Specifications for a Laboratory Information Management System for Alaska State Public Health Laboratories – drafted 11/26/2021

The Alaska State Public Health Laboratories (ASPHL) are seeking a laboratory information management system (LIMS) that can serve as the primary source of information regarding patient testing and reporting for up to 400,000 test results annually. A new system, if selected, should be implemented by June 2023.

ASPHL is made up of two distinct laboratories that reside in separate facilities 360 miles apart with one in Anchorage and the other in Fairbanks. ASPHL is accredited by the Centers for Medicare Services and follow the Clinical Laboratory Improvement Amendments of 1988 (CLIA). The ASPHL maintains a certificate of compliance for microbiology (bacteriology, mycobacteriology, parasitology, and virology), diagnostic immunology (syphilis serology and general immunology), and Chemistry (toxicology). Adopted LIMS systems must support and reflect the quality measures required to maintain accreditation.

CLIA addresses laboratory processes in three phases: pre-analytical, analytical, and post-analytical (Figure). Specific requirements are listed as part of nine primary categories in a logical workflow from specimen receipt through reporting. The system chosen may be hosted on local or cloud servers if specifications are met. The adoption of cloud-based systems must include mandatory additional security features and robust disaster recovery strategies (listed in specification #9).

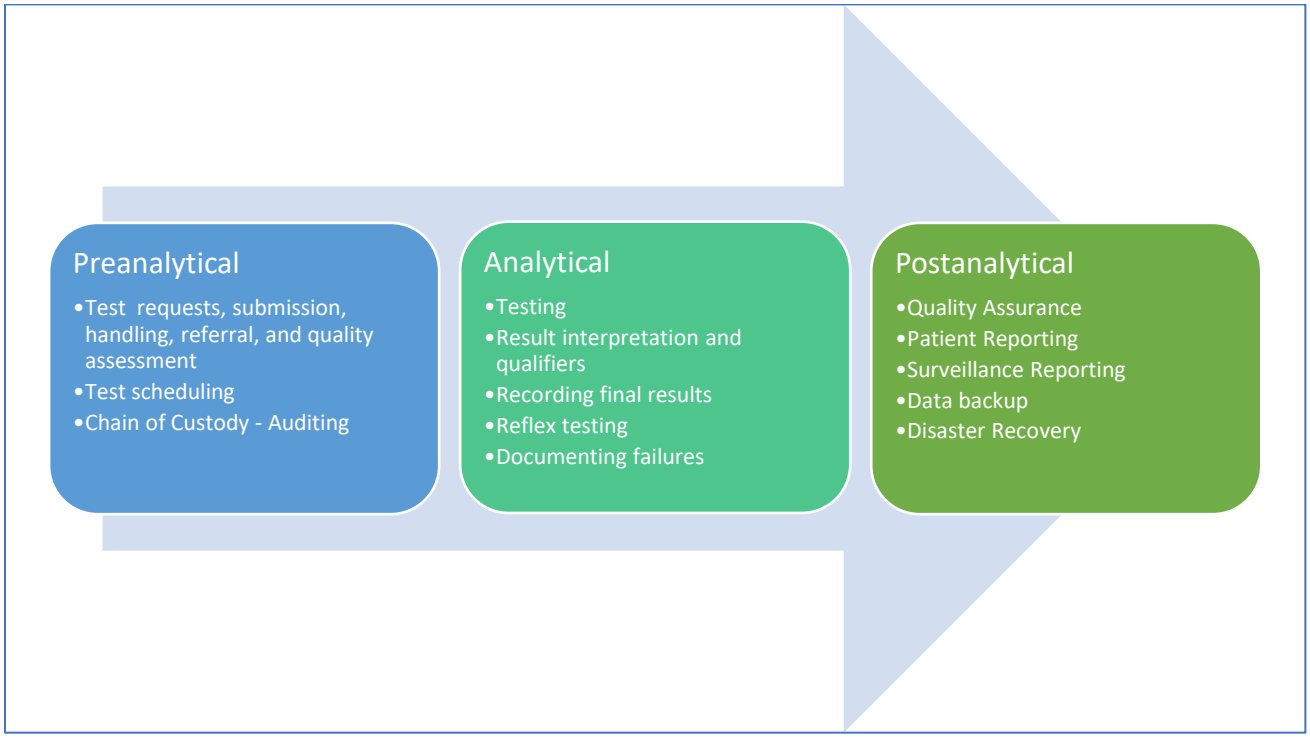

Figure. Required Clinical Specimen Workflow in LIMS

ASPHL Preanalytical LIMS Specifications

1. *The LIMS must demonstrate efficient processes to receive a clinical specimen and its associated test requests and information.*
   a. Test Requests
      i. The LIMS must obtain all written or electronic requests for patient testing from authorized persons. Complete paper or electronic requests must accompany each clinical specimen and be electronically retained for quick referral in the LIMS.
      ii. The request must include the name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life-threatening laboratory results or panic or alert values.
      iii. The request must include the patient's name or unique patient identifier, gender, date of birth, tests to be performed, and source of the specimen, and ad hoc auxiliary information critical for infectious disease epidemiology interpretation.
      iv. *Electronic Requests*
         - The LIMS must be capable of receiving electronic test request package messages from submitters and process the message using HL7 2.5.1 standard with appropriate LOINC and SNOMED and local codes, .csv file transfers, text, JSON, or submitter web portal.
         - Electronic requests must be paired with unique credentialing to authorize requests and maintain HIPAA-compliance.
         - The LIMS must meet multiple business partners' electronic messaging requirements for programs such as the health information exchange (HIE).

   b. Submission, handling, and referral
      i. LIMS informatics must demonstrate efficiency measures during clinical specimen receiving and accessioning. Options for individual sample and bulk sample ordering as well as pre-login must be available. Barcoding is required for positive identification and management of the entire clinical specimen lifecycle.
      ii. The LIMS must be capable of electronically defining and capturing required identifiers/core data elements (submitter information, package details, clinical specimen, tests, etc.) in the LIMS to initiate handling of any clinical specimen received or prepared, and add new data elements (i.e., metadata and demographics).
      iii. The LIMS must have the ability to pre-login clinical specimens for large planned clinical specimen collections to facilitate accessioning clinical specimens. The LIMS must be capable of handling receipt and processing of prescheduled clinical specimens.

iv. The LIMS must be able to be configured to refer specimens to other laboratories including maintaining supporting documents, memorandum of understandings, agreements, requisition forms, CLIA number documentation of the referral lab, chain of custody, and specimen routing. Electronic solutions for specimen referral are preferred.

c. Specimen quality assessment
   i. The LIMS must be capable of separating acceptable electronic requests from problematic ones, match acceptable requests to prescheduled submissions, and allow users to edit the data record for completeness. Unacceptable submissions received on paper requisitions should be able to be fully documented in LIMS.
   ii. The LIMS must be capable of sending and receiving acknowledgments between partners via electronic messages about the submission and physical clinical specimen when received. The acknowledgement must be capable of communicating issues related to metadata, test orders, and rejection information.
   iii. The LIMS must automatically track distribution of kits (for testing and/or clinical specimen collection), their expiration dates and associated forms (received and completed), and receipt of related clinical specimen/clinical specimens.

2. *The LIMS must handle laboratory test scheduling to maximize efficiency and test priority*
   a. The LIMS must be capable of handling adding electronic test requests, adding to test schedules, and prioritizing these test requests using laboratory-specified criteria.
   b. The LIMS must be capable of being configured to help drive various testing algorithms.
   c. The LIMS must remove and restore completed requests and transfer clinical specimens from active queues when they are finished.
   d. The LIMS must be capable of selecting tests and associated metadata for diversion to a reference or alternative laboratory if ASPHL tests are rendered inoperable.
   e. The LIMS must be capable of capturing specific data elements associated with process improvement indicators regarding test schedule.
      i. Create reports of test processing time by priority.
      ii. Create test status reports to monitor turnaround time, test volumes, and other quality metrics that evaluate laboratory performance.
      iii. Capable of receiving prescheduled surveillance clinical specimens in an efficient and timely manner and automate receipt and processing to predict workloads.

3. *The LIMS must handle clinical specimen tracking, chain of custody, and auditing*

a. The LIMS must track and document custody of the clinical specimen from receipt to disposal, storage, or return to submitter.
b. The LIMS must be capable of documenting a variety of clinical specimen receiving conditions such as temperature, specimens not chilled in transit, those that are expired, those that have leaked in transit, etc.
c. The LIMS must track the clinical specimen and its associated aliquots, their locations, and all steps in the clinical specimen's lifecycle. This includes clinical specimen storage, the duration for which a clinical specimen was removed for testing, and clinical specimen disposition.
d. The LIMS must track aliquot creation and hierarchy, including what tests were performed on which aliquot.
e. The LIMS must accurately record digital signatures of all staff that handled the clinical specimen and/or it's aliquots.
f. The LIMS must link demographic data on clinical specimens with data on chain of custody, clinical specimen integrity, clinical specimen handling and defined storage parameters.
g. The LIMS must demonstrate clear routing of the clinical specimen to a laboratory section, regardless of lab location.
h. The LIMS must be able to assign an identifier (batch number, worksheet number) to a group of clinical specimens that were analyzed together and assign associated identifiers for the instruments used for these analyses.
i. The LIMS must provide auditing tools to review all information associated with a particular specimen or aliquot of a specimen.

ASPHL Analytical LIMS Specifications

4. *The LIMS must prepare tests, process, record and verify test results.*
    a. Preprocessing
        i. The LIMS must assign one or more clinical specimens to individual tests or combinations of tests, instruments, runs and batches, prepare test queue, and prioritize through LIMS and/or other integrated systems.
        ii. The LIMS must allow for bidirectional/unidirectional interfaces between laboratory instruments and LIMS for large scale automation of clinical specimen transfers. Bidirectional capability is preferred. Instruments include, but are not limited, to: BioRad Evolis and BioPlex 2200, Thermofisher 7500 and Quantstudio real-time PCR thermalcyclers, the Becton Dickinson MGIT, Cepheid GeneXpert, and the Hologic Panther.
        iii. The LIMS must track reagents, test kits, QC lot numbers, manufacturers, expiration dates and associate them with batch or clinical specimens. If testing supplies/reagents are expired, the LIMS must alert the user.
        iv. The LIMS must identify clinical specimens received for individual patients and maintain a local master patient index that can be used to detect discrepancies and support ongoing treatment management and monitoring efforts of public health submitters.

v. The LIMS must identify duplicate patient entries.
vi. The LIMS must provide an integrated test directory for client reference including clinical specimen collection, storage and transport.
vii. The LIMS must produce standard barcoded labels for clinical specimens for different sized tubes as various stages of processing.
viii. The LIMS must grant users permission by laboratory sections, to approve, edit (amend and correct), and view a report. Users must be grouped and assigned permissions to roles. Only assign users the minimum appropriate permissions to complete their duties.

b. Testing and Analysis
   i. The LIMS must be able to meet changing business requirements by adopting new tests which would have multiple analytes and be able to customize reflexing logic based on measured results.
   ii. The LIMS must perform necessary calcuations for clinical specimens such as dilutions.
   iii. The LIMS must export all clinical specimen-associated data in flexible formats for further manipulation and analysis.
   iv. The LIMS must automatically flag and auto-assign tests to clinical specimens that need reflexing (individual or batch), and review and update clinical specimens and their results through the LIMS.
   v. The LIMS must auto-assign reflex testing to clinical specimens either individually or in a batch. LIMS must allow customized workflows to be created to match lab standard processes. LIMS processes should follow testing algorithms in their entirety.
   vi. The LIMS must populate test results data (i.e., clinical specimen and Quality Control (QC)) from instruments (see 4.a.ii) back into LIMS through a seamless integrated process.
   vii. The LIMS must perform verification for QC and test results for individual clinical specimens or batches within the LIMS and report QC parameters through the LIMS (see category 7).

c. Results
   i. The LIMS should have a system for alerting users (i.e., e-mail, pop-ups, SMS messages based on tests, results, patients, outliers, quality control, etc.) of significant results/outliers and other lab important information.
   ii. The LIMS must track reports created, the receiver of the report, the version it was created in, and maintain those logs.
   iii. The LIMS should be capable of blocking electronic messaging for clinical specimens which should not be reported (e.g., proficiency clinical specimens, surveillance clinical specimens, and validation clinical specimens). For instance, a user should be able to schedule result holding features manually.
   iv. The LIMS must be capable of auditing in easily understandable manners all data that was entered for the patient clinical specimen and all changes in the LIMS system.

ASPHL Postanalytical LIMS Specifications

5. *The LIMS must prepare and distribute patient reports accurately in a HIPAA and CLIA compliant manner.*
    a. General reporting
        i. LIMS must be capable of reporting in a variety of ways including by paper, fax, auto-fax, web portal (ETOR, electronic test ordering and reporting), and electronic messaging.
        ii. LIMS must modify and verify submitters and data requestors authorized to receive results through LIMS and keep a log of submitters.
        iii. Electronically modify and verify submitters and data requestors authorized to receive results by referencing a test/data requestor index.
        iv. Submitters using a LIMS-derived web portal must be able to query and filter their own data.
        v. The LIMS must have the ability to store and backup large amounts of accumulated documents, reports, and requisitions that can be quickly retrieved (i.e., content management).
        vi. The LIMS must use multiple standardized vocabulary formats and function as an integration broker (PHINVADS), integrate local and new codes and vocabulary standards, flexibly utilize vocabulary standards across parties (i.e., using different codes to report the same test to different entities such as from submitters to state to CDC).

    b. Electronic reporting
        i. LIMS must be capable of submitting results via a secure electronic message format. The LIMS must electronically submit results (i.e., via HL7 standards) of tests performed on the clinical specimen to recipients and electronically authenticate test results.
        ii. LIMS must be capable of creating an electronic message for test results using agreed-upon standards (i.e., HL7 version 2.5.1, upgradable to future versions of HL7 as needed) and vocabulary for message creation.
        iii. LIMS must be capable of sending an electronic message for test results using agreed-upon standards and vocabulary (i.e., SNOMED, LOINC, and CDC's PHINVADS) for message transmission.
        iv. LIMS must receive an acknowledgement about delivery of the electronic message using agreed-upon standards and vocabulary for message receiving.
        v. LIMS must comply with submitters' data exchange format requirements for electronic results submittal and reporting based on different business rules.

6. *The LIMS must be capable of data exchange and interoperability*
    a. The LIMS must be capable of exchanging data electronically with various entities such as other PHLs and federal, state, and local partners. This exchange must be flexible enough for customization to meet future interoperability requirements as necessary. Current configurations are based on Oracle packages but new methodologies could be adapted.
    b. LIMS must exchange bidirectional data, such as receiving electronic orders and test results with health facilities, sending electronic orders, and receiving results (i.e., exchange with healthcare providers, CDC and other PHLs using HL7 version 2.5.1 and upgrades, as needed). Current configurations utilize Rhapsody but new methodologies of data transfer could be adapted.
    c. LIMS must send automated electronic results to partners based on agreed-upon protocols.
        i. LIMS must have options to provide data electronically through a web portal for data and information exchange.
        ii. LIMS must create and manage data exchange channels in partnership with state and national efforts such as statewide HIEs.
        iii. LIMS must meet external reporting requirements of public health agencies and health departments using required electronic laboratory reports (ELR) standards. These requirements include the ability to:
            - Adopt required message specifications (e.g., Meaningful Use). Meaningful use refers to the minimum requirements (as defined by the final rule issued by the Centers for Medicare and Medicaid Services) that providers must meet through their use of certified Electronic Heath Record (EHR) technology.
            - Identify reportable laboratory events.
            - Deliver secure automated ELR to public health authorities.
            - Generate required HL7 messages for ELR messaging.
            - Use secure ELR transport mechanisms.
    d. LIMS must send messages using different secure transports such as Virtual Private Network (VPN), PHIN MS, bidirectional interfaces with instrumentation, or HIE Direct. Current configurations utilize Rhapsody (TLS1.2 and web certificates) sending messages via TCP Client/Server, Web Services, and Secure FTP.
    e. LIMS must map Logical Observation Identifiers Names and Codes (LOINC) for tests and Standardized Nomenclature of Medicine (SNOMED) codes for test results to national and local notifiable diseases and conditions by integrating with Nationally Notifiable Conditions Tables (i.e., RCMT within PHIN VADS).
        i. Interfacing the LIMS must be possible with a message broker that maps local codes to standard codes, validates that all required data elements are present, generates valid message structure and content, and securely transmits the message using the agreed-upon transport mechanism. The message broker/integration engine can be a separate stand-alone capability or integrated with the LIMS.

f. LIMS must connect to APHL advocacy data systems (e.g., PHLIP, AIMS).
g. The LIMS must communicate with other non-legacy systems (e.g., Pulse Net) and maintains real-time electronic access to the data residing in these systems.
h. LIMS must handle billing and financial transactions for testing or facilitate electronic linkages between the LIMS and accounting systems.

7. *The LIMS system must have integrated ability for statistical analysis and surveillance*
   a. LIMS must electronically capture and store both demographic data/metadata associated with clinical specimens/clinical specimens from submitters and non-test-specific data.
   b. Users must be able to add metadata fields and electronically transmit these data to specified users.
   c. LIMS must electronically query flagged data to perform statistical analyses and charting.
      i. LIMS must apply QC charting and statistical methods for all clinical specimens and analyze test results and data patterns (i.e., Levy-Jennings, cusum plots, Westgard Rules).
   d. Users must be able to query and create user-defined extracts of data on an ad hoc basis for electronic transmittal to specified formats.
   e. LIMS must perform analyses and study trends on performance data.
   f. LIMS must be able to be integrated with GIS data on clinical specimens, clinical specimen data, test results, and tabulated results for a given geographic area.
   g. LIMS must be able of handling sending results to multiple entities as needed to comply with diagnostic and surveillance reporting. For instance, a patient specimen for diagnostic influenza may also receive genetic characterization results from CDC. The LIMS must have the ability to report diagnostic results but not surveillance information on the same specimen.

8. *The LIMS must store and analyze quality control (QC) for the purposes of quality assurance (QA) management*
   a. LIMS with or without other integrated systems must electronically set up and capture raw data associated with clinical specimen testing, including QC parameters and associated data elements (e.g., the creation and maintenance of a master record for each QC test by instrument/method, parameters for reagent, and clinical specimen conditions).
   b. LIMS must electronically extract and transmit QC data associated with clinical specimen results.
   c. LIMS with or without other integrated systems must track, analyze, trend, export, and create reports, and electronically verify all QC measures associated with all tests and clinical specimens. LIMS must electronically revise output formats and data as required for trending, analyses, and reporting.
   d. LIMS must collect QC data associated with analytical sequences within the LIMS and validate results prior to reporting by comparing QC data to method

measurement quality objectives (e.g., recovery percent, completion of requested tests, frequency and sequence of blanks, spikes, and duplicates, etc.).

e. LIMS must validate data and provide qualifiers for test results qualifiers that indicate whether test results fail to meet QC requirements, meet QC requirements with notation, or fully meet QC requirements.

f. LIMS must restrict use of expired materials through data tracking.

9. *The LIMS System must be fully supported by the vendor and provide excellent customer service*

   a. Vendors must be capable of assisting with the transition to the new reporting system. This includes full support for reestablishing HL7 interfaces, instrument interfaces, and rebuilding reporting functionality for all tested analytes at the laboratory (see Appendix A).

   b. Maintenance costs should cover:
      - 24/7 emergency support such as down server on loss of production.
      - Non-emergency support must be available during working hours and have a ticket tracking system. Need to respond in agreed upon timeframe.
      - Vendors should assist with upgrades and patches to ensure up-to-date functionality.

   c. The vendor must provide user training

   d. The vendor must be able to meet State security requirements.

   e. Database backup and recovery systems should be supported, robust, inclusive, and automated.

   f. *Cloud-based systems*

      i. Systems that intend to store personal health information and patient results off site are expected to be secure and accessible to key entities. Cloud-based systems that do not meet State of Alaska security needs will not be considered. This includes acceptable foundations and descriptions such as:

         1. <u>Access control policies and procedures</u> including account management, access enforcement, information flow enforcement, separation of duties to prevent malevolent activity without collusion, session lock and termination conditions, least privilege or description of how the system only allows authorized accesses for users which are necessary to accomplish specific tasks, remote access including third-party access for electronic message transfer (i.e., Rhapsody, Biztalk, HIE, AIMES, CDC, etc.), and access control for mobile devices.
         2. <u>Security awareness and training policy and procedures</u> including details of security awareness training, role-based security training, and security training records.
         3. <u>Audit and accountability policy and procedures</u> including tracking of audit events and how these are displayed to end users, content of audit records, audit storage capacity, access control policy and procedures, audit review, analysis, and reporting, audit reduction and report generation, and audit record retention

4. Security assessment and authorization policy and procedures including system interconnections, plans for continuous monitoring, contingency planning policy and procedures, contingency plan training, contingency plan testing, alternate storage sites, alternate processing sites, telecommunications services, information system backup, and information system recovery and reconstitution
5. Identification and authentication (organizational users) and policies associated with device identification and authentication, identifier management, authenticator management, and authenticator feedback
6. Incident response policy and procedures such as incident response training, incident response testing, incident handling, incident monitoring, incident reporting, incident response assistance
7. System maintenance policy and procedures such as controlled maintenance, and maintenance personnel,
8. Media protection policy and procedures such as media access, media storage, media transport, media sanitization
9. Physical and environmental protection policy and procedures such as physical access authorizations, physical access control, access control for transmission medium, access control for output devices, monitoring physical access, visitor access records, alternate work site, and location of information system components
10. Security planning policy and procedures such as personnel security policy and procedures, position risk designation, personnel screening, personnel termination, personnel transfer, access agreements, third-party personnel security, and personnel sanctions
11. Risk assessment policy and procedures and security categorization.
12. Acquisition process such as external information system services, transmission confidentiality and integrity, and cryptographic key establishment and management
13. System and information integrity policy and procedures such as malicious code protection, information system monitoring, security alerts, advisories, and directives, software, firmware, and information integrity, spam protection and information input validation

Appendix A: List of analytes reported by the Alaska State Public Health Laboratories

Please note that analytes listed below may represent more than one reportable test methodology. Please visit https://dhss.alaska.gov/dph/Labs/Documents/LaboratoryTests.pdf for more details. Rank in terms of experience in configuring or reporting out these analytes of public health importance (*0 = no experience to 3 = extensive experience*).

Analytes/Experience Rank	**0**	**1**	**2**	**3**
Chemical Terrorism Events				
Cyanide				
Enteric stool culture				
Acetone				
Acid fast stain for Cystoisospora (Isospora), Cyclospora, and Cryptosporidium oocysts				
Adenovirus				
Aerobic bacterial culture identification				
Aeromonas spp				
Bacillus anthracis				
Blood parasites				
Botulinum neurotoxin, *Clostridium botulinum*				
Brucella spp.				
Burkholderia mallei, Burkholderia pseudomallei				
Campylobacter spp.				
Chikungunya virus				
Chlamydia & Gonorrhea				
COVID-19 (SARS-CoV-2, coronavirus disease 2019				
Coxiella burnetii				
Dengue virus				
Diphtheriae culture				
Ebola virus				
Ectoparasites				
Enterovirus				
Escherichia coli O157				
Ethanol				
Ethylene Glycol				
Francisella tularensis				
Giardia & Cryptosporidium				
Hepatitis A virus (HAV)				
Hepatitis B virus (HBV)				
Hepatitis C virus (HCV)				
Haemophilus influenzae				
Human Immunodeficiency Virus (HIV)				

Appendix A. *Continued*.

Analytes/Experience Rank	0	1	2	3
Herpes Simplex Virus (HSV)				
Human metapneumovirus				
Influenza virus				
Isopropanol				
Lead (Blood)				
Measles (Rubeola) virus				
Metals/Elements in Urine				
Neisseria meningitidis				
Pinworm Exam				
Rhinovirus				
Shiga-toxin testing (STEC)				
Trichomonas (NAAT)				
Yersinia pestis				
Methanol				
Middle East Respiratory Syndrome Coronavirus (MERS-CoV)/Novel Coronavirus 2012				
Mumps virus				
Mycobacterium Culture (Tuberculosis, TB)				
Neisseria gonorrhoeae Culture				
Norovirus				
Orthopox Viruses				
Ova & Parasite Exam				
Parainfluenza Virus				
Pertussis PCR				
Plesiomonas shigelloides				
Rabies				
Reference Bacterial Culture				
Respiratory Pathogen Panel (RPP)				
Ricin				
Ricinine				
Respiratory Syncytial Virus (RSV)				
Rubella				
Salmonella serotyping				
Shigella Serotyping				
Streptococcus Isolates				
Syphilis Screen – Rapid Plasma Reagin (RPR)				
Toxic Alcohols & Glycols				
Varicella Zoster Virus				
Vibrio species				
Whole Genome Sequencing (WGS)				
Yersinia enterocolitica				
Zika Virus				

Appendix B: Additional Aspects of the LIMS Environment to Address

In addition to listed specifications, please specifically address the issues found in this appendix.

1. The successful vendor will demonstrate an understanding of the complex nature of software/system upgrades in the Public Health LIMS environment.

2. Vendor-developed LIMS software upgrades and modifications provided to ASPHL must include an electronic copy of the test suite the vendor used to validate system compliance with expected performance. LIMS version upgrades and new features should utilize an implementation strategy which provides minimal interruptions to normal laboratory operations.

3. Instrument and Electronic Laboratory Reporting interfaces supported by the vendor must include an opportunity to verify software performance without forcing ASPHL to take instruments "offline" or requiring ASPHL to maintain instruments dedicated to application interface testing.
    a. What assurance does the State of Alaska have that the vendor has tested their system thoroughly?
    b. Are test environments available on a trial-basis?

4. The State of Alaska will be clear upon selection of a vendor the roles and responsibilities of both parties.
    a. Can end users make modifications/customizations to vendor coding? How does this affect the relationship between the vendor and the State of Alaska in terms of cost and/or warranty?

5. Training in a new LIMS environment will be adequate and continual and provided by the vendor.

6. Agreement on terms of evaluation such as subject matter expert reviews, quality assurance audits, and frequency of these audits.