



MEMORANDUM

DATE: March 15, 2021

TO: Non-diagnostic General Health Assessments (NGHA) Vendor/Industry Applicants

FROM: Godfred Masinde, PhD, MS, MBA
Laboratory Director, City and County of San Francisco
San Francisco Public Health Laboratories

RE: State regulations and local COVID-19 mitigation requirements for Nondiagnostic General Health Assessments (NGHA) Program in City & County of San Francisco

Non-Diagnostic General Health Assessment (NGHA) programs are regulated by local public health departments following the California Business and Professional Code, Chapter 195, Sections 1244, 1244.1, 1244.3 and 1233.4. The San Francisco Public Health Laboratory provides oversight for all NGHA testing events held in the City & County of San Francisco, California.

NGHA vendor/industry applicants should be aware of the laws and regulations that apply to non-diagnostic testing in the State of California in addition to the regulations for the City & County of San Francisco under the emergency COVID-19 health order.

To register a program, the State of California has the following requirements:

- **Must have a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver**
- **Committee must include a California Physician/Surgeon and a Clinical Laboratory Scientist who oversees testing personnel and quality control on its roster**
- **The Laboratory Director must be designated on the CLIA certificate**

Only **outdoor** events are permitted by the City & County of San Francisco. **NGHA vendor/industry applicants are required to comply with and implement the following when planning events in San Francisco:**

- [Appendix A: Social Distancing Protocol](#) (revised 3/2/2021) as outlined in [Health Order C19-07t](#) ;
- [Health & Safety Plan](#) Checklist under the [Farmers Market Directive](#); **and,**
- the **outdoor** [Health & Safety Plan](#) Checklist under the [Personal Services Directive](#), if vendor/event staff must touch or interact within 6' of attendees.



Instructions

1. Fill out the application completely. ***Remember to sign the application form.***
2. Use the checklist below to collate the following documentation:
 - Application form
 - Copy of current CLIA Certificate of Waiver
 - Copy of current Physician's license for Supervising Physician
 - Copy of current Clinical Laboratory Scientist (CLS) license for CLS overseeing testing
 - Copy of Medical Waste handling permit(s)
 - Copies of all other licensed personnel such as phlebotomists and/or training letters from physicians
 - Provide a copy of your Procedure Manual. It should contain QA's, blood collection and medical waste procedures, client consent forms, results forms, etc.
 - [Health & Safety Plan](#) Checklist under the [Farmers Market Directive](#)
 - [Outdoor](#) Health & Safety Plan Checklist
3. Submit your application and all documentation via email to the San Francisco Public Health Laboratory at Godfred.Masinde@sfdph.org
4. After review, applicants will be notified of the outcome of their application - approval or declination.

Summary of Process for NGHA Program Applications & Supplementary COVID-19 Health and Safety Plan Materials

- DPH PHL sends requirements of the emergency order or Applicant downloads application packet to complete
- DPH PHL receives application and supplementary materials via email
- DPH PHL reviews general overview of PHL aspects of application and State required supplementary materials
- DPH PHL sends application to CERT at HealthPlan@SFCITYATTY.org, if approved by DPH PHL.
 - Applications should include times/locations of events. CERT, or Community Emergency Response Team, may conduct periodic spot checks to ensure compliance with local regulations.