AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

BPA NO.	1. CONTRACT ID CODE	PAGE	OF PAGES
		1	139

2. AMENDMENT/MODIFICATION NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQ. NO.	5. PROJECT NO. (if applicable)
A00001	07-22-2016		None

6. ISSUED BY	CODE	7. ADMINISTERED BY (If other than Item 6)	CODE
Department of Veterans Affairs Network Contracting Office 20 5115 NE 82nd Ave, Suite 102 Vancouver WA 98662	260	Department of Veterans Affairs Network Contracting Office 20 5115 NE 82nd Ave, Suite 102 Vancouver WA 98662	

8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)	(X)	9A. AMENDMENT OF SOLICITATION NO.
To all Offerors/Bidders		VA260-16-Q-0037
	X	9B. DATED (SEE ITEM 11) 07-22-2016
		10A. MODIFICATION OF CONTRACT/ORDER NO.
		10B. DATED (SEE ITEM 13)
CODE / FACILITY CODE		

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

[X] The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers [ ] is extended, [X] is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods:

(a) By completing Items 8 and 15, and returning 1 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided each telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required) None

13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS, IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	
	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation date, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor [ ] is not, [ ] is required to sign this document and return 1 copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

A. Please see attached document.

Except as provided herein, all terms and conditions of the document referenced in Item 9A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
		Mary Accomando Contracting Officer	
15B. CONTRACTOR/OFFEROR (Signature of person authorized to sign)	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA BY (Signature of Contracting Officer)	16C. DATE SIGNED

A. The purpose of this amendment is to address the below concerns:

a. Remove the Technical Requirements on paragraph B.13, page 11 to paragraph 2, page 26. Replace the original Technical Requirements by the attached document.

b. Remove the (attachment D.1) Estimated Test volumes and replace with corrected (attachment D.1) Estimated Test Volumes dated 7/25/16.

c. Sub-factor 1 and 2 on page 44 of the solicitation is replaced with the following:

Sub-Factor 1 – Operational and Technical Features: The Contractor shall submit documentation illustrating: Technical capabilities to ensure they meet the following requirements. Contractor shall submit documentation illustrating the following minimum standard capabilities:

A. General Requirements
B. Primary Analyzer-Base equipment
C. Operational and Technical Features
D. Testing Instrumentation
E. Contractor Middleware management system
F. Hardware Features
G. Method Performance/Validation Requirements
H. Reference Range
I. Reports
J. Support Features

Sub-Factor 2 - Equipment Availability: The evaluation will consider available equipment and accessories to support the variances in requirements included in the Technical Evaluation Plan. This includes hardware and software available to support the estimated requirements as well as the ability to provide redundancy. Describe and justify recommendations for the type and number of systems, equipment, methodologies, accessories and software/hardware/middleware that will be utilized to support each VISN20 Chemistry and Immunochemistry CPRR testing site.

A. Describe reagent performance parameters
B. Describe testing methodologies
C. Describe unit configuration and ability to adapt to changes in volume and test mix
D. Describe your interconnection for exchanging data
E. Provide the necessary information to complete a signed MOU (Memorandum of Understanding) with the VA Network and Security Operations Center (NSOC)

d. The due date of the solicitation is clarified to be 08/15/2016. All solicitations must be received by 08/15/2016 at 04:00 PM Pacific standard time.

e. All vendor questions received to date are hereby addressed on attachment D.3.

f. Floor plans are attached as attachment D.4 through D.13 are hereby incorporated into this solicitation.

g. All other terms and conditions in this solicitation outlined in VA260-16-Q-0037 remain in effect.

See attached document: D.1 VISN 20 Estimated Test Volumes 7-25-16.

See attached document: Visn 20 Chemistry Immunochemistry Technical Requirements.

See attached document: D.3 Chemistry RFQ Questions 7-26-16.

See attached document: D.4 American Lake.

See attached document: D.5 Eugene HCC Lab.

See attached document: D.6 Lab-dimens - Spokane.

See attached document: D.7 LAB-North-Door Spokane.

See attached document: D.8 Laboratory Room 164 Floor Plans - White City.

See attached document: D.9 Portland lab layout.

See attached document: D.10 Schematic Plan-24X36 - BOISE.

See attached document: D.11 Seattle New Chemistry.

See attached document: D.12 Walla Walla.

See attached document: D.13 Alaska VA Laboratory Floorplan.

TECHNICAL EVALUATION PLAN – Clinical Laboratory Chemistry Immunochemistry Instrumentation

1. BPA LANGUAGE

1.1. **INTENT:** Pursuant to Federal Supply Schedule (FSS) and FSS Contract Clause I-FSS-646, it is the intent of the Department of Veterans Affairs, (herein afterwards referred to as VISN 20 to establish a Blanket Purchase Agreement (BPA) for Automated Chemistry Immunochemistry Instrumentation. The BPA shall be under the FSS Contract, Federal Supply Class (FSC) Group 66 III Cost Per Test (CPT)/ Cost Per Reportable Result (CPRR), Clinical Laboratory Analyzers. The Government will award a CPRR BPA to a single Contractor for Automated Chemistry Immunochemistry Instrumentation. Contractor agrees to the following terms of the BPA exclusively with the VISN facilities listed by Attachment/herein and awarded in the final BPA. However, as requirements change, facilities within VISN may be added or deleted by supplemental agreement of the Government and the Contractor. Additional tests/reagents/instrumentation may be added to the BPA as new technology becomes available on the market and added to the base FSS contract.

1.2. **ORDERS:** All products ordered under this BPA, placed against the Federal Supply Schedule Award Contract(s), are subject to the terms and conditions of the FSS contract. This BPA does not obligate any funds. The Government is obligated only to the extent of authorized orders actually issued under the BPA by authorized individuals.

1.3. **PRICES AND TERMS**: VISN will provide an estimated volume by test as reflected in Attachment D.1 for each site. Pricing is based on the AVERAGE daily test volume per instrument/analyzer for each facility. The Government estimates the volumes per facility as listed in Attachment D.1, but does not guarantee volumes as listed; they are estimates ONLY.

1.4. **TERM OF AGREEMENT**: This will be a single award, firm-fixed price BPA with one base year and four, one year options and shall be effective for the term of the FSS Contract including additional FSS extensions. The Contractor is required to immediately notify the CO (Government Contracting Officer), in writing, if at any time the FSS contract upon which this BPA is based, is no longer in force. The resulting BPA shall be automatically extended for the remaining term of the BPA without modification upon any extensions of the Contractor's FSS contract. In addition, where a new FSS contract replaces Contractor's current FSS contract, the resulting BPA may be reassigned under the new FSS contract for the remaining term of the BPA with written agreement between Contractor and the contracting officer. This BPA is not a contract. If the Contractor fails to perform in a manner satisfactory to the CO, this BPA may be canceled with thirty (30) days written notice to the Contractor by the CO. The Contractor shall also reserve the right to terminate this contract with 30 days notification to the CO. This BPA shall be reviewed annually. **VISN intends to establish the base year of the agreement for the period of** 10/1/2016 **through** 9/30/2017.

1.5. **IDENTIFICATION:** Delivery Orders issued shall be identified by their applicable FSS Contract Number and BPA Number. FSS & BPA identification numbers are assigned through the VHA Procurement Activity; CO: click here to insert identification numbers (BPA & FSS).

1.6. **ORDERING METHOD**: The participating facilities may order products via Electronic Data Interchange (EDI), telephone, facsimile or other written communication, identifying the products by number, quantity, purchase price, address for delivery, and any special instructions.

2. DESCRIPTION/SPECIFICATIONS/TECHNICAL EVALUATION PLAN

2.1. SCOPE OF PROCUREMENT:

2.1.1. The desired instrumentation shall have the capability of performing or reporting the clinical parameters as defined in the Technical Evaluation Plan. The instrument shall have random access capability (if discrete testing is required) and be able to simultaneously perform the complete profile as described below meeting the performance characteristics for accuracy and precision as defined by the 1988 Clinical Laboratory Improvement Act (CLIA) and the Clinical and Laboratory Standards Institute (CLSI).

2.1.2. Equipment must maintain, or preferably reduce the number of work stations or overall labor required to accomplish the required testing by each laboratory.

2.1.3. If Contractor offers an integrated family of analyzers, the technical evaluation panel will determine if instrumentation proposed meets needs of using facility.

2.1.4. Equipment shall be acquired for each of the clinical laboratories located at the VISN facilities listed in Attachment D.1.

2.1.5. The Contractor is required to provide a continuously stocked inventory of reagents, standards, controls, supplies, disposables and any other materials, to include replacement parts, required to properly perform tests on the equipment such that equipment operations are not interrupted. These items shall be of the highest quality, sensitivity, specificity and tested to assure precision and accuracy. Expiration date must be clearly marked on reagent, standards and control containers. Unexpected changes in methodology/technology shall be at the expense of the Contractor. Alert/Notification of any delays in shipment as well as any or all technical advisory/recalls/alerts, prior to or simultaneously with field alerts should be forwarded to the designated individuals determined at contract award.

2.1.6. The Contractor will provide a detailed list of all parts and supplies that are to be purchased by the facility and are not included in the CPRR contract.

2.1.7. Special handling for emergency orders of supplies: In the event that the supplies are found to be defective and unsuitable for use with the Contractor's equipment, or the Contractor has failed to comply with the requirements for routine supply delivery, the Contractor is required to deliver the supplies within 24 hours of receipt of a verbal order for emergency delivery. If either circumstance has occurred, the Contractor shall deliver to the Government site in the most expeditious manner possible without additional cost to the Government, the necessary consumables in sufficient quantity as required to allow operation of the Contractor's equipment for one week (under normal Government test load volume). If additional requests for emergency supply delivery are required by the Government, they shall be honored by the Contractor until the arrival at the laboratory of the monthly standing order/routine supplies delivery.

2.2. DEFINITIONS:

2.2.1. **Cost per Patient Reportable Result (CPRR)**- *as defined in the Federal Supply Schedule FSC Group 66, Part III, Cost-Per-Test Clinical Laboratory Analyzers* - Contractors are required to provide a price for a reportable patient result. The per patient reportable result price shall include costs covering: (1) 5 year equipment use, (2) all reagents, standards, quality controls, supplies, consumable/disposable items, parts, accessories and any other item required for the proper operation of the Contractor's equipment and necessary for the generation of a patient reportable result. This per patient reportable result price shall also encompass all costs associated with dilution; repeat and confirmatory testing required to produce a single patient reportable result. It shall also include the material to perform as well as all other costs associated

with quality control, calibration and correlation study testing that is prescribed by the Clinical and Laboratory Standards Institute (CLSI). (3) all necessary maintenance to keep the equipment in good operating condition (This element includes both preventive maintenance and emergency repairs) and (4) training for Government personnel. Contractors shall provide delivery, installation and removal of equipment at no additional charge.

2.2.2. **Cost per Test (CPT)-** *as defined in the Federal Supply Schedule FSC Group 66, Part III, Cost-Per-Test Clinical Laboratory Analyzers* – Contractors are required to provide a price for each test that can be performed on its equipment. The per test price shall include costs covering (1) 5 year equipment use, (2) all reagents, standards, quality controls, linearity material, calibration verification material, supplies, consumable/disposable items, parts, accessories and any other item required for the proper operation of the Contractor's equipment and necessary for the generation and reporting of a test result, (3) all necessary maintenance to keep the equipment in good operating condition (This element includes both preventive maintenance and emergency repairs) and (4) training for Government personnel. Contractors are required to provide delivery, installation and removal of equipment at no additional charge.

2.2.3. **Business Associate Agreement (BAA)-** A business associate is an entity, including an individual, company, or organization that, on behalf of VHA, performs or assists in the performance of functions or activities involving the use or disclosure of PHI, or that provides certain services involving the disclosure of protected health information (PHI). VHA is a covered entity under the HIPAA Privacy Rule (Privacy Rule). HIPAA regulations require VHA to execute HIPAA-compliant BAAs with certain entities that receives, uses, or discloses VHA PHI in order to perform some activity for VHA. These BAAs obligate VHA business associates to provide the same protections and safeguards to PHI that is required of VHA under the Privacy Rule.

2.2.4. **Specimen Processing Automation Line –** Pre-analytical processing and archival processing equipment offered to each of the VA laboratories listed on attachment D.1 that will automate these specimen processing functions, as indicated in the general requirements section.

2.2.5. **Specimen Management System** - A component of the Processing Automation Line that directs and manages the operation and components of the pre-analytical processing/automation system.

2.2.6. **Contractor Middleware Management System** - A server installed with software that interfaces the testing instrumentation to the Laboratory Information system and is able to receive, process and send data following CLSI guidelines.

2.2.7. **Throughput** – The speed that the equipment processes and/or operates reported in units per hour.

2.2.8. **TEST MENU**: Refer to Attachment D.1 for desired test menu and estimated annual volumes by laboratory.

2.2.8.1. **Special testing requirements:**

2.2.8.1.1. HIV Methodology shall be 4th generation or higher.

2.2.8.1.2. Rapid testing for cardiac marker Troponin (15 minutes or less)

2.2.9. **GENERAL REQUIREMENTS:**

2.2.9.1. Primary analyzer(s) – Base equipment offered that shall fully support the scope of operations (minimal requirements). Depending upon the technical functionality and the capabilities of the individual manufacturer's instrumentation, one analyzer or multiple analyzers may be required to meet the productivity specifications defined herein. In those instances, the additional analyzer(s) shall, likewise, be

considered primary instrumentation and shall meet all of the technical specifications of this solicitation. Those additional analyzer(s) offered meeting the definition of a primary analyzer may serve as a back-up analyzer (see definition below) and shall replace the requirement for offering that category of equipment.

2.2.9.2. (Applies only if selected) Back-up Analyzer; equipment required in support of operations for the VA laboratories in the event the primary analyzer(s) becomes non-operational/non-functional. This category of equipment shall only be operated during periods of time when the primary instrumentation is not available for use. As such, the requirements for consumable supplies, i.e. reagents, quality control material, calibrators, etc., shall be minimal and corollary to the successful operation of the primary instrumentation. Specific tests that require back-up performance are listed in Attachment D.1. Additional primary analyzers required for the performance of daily workload are not considered back-ups for the purposes of consumables, reagents, etc.

2.2.9.3. Installation (applies only if selected): Contractor will provide an alternate site for validation of the instrumentation if space is not available for side-by-side validation with existing instrumentation. Contractor will perform a mini-validation when instrumentation is installed in the final workspace.

2.2.10. **Operational and Technical Features-** The instrumentation offered shall be approved by the Food and Drug Administration (FDA) and Contractor's FSS Contract at the time of proposal submission and have the following:

2.2.10.1. **Primary Processing Automation Line Instrumentation**. Offering for an Integrated Clinical Laboratory Chemistry/Immunochemistry Instrumentation and Robotics System (Automated track or line) in accordance with the requirements of each respective laboratory, as listed in Attachment D.1, shall have the following:

2.2.10.1.1. Sufficient capacity and throughput to meet the volume and service demands as defined in Attachment D.1.

2.2.10.1.2. Includes a specimen management system to manage and track sample progress and position.

2.2.10.1.3. Specimen archival through mapping of specimens to racks; for easy retrieval once moved off-line. (Specimen Management System).

2.2.10.1.4. The ability, based on test requests, to sort and route specimens. (Line/track system/ Specimen Management System)

2.2.10.1.5. The ability to send the primary tube or processed aliquots by means of a tracking system to the proper testing instrumentation to maximize efficiency and to maintain and standardize turnaround times of results. (Line/track system/ Specimen Management System)

2.2.10.1.6. Minimal operator intervention to introduce STAT specimens or to change a routine specimen

2.2.10.1.7. The ability to detect processing errors and provide error notification. (Specimen Management System)

2.2.10.1.8. The ability to separate the serum/plasma from the blood cells through the process of centrifugation. (Centrifuge)

2.2.10.1.9. Ability to detect short samples and clots (Aliquoter)

2.2.10.1.10. The ability to remove caps from blood collection tubes. (Decapper)

2.2.10.1.11. The ability to recap and/or reseal - tubes. (Recapper)

2.2.10.1.12. The ability to remove an aliquot of serum/plasma using disposable pipette tips to prevent contamination and move into another specimen tube or cup for analysis. (Aliquoter)

2.2.10.1.13. The ability to print bar code labels and label daughter (aliquot) tubes to maintain positive specimen identification.

2.2.10.1.14. The ability to connect all primary and back-up testing analyzers offered in accordance with Attachment D.1

2.2.10.1.15. Ensure immediate availability of primary tube after processing.

2.2.10.1.16. The ability to auto-archive, store and retrieve specimens from 2-8 degrees centigrade. (Refrigerated archival storage). Capacity to be determined by Attachment D.1.

2.2.10.1.17. Barcode reader stations must have the following capabilities:

2.2.10.1.17.1. The accuracy of the barcode reading must have less than a 1.0 % failure rate.

2.2.10.1.17.2. Equipment must be able to support multiple barcode formats (Code 39, Code 128) that may be enabled concurrently.

2.2.10.1.17.3. Equipment must accept, at a minimum, 10 characters in specimen identifier that is alpha, numeric, and/or alphanumeric concurrently.

2.2.10.2. **Testing Instrumentation** The testing instrumentation must be an integrated platform with flexible, components that can be upgraded and or reconfigured on site and is approved by the Food and Drug Administration (FDA) and on Contractors' FSS Contract at the time of proposal submission and shall have the following:

2.2.10.2.1. The capability of performing analysis on 100% of the tests listed in Attachment D.1.

2.2.10.2.2. Sufficient capacity and throughput to meet the volume and service demands as defined in Attachment D.1.

2.2.10.2.3. An instrument management system (internal to testing instrumentation) that provides/maintains the following:

2.2.10.2.3.1. Ability to monitor instrument performance.

2.2.10.2.3.2. Continuous monitoring of vital functions with immediate operator notification of failure(s) and on-board storage of these records.

2.2.10.2.3.3. Capability to detect and alert operator of out of range quality control results via flagged results on QC printout and visual alerts on display monitor.

2.2.10.2.3.4. Ability to store and retransmit patient records to the VA Laboratory Information system for a minimum 48 hours in case of interface outage.

2.2.10.2.3.5. Capability to record, store and print the following information:

2.2.10.2.3.5.1. Required quality control and instrument maintenance information.

2.2.10.2.3.5.2. Patient demographic information and specimen results.

2.2.10.2.3.6. On board reagent inventory system.

2.2.10.2.4. A bi-directional, bar-coded computer interface compatible with the current VA laboratory information system. The fully operational interface (both hardware and software) shall be immediately available for implementation to the VA computerized hospital information system.

2.2.10.2.4.1. The accuracy of the barcode reading must have less than a 1.0 % failure rate.

2.2.10.2.4.2. Equipment must be able to support multiple barcode formats (Code 39, Code 128) that may be enabled concurrently.

2.2.10.2.4.3. Equipment must accept, at a minimum, 10 characters in specimen identifier that is alpha and/or numeric depending on site that may be enabled concurrently.

2.2.10.3. Bar coding of reagents and the ability to track reagent containers throughout the testing process through the use of bar code technology.

2.2.10.4. Ability to prioritize STAT testing without compromising existing programmed testing.

2.2.10.5. Minimal operator intervention to introduce STAT specimens or to change a routine specimen to a STAT specimen, as well as introduce STAT specimens during a test run without aborting a run.

2.2.10.6. On board reagent stability sufficient to accommodate both high and low volume use. See ATT A

2.2.10.7. The ability to detect and alert operator of low liquid levels and the potential of depletion.

2.2.10.8. The ability to load and unload all reagents from the equipment during operation (on the fly) without interrupting testing in progress.

2.2.10.9. The ability to support multiple reagent lots of the same reagent on the equipment at the same time with active, valid calibrations.

2.2.10.10. The ability to calibrate more than one lot of a reagent at a time.

2.2.10.11. The capability to calibrate assays during test run without aborting the run.

2.2.10.12. The capabilities to store, print, and retrieve calibration data.

2.2.10.13. For routine (general) chemistry tests, when more than one lot of a given reagent has a valid calibration and quality control material is programmed to run as a control (in the control mode):

2.2.10.13.1.1. Operatory shall be notified if a new lot number is about to be run to ensure that quality control material is performed.

2.2.10.13.1.2. Quality control results will be easily distinguishable i.e., identified by reagent lot number or similar mechanism, on instrument printout or display monitor.

2.2.10.13.1.3. Operator may select to run a test on only a specified lot of reagent even though more than one lot has a valid calibration

2.2.10.14. The ability to continuously load patient specimens.

2.2.10.15. The ability to detect short samples.

2.2.10.16. Clot detection with alert notification.

2.2.10.17. Primary tube sampling from various manufacturers and sizes of evacuated tubes.

2.2.10.18. The instrumentation shall be capable of handling all routine sample collection tubes eg: 13x75, 13x100, 16x100. plus other various sized sample containers i.e., sample cups (0.5, 1.0, and 2.0 ml), carrier tubes and tube inserts.

2.2.10.19. The capabilities to auto dilute a test when defined limits are exceeded. (Contractor shall list all analytes that can be set to auto dilute on each instrument model offered.)

2.2.10.20. The capability to program a test as a repeat with interfacing of results to overlay initial result.

2.2.10.21. Safety features to avoid unnecessary exposure to biohazardous and chemical material. The exposure to and the volume of biohazardous and chemical material generated by the equipment must be minimal and require a minimum amount of handling.

2.2.10.22. For those sites requiring back up analyzers, it is desirable for the backup analyzer to be a mirror image or have the same reagent requirement as the primary analyzer.

2.2.10.22.1. Ability to store and retransmit records (48 hours of maximal instrument throughput) in case of interface outage.

2.2.10.23. IDMS traceable Creatinine reagent.

2.2.10.24. Stable calibrations.

2.2.10.25. User defined/Open Channel test capability. In the event that the contractor cannot provide desired assays, the contractor will provide application development support for open channel test implementation.

2.2.11. **Contractor Middleware Management System**

2.2.11.1. The Contractor shall provide instrumentation that interfaces directly with Data Innovations' Instrument Manager Middleware.

2.2.11.2. The Middleware shall be able to communicate via HL7 messages version 1.5 or later.

2.2.11.3. Middleware for clinical chemistry systems should be open for bidirectional interfacing of front end automation, reference laboratories, and laboratory /clinical information systems, third party middleware applications, and laboratory instrumentation, current and future generations, for all other vendors and/or laboratory sections at no additional cost.

2.2.11.4. The Contractor shall provide the server(s) and Data Innovations' Instrument Manager Middleware software, and provide technical support for both the hardware and software for the duration of the contract.

2.2.11.5. All driver development shall be provided by the respective vender, free-of-charge.

2.2.11.6. The middleware should have the ability to interface with regulatory agency applications.

2.2.11.7. The Contractor shall assist in the provision of the appropriate software drivers and interfaces for effective use of automated regulatory agency reporting features.

2.2.11.8. The Contractor shall assist in the establishment, testing, deployment, and troubleshooting of the full capacity of the Middleware.

2.2.11.9. The Middleware shall contain systems that facilitate the analysis of laboratory pre-analytic, analytic, and post-analytic processes and the generation of summary reports for quality improvement and monitoring efforts.

2.2.11.10. Summary reports shall be interactive, customizable, and accessible on-demand.

2.2.11.11. Reports shall have, at a minimum, the flexibility to display information organized by department, workflow unit, desired time frame, production phase and priority. Software shall have the capability to drill down within the summary reports, identify problematic data and generate corrective action plans.

2.2.11.12. Canned summary reports shall include, at a minimum: Turnaround time, specimen and test volumes, instrument quality control, specimen quality indicators, and % auto-verification, % (and number) repeat tests.

2.2.11.13. The Middleware shall include moving averages system. The Contractor shall establish, test, deploy and troubleshoot the functionality of the moving averages system.

2.2.11.14. The moving average system should have real-time, failure notification capability and an auto verification interrupt function at the analyte, specimen, and patient or instrument level.

2.2.11.15. The Middleware shall include Boolean logic rule writing applications and vendor developed drivers or functionality that enable the use auto-validation/auto-verification in accordance with CAP regulations.

2.2.11.16. The Middleware shall facilitate the development of compound, nested rules with multiple event actions.

2.2.11.17. The middleware rule-writing application should have a visual (point-&-click) graphical user interface consistent with Microsoft Windows application and not require complex programming or coding. It should provide sufficient data elements & granularity so criteria can be defined for patient, specimen and test-level conditions.

2.2.11.18. The Middleware shall be able to query incoming orders and outgoing results and hold either for user review and action.

2.2.11.19. The Middleware shall contain a specimen management system that allows the user to quickly locate any specimen in the system.

2.2.11.20. The Middleware shall have the ability to transmit QC data directly to Bio-Rad Unity Real Time or any other comparable online Quality Control program.

2.2.11.21. The Middleware shall have a system for inventory management that facilitates the tracking of consumables and ordering of supplies, and include pertinent information about the consumables, including, lot numbers, expiration dates, and item numbers.

2.2.11.22. The server(s) must have sufficient memory to store all middleware records for a minimum of 14 days with downloading capability to an external medium for long term storage of patient records and other information.

2.2.11.23. The vendor shall provide an accessible online medium for long term storage for patient records, results and other information with storage capacity to maintain 2 years' worth of information.

2.2.11.24. Patient status display for technologist review and workflow management for all integrated (linked) testing instrumentation.

2.2.11.25. Ability to retransmit patient records to universal interface system in case of interface outage.

2.2.11.26. Technology to automatically repeat testing based on customer configurable testing criteria (repeat testing)

2.2.11.27. Technology to automatically direct additional specimen testing based on customer-configurable testing criteria (reflex technology).

2.2.11.28. "Hot Backup" server capable of taking over system functionality in event of primary server failure

2.2.11.29. Test Environment or Test Instance of the Middleware in order to be utilized as an isolated environment for testing new systems, configuration changes, instrument interfaces, upgrades, etc. Test System should have the ability to interface with VistA Test Account.

2.2.11.30. It is preferable that the vendor utilize the VA national site-to-site VPN or work with the VA Officer of Cyber and Information Security and Information Security Officers to establish a client-based VPN.

2.2.11.31. Provide a completed copy of the Manufacturer Disclosure Statement for Medical Device Security (MDS2) and VA Form 6550.

2.2.11.32. Contractor shall collaborate with each lab to write/develop protocols to establish customer configurable rules to enhance workflow management and productivity.

2.2.11.33. Contractor shall assist customer with optimizing operation and utilization of the data management system to fully integrate desired testing instrumentation enhancing productivity and management of workflow.

2.2.11.34. The Contractor shall provide all hardware, software, lines, adapters, and devices required to connect all Laboratory instruments to the Middleware, including, but not limited to, Lantronix devices or equivalent that are capable of converting DB9 serial to RJ45 Ethernet following RS232 protocols.

2.2.11.35. The Contractor shall provide 24/7 technical support for all hardware and software of the Middleware and its' connections.

2.2.11.36. The Contractor shall provide all updates, upgrades, revisions, patches, and fixes at no cost to the Contractee.

2.2.11.37. The Contractor shall provide all necessary information to complete an ISA/MOU, if necessary, to create a VPN for the contractor to directly connect to the Middleware for troubleshooting purposes.

2.2.11.38. The Contractor shall provide all necessary licenses and support for licenses in order for the Laboratory to optimize the utility of the Middleware; i.e. licenses for connections and Thin Client licenses.

2.2.11.39. Remote-access to server for multiple VA users, either with dedicated thin client terminals or via Windows Remote Desktop Connection

2.2.11.40. The Contractor shall provide training for the Middleware prior to implementation, annually thereafter and anytime there is an upgrade where additional training would be beneficial.

2.2.12. **Hardware Features-** The instrumentation shall have the following:

2.2.12.1. A total equipment footprint that when installed in the laboratory shall not impact the functionality/operations of that laboratory. See Attachment D.2 for current specifications.

2.2.12.2. All monitors/screens will clearly display information in all light conditions.

2.2.12.3. A printer(s) that has the capability of printing a patient report with patient demographic information that includes minimally the patient's name and accession or unique identifier number (UID).

2.2.12.4. An uninterruptible power supply (UPS) with line conditioner for each instrument provided. (This includes UPS units for sites with automation lines, specimen management systems, data management systems, refrigerated archive storage, etc.,) Each UPS must provide electrical power for a minimum of 15 minutes after electrical power fails and the system must allow for an automatic controlled shutdown to prevent damage to the instrument and data records.

2.2.12.5. If the proposed instrument system requires an independent water system to operate, the manufacturer will offer an option to include the water system and all maintenance of the system as part of the CPRR package.

2.2.13. Specific Equipment Requirements- -

2.2.13.1. Single lot of reagent for each test/analyte per shipment with a minimum dating of 90 days.

2.2.13.2. Patient testing is disabled if QC failure occurs.

2.2.13.3. The printer should be user defined to print the results real-time or on demand as well as option to print exceptional reports held in the middleware for auto verification purposes.

2.2.13.4. Equipment installation and possible reinstallation should the equipment need to be moved due to construction or laboratory redesign at no additional cost for one (1) location within each site.

2.2.14. Method Performance/Validation Requirements

Method performance/comparison shall be at the expense of and performed by the Contractor, shall include linearity material and reagents, and be consistent with current CLSI guidelines and related documents, College of American Pathologists (CAP) standards and Federal regulations. All studies performed will be appropriate for the test menu of the respective laboratory to include serum, plasma, urine and body fluids as applicable. All studies must be approved by the local Laboratory Medicine Medical Director and made electronically available. These requirements shall be in effect during installation and any future changes to the test menu and/or method updates.

2.2.14.1.1. Correlation studies for each analyte. A minimum of 20 samples spanning the reportable range shall be run by the present and the proposed method. In systems where multiple sampling modes exist, mode to mode correlation studies must also be performed. Contractor shall analyze results and provide statistical data to support acceptance of the new method for above studies. Statistics shall consist of at least mean, bias, slope, y-intercept, correlation coefficient, ROC analysis, and meet current standards defined by CLSI.

2.2.14.1.2. Analytical Measurement Range (AMR) Validation shall be performed on proposed instrument(s) for each analyte to validate the reportable range. The material must have values, which are near the low, mid, and high values of the AMR and be of appropriate matrix for the clinical specimens assayed by that method. A minimum 5-point linearity analysis that adheres to the Beer-Lambert Law and spans the entire range shall be performed as a minimum.

2.2.14.1.3. Precision study using normal and abnormal control material. This shall include, at a minimum, within run precision study of 10 normal and 10 abnormal controls. Intra-VISN facility variations should be kept at an absolute minimum.

2.2.14.1.4. Sensitivity. Sensitivity may be validated concurrently with correlation studies. Mathematical calculations to determine efficiency, sensitivity, false positive rate and false negative rate are applied.

2.2.14.1.5. Specificity Studies. A review of product literature and assay inserts to determine any adverse effects for increased bilirubin, hemolysis, lipemia, or other interfering substances.

2.2.14.1.6. Carryover Studies. Successful carryover studies shall be completed by the contractor on all analyzers during installation, if required. These studies shall be performed using either contractor developed program(s) or program(s) developed by a third party (CAP/CLSI). The programs shall be provided to each laboratory at no charge.

2.2.15. **Reference Range-** A reference range must be determined for each test following CLSI guidelines. Samples used for

the reference range study must be representative of the patient population being tested. Reference range assessment must be performed for each lab. One of the following protocols shall be used:

2.2.15.1. A verification of the manufacturer's suggested reference range may be performed as long as the suggested range is based on a comparable population of test subjects. The manufacturer shall provide specific information defining how the suggested range was determined. A minimum of 20 reference individuals shall be used to verify the manufacturer's range. Any apparent outliers should be discarded and new specimens obtained to provide a statistically valid verification.

2.2.15.2. If the suggested manufacturer's range is not appropriate for the patient population, a reference range shall be established. Establishing a reference must follow CLSI guidelines. This requires a minimum of 120 reference individuals to be used to establish a reference range. The reference interval should be determined using the nonparametric method.

2.2.15.3. If a laboratory is currently using the proposed instrument/reagent system, the "in-use" reference range can be transferred to the "new" system if a method comparison study between the two systems proves to be acceptable. If comparison studies are not acceptable, one of the two above items must be performed.

2.2.16. **Reports-** The Contractor shall provide to the Contracting Officer and other individuals (designated post-award) a copy of a **quarterly report of sales, by ordering facility, within 30 calendar days after the close of each quarter's business.** Reports are to reflect, at a minimum, total net sales amounts before discount, and discount amounts by ordering facility as well as the raw data used to develop these reports. These reports shall be used to monitor the commitment of each facility, reporting the savings realized and shall be shared with each participating facility, personnel associated with acquiring the products, and respective laboratory personnel. Additional invoice charges associated with reagent and/or supply wastage or repair parts included at no charge (per FSS awarded contract) shall not be accepted. There will be no additional charges for any reports required as part of the BPA. These reports will be in an Excel spreadsheet, multiple tabs may be used, to include a VISN summary tab.

2.2.17. **Support Features-**

2.2.17.1. Commercial marketing. The equipment models being offered shall be in current production as of the date this offer is submitted. For purposes of this solicitation, "current production" shall mean that the clinical laboratory analyzer model is being offered as new equipment. Discontinued models that are only being made available as remanufactured equipment are not acceptable.

2.2.17.2. Start-Up Reagents. The Contractor shall provide all reagents, calibrators, controls, linearity materials, consumable/disposable items, parts, accessories and any other item included on the list of supplies defined in the Federal Supply Schedule contract and required to validate instruments for operation for performance of acceptance testing. This applies to all equipment as well as additional or replacement equipment placed under the terms and conditions of this BPA. The Contractor shall perform/assist, to the satisfaction of the Government, all validation studies including: precision, method comparison with current analyzer, accuracy (recovery), linearity (reportable range), calibration verification, verification of reference interval, and determination of sensitivity and specificity at no cost to the Government. The Contractor shall perform all of the statistical analysis as stated in the Method

Performance/Validation section above and provide a hard-copy and electronic copy of data in an organized, clearly comprehensible format.

2.2.17.3. Training. The Contractor shall provide an instrument training program that is coordinated with and timely to the equipment installation, sufficient to the size and scope of the facility's services and minimally equivalent to the terms and conditions for training defined in the Contractor's Federal Supply Schedule FSC Group 66, Part III, Cost-Per-Test Clinical Laboratory Analyzers contract. This key operator training for 2 operators shall include training on the operation of the system, data manipulation, and basic trouble shooting and repair. Thereafter, the Contractor shall provide training for minimally one operator per facility per year at the discretion of the Government for each model of instrumentation placed. Utilization of the training slots shall be mutually agreed upon between the VA and the Contractor. A training program that involves off-site travel shall include the cost of airfare, room and board for each participant.

2.2.17.3.1. In addition, basic operator training shall be provided by Contractor on-site for all operators on all shifts, as applicable.

2.2.17.4. Equipment Preventative Maintenance/Repair Service. The Contractor shall be able to provide, at no cost to the contractee, emergency equipment repair and preventative maintenance on all primary and back-up instrumentation, primary processing automation line instrumentation and any incremental support/ancillary equipment, e.g. water system, printers, etc. offered according to the following terms:

2.2.17.4.1. Service Requirements

2.2.17.4.1.1. A technical assistance center shall be available by telephone 24 hours per day, 7 days per week with a maximum call back response time of 1 hour

2.2.17.4.1.2. Locations and hours of operations are as follows:

Portland - 648

Portland Campus, 3710 SW U.S. Veterans Hospital Road, Portland, OR 97239

24hrs, 7 days a week

Vancouver Campus, 1601 E. 4th Plain Blvd, Vancouver, WA 98661

Seattle - 663

Seattle Campus, 1660 South Columbian Way, Seattle, WA, 98108

24hrs, 7 days a week

American Lake - 663

American Lake Campus, 9600 Veterans Way, Tacoma, WA 98493

Mon-Fri 06:30am-6:00pm PST

Roseburg - 653

Roseburg Campus, 913 NW Garden Valley Blvd. Roseburg, OR 97471

Mon-Fri 7:00am - 4:30pm PST

Eugene - 653

Eugene, Campus, 3355 Chad Drive, Eugene, OR 97408

Mon-Fri 7:00am - 4:30pm PST

Spokane - 668

Spokane Campus, N. 4815 Assembly Street, Spokane, WA 99205

24hrs, 7 days a week

White City - 692

White City Campus, 8496 Crater Lake Highway, White City, OR 97503

Mon-Fri 07:30am - 05:00pm PST

Walla-Walla - 687

Walla Walla Campus, 77 Wainwright Drive, Walla Walla, WA 99362

Mon-Fri 06:30am – 6:00pm PST

Alaska - 463

Alaska Campus, 1201 North Muldoon Rd, Anchorage, AK 99504

Mon-Fri 07:30am - 04:00pm

2.2.17.4.1.3. Equipment repair service shall be provided 24/7 for medical center based laboratories and 5 days per week during core business hours for outpatient clinic laboratories. Certain circumstances may dictate the need for repair service to be conducted outside routine business hours. All such arrangements shall be coordinated between the Contractor and VA laboratory personnel. Equipment repair response time shall be no more than 24 hours.

2.2.17.4.1.4. Remote Access diagnostic trouble shooting capabilities available with a national ISO Internet Security agreement.

2.2.17.4.1.5. Preventative maintenance will be performed as frequently as published in manufacturer's operator's manual and within 2 weeks of the scheduled due date.

2.2.17.4.1.6. A malfunction incident report shall be furnished to the Laboratory upon completion of each repair call. The report shall include, as a minimum, the following:

2.2.17.4.1.6.1. date and time notified

2.2.17.4.1.6.2. date and time of arrival

2.2.17.4.1.6.3. serial number, type and model number of equipment

2.2.17.4.1.6.4. time spent for repair, and

2.2.17.4.1.6.5. proof of repair that includes documentation of a sample run of quality control verifying acceptable performance.

2.2.17.4.2. Each notification for an emergency repair service call shall be treated as a separate and new service call.

2.2.17.5. Upgrades - The Contractor shall provide upgrades to both the equipment hardware and software in order to maintain the integrity of the system and the state-of –the art technology, at no additional charge to the Government. These shall be provided as they become commercially available and at the same time as they are being provided to commercial customers. This requirement only applies to "system upgrades" that enhance the model of equipment being offered, i.e. new version of software, correction of hardware defect, upgrade offered to commercial customers at no additional charge, upgrade to replace model of

equipment no longer Contractor supported, etc. This does not refer to replacing the original piece of equipment provided under the BPA; however, it does refer to significant changes in the hardware operational capability.

2.2.17.6. Ancillary support equipment - The Contractor shall provide, install and maintain through the life of the BPA , as indicated, any and all ancillary support equipment to fully operate the analyzer as defined in these specifications, e.g. cabinetry to support/house the analyzer (if necessary), water systems (including consumable polishers, filters, preventative maintenance and repair, etc.), printers and universal interface equipment, etc. In addition, the Contractor shall include all ancillary components that are customarily sold or provided with the model of equipment proposed, e.g. starter kits, tables/stands, etc

2.2.17.7. Characterization of waste – The Contractor shall provide documentation that it has characterized the hazardous nature of all wastes produced by all equipment, devices, reagents, and discharges in accordance with the requirements of the Code of Federal Regulations Title 40 "Protection of the Environment" Part 261 et seq. and applicable state and local requirements. Documentation shall include a description of the characteristics of the hazardous waste produced as a byproduct of the instrument operations, Safety Data Sheets (SDS) meeting the requirements of the Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA), the analytical process used to determine the hazardous nature and characteristics of the waste, and the analytical test results. Testing of hazardous waste is to be done in accordance with testing protocol specified for each individual waste as described in the Code of Federal Regulations Title 40 to make a determination if the waste is a hazardous waste or otherwise regulated.

2.2.17.7.1. The determination and description shall address the following:

2.2.17.7.1.1. Waste toxicity (Reference 40 CFR §261.11 and 40 CFR §261.24)

2.2.17.7.1.2. Waste ignitability (Reference 40 CFR §261.21)

2.2.17.7.1.3. Waste corrosivity (Reference 40 CFR §261.22)

2.2.17.7.1.4. Waste reactivity (Reference 40 CFR §261.23)

2.2.17.7.1.5. Hazardous waste from non-specific sources (F-listed) (Reference 40 CFR §261.31)

2.2.17.7.1.6. Discarded commercial products (acutely toxic or P-listed and toxic or U-listed) (Reference 40 CFR §261.33)

2.2.17.7.1.7. Solid Waste (Reference 40 CFR §261.2)

2.2.17.7.1.8. Exclusions (Reference 40 CFR §261.4)

2.2.17.7.2. The contractor will provide written instructions and training material to ensure VHA laboratory staff are trained as needed to properly operate devices with special emphasis to managing and disposing of hazardous waste in accordance with EPA and state requirements. Additionally, the training provided by the contractor must fulfill Resource Conservation and Recovery Act (RCRA) requirements for training as applicable to devices.

2.2.17.7.3. Contractor shall provide a description of all wastes the process or equipment may discharge so that the facility can determine whether the discharge meets Local Publicly Owned Treatment Works (POTW), State and Federal discharge requirements. At a minimum the characteristics of

ignitability, corrosivity, reactivity and toxicity as defined in 40 CFR §261 must be determined and documented. Any mercury containing reagents must be identified in any concentrations. All test results shall be provided. All listed chemicals (F, U, K and P) found in 40 CFR §261 shall be provided in product information and their concentrations documented. For those materials with a positive hazardous waste determination, a mechanism for the laboratory to meet local discharge requirements (i.e. mercury, thimerosol and formaldehyde) must be developed and SDS sheets must be provided in advance for review. At a minimum, documentation shall include, but not be limited to the concentration/measures of the elements and parameters listed below and must be included with vendor response:

2.2.17.7.3.1. Barium (Total)
2.2.17.7.3.2. Cadmium (Total)
2.2.17.7.3.3. Chromium (Total)
2.2.17.7.3.4. Copper (Total)
2.2.17.7.3.5. Cyanide (Total)
2.2.17.7.3.6. Lead (Total)
2.2.17.7.3.7. Mercury (Total)
2.2.17.7.3.8. Nickel (Total)
2.2.17.7.3.9. Silver (Total)
2.2.17.7.3.10. Zinc (Total)
2.2.17.7.3.11. Arsenic (Total)
2.2.17.7.3.12. Selenium (Total)
2.2.17.7.3.13. Tin (Total)
2.2.17.7.3.14. pH
2.2.17.7.3.15. Flash point (to higher than 200□F)
2.2.17.7.3.16. BOD; biochemical oxygen demand

2.2.17.7.4. The documentation the contractor provides will be used to work with the VAMC and the public and/or private organization (e.g., POTW) to determine whether or not the waste from each device can legally be disposed of via the sewerage system

2.2.17.8. Implementation/transition timeframe - The implementation of the services/requirements described in this solicitation shall be completed no later than 90 days after the award of the BPA. This timeline is based on a reasonable attempt of the Contractor to complete all of the necessary implementation requirements within the stated timeframe. Contractor shall not be penalized for implementation timelines that extend beyond the 90 day timeframe, if the extension is through no fault of the Contractor and is a result of delays due to the Government.

Comment [hcg1]: Macro will populate

2.2.17.8.1. Upon award of a BPA, the transition period for the awarded BPA to have all equipment and peripherals installed and operational shall be from date of award through 90 days. During this same period all initial training of VA personnel in the operation and maintenance of said award shall also be completed.

2.2.17.8.2. Contractor shall provide with its quotation an implementation plan for installation of new equipment. Contractor's submitted plan shall not exceed 90 days for the transition of all services under the awarded BPA including installation and training of personnel, transition of all testing materials, reagents and supplies, etc., performance of all correlations and validations. Failure of the Contractor to conform to the transition period shall be considered as sufficient cause to terminate BPA for cause under the Termination for Cause clause of the BPA.

2.2.17.8.3. At the end of 90 days from award of the BPA, the awarded Contractor shall have full and sole responsibility for services under the awarded BPA.

2.2.18. **Standard and Quality of Performance-** This paragraph establishes a standard of quality performance that shall be met before any equipment listed on the delivery order [or BPA] is accepted by the Government. This also includes replacement, substitute machines and machines that are added or field modified after a system has demonstrated successful performance. The acceptance period shall begin on the installation date. It shall end when the equipment has met the standard of performance for a period of 30 consecutive calendar days by operating in conformance with the Contractor's technical specification or as quoted in any BPA at an effectiveness level of 90% or more.

2.2.18.1. In the event that equipment does not meet the standard of performance during the initial 30 consecutive calendar days, the standard of performance tests shall continue on a day-by-day basis until the standard of performance is met for a total of 30 consecutive days.

2.2.18.2. If the equipment fails to meet the standard of performance after 90 calendar days from the installation date, the user may, at his/her option, request a replacement or terminate the order in accordance with the provisions of FAR 52.212-4 entitled "Termination for cause." (The Contractor shall receive revenue for tests reported during the 90-day acceptance period.)

2.2.18.3. Operational use time for performance testing for a system is defined as the accumulated time during which the machine is in actual use. System failure downtime is that period of time when any machine in the system is inoperable due to equipment failure. Downtime for each incident shall start from the time the Government makes a bona fide attempt to contact the Contractor's designated representative at the prearranged contact point until the system or machine(s) is returned to the Government in proper operating condition.

2.2.18.4. During the performance period for a system, a minimum of 100 hours of operational use time with productive or simulated work shall be required as a basis for computation of the effectiveness level. However, in computing the effectiveness level, the actual number of operational use hours shall be used when in excess of the minimum of 100 hours. [reference: Master FSS]

2.2.18.5. The Government will maintain daily records to satisfy the requirements of the Standard and Quality of Performance section and shall notify the Contractor in writing of the date of the first day of the successful period of operation. Operations use time and downtime shall be measured in hours and whole minutes.

2.2.18.6. During the term of the BPA, should the repair record of any individual piece of laboratory equipment reflect a downtime of 10% or greater of the normal working days in one calendar month, a determination shall be made by the COR and/or contracting officer to replace the malfunctioning

equipment with new equipment. The responsibility for maintaining the equipment furnished in good condition in accordance with manufacturer's instructions, shall be solely that of the Contractor. [reference: Master FSS] Each instrument provided by the Contractor shall maintain an uptime of 90% in each month of the term of the agreement for equipment. The same terms and conditions apply to ancillary/support equipment provided under this BPA, i.e., water system UPS, etc.

2.2.19. **Government's Responsibility-** The user will perform routine maintenance and cleaning as required in the manufacturer's operation and maintenance instructions. The user shall maintain appropriate records to satisfy the requirements of this paragraph.

2.2.20. **Ownership of Equipment-** Title to the equipment shall remain with the Contractor. All accessories (unused consumables, etc.) furnished by the Contractor shall accompany the equipment when returned to the Contractor. The Contractor, upon expiration of order(s), at termination and/or replacement of equipment, shall remove the equipment. The Contractor shall disconnect the analyzer (gas, water, air, etc.) and shall be responsible for all packing and shipping required to remove the analyzer.

2.2.21. The Contractor will identify if removable media is required to perform their duties. The Biomedical Engineering Department will ensure the removable media is scanned with anti-virus software running current virus definitions prior to connection to any medical device/system. Any Contractor with patient sensitive information that is imported into the removable media device for any reason must purge all patient sensitive information prior to departure from the facility.

2.2.22. Prior to termination or completion of this BPA, Contractor/subcontractor must not destroy information received from VA, or gathered/created by the Contractor in the course of performing this BPA without prior written approval by the VA. Any data destruction done on behalf of VA by a Contractor/subcontractor must be done in accordance with National Archives and Records Administration (NARA) requirements as outlined in VA Directive 6300, *Records and Information Management* and its Handbook 6300.1 *Records Management Procedures*, applicable VA Records Control Schedules, and VA Handbook 6500.1, *Electronic Media Sanitization*. Self-certification by the Contractor that the data destruction requirements above have been met must be sent to the VA Contracting Officer within 30 days of termination or completion of the BPA.

2.2.23. All electronic storage media used on non-VA leased or non-VA owned IT equipment that is used to store, process, or access VA information must be handled in adherence with VA Handbook 6500.1, *Electronic Media Sanitization* upon: (i) completion or termination of the BPA or (ii) disposal or return of the IT equipment by the Contractor/subcontractor or any person acting on behalf of the Contractor/subcontractor, whichever is earlier. Media (hard drives, optical disks, CDs, back-up tapes, etc.) used by the Contractors/subcontractors that contain VA information must be retained by the VA for sanitization or destruction or the Contractor/subcontractor must self-certify that the media has been disposed of per 6500.1 requirements. This must be completed within 30 days of termination or completion of the BPA or disposal or return of the IT equipment, whichever is earlier

2.2.24. Bio-Medical devices and other equipment or systems containing media (hard drives, optical disks, etc.) with VA sensitive information must not be returned to the Contractor at the end of lease, for trade-in, or other purposes. The options are:

2.2.24.1. Contractor must accept the system without the drive;

2.2.24.2. VA's initial medical device procurement includes a spare drive which must be installed in place of

the original drive at time of turn-in; or

2.2.24.3. VA must reimburse the company for media at a reasonable open market replacement cost at time of purchase.

2.2.25. Due to the highly specialized and sometimes proprietary hardware and software associated with medical equipment/systems, if it is not possible for the VA to retain the hard drive, then;

2.2.25.1. (a) The equipment Contractor must have an existing BAA if the device being traded in has protected health information stored on it and hard drive(s) from the system are being returned physically intact; and

2.2.25.2. (b) Any fixed hard drive on the device must be non-destructively sanitized to the greatest extent possible without negatively impacting system operation. Selective clearing down to patient data folder level is recommended using VA approved and validated overwriting technologies/methods/tools. Applicable media sanitization specifications need to be pre-approved and described in the purchase order or BPA.

2.2.25.3. A statement needs to be signed by the Director (System Owner) that states that the drive could not be removed and that (a) and (b) controls above are in place and completed. The Information Security Officer (ISO) needs to maintain the documentation.

VA260-16-Q-0037
Chemistry BPA
RFQ Questions

1. Is AUSAB the same as ANTI-HBS?
    a. They are the same.

2. There are two lines for Albumin. Are they added together?
    a. One is for Micro and the other is for regular albumin.

3. Is American Lake costs included in Puget Sound Costs?
    a. Yes they are together.

4. Regarding –CK-MB and CK-MB stat, is this mass CK MB?
    a. In biorad it is classified as mass. They are classified the same.

5. Test column total for "Total Estimated Quantity All Stations" is incorrect and should add up to 8,154,449 instead of 6,800,012.
    a. Corrected

6. Need clarification on HAVIgg. There is a total HAV and an HAVIGM.
    a. There are three tests that can be offered. The total, the IGG and the IGM.

7. Test Volume Total for "VA Seattle" is incorrect and should be 1,912,349 from 1,865,939.
    a. Correct.

8. Contract requires Troponin T, but most companies use Troponin I.
    a. Corrected in spreadsheet to Troponin.

9. Attachment D.1-Estimated Test Volumes - Line 37. AFP listed only for Portland, Should Puget Sound have some volume?
    a. Puget Sound does not do AFP.

10. Attachment D.1-Estimated Test Volumes - Line 60. Should there be some PTH volume at Portland?
    a. Added

11. Attachment D.1-Estimated Test Volumes - Line 66. Troponin is a common test, and there is no volume at Anchorage and White City, is this correct?
    a. Adding Volume

12. Attachment D.1-Estimated Test Volumes - Line 91. Should there be lactic acid volume for Portland?
    a. Done on Blood gas analyzer

13. Attachment D.1-Estimated Test Volumes - Line 120, what is the common name of this particular assay?
    a. This is searching for a particular drug called Vancomycin.

14. SOW - Portland and Seattle are clear with automation. Spokane has specifically discussed automation and is listed as a specific line item. Boise is listed in this section. Can you articulate the automation goals for Boise and Spokane?
    a. Addressed in new statement of work.

15. SOW-According to b. you are only asking for business hours service for all locations, is this correct?
    a. Addressed in new statement of work.

16. Evaluation Criteria - Sub Factor 1-B. Cap piercing technology, we assume the requirements are for De-Capping. If that is the case do the non-automation locations require a de-capper module in each location?
    a. Addressed in new statement of work.

17. We have not found any specifications for the Data Management for the solution. This includes auto-verification, control tracking and monitoring, rules writing, and reports. Are there any specifications around Data Management?
    a. Addressed in new statement of work.

18. SOW - Under automation section (page 12 of 48 D- future equipment requirements) - Spokane and Tacoma are missing. Can you please clarify if this was an oversight?
    a. Addressed in new statement of work.

19. SOW - The research claim stated on pages 13 ii.f, and page 14 v.a, should not be a requirement as this assay has been on the market for several years and there are newer assays available.
    a. Addressed in new statement of work.

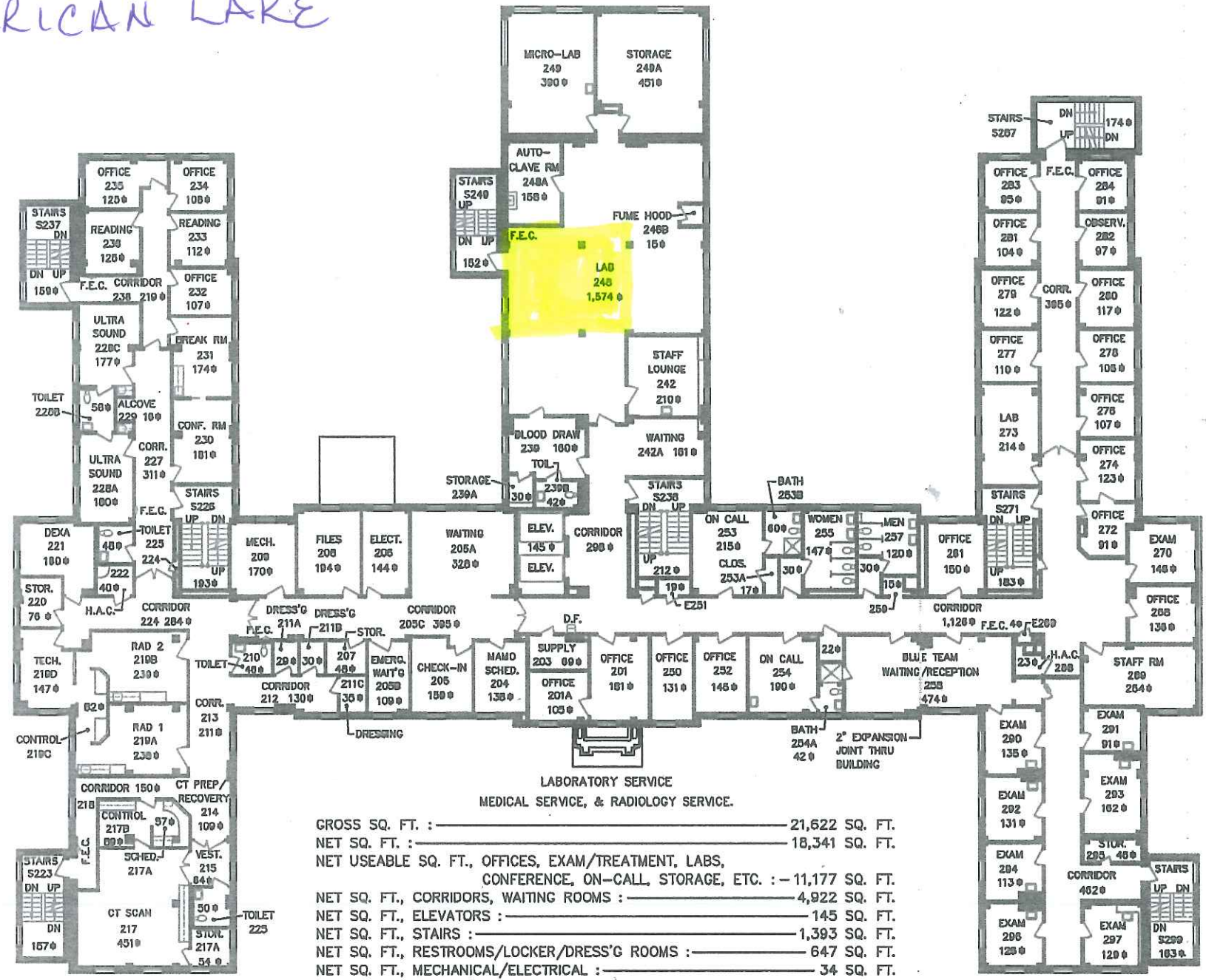
20. SOW - Page 12- c viii states “Contract shall provide at no cost auto-verification programming and validation when available” and is followed by 3 requirements that is not applicable to either auto validation programming or auto validation.
    a. Addressed in new statement of work.

21. SOW - Page 12 i.b.i states a requirement of utilizing a five position rack.
    a. Addressed in new statement of work.

22. SOW - Page 13 i.d has a requirement that the Chemistry and Immunochemistry modules must be modular.
    a. Addressed in new statement of work.

23. SOW - Page 13 ii.d has a requirement the instrument must be able to produce a nine minute turnaround time on specific markers such as TnT,HCG and Parathyroid Hormone.
    a. Addressed in new statement of work.

AMERICAN LAKE



LABORATORY SERVICE
MEDICAL SERVICE, & RADIOLOGY SERVICE.

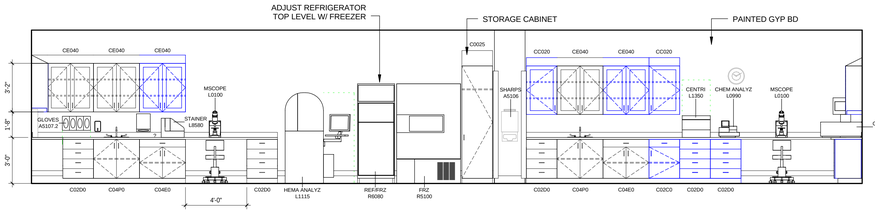
GROSS SQ. FT. :	21,622 SQ. FT.
NET SQ. FT. :	18,341 SQ. FT.
NET USEABLE SQ. FT., OFFICES, EXAM/TREATMENT, LABS, CONFERENCE, ON-CALL, STORAGE, ETC. :	11,177 SQ. FT.
NET SQ. FT., CORRIDORS, WAITING ROOMS :	4,922 SQ. FT.
NET SQ. FT., ELEVATORS :	145 SQ. FT.
NET SQ. FT., STAIRS :	1,393 SQ. FT.
NET SQ. FT., RESTROOMS/LOCKER/DRESS'G ROOMS :	647 SQ. FT.
NET SQ. FT., MECHANICAL/ELECTRICAL :	34 SQ. FT.
NET SQ. FT., H.A.C.S/UTILITY ROOMS :	23 SQ. FT.

SCALE: 1" = 30'-

one inch = thirty feet

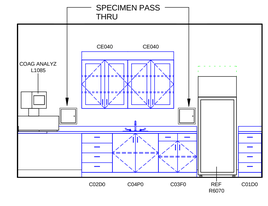
1 = ten feet

Approved For | Drawing Title: SECOND FLOOR | Project Title: DENTAL LABORATORY, MEDICAL | Date: 7-27-09



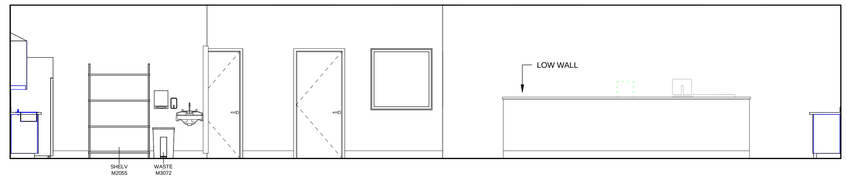
3 HEMATOLOGY, SPECIMEN PROCESS - T1DE12

1/4" = 1'-0"



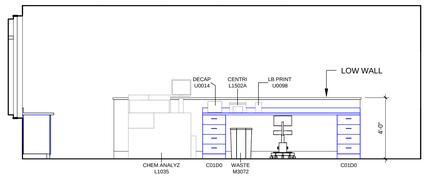
4 URINALYSIS - T1DE13

1/4" = 1'-0"



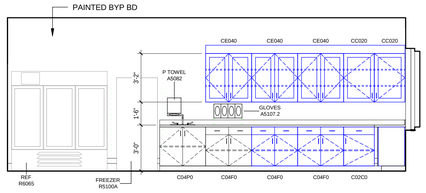
5 URINALYSIS - T1DE13

1/4" = 1'-0"



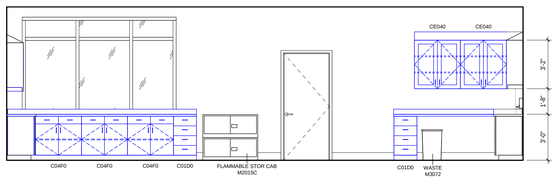
6 CHEMISTRY - T1DE11

1/4" = 1'-0"



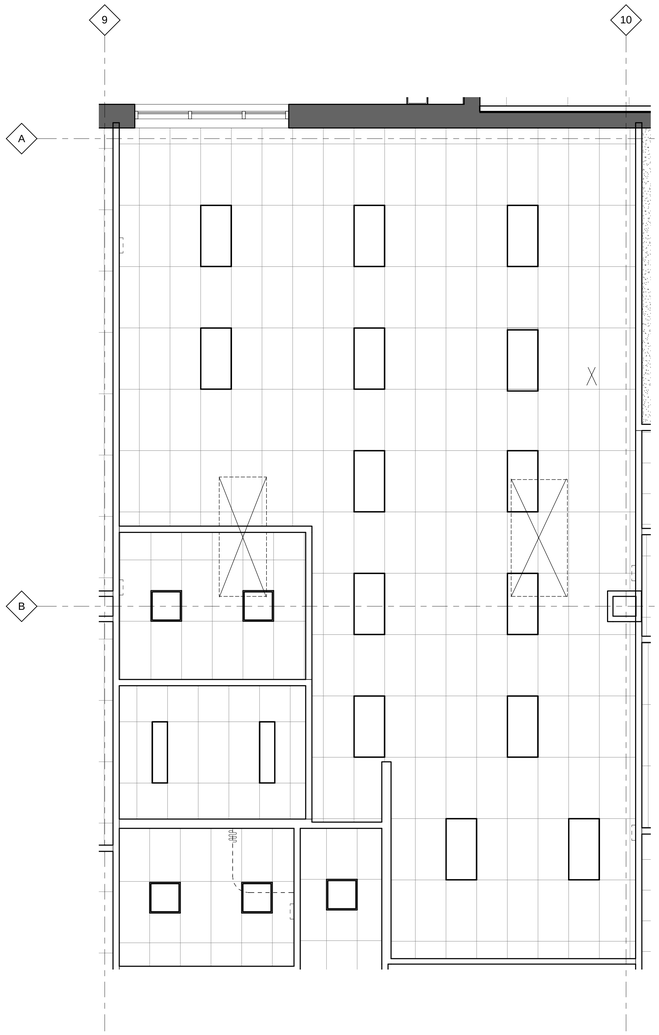
7 CHEMISTRY - T1DE11

1/4" = 1'-0"



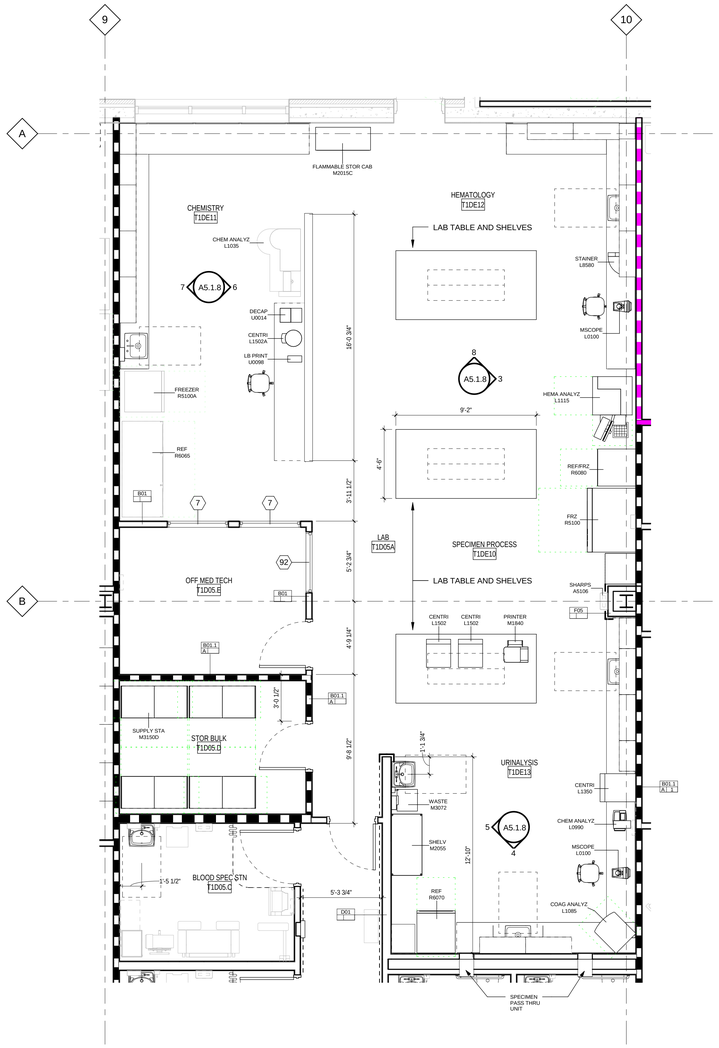
8 CHEMISTRY, HEMATOLOGY

1/4" = 1'-0"



2 LAB - RCP

1/4" = 1'-0"



1 LAB

1/4" = 1'-0"

GENERAL NOTES

1. SEE FLOOR PLAN FOR OVERALL WALL DIMENSIONS, DOOR, FIXTURE AND WALL ORIENTATION
2. FOR ADDITIONAL INTERIOR FINISHES, SEE INTERIOR DESIGN SERIES DRAWINGS.
3. REFER TO STRUCTURAL DRAWINGS FOR SLAB DEPRESSIONS AND CONCRETE WALL DIMENSIONS.
4. REFER TO G SERIES SHEETS FOR TYP. MOUNTING HTS.
5. PROVIDE 2% SLOPE MAX. AT TOILET/SHOWER ROOMS, U.O.N.
6. MAINTAIN SAME FLOOR ELEVATION AT PERIMETER OF SLOPED SHOWER AREA
7. MAINTAIN SAME FLOOR ELEVATION AT PERIMETER OF TOILET ROOMS, EXCEPT FOR AREAS WHERE TRANSITION OCCURS AT IMMEDIATE SHOWER AREA
8. TOP OF DRAIN STRAINER TO BE FLUSH WITH ADJACENT FLOOR FINISH
9. PROVIDE 1/4" MIN. BETWEEN TOP OF DRAIN STRAINER AND TOP OF SLAB
10. REFER TO INTERIOR DESIGN SHEETS FOR WALL PROTECTION
11. LAYOUT CEILING TILE FROM CENTER OF ROOMS, AND/OR AREAS BOTH DIRECTIONS, U.O.N. AN AREA IS DEFINED AS A GROUP OF ROOMS WITH PARTITIONS EXTENDING ONLY TO THE UNDERSIDE OF CEILING AND BORDERED BY PARTITIONS EXTENDING TO THE UNDERSIDE OF STRUCTURAL SLAB ABOVE.
12. LOCATE ALL SPRINKLER HEADS, SMOKE DETECTORS, SPEAKERS AND OTHER CEILING MOUNTED MECHANICAL, ELECTRICAL, PLUMBING AND SECURITY ITEMS AT THE CENTER OF ACOUSTICAL CEILING PANELS U.O.N.
13. WHERE SPRINKLER HEADS ARE NOT SHOWN, ADJUST SPRINKLER HEAD LOCATIONS TO CLEAR OTHER CEILING FIXTURES AND ELEMENTS AS REQUIRED
14. THE EXTENT OF ACCESS DOORS AND EQUIPMENT, AS SHOWN ON THE REFLECTED CEILING PLANS, DOES NOT NECESSARILY REPRESENT THEIR FULL LIMITS OR EXACT LOCATIONS. ADDITIONAL ACCESS DOORS MAY BE REQUIRED TO SERVE EQUIPMENT NOT SHOWN ON PLANS. PROVIDE ACCESS DOORS AS REQUIRED BY CODE.
15. PROVIDE BLOCKING AT ALL FIXTURES, GRAB BARS AND TOILET PARTITION ATTACHMENTS.

KEYNOTES

- +1'-0" — FINISH CEILING HEIGHT
- ROOM NAME — ROOM IDENTIFICATION
- SUSPENDED 2' x 4' ACT CEILING
- SUSPENDED 2' x 2' ACT CEILING
- SUSPENDED GWB CEILING
- PERFORATED WOOD CEILING PANELS
- SPECIALITY LIGHT PANEL
- CUBICLE OR SHOWER CURTAIN AND TRACK, SEE SPECIFICATIONS, ENLARGED PLANS, AND
- EXAM LIGHT
- LINEAR WALL SCONCE
- 1X4 FLUORESCENT
- 2X4 FLUORESCENT
- 2X2 FLUORESCENT
- VANITY SCONCE
- DECORATIVE PENDANT
- EXTERIOR WALL SCONCE
- INTERIOR WALL SCONCE
- RECESSED CAN
- RECESSED WALL WASHER
- EXIT LIGHT
- NURSE CALL LIGHT FIXTURE

LEGEND

KEY PLAN

TENANT IMPROVEMENT
ISSUE FOR PERMIT

Revisions:	Date

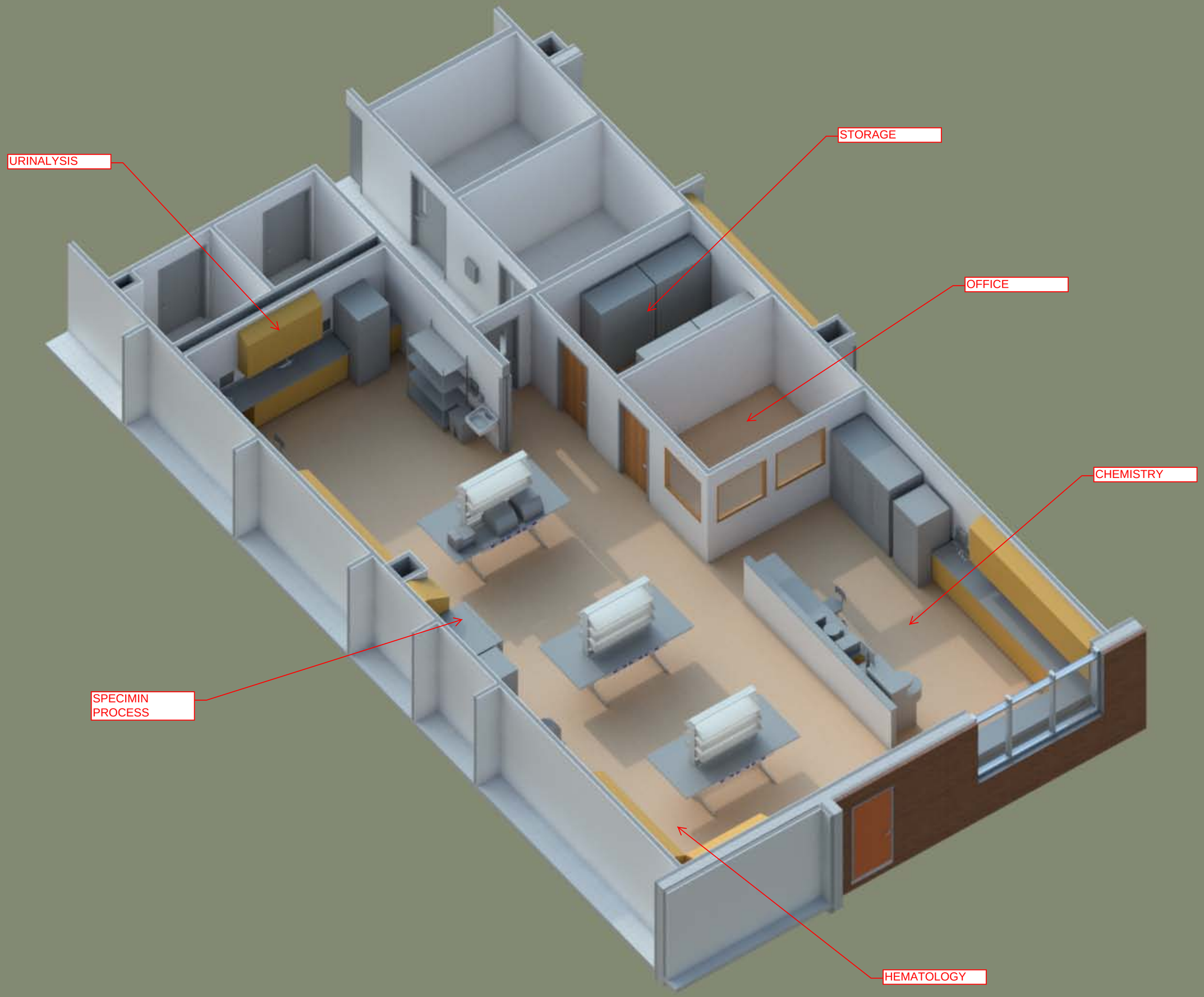
ARCHITECT:

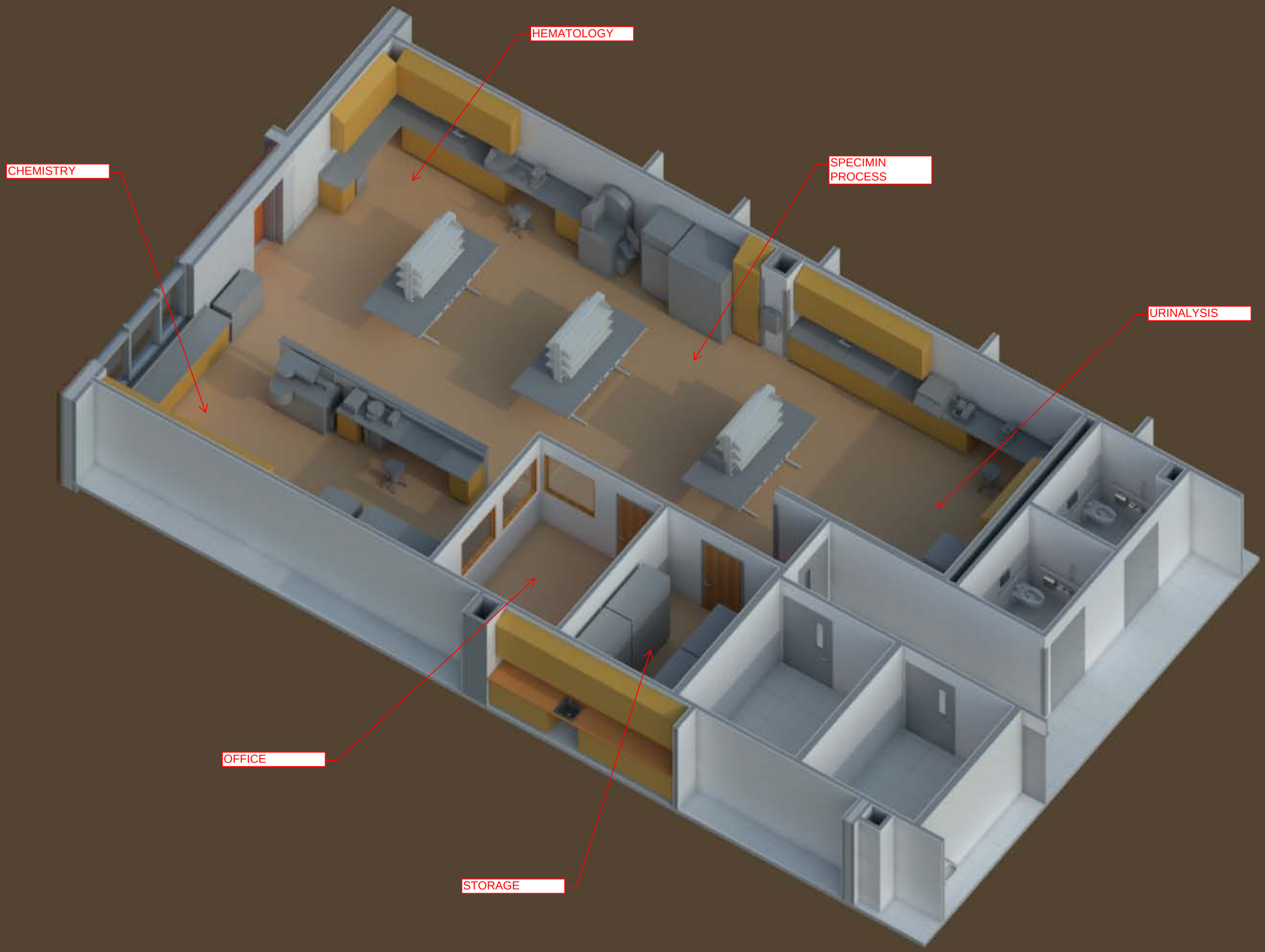
SODERSTROM ARCHITECTS, Ltd.
architecture | planning | exterior restoration | interior design
1200 NW Naito Parkway, Suite 410
Portland, Oregon 97209
MAIN 503.228.5617 FAX 503.273.8584
www.sdra.com

Drawing Title	GENERAL ENLARGED PLANS
Approved: Project Director	
Project Title	DEPARTMENT OF VETERAN AFFAIRS OUTPATIENT CLINIC
Location	EUGENE/SPRINGFIELD OREGON
Date	08/04/2014
Checked	Checker
Drawn	Author
Project Number	VA-101-11-RP-0136
Building Number	1
Drawing Number	A5.1.8

Office of Construction and Facilities Management

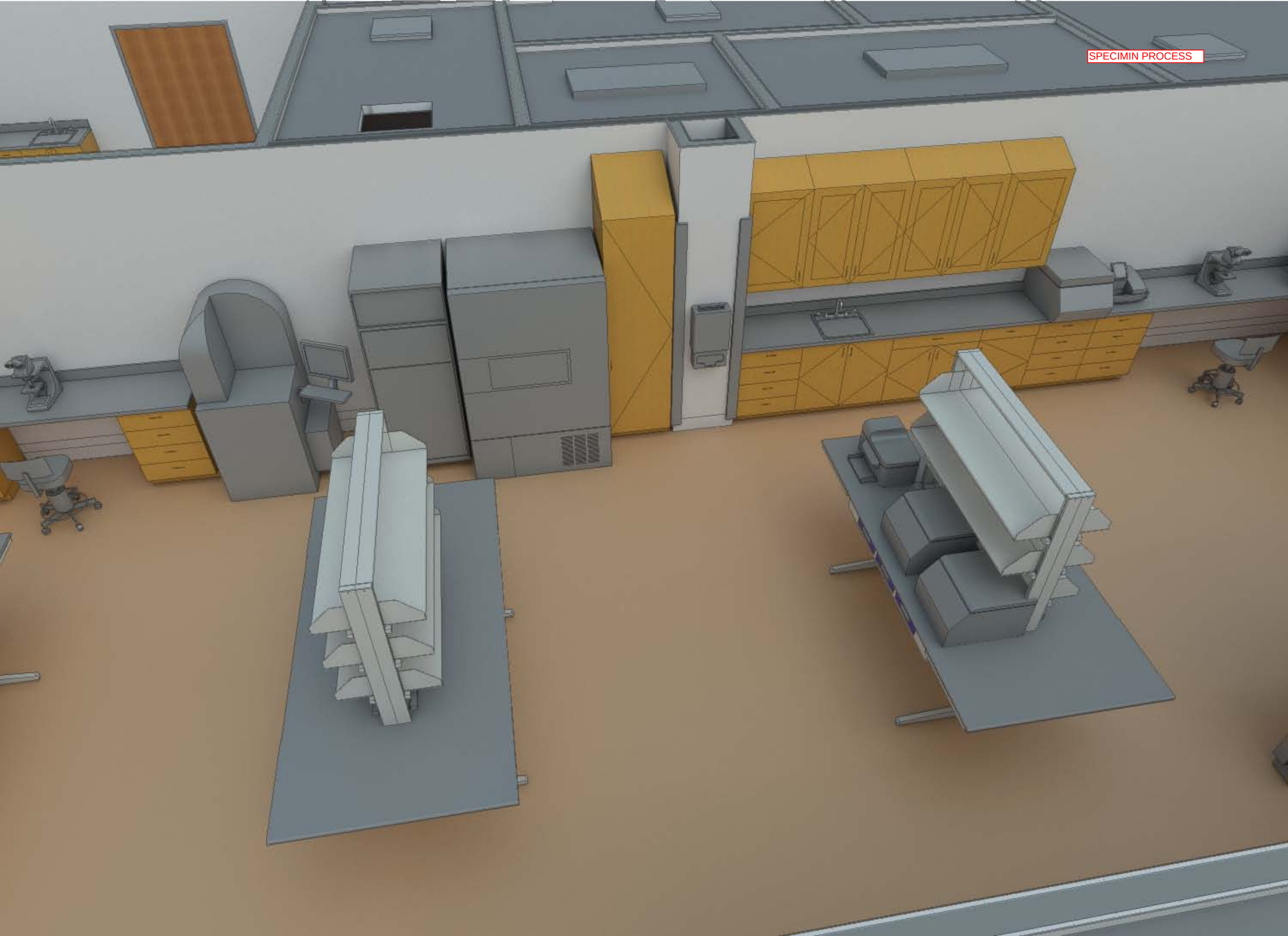
Department of Veterans Affairs


URINALYSIS
STORAGE
OFFICE
SPECIMIN
PROCESS
CHEMISTRY
HEMATOLOGY


HEMATOLOGY
CHEMISTRY
SPECIMIN
PROCESS
URINALYSIS
OFFICE
STORAGE


CHEMISTRY

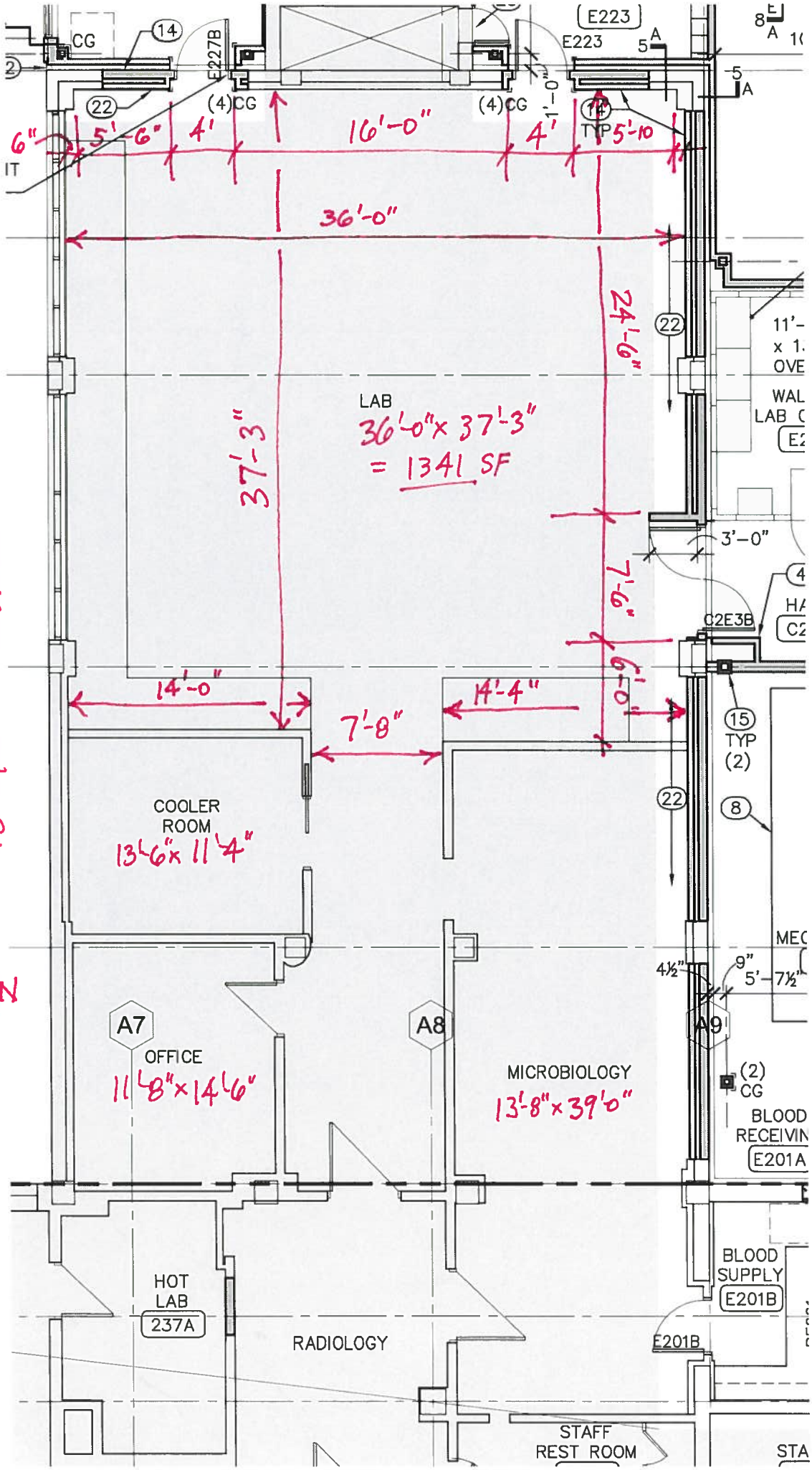
HEMATOLOGY

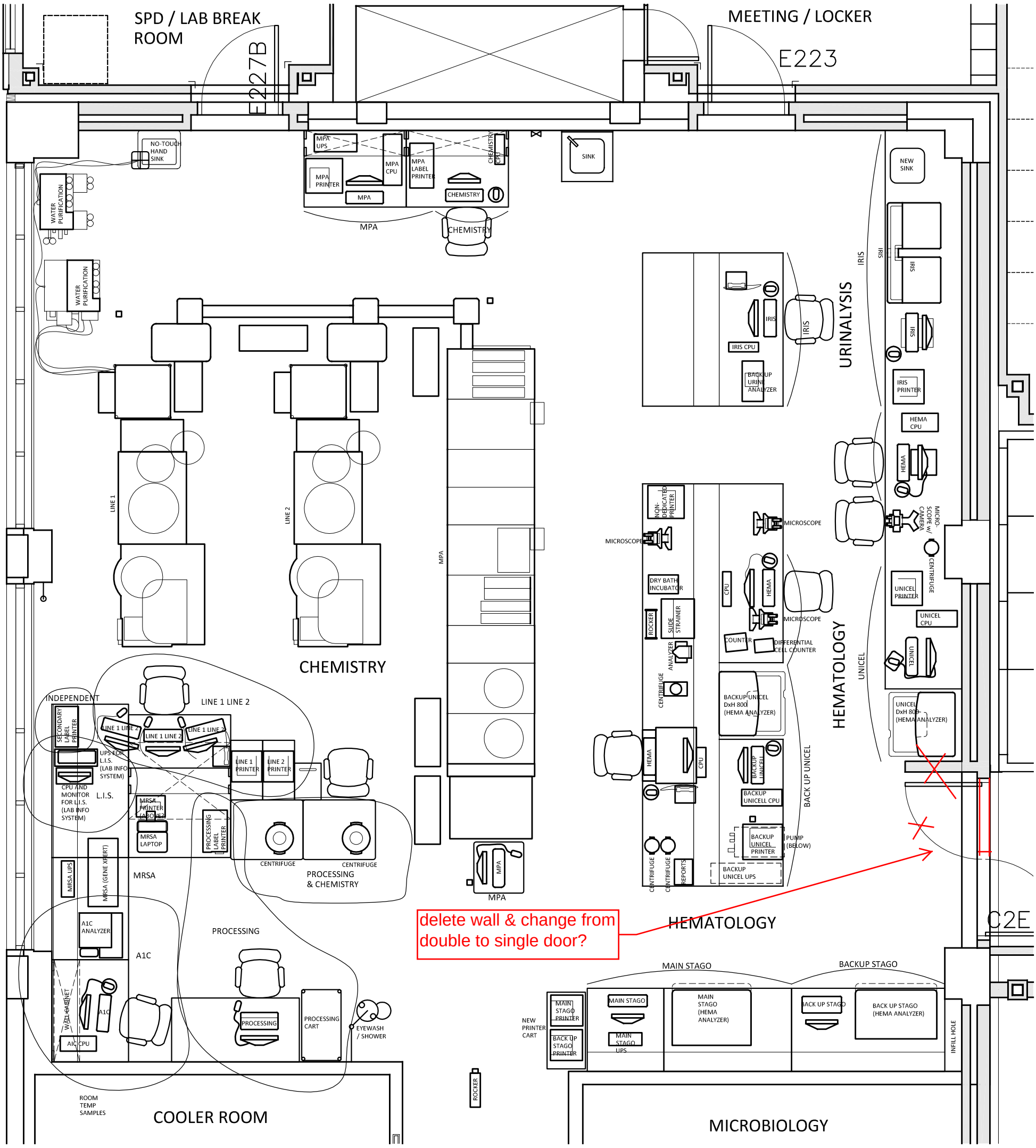

SPECIMIN PROCESS

URINALYSIS

NAC

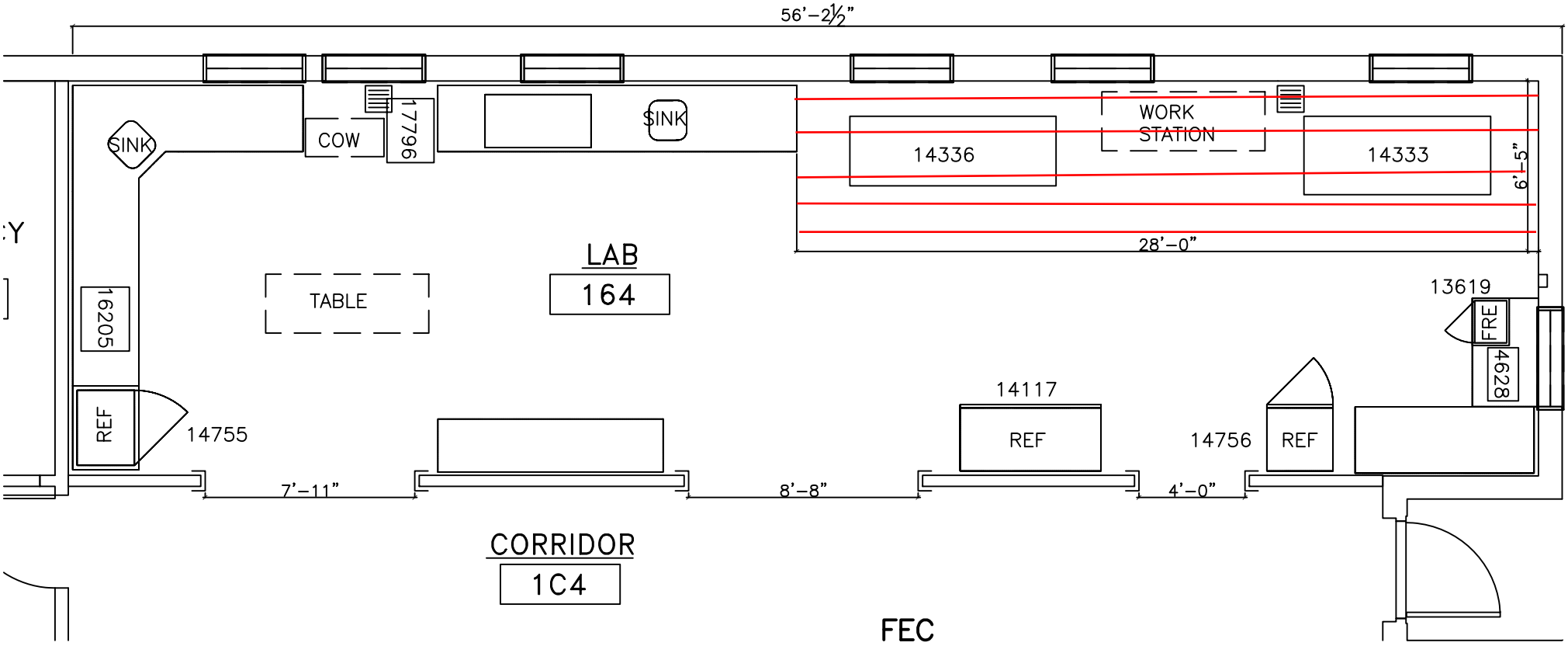
EXISTING LAB PLAN
1/8" = 1'-0" 11-21-12




SPD / LAB BREAK ROOM
E227B
MEETING / LOCKER
E223
NO-TOUCH HAND SINK
WATER PURIFICATION
MPA UPS
MPA PRINTER
MPA CPU
MPA LABEL PRINTER
CHEMISTRY CPU
MPA
CHEMISTRY
SINK
NEW SINK
IRIS
IRIS CPU
BACKUP URINE ANALYZER
IRIS PRINTER
HEMA CPU
HEMA
MICRO-SCOPE w/ CAMERA
CENTRIFUGE
UNICEL PRINTER
UNICEL CPU
UNICEL
UNICEL DxH 800 (HEMA ANALYZER)
URINALYSIS
HEMATOLOGY
LINE 1
LINE 2
CHEMISTRY
NON-DEDICATED PRINTER
MICROSCOPE
DRY BATH INCUBATOR
ROCKER
SLIDE STRAINER
ANALYZER
CENTRIFUGE
CPU
HEMA
COUNTER
DIFFERENTIAL CELL COUNTER
BACKUP UNICEL DxH 800 (HEMA ANALYZER)
BACKUP UNICEL
BACKUP UNICELL CPU
BACK UP UNICEL
BACKUP UNICEL PRINTER
PUMP (BELOW)
BACKUP UNICEL UPS
REPORTS
INDEPENDENT
LINE 1 LINE 2
SECONDARY LABEL PRINTER
UPS FOR L.I.S. (LAB INFO SYSTEM)
CPU AND MONITOR FOR L.I.S. (LAB INFO SYSTEM)
L.I.S.
LINE 1 PRINTER
LINE 2 PRINTER
MRSA PRINTER (ABOVE)
MRSA LAPTOP
PROCESSING LABEL PRINTER
CENTRIFUGE
PROCESSING & CHEMISTRY
MRSA
MRSA UPS
MRSA (GENE XPERT)
A1C ANALYZER
A1C
PROCESSING
PROCESSING CART
EYEWASH / SHOWER
WASTE CABINET
A1C CPU
ROOM TEMP SAMPLES
COOLER ROOM
delete wall & change from double to single door?
HEMATOLOGY
MAIN STAGO
BACKUP STAGO
NEW PRINTER CART
MAIN STAGO PRINTER
BACK UP STAGO PRINTER
MAIN STAGO UPS
MAIN STAGO (HEMA ANALYZER)
BACK UP STAGO
BACK UP STAGO (HEMA ANALYZER)
INFILL HOLE
ROCKER
MICROBIOLOGY
C2E

White City VA Laboratory Floor Plans

Red area indicates Chemistry Section
6'5"W X 28'L

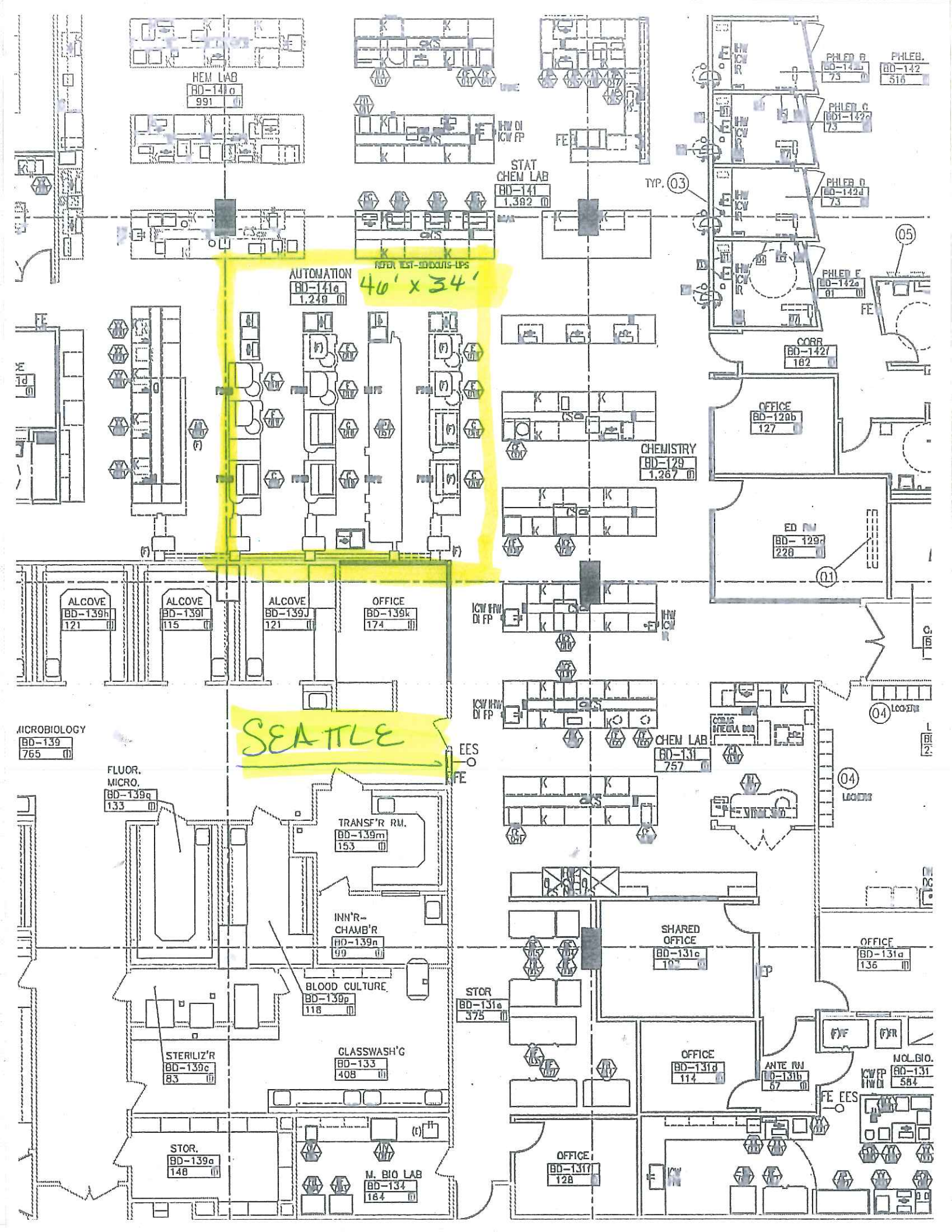


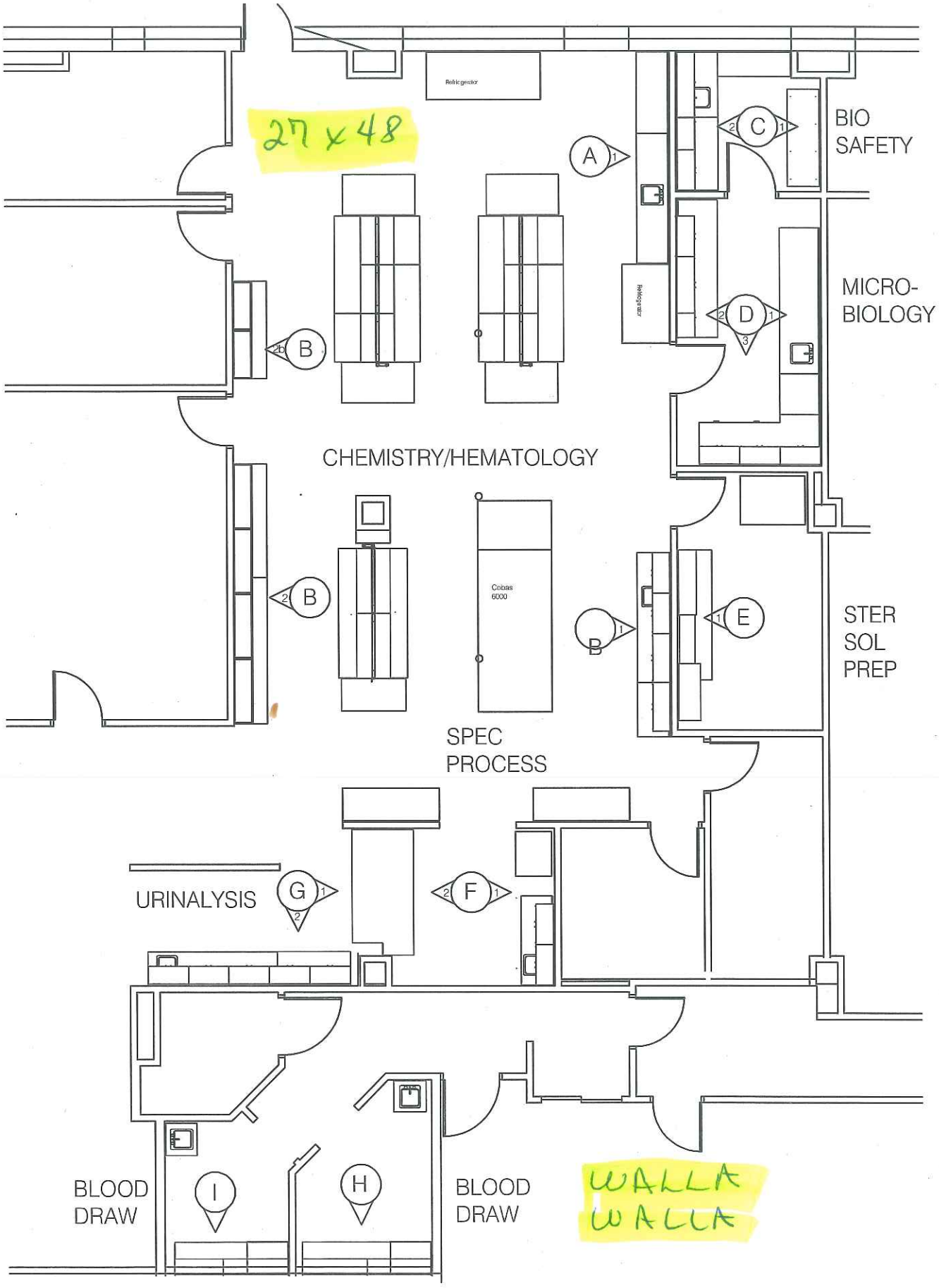
SCHEMATIC PLAN – EXPAND LAB SERVICES – 2ND FLOOR

SCALE: 1/8" = 1'-0"

NOVEMBER 4, 2014

PLAN NORTH


HEM LAB
BD-141a
991
STAT
CHEM LAB
BD-141
1,382
AUTOMATION
BD-141a
1,249
46' x 34'
PHLEB B
BD-142
73
PHLEB.
BD-142
516
PHLEB C
BD-142c
73
PHLEB D
BD-142d
73
PHLEB E
BD-142e
91
TYP. 03
05
CORR
BD-142f
182
OFFICE
BD-129b
127
CHEMISTRY
BD-129
1,267
ED RM
BD-129c
228
01
ALCOVE
BD-139h
121
ALCOVE
BD-139i
115
ALCOVE
BD-139j
121
OFFICE
BD-139k
174
SEATTLE
MICROBIOLOGY
BD-139
765
FLUOR.
MICRO.
BD-139q
133
TRANSF'R RM.
BD-139m
153
INN'R-
CHAMB'R
BD-139n
99
BLOOD CULTURE
BD-139p
118
STERILIZ'R
BD-139c
83
GLASSWASH'G
BD-133
408
STOR.
BD-139a
148
M. BIO LAB
BD-134
164
CHEM LAB
BD-131
757
04
LOCKERS
SHARED
OFFICE
BD-131c
102
OFFICE
BD-131a
136
STOR
BD-131e
375
OFFICE
BD-131d
114
ANTE RM
BD-131b
67
MOL.BIO.
BD-131
584
OFFICE
BD-131f
128
FE
EES


27 x 48
Refrigerator
A
1
C
2
1
BIO
SAFETY
MICRO-
BIOLOGY
Refrigerator
D
2
1
3
B
2b
CHEMISTRY/HEMATOLOGY
B
2
Cobas
6000
B
1
E
1
STER
SOL
PREP
SPEC
PROCESS
URINALYSIS
G
1
2
F
2
1
BLOOD
DRAW
I
H
BLOOD
DRAW
WALLA
WALLA

From: Jordan, Judith R.
To: Aldridge, Kathleen V
Subject: Alaska VA Laboratory Floorplan
Date: Tuesday, August 25, 2015 10:30:02 AM
Attachments: Scanned from a Xerox Multifunction Device.pdf

Kathy,
Here is the floor plan for the Alaska VA (it's an 8.5x14). We will not be putting in any front end automation. I think we will keep our COBAS 6000 until it starts to give us problems. So far it's working great, but we'll need the flexibility to replace it when necessary.
Judie

Judie Jordan, MT(ASCP), Chief of Laboratory and Radiology
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