City of Pasadena
Pasadena Public Health Laboratory
1845 N. Fair Oaks Avenue
Pasadena, CA 91103

NONDIAGNOSTIC GENERAL HEALTH ASSESSMENT REGISTRATION FORM

This registration form must be completed and received by the City of Pasadena Public Health Department at least 30 days prior to operating a program of nondiagnostic general health assessment.

PART 1: ADMINISTRATION

A.			
Name of Organization or Operator:			
Permanent address:		City:	State:
ZIP Code:	Business Phone: Fax:	CLIA #:	
B.			
Name of Owner:			
Address if Different Than Above:		City:	State:
ZIP Code:	Business Phone: Fax:		
C. Supervisory Committee Membership:			
Name of Physician:			
Address:		City:	State:
ZIP Code:	Telephone:	California Medical License Number: Expiration Date:	
Name of Laboratory Technologist:			
Address:		City:	State:
ZIP Code:	Telephone:	California Clinical Laboratory Technologist License Number: Expiration Date:	

PART 2A: ADDITIONAL ASSESSMENT PROGRAM LOCATION

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

Site Number: -

A. Location Where Assessments are to be Performed:			
Name of Location:	Address:		City:
State:	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
	❑ 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.

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.
❑ Yes ❑ No	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.
❑ Yes ❑ No	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.
❑ Yes ❑ No	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.)
❑ Yes ❑ No	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.)
❑ Yes ❑ No	6. The written information to individuals includes the potential risks and benefits of assessment procedures to be performed in the program.
❑ Yes ❑ No	7. The written information includes the limitations, including the nondiagnostic nature, of assessment examinations of biological specimens performed in the program.

❑ Yes ❑ No	8. The written information includes information regarding the risk factors or markers targeted by the program.
❑ Yes ❑ No	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.
❑ Yes ❑ No	11. The written protocols contain the proper procedures to be employed when drawing blood, if blood specimens are to be obtained.
❑ Yes ❑ No	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.
❑ Yes ❑ No	13. The written protocols contain proper procedures to be employed in response to fainting, excessive bleeding, or other medical emergencies.
❑ Yes ❑ No	14. The written protocols contain procedures for reporting of assessment results to the individual being assessed (please attach a copy of your report form).
❑ Yes ❑ No	15. 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.
❑ Yes ❑ No	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.	

PART 4

Name of Person Requesting Registration:			
Address if Different than Above:	City:	State:	ZIP Code:
Business Telephone: 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	

FOR OFFICIAL USE ONLY

Reviewed by:	Date:
Registration Number:	Date Issued: Expiration Date:

NONDIAGNOSTIC GENERAL HEALTH ASSESSMENT PROGRAM CLIENT INFORMATION AND EDUCATION REVIEW

☐ Yes	☐ No	☐ N/A	The potential risks and benefits of the nondiagnostic general health assessment (NDGHA) procedure in written form is given to client prior to performing any procedure
☐ Yes	☐ No	☐ N/A	Client information has low, borderline, high and normal values listed.
☐ Yes	☐ No	☐ N/A	The name of the program operator and the client assessed should be on the report form.
☐ Yes	☐ No	☐ N/A	Reports should have written results and the date performed on the report form.
☐ Yes	☐ No	☐ N/A	Client information includes a statement indicating that self referral to medical care may be necessary.
☐ Yes	☐ No	☐ N/A	Client information contained in written material should be based upon National Guidelines.
☐ Yes	☐ No	☐ N/A	Risks of skin puncture should be spelled out, e.g., possibility of infection.
☐ Yes	☐ No	☐ N/A	NDGHA written information should clearly indicate that the NDGHA is not a means of continuing care for chronic disease and that this is best performed in the medical care system.
☐ Yes	☐ No	☐ N/A	Risk of inadequate or erroneous results is listed on client information material.
☐ Yes	☐ No	☐ N/A	Limitations of procedure based on manufacturer written material are given to client.

HEALTH JURISDICTION: _____

NAME OF PROGRAM: _____

REGISTRATION #: _____

DATE: _____

REVIEWED BY: _____