



GOVERNMENT OF GUAM

DEPARTMENT OF PUBLIC HEALTH AND SOCIAL SERVICES
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**DEPARTMENT OF PUBLIC HEALTH & SOCIAL SERVICES
REQUEST FOR INFORMATION NO. 2021-001**

**To Determine Public Interest in the Development and Implementation of a CLIA
Compliant Biosafety Level 2/2+ Containerized Modular Laboratory System Goods and Services**

RFI Issue Date: October 1, 2021	No. of Pages: 6
<p align="center">Proposal Submission Due Date: October 29, 2021 5:00 p.m. Chamorro Standard Time</p>	
ISSUING AGENCY	
<p align="center">Department of Public Health & Social Services Division of Public Health and Division of Environmental Health Epidemiology Laboratory Capacity, Guam Public Health Laboratory, and Mosquito Laboratory 155 Hesler Place Hagatna, Guam 96910</p>	
<p align="center">Point of Contact Estelle Ada Department of Public Health & Social Services 155 Hesler Place Hagatna, Guam 96910 Tel.: 671-300-5874 Fax: 671-300-5566 Email: estelle.ada@dphss.guam.gov</p>	
INSTRUCTIONS TO OFFERORS	
<p>Return Proposal to:</p> <p>Estelle Ada, ELC Program Manager Department of Public Health & Social Services Division of Public Health Epidemiology & Laboratory Capacity 155 Hesler Place Hagatna, Guam 96910</p>	<p>Mark Face of Envelope / Package:</p> <p>RFI Number: RFI/DPHSS 2021-001 RFI Title: To Determine Public Interest in the Development and Implementation of a CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory Good and Services System</p>
OFFERORS MUST COMPLETE THE FOLLOWING	
<p>Offeror Name/Point of Contact/Address:</p>	<p>Authorized Offeror Signatory:</p> <p align="center">(Print Name and Sign in Black or Blue Ink)</p>
<p>Offeror Phone Number:</p>	<p>Offeror FAX Number:</p>
<p>Offeror Federal I.D. Number:</p>	<p>Offeror E-mail Address:</p>
OFFERORS MUST RETURN THIS COVER SHEET WITH RFI RESPONSE	

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**REQUEST FOR INFORMATION
CLIA COMPLIANT BIOSAFETY LEVEL 2/2+ CONTAINERIZED MODULAR
LABORATORY SYSTEM GOODS & SERVICES
DEPARTMENT OF PUBLIC HEALTH & SOCIAL SERVICES, DIVISION OF PUBLIC
HEALTH, EPIDEMIOLOGY LABORATORY CAPACITY AND
GUAM PUBLIC HEALTH LABORATORY**

RFI/DPHSS – 2021 – 001

1.0 OBJECTIVES

The Epidemiology Laboratory Capacity (ELC) Program and Guam Public Health Laboratory (GPHL) under the Division of Public Health (DPH), and the Mosquito Laboratory under the Division of Environmental Health (DEH), Department of Public Health & Social Services (DPHSS) is soliciting information from interested vendors to procure a Clinical Laboratory Improvement Amendments (CLIA) Compliant Biosafety Level 2/2+ Containerized Modular Laboratory that is qualified and is able to work with ELC and GPHL to implement and maintain compliance with the Centers for Medicare and Medicaid Services (CMS) through the CLIA Law & Regulations Part 493 implemented under the CMS Division of Clinical Laboratory Improvement & Quality, within the Quality, Safety & Oversight Group, under the Center for Clinical Standards and Quality (CCSQ) and federal standards, scientific technical guidance for CLIA Compliant Biosafety Level 2/2+ Laboratory in the 6th Edition of the Biosafety in Microbiological and Biomedical Laboratories (BMBL 6th Ed. Revised June 2020) by Centers for Disease Control and Prevention (CDC), National Institute of Health (NIH) and the Department of Health & Human Services (HHS). DPHSS is to develop and implement a CLIA Compliant Biosafety Level 2/2+ Laboratory for all biosafety level 2/2+ laboratory testing performed on humans under Medicaid and Medicare care services. The compliance is also applied to CLIA Law United States code provided under CLIA 1988 102 Stat. 2903, Public Law 100-578, Food and Drug Administration (FDA) Modernization Act of 1997 111 Stat. 2324, Public Law 105-115, Sec. 123(h), Taking Essential Steps for Testing Act of 2012 126 Stat. 1483, Public Law 112-202, Sec. 2.

The DPHSS has established a committee that will draft the technical specifications that will form the body for an Invitation For Bid (IFB) for goods and services and other technical support services within the span of the awarded contract. The committee will use the information received as a result of this Request for Information (RFI) to assist in developing required specification and cost estimation.

All information submitted as a result of this RFI will be considered during the development of the IFB. Any of the responses to this RFI do not guarantee that the information offered will be integrated into the IFB, nor shall it prohibit any vendor from receiving or responding to the IFB when and if it is issued.

The specific objectives of ELC, DEH and GPHL to accomplish compliance with the CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory mandate(s) of CMS, CLIA, CCSQ, CDC, HHS, and FDA for CLIA Compliant Biosafety Level 2/2+ Containerized Modular

Laboratory goods and services for all laboratory testing performed in a biosafety level 2/2+ laboratory through this RFI are as follows:

- Identify vendors who already have established experience in developing and implementing a CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory goods and services that includes all necessary compliant biosafety level 2/2+ standards and capturing requirements for CMS, CLIA, CCSQ, CDC, HHS, and FDA which include but not limited to the six (6) points of CMS Survey Procedures and Interpretive Guidelines for Laboratories and Laboratory Services CMS.gov Appendix C som107ap_c_lab. The Compliant Biosafety Level 2/2+ Containerized Modular Laboratory Goods and Services System must be able to contain CLIA compliant equipment, operated by competent and trained laboratory personnel to perform biosafety level 2/2+ laboratory testing on human specimens, such as blood, body fluids and tissue, for the purpose of diagnosis, prevention, treatment of disease, assessment of health, as well as environmental health arboviral testing to support epidemiology and surveillance with the following, but not limited to:
 1. the biosafety level 2/2+ material of system;
 2. the quality control and biosafety level 2/2+ standards of goods;
 3. the timely delivery of the goods and service;
 4. the location of service delivery;
 5. the individual providing the service; and
 6. the time the service begins and ends.
- Identify vendors and consultants offering technical support services and goods for CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory;
- Identify vendors and consultants offering CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory System goods and services;
- Identify vendors offering CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory System goods and services that are able to assist the Guam Public Health Laboratory to obtain and maintain certification of compliance with the CMS CDC NIH HHS BMBL guidance;
- Identify a vendor that is OSHA compliant; and
- Identify a vendor who can provide a timeline of when and what goods and services are to be turnkey commissioned from awarded date, for a time frame of six to twelve months.

2.0 BACKGROUND INFORMATION

Guam DPHSS was created by 5 GCA, Government Operations, Chapter 3, Departments of the Government, Article 1, §3111, Department of Public Health and Social Services. ELC and GPHL fall under the Division of Public Health within the DPHSS agency. GPHL serves as the CLIA compliant public health laboratory for biosafety level 2/2+ laboratory testing services provided to Guam's eligible population. The Guam Environmental Public Health Laboratory falls under DEH.

3.0 CURRENT TECHNICAL INFRASTRUCTURE

GPHL is currently located temporarily at RANCARE Commercial building in Tamuning and worked with building owner to support dividing structures to comply with biosafety level 2/2+ standards and requirements. The prospective specific CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory System goods and services vendor will have to work closely with the ELC, GPHL, and DEH staff of DPHSS. The focus is to integrate the goods and services, and capture six points that will be used for compliance with certification of CMS standards.

4.0 STATEMENT OF NEEDS

ELC, GPHL, and DEH are seeking to determine specific CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory System goods and services in order to reach compliance with the CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory. Interested Vendors are asked to provide the following information:

- Describe the biosafety level 2/2+ equipment and material of system to provide a CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory System goods and services, include developing and implementing containerized modular laboratory facility for infectious diseases and arboviral testing performed by GPHL and DEH staff of DPHSS;
- Describe the equipment and accessories, quality and performance requirements to be supplied;
- Describe the necessary information and instructions for the proper operation, development and implementation of system and equipment;
- Describe the new fit to size biological safety cabinets, refrigerators, freezers, and workstations, meeting all applicable local and federal requirements;
- Describe the CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory System to be integrated into three (3) 2.4m by 12.2m (W x L) new, high cube and re-insulated containers, designed to allow larger openings to join rooms in adjoining containers;
- Describe the stainless-steel door frames, vents, and other penetration fittings;
- Describe the aluminum plate sub-floor over the structural steel floor framing of the containers allowing the safe movement and installation of heavy equipment;
- Describe the seamless vinyl floor and covered up wall to contain spills;
- Describe the aluminum and stainless-steel interior and exterior wall framing;
- Describe the consultancy services it offers for biosecurity and OSHA compliance issues;
- Describe the interior walls, ceilings, exterior and interior that meet and/or exceed CMS, CLIA, CCSQ, CDC, HHS, and FDA for CLIA compliant biosafety level 2/2+ containerized modular laboratory, detailed specifications will follow at a later date.

5.0 PLANNING

Development and Implementation Cost Estimate: Submit a budgetary cost estimate for goods and services for your CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory.

Container System Quality: Provide a description of how your system will comply with the guidance requirements by CMS, CLIA, CCSQ, CDC, HHS, and FDA.

Company Background: Provide your company's name and other names it may have used previously.

Company Experience: Provide information regarding where the proposed specific CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory System goods and services or if similar goods and services have been provided (successfully and unsuccessfully). Include the length of how long your company is able to provide these goods and services.

System Partners: Does your company provide an entire solution for specific CLIA Compliant Biosafety Level 2/2+ Containerized Modular Laboratory System goods and services, or does it utilize affiliated companies to provide portions of the services offered? If your company does outsource some of your services, please provide background and experience information for the respective affiliations.

6.0 RESPONSES

Inquiries: Inquiries of a technical nature may be directed to:

Department of Public Health & Social Services
Division of Public Health
Epidemiology & Laboratory Capacity Program
ATTN: Estelle A. Ada, Project Director
Email: estelle.ada@dphss.guam.gov

Submission: Submit or email a complete copy of the requested information with all the necessary attachments. The responses to this document must be received no later than **5:00 p.m., Chamorro Standard Time (GMT+10), Friday, October 29, 2021.**

Responses should be sent to:

Department of Public Health & Social Services
Division of Public Health
Epidemiology & Laboratory Capacity and Guam Public Health Laboratory
155 Hesler Place, Hagatna, Guam 96910

AND

Email: estelle.ada@dphss.guam.gov

Format: Please submit the requested information in the order found in this document.