

performance of functions or activities involving the use or disclosure of protected health information (PHI), or that provides certain services involving the disclosure of PHI. VHA is a covered entity under the Health Insurance Portability and Accountability Act (HIPAA) 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.

3. **TEST MENU:** Refer to Attachment A for required test menu and estimated annual volumes.
4. **GENERAL REQUIREMENTS:**
 - a. **Primary analyzer(s)** – Base equipment offered 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. If a back-up analyzer is required, the back-up analyzer shall meet the technical functionality and the capabilities of the primary analyzer, to include additional analyzer(s) that meet the definition of a primary analyzer.
 - i. For VISN 22; VAGLAHS, VASDHS, VALBHS, VALLHS and VASNHS, an Instrument for Rapid Automated Multiplex Polymerase Chain Reaction (PCR) Diagnostics for Pathogens testing, shall be required as an additional, faster bacterial identification system.
 - (1) The instrument shall be able to simultaneously perform the testing as described below and meet 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) The instrument must have capabilities of identifying organisms directly from specimens including positive blood cultures, respiratory and stool within 1 hour.
 - (3) The instrument shall be Food and Drug Administration (FDA) 21 Code of Federal Regulations (CFR) Part 11 Compliant.
 - (4) The instrument must include an FDA-approved broad library of bacteria, yeast, parasites, and viruses.
 - (5) The system must include the ability to detect antimicrobial resistance genes.
 - (6) The platform must have minimal hands on time (5 minutes or less) without batching.
 - b. The instrument must perform amplification, detection and analysis in one self-contained system.
 - c. **Operational Features** - The instrumentation offered shall have the following, at a minimum:
 - i. The capability of performing analysis on 100% of the test panels listed in Attachment A.

- ii. Sufficient capacity and throughput to meet the volume and service demands as defined in Attachment A.
 - iii. Safety features to avoid exposure to biohazardous and chemical material. The exposure to and the volume of biohazardous and chemical material generated by the equipment shall be minimal and require a minimum amount of handling.
 - iv. A bi-directional, bar-coded computer interface compatible with the current VA laboratory information system (VISTA). The fully operational interface (both hardware and software) shall be available from the start of the performance for implementation to the VA computerized hospital information system (middleware may be required).
 - (1) The accuracy of the barcode reading shall have less than a 1% failure rate.
 - (2) Equipment shall be able to support multiple barcode formats (Code 39, Code 128) that may be enabled concurrently.
 - v. Equipment shall accept, at a minimum, BCBC characters in specimen identifier that is alpha and/or numeric, depending on the facility.
 - vi. Minimal daily, monthly, and periodic maintenance.
 - vii. Ability to store and retransmit records (twenty-four (24) hours of maximal instrument throughput) in case of interface outage.
- d. **Technical Features** - The instrumentation shall be approved by the FDA and shall have the following, at a minimum:
- i. The capability of accurately and reliably identifying organisms directly from specimens including positive blood cultures, respiratory and stool.
 - ii. Positive blood cultures target organisms and antibiotic resistance genotypes should include:
 - a. Positive blood cultures
 - i. ☒ Enterococcus
 - ii. ☒ Listeria monocytogenes
 - iii. ☒ K. oxytoca
 - iv. ☒ K. pneumoniae
 - v. ☒ Proteus
 - vi. ☒ S. marcescens
 - vii. ☒ C. albicans
 - viii. ☒ C. glabrata
 - ix. ☒ C. krusei
 - x. ☒ C. parapsilosis
 - xi. ☒ C. tropicalis
 - xii. ☒ S. aureus
 - xiii. ☒ S. agalactiae
 - xiv. ☒ S. pyogenes
 - xv. ☒ S. pneumoniae

- xvi. ☒ A. baumannii
- xvii. ☒ H. influenza
- xviii. ☒ N. meningitidis
- xix. ☒ P. aeruginosa
- xx. ☒ E. cloacae complex
- xxi. ☒ E. coli
- xxii. ☒ mecA
- xxiii. ☒ vanA/B
- xxiv. ☒ KPC

iii. Respiratory specimen target organisms should include:

a. Respiratory:

- i. ☒ Adenovirus
- ii. ☒ Coronavirus
- iii. ☒ Influenza A and B
- iv. ☒ Metapneumovirus
- v. ☒ Parainfluenza
- vi. ☒ RSV
- vii. ☒ Rhinovirus/Enterovirus
- viii. ☒ Bordetella pertussis
- ix. ☒ Chlamydomphila pneumonia
- x. ☒ Mycoplasma pneumonia

iv. Stool specimen target organisms should include:

a. Stool specimen:

- i. ☒ Campylobacter
- ii. ☒ C. difficile (ToxA/B)
- iii. ☒ P. shigelloides
- iv. ☒ Salmonella
- v. ☒ Vibrio
- vi. ☒ V. cholera
- vii. ☒ Y. enterocolitica
- viii. ☒ E. coli 0157
- ix. ☒ EAEC
- x. ☒ EPEC
- xi. ☒ ETEC
- xii. ☒ STEC
- xiii. ☒ EIEC
- xiv. ☒ Adenovirus
- xv. ☒ Astrovirus
- xvi. ☒ Norovirus
- xvii. ☒ Rotavirus
- xviii. ☒ Sapovirus
- xix. ☒ Cryptosporidium
- xx. ☒ Cyclospora cayetanensis

- iii. The capability of detecting emerging antimicrobial resistance.
 - iv. Built-in quality control program to monitor system performance.
 - v. Estimated quantities in attachment A may vary depending on VA workloads. An estimated variance of 15% shall be considered to allow for any fluctuation in quantities needed.
- e. **Data Management** - The System shall have the following,:
- (1) Capability to connect to the VISTA interface.
 - a. The Contractor shall supply IT personnel support to implement a Veterans Health Information Systems and Technology Architecture (VISTA) verification from the supplied equipment middleware interface.
 - i. Capability to record, store and print the following information:
 - (1) Required quality control and instrument maintenance information
 - (2) Patient demographic information and specimen results
 - (3) Sufficient memory to store patient information and test results with downloading capability to an external medium for long term storage of patient records and other information.
- f. **Hardware Features** - The instrumentation shall have the following:
- i. A total equipment footprint that when installed in the laboratory shall not impact the functionality/operations of that laboratory.
 - ii. An on-board monitor/screen
 - iii. A printer that has the capability of printing a patient report with patient demographic information that includes the patient's name and accession or unique identifier number (UID).
 - iv. An uninterruptible power supply with line conditioner for each instrument provided.
- g. **Support Features** –
- i. Commercial marketing. The equipment models being quoted shall be in current production as of the date this quote is submitted. For purposes of this solicitation, “current production” shall mean that the clinical laboratory analyzer model is being quoted as new equipment. Discontinued models that

are only being made available as remanufactured equipment are not acceptable. Gray market equipment, supplies, reagents are not acceptable.

- ii. **Start-Up Reagents.** The Contractor shall provide all reagents, calibrators, controls, consumable/disposable items, parts, accessories and any other item required to establish instruments for operation for performance of acceptance testing.
- iii. **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 equivalent to a training program that the Contractor provides in the commercial market. This shall include, but is not limited to, 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.
- iv. **Service Requirements**
 - (1) A technical assistance center shall be available by telephone twenty-four (24) hours per day, seven (7) days per week with a maximum call back response time of one (1) hour.
 - (2) Equipment repair service shall be provided on site during core business hours, 8:00am – 4:00pm, within twenty-four (24) hours. If equipment malfunction is deemed to jeopardize the need for continuation of patient care, then the Contractor will provide an emergent on-site repair service to be conducted outside routine business hours within twenty-four (24) hours. All such arrangements shall be coordinated between the Contractor and VA laboratory personnel.
 - (3) Equipment repair response time shall be no more than two (2) hours.
 - (4) Preventative maintenance will be performed on all primary and back-up instrumentation and any incremental support equipment as frequently as published in manufacturer's operator's manual and within 2 weeks of the scheduled due date.
 - (5) A malfunction incident report shall be furnished to each facility upon completion of each repair call. The report shall include, as a minimum, the following:
 - a. date and time notified
 - b. date and time of arrival
 - c. serial number, type and model number of equipment
 - d. time spent for repair, and
 - e. proof of repair that includes documentation of a sample run of quality control verifying acceptable performance.
 - f. Each notification for an emergency repair service call shall be treated as a separate and new service call.
- v. **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