

Purpose:

To request cost information related to the purchase of a cloud-based Laboratory Information Management System (LIMS). This LIMS should handle all clinical, environmental, and advanced molecular workflows for a high-volume state public health laboratory (PHL) while meeting the goals of CDC data modernization initiatives.

This is not a solicitation or a contractual document; the intent is simply to gather information for a future request for proposal. However, when a solicitation is created the respondents of this request will be notified immediately.

Instructions and Deadline:

Interested providers should send in the following four items:

- 1. A very brief **executive summary** (1-2 pages) of the respondent's' experience and qualifications as a LIMS provider.
- 2. An electronic **response** to the outline of DHEC's key functional and technical requirements (see pages 3-5). Vendors should respond to each requirement as unavailable (NO), available out of the box (OOTB), configurable (CON), or would require customization/hard coding (CUST). Any clarifying comments are welcome.
- One pricing estimate estimating work categorized as "minimum" in the table beginning on page
 Please label this estimate "Minimum Estimate". The Minimum Estimate should also include any fees associated with:
 - a. licenses
 - b. software with all modules
 - c. hosting
 - d. maintenance
 - e. trainings for end users and super users
 - f. training documentation and SOPs
 - g. project management
 - h. service implementation for interfacing LIMS with Cerner EHR, Instrument Interfaces (see below for sample list), HL7 interface to Electronic Disease Surveillance System and AIMS.
- 4. A **second estimate** that includes all technical requirements (minimum and optional). Please label this quote **"All Estimate"**.

Please submit electronic copies of responses to the following email addresses no later than 4pm EST on Friday, July 7 2023: clarkhc@dhec.sc.gov. Please use the email subject "LIMS RFI Response"

Questions regarding this RFI may be submitted in writing by no later than June 20, 2023 and 4pm EST to clarkhc@dhec.sc.gov. The subject line of the email must be "LIMS RFI Questions." Responses to all questions will be publicly posted at as an amendment to this RFI and will be posted on or before June 23, 2023 4pm EST.



Confidential Information: Any information submitted to DHEC is subject to the South Carolina Freedom of Information Act and is not considered confidential.

Background:

Program Overview:

The SC DHEC PHL provides diagnostic and analytical services for surveillance of infectious/communicable diseases, foodborne outbreak, biological and chemical analyses. The PHL is comprised of 11 specialty laboratories and 6 support sections:

- Chemistry
- Microbiology
- Virology and Serology
- Laboratory Support
- Logistics
- LIMS Administration
- Quality Assurance
- Laboratory Safety
- Assay Development

Test volume and workflows:

Annually, the South Carolina PHL performs over 1 million routine tests in the specialty areas of Advanced Molecular (Whole Genome Sequencing), Clinical Microbiology, Foodborne Pathogens, Mycobacteriology, Diagnostic Serology, Virology, Clinical/Newborn Screening, Analytical Chemistry, Vector-borne diseases, and Laboratory response network labs (BT and CT) to ensure public health and safety in South Carolina. In 2020, amidst the immense public health response to the COVID-19 pandemic, the PHL performed approximately 3.1 million reportable laboratory tests (including ~600,000 COVID-19 tests) on over 467,000 specimens.

Staff:

The PHL employs 120 personnel who require concurrent access to the proposed LIMS.

Web Portal Clients:

As the PHL serves many small facilities and clinics without their own EHR, it is necessary that an online portal exists for these clients to order tests from the PHL's lab testing menu, print and send in samples, receive reports after being notified/alerted by the LIMS.

Instrument Interface:

We have several instruments that require integration listed in the reference section below (page 6).

Executive Summary:



Briefly highlight the experience, qualifications, or certifications provider may have as a cloud-based LIMS provider. Please indicate whom the point of contact(s) should be if needed for any future communication including their title, email address, and phone number.

Other helpful information to include:

- a. Frequency of release cycle(s) for patches and major releases
- b. Size of community of fellow state PHL clients
- c. Any minimum system uptime guarantees offered to clients
- d. Typical timeline from contract signing to LIMS go-live in state public health laboratories
- e. General outline of typical implementation process

Minimum Technical Requirements:

#	Requirement	Category	Responses (No, OOTB, CON, CUST)	Additional comments
1	Should include typical LIMS functionality including out of the box functionality for the following: Specimen management, patient management, Client management, Testing Management, Reagent Supply Inventory, Instrument Interfacing, Quality Management, Reports Management, Roles and Permissions administration, Ad-hoc queries, Audit trails, Document Management	minimum		
2	Capable of FHIR or comparable API configuration	minimum		
3	Capable of supporting complete whole genome sequencing workflow (receiving, sample tracking, reporting).	minimum		



4	Web portal for test ordering and result retrieval for entire test menu	minimum	
5	Data modernization capable: highly interoperable to support ELR into data warehouse and EDSS, scalable, recorded uses of API architecture, supports data visualization and dashboarding within software or through enabling manual/automated export of records to other applications.	minimum	
6	highly configurable enabling end users (e.g DHEC LIMS admin team) to add new workflows or tests easily and rapidly to system.	minimum	
7	Routinely updated to ensure security of data systems and compliance to new security recommendations (e.g TLS 1.2 minimum compliance for AWS).	minimum	
8	Cloud based SAAS	minimum	
9	AWS or comparable server infrastructure	minimum	
10	No multi-tenancy	minimum	



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11	Data center routinely audited (e.g. SOC 2, type II) from third party	minimum		
12	Disaster recovery plan available and implemented	minimum		
13	Migration of legacy data into new system	minimum		
14	Implementation of chemistry workflows	minimum		
15	Implementation of Newborn screening workflows	optional		
16	Implementation of Inventory management module	optional		



Reference Instruments

Type of Instrument (# of known instruments)	Vendor	Lab
Miseq (4)	Illumina	Advanced Molecular
Miniseq (2)	Illumina	Advanced Molecular
Nextseq 1000 (1)	Illumina	Advanced Molecular
ClearDx	Clear Lab	Advanced Molecular
Architect i1000sr (1)	Abbott	Diagnostic Serology
Serology Panther (4)	Hologic	Diagnostic Serology
BioPlex (1)	Bio Rad	Diagnostic Serology
Geenuis (1)		Diagnostic Serology
Roche Cobas or Abbott Alinity (1)		Diagnostic Serology
Virology Panther (1)	Hologic	Virology
Biofire Torch (1)	Biofire	Virology
7500 Fast Dx (5- 10)	ABI	Virology
Elx-800 Plate reader	Qiagen	Virology
Diasorin Liaison XL (1)	Diasorin	Virology
Dynex DSW (1)	N/A	Virology
Versa Trek	Thermo Fisher	ТВ
Vitek MS 3 Maldi	Biomerieux	ТВ
Cepheid - Xpert 16 with 8 bays	Cepheid	ТВ

THIS IS NOT A SOLICITATION



Bac-Tec FX 40	BD	ТВ
(blood culture)		
Accuprobe	Genprobe	ТВ
7500 fast Dx	ABI	Clinical Microbiology
Cepheid Gene Xpert	Cepheid	Clinical Microbiology
Biomic	Giles Scientific	Clinical Microbiology
Vitek MS3	Biomerieux	Clinical Microbiology
VIDAS	Biomerieux	Food
VITEK 2	Biomeuriux	Food
Тетро	BioMerieux	Food
BAX Q7	Hygiena	Food
GeneUP	Biomeurieux	Food
Cephied Smart Cycler	Cepheid	Food
7500 Fast	ABI	Food
3M MDS		Food
QTOF X500R		Analytical Chemistry
7700 Series ICP MS	Perkin Elmer	Analytical Chemistry
ICP MS	Perkin Elmer	Analytical Chemistry

7 | Page



		1
GC MS 5975C	Agilent	Analytical Chemistry
GC MS 5977B		
GC MS 5973		
Q TOF	Sciex	Analytical Chemistry
LC MS	Sciex	Analytical Chemistry