood specimens are to be obtained.
[ ]	[ ]	Written protocols contain procedures to be employed in handling and disposing of all biological specimens to be obtained and material contaminated by biological specimens.
[ ]	[ ]	Written protocols contain proper procedures to be employed in response to fainting, excessive bleeding, or other medical emergencies.
[ ]	[ ]	Written protocols contain procedures for reporting of assessment results to the individual being assessed (please attach a copy of your report form).
[ ]	[ ]	Written protocols contain procedures for referral and follow up to licensed sources of care as indicated. 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 the county health officer or designee.

B. If a skin puncture to obtain a blood specimen is to be performed:

YES	NO	
[ ]	[ ]	The individual performing skin punctures shall be authorized to do via (a) their professional scope of

practice or (b) meet California phlebotomy regulations as identified in the California Business and Professions Code, Sections 1242.5, 1246, and 1282.2; California Code of Regulations, Title 17, Sections 1029.31–1029.35, 1031.4, 1031.5, and 1034; and Health and Safety Code, Section 120580 and possess a current phlebotomy license issued by the CA Dept. of Public Health, Laboratory Field Services Program. (Documentation must be submitted with this application.)

[ ] [ ] It is understood that "skin puncture" as related to this program means the collection of a blood specimen by the finger stick method only and does not include venipuncture, arterial puncture, or any other procedure for obtaining a blood specimens.

PART 5: LICENSE

A legible copy of the registration certificate for the testing organization must be posted during operation of a non-diagnostic general health assessment program.

Name of Person Requesting License: _____

Address (where to mail license): _____

_____
City 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 City & County of San Francisco in which testing is to be performed.

_____ _____
Applicant's Signature Date of Application

FOR OFFICIAL USE ONLY

Application Received:	Reviewed by:
Approved:	Date: