HEALTH SERVICES AGENCY
Public Health Division
P.O. Box 3271, Modesto, CA 95353
Phone: 209.558.8804 Fax: 209.558.7286
schsa.org

NONDIAGNOSTIC GENERAL HEALTH ASSESSMENT APPLICATION (NGHA)

This registration form must be completed and received by Stanislaus County Health Services Agency - Public Health ***at least 30 days*** before the operation of a program of nondiagnostic general health assessment (NGHA).

Applications that are incomplete and/or fail to submit all required documents may delay your application's processing.

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:**

D. **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 Medical License #: _____ Exp.: _____

E. **Record Storage:**

All operators must have a permanent address where records of testing and protocols can be stored for review for at least one year after testing has been completed. The Stanislaus County Public Health 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 Part 2 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 locations must be reported in writing to Public Health at least 24 hours before the program's operation starts.

C. Nondiagnostic test 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 all employees for this location (attach additional sheets if necessary):

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

Note: Submit proof of authorization to perform skin puncture for individuals marked "Yes" above.

For Official Use Only:

Approved/Not Approved: _____ **Date License Issued:** _____ **Fee Received:** _____

Date Fee Submitted: _____ **License No.:** _____ **Check No. :** _____

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 (NGHA) that refers individuals to licensed sources of care as indicated.
		This program will utilize only those devices which comply with all of the following: Meet applicable state and federal performance standards under Section 26605 of the Health and Safety Code. Are not adulterated as specified in Article 2 (commencing with Section 26610) of Chapter 6 of Division 21 of the Health and Safety Code. Are not misbranded as specified in Article 3 (commencing with Section 26630) of Chapter 6 of Division 21 of the Health and Safety Code. 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 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 for individuals to be assessed. (Include a copy of all written information provided to individuals in this program.)
		Written information to individuals includes the potential risks and benefits of assessment procedures 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 device 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 per instructions provided by the manufacturer of the assessment device used.
		Written protocols contain the proper procedures for drawing blood and obtaining blood specimens.
		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 assessment results to the assessed individual (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 the 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 specimen.

PART 4:FEES

Annual fee:	**$100**
Additional Site/day	**$30**
Make Checks Payable To	**Stanislaus County Public Health**
Return Application To	**Stanislaus County Public Health** **Re: Nondiagnostic General Health Assessment Application** **P.O. Box 3271,** **Modesto, CA, 95355**

PART 5: LICENSE

The original license for the specific location address must be posted during the operation of a nondiagnostic general health assessment program.

Name of Organization or Operator: _____

Permanent Address: _____

_____

City *Zip Code*

Business Phone: ( ) _____ Fax: ( ) _____

For Official Use Only:

Reviewed By:		**Date:**		**License Number:**	
Date Issued:		**Date Expires:**			
Fees Received:		**Date Received:**			

Name of Organization or Operator	**Hours**	**Dates**	**Hours**
Permanent Address			
	City	Zip Code	

Note: Any changes in times, dates, or locations must be reported in writing to Public Health at least 24 hours before the program's operation starts.