

Nondiagnostic General Health Assessment

NGHA Frequently Asked Questions (FAQ)

Reference: 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 1244.4 in Chapter 195 of the California Business and Professions Code regulate NGHA programs.

1244. (a) *Nothing in this chapter shall restrict, limit, or prevent a program of nondiagnostic general health assessment provided that:*

(1) *The program meets the requirements of Section 1265 and complies with the requirements of CLIA for waived testing.*

(2) *The purpose of the program is to screen asymptomatic individuals for chronic health disorders and to refer individuals to licensed sources of care as indicated.*

(3) *The program does not test for human immunodeficiency virus or any reportable disease or condition identified in Section 120130 of the Health and Safety Code or the regulations adopted under that section.*

1244.1. *Thirty days prior to operating a program of Nondiagnostic general health assessment, the entity or person operating that program shall file the following documentation with the local health officer in each county in which the program shall operate:*

(a) The location of the program, the type and kind of nondiagnostic general health assessments being conducted, the dates and times of operation of programs, and evidence that the program shall be operated in compliance with Section 1244.

(b) The local health officer shall be notified in writing of any changes to occur in locations, dates, or times indicated in the documentation required in subdivision (a). The local health officer shall be notified of any changes at least 24 hours prior to the program operating at the different locations, dates, or times.

1244.3. *Responsibility for enforcement of Sections 1244 and 1244.1 shall be with the local health officer or his or her authorized designee, including public health laboratory directors. Nothing in this section shall prevent the department from using any necessary enforcement actions for the protection of the public health and safety.*

1244.4. *Any fee for the filing of documentation and related enforcement activities pursuant to Section 1244, 1244.1, and 1244.3 shall be determined by the local enforcement agency and shall not exceed one hundred dollars (\$100) except that those fees shall be adjusted annually by any annual increase in the California Consumer Price Index as determined pursuant to Section 2212 of the Revenue and Taxation Code. All moneys collected as fees pursuant to this section shall be deposited in the appropriate city, county, or city and county treasury and shall only be expended in carrying out Sections 1244, 1244.1, and 1244.3.*

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 Merced County you must have an NGHA license in Merced 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 NGHA programs.

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

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

10. Why do fees for operation of NGHA 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 Merced County Public Health Division of Environmental health at **(209) 381- 1100** for specific requirements.

12. Must NGHA programs comply with CLIA '88?

- Yes

13. How do I apply for a Nondiagnostic general health assessment license in Merced County?

- You can either contact the Merced County Public Health Laboratory at **(209) 381-1290**, or download the application from the link below.

<https://www.co.merced.ca.us/2109/Non-Diagnostic-General-Health-Assessment>

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.
 - Any applicable fees.