

Public Health Sofia Pereira, Director 529 I Street, Eureka, CA 95501

phone: (707) 445-6200 | fax: (707) 445-6097

## NGHA Frequently Asked Questions (FAQ)

(Taken in part from the California Association of Public Health Laboratory Department's (CAPHLD) Nondiagnostic General Health Assessment Registration and Enforcement Program Implementation Manual.)

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

An 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 fingerstick or venous blood.

3. 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.

4. Which method may be used to collect blood samples during an 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.

5. What types of tests are considered NGHAs?

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 on site and



DHHS Administration phone: (707) 441-5400 fax: (707) 441-5412 Mental Health phone: (707) 268-2990 fax: (707) 476-4049 Social Services phone: (707) 476-4700 fax: (707) 441-2096 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.
- 6. What types of programs are not classified as NGHAs?
  - 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
- 7. I'm performing NGHAs 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 Humboldt County you must have an NGHA license in Humboldt County.

8. 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.
- 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 <u>not NGHA</u> programs.

10. What must be done before an NGHA program can be operated?



Necessary documentation must be filed with the local health officer (or his/her designee – in Humboldt 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.

11. 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.

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

Contact the Humboldt County Department of Environmental Health at (707) 445-6215 for specific requirements.

13. How do I apply for an NGHA license in Humboldt County?

You can either contact the Humboldt County Public Health Laboratory by phone at (707) 268-2179 or by email at <a href="mailto:phlabnghamailbox@co.humboldt.ca.us">phlabnghamailbox@co.humboldt.ca.us</a>. An application can also be downloaded from this link:

http://www.co.humboldt.ca.us/hhs/phb/publichealthlaboratory.asp

- 14. What items must be submitted for a complete application?
- A completed application.
- Copies of Clinical Laboratory Improvements Amendments (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 (QC) and quality assurance (QA) plans with supporting QC and QA logs; emergency medical plan; instrument procedure manual for each analyte; and patient education and referral information sheets.
- \$100 annual fee.
- 15. Are there additional fees for additional locations?

There are no additional fees for additional locations. Send a Form 2A by mail or email at least 30 days prior to any event additional locations added after the annual application and fee are turned in.

