

NGHA Frequently Asked Questions (FAQ)

(taken in part from CAPHLD's "Nondiagnostic General Health Assessment Registration and Enforcement Program Implementation Manual")

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. Which laws govern regulation of NGHA programs in California?

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

3. Which method may be used to collect blood samples during a NGHA 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, 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.
- Examination of stool for occult blood at a senior citizens' community center.

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 Santa Clara County you must have an NGHA license in Santa Clara County.

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

Programs that meet the definition of NGHA conducted by hospitals are NGHAs 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 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.

9. 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 Santa Clara 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.

10. Why do fees for operation of NGHAs 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?

Contact the Santa Clara County Department of Environmental health at (408) 918-3400 for specific requirements.

12. Must NGHAs programs comply with CLIA '88?

Yes.

13. How do I apply for a nondiagnostic general health assessment license in Santa Clara County?

You can either contact the Santa Clara County Public Health Laboratory at (408) 885-4272, or at phlab@phd.sccgov.org

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

- A completed application.
- Copies of CLIA certificate, clinical laboratory scientist current license, physician's current medical license, and certificates for all staff in instrument training and fingerstick.
- Policies and procedures manual containing biohazard/medical waste disposal plan, quality control and quality assurance plans with supporting QC and QA logs, emergency medical plan, instrument procedure manual for each analyte, and patient education & referral information sheets.
- Any applicable fees.