



# CITY OF LONG BEACH

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Laboratory  
Miriam Lachica, Laboratory Services Officer  
2525 Grand Avenue, Suite 260, Long Beach, CA 90815 T (562) 570-4077 F (562) 570-4070

DATE: May 27, 2016

TO: Non-Diagnostic General Health Assessment Event Client

SUBJECT: Revised Non-Diagnostic General Health Assessment Certificates

The Long Beach Public Health Laboratory is the oversight organization for all Non-Diagnostic General Health Assessment (NGHA) testing events held in the City of Long Beach, California. Under *Sections 1244, 1244.1, 1244.3 and 1244., Chapter 195 of the California Business and Professions Code*, regulatory authority requires:

- Thirty days prior notification of intent to operate a NGHA program in California. The entity operating that program must file with the organization having jurisdiction, written notification of the program location, type, and kind of non-diagnostic general health assessments conducted, dates and times of operation, and evidence that the program will be operated in compliance with Section 1244.
- Incomplete applications (either yearly registration packets or registration for specific events) will delay processing, and a NGHA program failing to meet the requirements, as specified in Section 1244 of the California Business and Professions Code, shall not operate.
- The regulatory organization must be notified in writing, at least 24 hours prior to event's commencement, of any changes occurring in locations, dates or times indicated in the registration documentation.
- Enforcement responsibility rests with the local health officer or public health laboratory director. There is no wording in the Code that prevents the California Department of Public Health from using any necessary enforcement actions for the protection of the public health and safety. Personal inspection at the event site is authorized without prior notice.
- Event sponsors located outside of California must register with California Laboratory Field Services for a Clinical Laboratory Registration number. Refer to: <http://www.cdph.ca.gov/programs/lfs/Pages/default.aspx>. (Go to **Certificates and Licenses**, then **California Laboratory Facility and Personnel Licenses**.)
- Quality control (positive and negative or high and low controls) is required to be performed by the person actually performing the test on site and on the day of the non-diagnostic general health assessment. This performance of quality control is now shown as a part of the written procedure in the registration packet.



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## Registration Packet:

- Revised as of May 2016.
- All pages must be completed, with all documentation included, or the registration will not be reviewed.
- Current fees are shown on Page 6 of the registration form.
- Registrations are valid for the City's fiscal year, October 1<sup>st</sup> to September 30<sup>th</sup> (or part thereof).
- Page 7 must be completed and signed.

To add events or tests as the year progresses, the cost decreases. Pages 2, 3 and 7 must be completed for each added event and each added test, and send proof of California phlebotomy certificate. Make checks payable to Long Beach Public Health Laboratory.

The City of Long Beach requires a Medical Waste License, which is not issued by the Public Health Laboratory. Please contact Mr. Glen Fong at [glen.fong@longbeach.gov](mailto:glen.fong@longbeach.gov) or 562-570-4147 for assistance.

We thank you for helping us comply with the requirements for offering this type of testing in our community, and if you have any questions, please contact us using the information on this letterhead.

Sincerely,

Miriam Lachica, M.A.  
Laboratory Services Officer



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## NON DIAGNOSTIC GENERAL HEALTH (NGHA) ASSESSMENT CHECKLIST

Name of Organization or Operator: \_\_\_\_\_

Name of Owner: \_\_\_\_\_

Location: \_\_\_\_\_

Date: \_\_\_\_\_

Registration Number **(To be provided by Long Beach Public Health Laboratory):**  
\_\_\_\_\_

- California License Number (CLF)
- Supervisory Committee with physician and clinical laboratory scientist
- Employees duly licensed to draw blood and/or perform procedures

### Type of NGHA tests offered:

- Blood Glucose
- Triglycerides
- Occult Blood
- Other:
- Total Cholesterol
- ALT – AST
- High-Density Lipoproteins (HDL)
- Low-Density Lipoproteins (LDL)

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_

### Testing equipment to be used for all NGHA tests offered:

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_



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## NON-DIAGNOSTIC GENERAL HEALTH ASSESSMENT REGISTRATION FORM

This registration form must be completed and received by the Long Beach Public Health Laboratory at least 30 days prior to operating a program of non-diagnostic general health assessment. Incomplete applications or failure to submit all required documents may result in delays in the processing of your application.

### **PART 1: ADMINISTRATION**

**A. Name of Organization or Operator:** \_\_\_\_\_  
Permanent Address: \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_  
Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_  
CLIA Number: \_\_\_\_\_

**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 \_\_\_\_\_  
Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_  
California Medical License Number: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

**Name of Laboratory Technologist:** \_\_\_\_\_  
Address: \_\_\_\_\_  
City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_  
Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_  
California Clinical Laboratory Scientist License No.: \_\_\_\_\_ Exp. Date: \_\_\_\_\_

Name of Organization \_\_\_\_\_

**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 \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_

**PART 2: ASSESSMENT PROGRAM**

**A. Location Where Assessments Are To Be Performed: (Please also send this page with additional site event registrations)**

Name of Location: \_\_\_\_\_

Address: \_\_\_\_\_

City \_\_\_\_\_ Zip Code \_\_\_\_\_

Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_

**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 THE LONG BEACH PUBLIC HEALTH LABORATORY AT LEAST 24 HOURS PRIOR TO THE OPERATION OF THE PROGRAM.**

**C. Type Or Kind Of Non-Diagnostic Tests Being Conducted At This Location:**

<input checked="" type="checkbox"/>	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:		



Non-Diagnostic General Health Assessment Registration Form

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Name of Organization \_\_\_\_\_

**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 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, 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. 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. 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 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 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 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.

**NOTE: THE LONG BEACH PUBLIC HEALTH LABORATORY REQUIRES QUALITY CONTROL (POSITIVE AND NEGATIVE OR HIGH AND LOW CONTROLS) TO BE PERFORMED BY THE PERSON ACTUALLY PERFORMING THE TEST ON SITE AND ON THE DAY OF THE NON-DIAGNOSTIC GENERAL HEALTH ASSESSMENT. PLEASE BE CERTAIN THIS PERFORMANCE OF QUALITY CONTROL IS IN THE WRITTEN PROCEDURES.**

- [ ] [ ] 11. The written protocols contain the proper procedures to be employed when drawing blood, if blood specimens are to be obtained.
- [ ] [ ] 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 (**PLEASE ATTACH A COPY OF YOUR REPORT FORM.**)
- [ ] [ ] 15. The written protocols contain proper 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. The individual performing skin punctures shall be authorized to do so 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.**)

**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.**

Name of Organization \_\_\_\_\_

**PART 4. FEES/REGISTRATION**

- A. Non-refundable fee is for licenses issued on a fiscal year basis from the date of issuance through September 30<sup>th</sup> (based on City of Long Beach fiscal year, which runs from October 1st through September 30th of the following year.)**

**Registration:**

Full Year Registration, Unlimited Sites and Unlimited Tests (From October through September)	\$675.00
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Non-Diagnostic General Health Assessment Registration Form

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Name of Organization \_\_\_\_\_

**B. Licenses, Certifications and California Clinical Laboratory Registration (CLR) Number:**

The original signed Certificate from the Long Beach Public Health Laboratory for the specific location address must be posted during operation of a non-diagnostic general health assessment program.

Please be advised that the State of California requires non-diagnostic general health assessment sponsors from outside the State obtain a Clinical Laboratory Registration number. This license must be renewed each year. Please include that number here if you are an out-of-state sponsor: \_\_\_\_\_.

Refer to: <http://www.cdph.ca.gov/programs/lfs/Pages/default.aspx>

To obtain a CLR number, under *Certificates and Licenses*, go to the category *California Laboratory Facility and Personnel Licenses*.

**C. Name of Person Requesting Registration:** \_\_\_\_\_

Address if different than previously given: \_\_\_\_\_

City \_\_\_\_\_ State \_\_\_\_\_ Zip Code \_\_\_\_\_

Business Phone: ( ) \_\_\_\_\_ Fax: ( ) \_\_\_\_\_

**Make checks payable to:**

Long Beach Public Health Laboratory-Department of Health and Human Services

**Return application with check to:**

Long Beach Public Health Laboratory  
Non-Diagnostic Health Assessment Program  
2525 Grand Avenue, Suite 260  
Long Beach, CA 90815

**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/City in which testing is to be performed.**

\_\_\_\_\_  
Signature of Applicant

\_\_\_\_\_  
Date of Application

-----  
**For LBPHL Use Only**

**Reviewed by:** \_\_\_\_\_

**Date:** \_\_\_\_\_

**Registration Number:** \_\_\_\_\_

**Date Issued:** \_\_\_\_\_

**Fees Received:** \_\_\_\_\_

**Date Expired:** \_\_\_\_\_



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### Written information to be provided to individuals seeking NGHA:

- The potential risks and benefits of assessment procedure being performed
- The limitations, including non diagnostic nature, of assessment examinations of biological specimens performed in the program
- Information regarding the risk factors or markers targeted by the program
- The need for follow-up with licensed sources of care for confirmation, diagnosis, and treatment as deemed appropriate

### Written protocols for the following:

- Proper use of each device utilized in the program, including:
  - The operation of the analyzers
  - Maintenance of equipment and supplies
  - 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
- Proper procedures to be employed when drawing blood by finger stick, if blood specimens are obtained
- Proper procedures to be employed in handling and disposing of all biological specimens to be obtained and materials contaminated by those biological specimens
- Proper procedures in response to fainting, excessive bleeding, other medical emergencies
- Reporting of assessment results to the individual being assessed
- Referral and follow-up to licensed health care providers