

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 register with 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 Napa, Solano, Yolo or Marin county you must have an NGHA registration and a permit to operate your event in that 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(g) 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 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 Resource Management division of the county in which the event is being held.
Napa County Public Works: 707-253-4351
Solano County Resource Management: 707-784-6765
Yolo County Division of Integrated Waste Management: 530-666-8856
Marin County Medical Waste Program: 415-473-6907

12. Must NGHAs programs comply with CLIA '88?

Yes.

13. How do I apply for a nondiagnostic general health assessment permit in Napa, Solano, Yolo, or Marin county?

Contact the Napa-Solano-Yolo-Marin County Public Health Laboratory at 707-784-4410 or ngha.permits@solanocounty.com

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

- A completed annual registration application
- A completed event permit 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

15. When do the annual registration and event permit applications expire?

- An annual registration is valid until the end of the calendar year, and expires on December 31.
- An event permit is valid for a 7-day timeframe, starting from the first day an event will be held.

16. What are the current fees?

The fees, as of January 2019, are listed below. These fees are subject to change.

Annual registration fee:	\$80
Event permit, per site:	\$40
Consultation (per hour):	\$100