COUNTY OF LOS ANGELES - DEPARTMENT OF PUBLIC HEALTH

NON-DIAGNOSTIC GENERAL HEALTH ASSESSMENT INITIAL APPLICATION

This registration form must be completed annually and received by the County of Los Angeles Public Health Laboratory at least 30 days prior to operating a program of non-diagnostic general health assessment (NGHA). All required documentation must be received before issuance of site license(s). Site-specific licenses must be posted during each program operation.

PART 1: ADMINISTRATION:

A. Name of Organization or Operator____________________

Permanent Address:____________________

____________________ City __________ Zip Code

Bus Ph :( ) __________ 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: ( ) __________

California Medical License #:____________________ Expiration:__________

Name of Clinical Laboratory Scientist:____________________

Address:____________________

__________ City __________ Zip Code Business Phone: ( ) __________

California Clinical Laboratory Scientist License #:____________________ Expiration:__________

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: ( ) __________

PART 2: ASSESSMENT PROGRAM

A. Location where assessments are to be performed (complete a separate Supplemental form 2A for each additional location):

Name of Location:____________________

Permanent Address:____________________

__________ City __________ Zip Code Business Phone: ( ) __________

B. Dates and hours program will be operating 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. Non-diagnostic tests being conducted at this location.

(✓)	Test	Equipment Name	Manufacturer
	TOTAL CHOLESTEROL		
	HIGH DENSITY LIPOPROTEIN (HDL)		
	TRIGLYCERIDES		
	BLOOD GLUCOSE		
	HEMOGLOBIN		
	DIPSTICK URINALYSIS		
	FECAL OCCULT BLOOD		
	URINE PREGNANCY		

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

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

NOTE: Include documentation of authorization to perform skin puncture for each individual checked "YES" above.

PART 3 COMPLIANCE

A. This assessment program must be operated per §1244 of the California Business and Professions Code. Please answer each of the questions listed below. Include a copy of procedures for each starred (*) item.

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 utilizes only those devices that comply with all of the following:

[ ] [ ] a. Meet applicable state and federal performance standards pursuant to §111245 of the Health and Safety Code.

[ ] [ ] b. Are not adulterated as specified in Article 2 (commencing with §111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

[ ] [ ] c. Are not misbranded as specified in Article 3 (commencing with §26630) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code.

[ ] [ ] d. Are not new devices unless they meet the requirements of §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 clinical laboratory scientist licensed pursuant to the California Business and Professions Code.

4.* Protocols review:

[ ] [ ] a. All written protocols that are followed in the program have been reviewed by the supervisory committee and documented in writing with signatures and date(s) of review.

[ ] [ ] b. Protocols have not changed since last renewal.

5.* The protocols contain provision of written information to individuals to be assessed that includes all of the following:

[ ] [ ] a. The potential risks and benefits of assessment procedures to be performed in the program.

[ ] [ ] b. The limitations, including the non-diagnostic nature, of assessment examinations of biological specimens performed in the program.

[ ] [ ] c. Information regarding the risk factors or markers targeted by the program.

[ ] [ ] d. The need for follow-up with licensed sources of care for confirmation, diagnosis, and treatment as appropriate.

6.* Written protocols contain the following:

[ ] [ ] a. Proper use of each device utilized in the program including 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 device used.

[ ] [ ] b. Proper procedures to be employed when drawing blood, if blood specimens are to be obtained.

[ ] [ ] c. Proper procedures to be employed in handling and disposing of all biological specimens to be obtained and material contaminated by those biological specimens.

[ ] [ ] d. Proper procedures to be employed in response to fainting, excessive bleeding, or other medical emergencies.

[ ] [ ] e. Procedures for reporting of assessment results to the individual being assessed.

[ ] [ ] f. Procedures for referral and follow-up to licensed sources of care as indicated.

Yes No
[ ] [ ] 7. The written protocols adopted by the supervisory committee shall be maintained for a least one year following completion of the assessment program during which period they shall be subject to review by the county health officer designee.

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

Yes No
[ ] [ ] 1. Individuals performing skin punctures shall be authorized to do so under the Business and Professions Code.

[ ] [ ] 2. 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 specimen.

PART 4: FEES: Licenses is issued on a fiscal year basis from date of issuance through June 30th of the following year.

	July-Sep	**Oct-Dec**	**Jan-Mar**	**Apr-June**
Annual Fee (*Includes one site and one test*)	$150.00	$112.50	$ 75.00	$ 37.50
Additional Site	$ 48.00	$ 36.00	$ 24.00	$ 12.00
Additional Non-diagnostic tests	$144.00	$ 108.00	$ 72.00	$ 36.00

Make checks payable to: **Department of Public Health**

Return application to: Public Health Laboratory
NGHA Program
12750 Erickson Ave, Room 107
Downey, CA 90242

PART 5: LICENSE:

A license for the specific location address must be posted during operation of a non-diagnostic general health assessment program.

Name of Person Requesting License:________________________ ________________
Telephone No.

Address if different than above:____

________________ ________________ ________________ ________________
City State Zip code E. Mail 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 and in the County of Los Angeles in which testing is to be performed.

________________________ ________________________
Applicant's signature Date of Application

FOR OFFICIAL USE ONLY

Reviewed by: ________________________ Date: ________________

License Number: ________________Date Issued:____________ Expiration Date:____________

Fees Received: $________________Check #:____________ Date Received:____________

Balance Due: $________________________ Overpayment: $________________________

SUPPLEMENTAL FORM 2A

COUNTY OF LOS ANGELES - DEPARTMENT OF PUBLIC HEALTH

NON-DIAGNOSTIC GENERAL HEALTH ASSESSMENT

PART 2A: ADDITIONAL NGHA PROGRAM LOCATION

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

A. Name of Organization or Operator:______________________________

Permanent Address:______________________________

______________________________ City ______________ Zip Code

Business Phone:( ) ______________ Fax:( ) ______________ CLIA #______________

B. Location where assessments are to be performed (complete a separate Supplemental form 2A for each additional location):

Name of Location:______________________________

Permanent Address:______________________________

______________ City ______________ Zip Code Business Phone:( ) ______________

C. Dates and Hours program will be operating 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.

D. **Non-diagnostic tests being conducted at this location.**

(✓)	Test	Equipment Name	Manufacturer
	TOTAL CHOLESTEROL		
	HIGH DENSITY LIPOPROTEIN (HDL)		
	TRIGLYCERIDES		
	BLOOD GLUCOSE		
	HEMOGLOBIN		
	DIPSTICK URINALYSIS		
	FECAL OCCULT BLOOD		
	URINE PREGNANCY		

E. Employee List for this location (attach additional sheets if necessary).

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

NOTE: Include documentation of authorization to perform skin puncture for each individual checked "YES" above.

F. FEES: Licenses are issued on a fiscal year basis from date of issuance through June 30th of following year.

Month of License Issuance	July-Sep	Oct-Dec	Jan-Mar	Apr-June
Additional Site	$ 48.00	$ 36.00	$ 24.00	$ 12.00
Additional Non-diagnostic Tests	$144.00	$108.00	$ 72.00	$ 36.00

Make checks payable to: **Department of Public Health**

Return application to: Public Health Laboratory
NHGA Program
12750 Erickson Ave, Room 108
Downey, CA 90242

G. LICENSE:

A license for the specific location address must be posted during operation of a non-diagnostic general health assessment program.

Name of Person Requesting License:______________________________ ____________________
Telephone No.

Address if different than above:____

______________ ______________ ______________ ______________
City State Zip code E- mail 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 and in the County of Los Angeles in which testing is to be performed.

______________________________ ____________________
Applicant's signature Date of Application

FOR OFFICIAL USE ONLY

Reviewed by: ______________________________ Date: ____________________

License Number: ________________ Date Issued:____________ Expiration Date:______________

Fees Received: $________________ Check #:______________ Date Received:______________

Balance Due: $______________________ Over Payement: $ __________________