VENTURA COUNTY PUBLIC HEALTH

A Department of Ventura County Health Care Agency

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July 1, 2025

NON-DIAGNOSTIC GENERAL HEALTH ASSESSMENT (NGHA) REGISTRATION FORM INSTRUCTIONS/GUIDELINES

1. Fill out the registration form completely. Registration must be signed by the applicant.
2. Attach the following supporting documentation as described in the registration application:
    - Copies of unexpired certificates for Clinical Laboratory Improvement Amendments (CLIA), clinical laboratory scientist license and physician medical license.
    - Copies of unexpired certificates for all staff performing skin puncture and testing must be submitted for each event.
    - Policies and procedures manual containing biohazard/medical waste disposal plan, quality control (QC) and quality assurance (QA) plans with supporting QC and QA logs, emergency medical plan, instrument procedure manual for each analyte and patient education and referral information sheets.
3. Registration Fees:
    - Annual Registration from July 1, 2025, to June 30, 2026: $100.00
    - Make checks payable to: Ventura County Public Health Laboratory
    - Return application with check to:
        - Ventura County Public Health Laboratory
        - Non-Diagnostic Health Assessment Program
        - 2240 E. Gonzales Road, Suite 160
        - Oxnard, California 93036
4. Registration must be received at least 30 calendar days prior to any non-diagnostic health assessment testing event or program covered by this registration.
5. All regulations must be met before registration is complete.
6. Any events submitted with the annual application will be included in the annual registration fee and verification letter.
7. After approval of your application and receipt of registration fee, a verification letter and certificate will be sent to the applicant with registration number and expiration date. The registration is valid through June 30, 2025. Renewal of this application will be required for any event scheduled after this date.
8. Notify the Ventura County Public Health Laboratory by email of any changes in locations, dates, times, or personnel listed in the amendment prior to the event. Changes in location, date or time will require a revised verification letter but no additional fee.

If you have any further questions or concerns, please do not hesitate to call the laboratory (805) 981-5131.

Thank you for your cooperation,

Brett Austin, Laboratory Director

NON-DIAGNOSTIC HEALTH ASSESSMENT REGISTRATION FORM

This registration form must be completed and submitted to Ventura County Public Health Laboratory at least 30 days prior to operating Non-Diagnostic General Health Assessment (NGHA) program.

PART 1: ADMINISTRATION

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

Permanent Business Address: _____

City: _____State: _____Zip Code: _____

Business Phone: _____

CLIA #: _____Expiration Date: _____

B. **Name of Owner**: _____

Business Address: _____

City: _____State: _____Zip Code: _____

Business Phone: _____

C. **Supervisory Committee Membership**:
Name of Supervising Physician: _____

Business Address: _____

City: _____State: _____Zip Code: _____

Business Phone: _____ Email Address: _____

California Medical License Number: _____ Expiration Date: _____

Name of Clinical Laboratory Scientist: _____

Business Address: _____

City: _____ State: _____ Zip Code: _____

Business Phone: _____Email Address: _____

California Clinical Laboratory Scientist License Number: _____

Expiration Date: _____

D. **Record of Storage**:

All operators must have a permanent address where records of testing and protocols shall be stored for the purpose of testing and protocols shall be stored for the purpose of review for at least one year after testing has been completed. The Ventura County Public Health Laboratory must be notified in writing within 30 days of any change in record storage location.

PART 2: ASSESSMENT PROGRAM

A. **Location Where Assessments Are To Be Performed**:

Name of Location: _____

Address: _____

City: _____State: _____Zip Code: _____

Business Phone: _____

B. **Dates and Hours Program Will Be Operating At This Location**:

Dates	Hours	Dates	Hours

NOTE: **Any changes in Times, Dates, or Location must be reported in writing to Ventura County Public Health Laboratory at least 24 hours prior to the operation of the program.**

C. **Check all Non-Diagnostic test(s) being conducted at this location**:

√	Test	Equipment Name	Manufacturer
	Total Cholesterol		
	Low Density Lipoproteins (LDL)		
	High Density Lipoproteins (HDL)		
	Triglycerides		
	Blood Glucose		
	Occult Blood		
	Other (please describe)		

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PART 2: ASSESSMENT PROGRAM

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.

PART 3: COMPLIANCE

A. **This assessment program must be operated per Section 1244 of the California Business and Professions Code. Please answer the following questions.**

Yes No

☐ ☐ 1. This program will be a non-diagnostic health assessment program with the purpose of referring individuals to licensed sources of care as indicated.

☐ ☐ 2. This program will utilize only those devices which comply with all 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 (commending 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. The program maintains a supervisory committee consisting of, at a minimum, a licensed physician and surgeon and a clinical laboratory scientist licensed pursuant to the Business and Professions Code.

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PART 3: COMPLIANCE

Yes No

☐ ☐ 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 registration 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 as a part of this program).

☐ ☐ 6. The written information to individuals includes the potential risks and benefits of assessment procedures to be performed in the program.

☐ ☐ 7. The written information includes the limitations, including the nondiagnostic 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.

☐ ☐ 10. The written protocols contain the 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 assessment device used.

☐ ☐ 11. The written protocols contain the proper procedures to be employed when collecting blood by skin puncture, if blood specimens are to be obtained.

☐ ☐ 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.

☐ ☐ 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 procedures for reporting of assessment results to the individual being assessed. (Please attach a copy of report form).

☐ ☐ 15. The written protocols contain procedures for referral and follow-up to licensed sources of care as indicated.

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PART 3: COMPLIANCE

B. If a skin puncture to obtain a blood specimen is to be performed, please complete the following:

Yes	No	
☐	☐	All individuals performing skin puncture shall be authorized to do so under the California Business Professions Code.
☐	☐	All individuals performing the skin puncture procedure possess a statement signed by a California licensed physician and/or surgeon which attests that the named individual has received adequate training in the proper procedure to be employed in skin puncture.
☐	☐	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.

C. **CERTIFICATION**

I certify that the above information is accurate and complete and that I am aware of the laws and regulations that apply to NGHA programs in the State of California and in the County in which the testing is to be performed.

Name of Applicant: _____

Signature of Applicant: _____

Date signed: _____

FOR OFFICIAL USE ONLY

Reviewed by: _____

Date Application received: _____

Payment Received: _____ Check #_____

Registration Number: _____

Date Issued: _____Expiration date: _____

Date Certificate/Verification Mailed: _____

Date Approved: _____

Health Officer Designee Signature: _____