NON-DIAGNOSTIC GENERAL HEALTH ASSESSMENT REGISTRATION FORM

This registration form must be completed and received by the Imperial County Public Health Laboratory at least 30 days prior to operating a program of non-diagnostic general health assessment.

DATE OF APPLICATION: _____

PART 1: ADMINISTRATION

- **Name of Organization or Operator:**

Permanent Business Address: _____
City: _____
State: _____
Zip Code: _____
Business Phone: _____
Fax Number: _____

CLIA Number: _____

- Name of Business Owner:
  _____

Address if Different than Above: _____
City: _____
State: _____
Zip Code: _____
Business Phone: _____
Fax Number: _____

- Name and title of Clinical Consultant or Supervising Physician:
  _____

Business Address: _____
City: _____
State: _____
Zip Code: _____
Business Phone: _____
Fax Number: _____
California Medical License Number: _____
Expiration Date: _____

- Name of Laboratory Technologist:

  _____

Business Address: _____
City: _____
State: _____
Zip Code: _____
Business Phone: _____
Fax Number: _____
California Clinical Laboratory Scientist License Number: _____
Expiration Date: _____

- Name of person requesting registration (Licensee):

  _____

Business Address: _____
City: _____
State: _____
Zip Code: _____
Business Phone: _____
Fax Number: _____

- Record Storage

For the purpose of review, all organizations or operators must have a permanent address where records of testing and protocols are stored for at least one year after testing has been completed.

Record Storage Address: _____
City: _____
State: _____
Zip Code: _____
Business Phone: _____

PART 2: ASSESSMENT PROGRAM

Please complete a separate "Part 2" for each location where assessments are to be performed.

- **Name of location where assessments are to be performed**:

Business Address: _____
City: _____
State: _____
Zip Code: _____

Business Phone: _____

Fax Number: _____

- Dates and hours program will be operating at this location:

Date	Hours of operation	Days of the week

NOTE: Any changes in times, dates or location(s) must be reported in writing to the Health Department Laboratory at least 24 hours prior to the operation of the program.

- Type or kind of Non-diagnostic General Health Assessment tests 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		
	Other		
	Other		

- List of employees:

Please list all employees who will participate in the non-diagnostic testing at this location.
(Attach additional sheets if necessary)

Name and Title	Will perform skin puncture? (Yes/No)

PART 3: COMPLIANCE

This assessment program must be operated per Section 1224 of the California Business and Professions Code. Please answer each of the following questions.

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 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 California 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 California 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 California Health and Safety Code.
D. Are not new devices unless they meet the requirements of Section 26670 of the California Health and Safety Code.

[ ] [ ] 3. This program maintains a supervisory committee consisting of, at minimum, a California licensed physician and surgeon and a clinical laboratory scientist licensed pursuant to the California Business and Professions Code.

[ ] [ ] 4. The supervisory committee for the program has adopted and signed written protocols which shall be followed in the program.

Documents required: Please include a copy of the written protocols with this application.

[ ] [ ] 5. The protocols contain copies of written information which will be provided to individuals at assessment.

Documents required: Please include a copy of any written information that will be provided to individuals as 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 non-diagnostic 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 assessment test(s).

[ ] [ ] 9. The written information informs the individuals of the need for follow up with licensed care providers for confirmation, diagnosis, and treatment as appropriate.

[ ] [ ] 10. The written protocols contain proper procedures for referral and follow up to licensed care providers as indicated.

[ ] [ ] 11. 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.

[ ] [ ] 12. The written protocols contain the 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 proper procedures for reporting of assessment results to the individual being assessed.

Documents required: Please attach a copy of the report form which will be provided to individuals with their results.

NOTE: The written protocols adopted by the supervisory committee shall be maintained for at least one year following completion of the assessment program. The written protocols 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.

- 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 California Business and Professions Code.

[ ] [ ] 2. All individuals performing the skin puncture possess a statement signed by a California licensed physician and surgeon which attests that the named person has received adequate training in the proper procedure to be employed in skin puncture.

Documents required: Please include documentation of certification to perform skin puncture for each individual listed above who will perform this procedure.

[ ] [ ] 3. Written protocols contain the proper procedures to be employed when obtaining blood specimens.

Documents required: Please include a copy of the written protocols with this application.

NOTE: Skin puncture means the collections 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: FEES/REGISTRATION

- Non-Refundable Annual Registration Fee: $100.00
- Make checks payable to: County of Imperial
- Return application with check to:

Imperial County Public Health Laboratory
Non-Diagnostic Health Assessment Program
935 Broadway
El Centro, California 92243

For questions or further information, please contact:

Holly Maag, MHA, JD
Laboratory Director
Imperial County Public Health Laboratory
935 Broadway
El Centro, California 92243
760.482.4437
760.353.9736 Fax
hollymaag@co.imperial.ca.us

CERTIFICATION

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 in which testing is to be performed.

Name of Applicant _____

Signature of Applicant _____

Date signed _____

FOR OFFICIAL USE ONLY

Reviewed by: _____

Date: _____

Registration Number: _____

Date Issued: _____

Expiration Date: _____

Fee Received: _____

Imperial County Department of Public Health

A copy of this page will be returned to the Applicant upon receipt, review and approval of application, all required documents, and fee.