



Public Health Laboratory

Nondiagnostic General Health Assessments Frequently Asked Questions

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

A NGHA 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 care for appropriate follow up. NGHA programs must provide significant public health benefit as determined by accepted public health protocols and practice.

2. How is this different from a health fair?

Per California Health and Safety Code, a “health fair” means a program of health assessment procedures offered to the general public that many include screening, self-ordered, or diagnostic clinical laboratory tests or examinations **performed by a clinical laboratory** licensed or registered under subdivision (a) of Section 1265 and meets all the requirements of that chapter. This can include finger stick or venous blood.

3. Which laws govern regulation of NGHA programs in California?

Sections 1244, 1244.1, 1244.3, and 1244.4 in Chapter 195 of the California Business and Professions Code regulate NGHA programs.

4. Which method may be used to collect blood samples during a NGHA program?

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

5. What types of tests are considered non-diagnostic general health assessments?

Non-diagnostic general health assessments include total cholesterol, high-density lipoprotein (HDL), triglycerides, blood glucose, hemoglobin, 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 finger stick and tested onsite using a portable machine.
- Glucose testing performed at a pharmacy in which blood is collected by finger stick and tested onsite using a portable analyzer.
- Examination of stool for occult blood at a senior citizens’ community center.

6. What types of programs are not classified as non-diagnostic general health assessments?

- Collection of blood by venipuncture which is subsequently tested for glucose (or other components) at a licensed medical laboratory.
- Body fat content
- Blood pressure screening

7. I'm performing non-diagnostic 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 Bernardino County you must have an NGHAs permit in San Bernardino County.

8. Are testing programs conducted at hospitals exempt from regulations relating to NGHAs programs?

Programs that meet the definition of NGHAs conducted by hospitals are NGHAs except those where testing is performed within the hospital's licensed clinical laboratory

9. Are testing programs conducted at clinics NGHAs?

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 NGHAs programs.

10. What must be done before a NGHAs program can be operated?

Necessary documentation must be filed with the local health officer (or his/her designee – in San Bernardino County, the Public Health Laboratory Director) at least 30 days prior to the date the NGHAs will be operated. In most cases, a registration form together with supporting documents must be submitted.

11. Why do fees for operation of NGHAs programs differ among various counties?

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

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

Contact the San Bernardino County Division of Environmental Health Services at (800) 442-2283 for specific requirements.

13. How do I apply for a non-diagnostic general health assessment license in San Bernardino County?

You can either contact the San Bernardino County Public Health Laboratory at (909) 458-9430, or email the laboratory director, Linda Ward at LWard@dph.sbcounty.gov.

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

- A completed application.
- Copies of Clinical Laboratory Improvement Amendments (CLIA) certificate, California Clinical Laboratory Registration, clinical laboratory scientist current license, physician's current medical license, and certificates for all staff in instrument training and finger stick.
- 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 & referral information sheets.
- \$132 annual fee. Make checks out to County of San Bernardino and mail to the Public Health Laboratory at 150 E. Holt Blvd., Ontario, CA 91761.