



COUNTY OF SAN DIEGO
HEALTH AND HUMAN SERVICES AGENCY
Public Health Laboratory
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Non- Diagnostic General Health Assessment Program Frequently Asked Questions (FAQ)

1. What is the definition of a nondiagnostic general health assessment (NDGHA) program?

A NDGHA program is a program in which bioanalytical screening is provided to an asymptomatic individual to screen for a non-infectious chronic health condition. Individuals who appear likely to have a marker or risk factor are then referred to licensed sources of clinical care for appropriate follow up. NDGHA programs must provide significant public health benefit as determined by accepted public health protocols and practice.

2. Which laws govern regulation of NDGHA programs in California?

Sections 1244, 1244.1, 1244.3, and 1233.4 in Chapter 195 of the California Business and Professions Code regulate NDGHA programs.

3. Which method may be used to collect blood samples during a NDGHA program?

If blood must be collected, it shall be obtained by the fingerstick method, not by venipuncture, arterial puncture, or any other procedure for obtaining a blood specimen.

4. What types of tests are considered nondiagnostic general health assessments?

Non-diagnostic general health assessments include total cholesterol, high-density lipoprotein (HDL), triglycerides, blood glucose, hemoglobin, hemoglobin A1c, dipstick urinalysis, fecal occult blood, urine pregnancy, and other tests in which the sample is tested onsite, and results are provided on the same day at the same place where the test was administered. Some examples include:

- A cholesterol screening program held at a shopping mall and sponsored by a hospital, in which blood is collected by fingerstick and tested onsite using a portable machine.
- Glucose testing performed at a pharmacy in which blood is collected by fingerstick and tested onsite using a portable analyzer.

5. What types of programs are not classified as nondiagnostic general health assessments?

- Collection of blood by venipuncture at a shopping mall which is subsequently tested for glucose (or other components) at a licensed medical laboratory. (Note: this may be illegal in California unless the shopping mall location is approved as a blood drawing station.)
- Body Fat Content

- Blood Pressure Screening

6. I'm performing nondiagnostic general health assessments in your county, but I'm located in a different county. Do I still have to be licensed by your county?

Yes. It doesn't matter if you're located in a different county or state; if you are performing non-diagnostic general health assessments in San Diego County your program must be registered in San Diego County.

7. Are testing programs conducted at hospitals exempt from regulations relating to NDGHA programs?

Programs that meet the definition of NDGHA conducted by hospitals are NDGHA programs except:
(a) those where testing is performed within the hospital's licensed clinical laboratory
(b) those exempted by 1241 of the Business and Professions Code

8. Are testing programs conducted at clinics NDGHAs?

Testing programs conducted at licensed community clinics, free clinics, and employee clinics (as defined in subdivision (a) of Section 1204 of the California Health and Safety Code) are not NDGHA programs.

9. What must be done before a NDGHA program can be operated?

Necessary documentation must be filed with the local health officer or his/her designee such as the NDGHAP Coordinator at least 30 days prior to the date the NDGHA will be operated. In most cases, a registration form together with supporting documents must be submitted.

10. Why do fees for operation of NDGHA programs differ among various counties?

Fees are calculated separately by each county or city health department using their own individual methods. Costs of operating programs may be high in some areas depending on the number and complexity of programs being regulated, number of personnel required, and size of geographic area covered.

11. Is a separate permit for transport and disposal of biomedical waste required?

Permits are required for both transport and disposal of biomedical waste unless waste will be mailed from the screening site to a medical waste disposal company. Companies offering these services must be approved by the California Department of Public Health (see list of approved companies on the CDPH website).

Contact the San Diego County Department of Environmental Health Hazardous Waste Duty Specialist at (858) 505-6880 or more information regarding permits for transport and disposal of biomedical waste.

12. Must NDGHA programs comply with CLIA '88?

Yes.

13. How do I apply for nondiagnostic general health assessment registration in San Diego County?

Contact the San Diego County Public Health Laboratory via email at ndgha.hhsa@sdcounty.ca.gov or by phone at (619) 692-8500. Please visit the San Diego County Public Health Laboratory [website](#) for more information.

14. What items must be submitted for a complete application?

Each organization or operator will need to verify each item on this list prior to returning an application and supporting documentation below:

Application

- NDGHA Operator Registration Form

Certificates and Licensure

- CLIA Certificate of Waiver
- Clinical and Public Health Laboratory Registration License
- Clinical Laboratory Scientist License
- Physician Medical License
- Licenses for Staff
- Certificate of Competency for Instrument and Fingerstick Training for Staff

Plans and Procedures

- Policy and Procedures Manual including instrument procedure for each analyte
- Signed acknowledgement and approval of written Policy and Procedures Manual
- Biohazard/Medical Waste Disposal Plan
- Emergency Medical Plan
- Patient education and referral information sheets

Quality Control and Quality Assurance

- Quality Control and Quality Assurance Plans
- Blank Quality Control and Quality Assurance logs

Miscellaneous and Fees

- Copy of agreement with medical waste disposal company, Small Quantity Medical Generator registration (UPFP), or copy of an agreement with a medical waste mail-back program
- Registration Fee (please refer to fee schedule for the current fiscal year)
- Mail check to:
County of San Diego
Health & Human Services Agency
Financial & Support Services Division
PO Box 122028
San Diego, CA 92112-2028
Attn: Teresalina Almazan MS W40