

<b>AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT</b>				1. CONTRACT ID CODE <div style="text-align: center;">J</div>		PAGE OF PAGES <div style="text-align: center;">1   13</div>	
2. AMENDMENT/MODIFICATION NO. <div style="text-align: center;">0003</div>		3. EFFECTIVE DATE <div style="text-align: center;">20-Jan-2023</div>		4. REQUISITION/PURCHASE REQ. NO. <div style="text-align: center;">0011878015</div>		5. PROJECT NO.(If applicable)	
6. ISSUED BY W40M USA HLTH CONTRACTING ACT REGIONAL HEALTH CONTRACT OFF CENTRAL 2539 GARDEN AVENUE FT SAM HOUSTON TX 78234-0000		CODE <div style="text-align: center;">W81K00</div>		7. ADMINISTERED BY (If other than item 6) W40M USA HLTH CONTRACTING ACT REGIONAL HEALTH CONTRACT OFF CENTRAL POC: TROY LOGE 1650 COCHRANE CIRCLE, BLDG 7500 FORT CARSON CO 80913-4604		CODE <div style="text-align: center;">W81K00</div>	
8. NAME AND ADDRESS OF CONTRACTOR (No., Street, County, State and Zip Code)				X		9A. AMENDMENT OF SOLICITATION NO. W81K0023Q0013	
				X		9B. DATED (SEE ITEM 11) 28-Dec-2022	
						10A. MOD. OF CONTRACT/ORDER NO.	
						10B. DATED (SEE ITEM 13)	
CODE		FACILITY CODE					
11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS							
<input checked="" type="checkbox"/> The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offer <input type="checkbox"/> is extended, <input checked="" type="checkbox"/> is not extended. Offer 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 <u>1</u> 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)							
13. THIS ITEM APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.							
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 <input type="checkbox"/> is not, <input type="checkbox"/> is required to sign this document and return _____ copies to the issuing office.							
14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)  A. The purpose of this amendment 0003 is to remove the period of performance from each CLIN description, indicate in each CLIN that two (2) each analyzers are required, specify training for two (total) key operators in each CLIN description, and remove the requirement for antigen typing from the table at 1.2 of the Purchase Description.  B. All other solicitation terms and conditions remain unchanged.  See SUMMARY OF CHANGES							
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)			
				TEL: _____ EMAIL: _____			
15B. CONTRACTOR/OFFEROR		15C. DATE SIGNED		16B. UNITED STATES OF AMERICA		16C. DATE SIGNED	
_____ (Signature of person authorized to sign)				BY _____ (Signature of Contracting Officer)		20-Jan-2023	

## SECTION SF 30 BLOCK 14 CONTINUATION PAGE

## SUMMARY OF CHANGES

## SECTION SF 1449 - CONTINUATION SHEET

## SUPPLIES OR SERVICES AND PRICES

## Global Changes

## CLIN 0001 -- CLIN 4001

The CLIN description has changed from Blood Bank Automated Analyzer to Blood Bank Automated Analyzers (2).

The CLIN extended description has changed from:

Contractor shall provide the equipment, service and consumables (all reagents, controls and calibrators necessary to operate the system without interface with the network). Training and associated expenses for two key operators is included (Training positions must be used within 12 months of installation). Delivery and installation at no extra cost to the government. Volumes: ABORH 11400 samples, antibody screen 6000 samples, antibody identification 240 samples, direct antiglobulin test (DAT 120 samples. POP 1 Oct 2023 - 30 Sep 2024).

To:

Contractor shall provide the equipment, service and consumables (all reagents, controls and calibrators necessary to operate the system without interface with the network). Training and associated expenses for two (total) key operators is included (Training positions must be used within 12 months of installation). Delivery and installation at no extra cost to the government. Volumes: ABORH 11400 samples, antibody screen 6000 samples, antibody identification 240 samples, direct antiglobulin test (DAT 120 samples).

The following have been modified:

PURCHASE DESCRIPTION

**1. DESCRIPTION:** William Beaumont Army Medical Center (WBAMC) is in need of two (2) blood bank analyzers, with all equipment, reagents, consumables, controls, and any necessary services (e.g. maintenance of furnished equipment) for the purpose of automated blood bank testing under a cost-per-test (CPT) agreement. All equipment, parts, and reagents/consumables shall be supplied and serviced through the Contractor to ensure WBAMC is able to perform estimated annual workload. The Contractor shall perform to all the standards contained within this PD. The Contractor shall provide blood bank reagents, equipment, maintenance, and support at no extra cost to the government. Contractor shall be responsible for furnishing maintenance, services, repairs, and parts as required in order to maintain the systems in optimal operating condition.

1.1 WBAMC requires two identical, FDA-approved walk-away blood bank analyzers capable of providing a fast result turnaround time (<1 hour), continuous access for STAT priority, as well as the ability to communicate with the Laboratory Information System (LIS), currently Cerner/MHS Genesis. Analyzers will be used for fully automated blood bank performance of blood typing with hemagglutination reagents, weak D testing, Red Blood Cell phenotyping for Rh/K antigens, antibody screening (3 cell) and identification (3 panels, with one panel being an Rh negative panel due to our high volume of prenatals), direct anti-globulin testing (DAT-IgG), and blood unit compatibility testing, donor confirmations using hemagglutination. Analyzers will have the ability to automatically reflex test any Rh negative sample for Weak-D testing. Technology used for antibody screening and identification will be highly sensitive so as not to miss clinically significant antibodies and highly specific so as not to detect clinically insignificant antibodies. Vendor shall also supply WBAMC Blood Bank with automation competency kits to confirm staff competency in test menu items.

## 1.2. Estimated annual workload numbers:

Description	Est. Annual Workload
ABO/Rh Blood Typing	11,400
Antibody Screen	6,000
Antibody ID (~30% Anti-D Prenatals)	240
Antibody Titer	1,200
Direct Anti-Globulin Test (DAT)	1,200
Donor Blood Type Confirmations / Infant Studies	3,000

1.2.1. The Contractor shall provide two (2) duplicate, self-contained, fully automated blood bank analyzer systems capable of performing all of the required assays. The analyzer system shall be from a single Contractor. Instruments shall be small enough to fit on a standard bench (24") without additional reinforcement requirements. All equipment displays and supporting literature shall be in the English language. Contractor shall include delivery, installation, all calibrators/standards, reagents/reagent packs, and quality control materials necessary to perform the specified assays, initial Method Validations per CLIA/NCCLS/DPALS QM guidelines, and analyzer removal at the termination of the contract. Any and all costs associated with this contract, to include shipment of supplies, testing of samples and functionality of analyzers, shall be reflected in the offeror's bid. Period of performance is shown below.

## Period of Performance:

Base year: 1 October 2023 – 30 September 2024

Option 1: 1 October 2024 – 30 September 2025

Option 2: 1 October 2025 – 30 September 2026

Option 3: 1 October 2026 – 30 September 2027

Option 4: 1 October 2027 – 30 September 2028

1.3. **Installation:** The equipment will be installed at the following location:

William Beaumont Army Medical Center

Blood Bank, Department of Pathology

18511 Highlander Medics Way

Fort Bliss, TX 79918

1.3.1. Equipment installation shall happen within 2 weeks of award of the contract. Equipment shall be onsite 30 days prior to 01 October 2023 to ensure patient testing is ready to start on the POP date. All validations shall be completed prior to 01 October 2023.

1.3.2. This contract is a NON-PERSONAL SERVICES contract under which the personnel rendering the services are not subject, either by the contract's terms or by the manner of its administration, to the supervision and control usually prevailing in relationships between the government and its employees.

1.3.3. The inspection and acceptance point for all services rendered under this contract will be performed by the Contracting Officer's Representative (COR), Clinical Engineering Branch. The performance by the Contractor technician, the quality of services rendered, and any documentation or written material in support of same, shall be subject to continuous inspection, surveillance and review for acceptance by the COR or designated representative. Other performance evaluation factors will be monitored that are not quantified by numerical measurements, Contractor technician relationship with hospital staff/government contracting personnel and compliance with hospital policy and procedures.

1.4 **Reagent/Consumables:** Reagents shall be shipped in pre-determined drop shipments.

1.4.1. All reagents, consumables, controls, and calibrators shall be at no additional cost to the government.

1.4.2. All reagents and equipment shall be approved by the US Food and Drug Administration (FDA).

1.4.3. The Contractor shall provide all reagents/reagents packs, calibrators/standards, quality control materials, user-replaceable maintenance items, and analyzer specific tools/supplies to support the ongoing delivery of laboratory services using the equipment outlined in this section.

1.4.4. All assays and reagents shall be FDA-approved. All related approvals or modifications to equipment, reagents, or parts of assay related to the testing product shall be provided in the event any changes are made during performance of the contract.

1.4.5. Reagents/consumables shall meet the requirements of the 24/7 WBAMC mission, workload, and test menu. The Contractor shall provide the necessary materials in accordance with (IAW) the equipment's operators manual.

1.4.6. Reagents used for troubleshooting analytical systems shall be reimbursed (or replaced) by the Contractor at no additional cost.

1.4.7. Reagents shall have a shelf life of at least 4 months upon receipt, or as stated within the individual line item on the delivery ticket or invoice. Controls shall have a shelf life of 12-24 weeks. Shall be clearly marked with any required temperature controls, as necessary.

1.4.8. Emergency orders shall be delivered within 24 hours after the order is placed

1.4.9. Contractor shall ensure all deliveries arrive within 1 week of the order being received.

1.5. **Preservation and packing:** Preservation and packing shall be performed IAW the best commercial practice and in such a manner to afford adequate protection against any damage during shipment from source to destination. All packaging and shipping information shall be clearly marked as to contents on both the shipping documents and the shipping container/box. All deliveries shall be made Tuesday through Thursday, to exclude federal holidays.

1.6. **Maintenance/Services:** Contractor service representative shall provide telephonic phone services for support of technical/equipment concerns.

1.6.1. Contractor shall provide 24/7 phone support for all technical questions and troubleshooting. Should it be determined that a module has been broken and repair cannot be done onsite by the technologist, the Contractor shall have a replacement module shipped to arrive within 24 hours of the notification.

1.6.2 **GOVERNMENT HOLIDAYS.** The following government holidays are observed:

New Year's Day, January 1

Martin Luther King, Jr.'s Birthday, 3rd Monday in January

President's Day, 3<sup>rd</sup> Monday in February

Memorial Day, Last Monday in May

Juneteenth, June 19

Independence Day, July 4

Labor Day, 1st Monday in September

Columbus Day, 2nd Monday in October

Veteran's Day, November 11

Thanksgiving Day, 4th Thursday in November

Christmas Day, December 25

Any holidays that are declared by Presidential Executive Order shall be observed in the same manner as the holidays listed above. If the area in which a Contractor employee is scheduled to work is closed due to a holiday declared by an Executive Order and the employee is not required to report in, payment will not be made for those hours.

Closures of the installation due to inclement weather or other such acts of God shall be handled in the same manner.

## 2. CONTRACTOR PERSONNEL REQUIREMENTS.

2.1. Service personnel shall have a good working knowledge of SB 8-75-11 paragraph 6-5a.(f): "Contractor's service representative will be factory trained and have a minimum of two years of experience working on the contracted MD/MDS."

2.2. The Contractor shall not hire off-duty government employees who serve as inspector or COR in their government position, or any other persons whose employment would result in a conflict of interest.

2.3. "Contractor shall use only OEM new or OEM refurbished repair parts." (SB 8-75-11, par 6-5a.(i))

2.4. Contractor Employees. The Contractor shall not employ persons for work on this contract if such employee is identified to the Contractor by the Contracting Officer as a potential threat to the health, safety, security, general well-being or operational mission of the installations and their population.

2.5. Contractor employees shall present a neat appearance and be easily recognized as Contractor employees. Contractor personnel shall either wear a distinguishable uniform or badge on the exterior of their clothing while performing any service at any Government facility.

2.6. The Contractor shall not employ any person who is an employee of the US Government or any person who is an employee of the Department of Defense, either military or civilian, unless such person seeks and receives

approval according to DOD 5500.7R, "Joint Ethics Regulation". The Contractor shall not employ any person who is an employee of the Department of Defense, if such employment would be contrary to local policies.

2.7. All Contractor employees, minus maintenance, must be registered with the SYMPLR© system for access at WBAMC. With SYMPLR© access vendor representative shall have a badge. Contractors shall check in with SYMPLR© upon arrival to the facility and report to PMO to check in. There the Contractor will have PMO escort the Contractor personally or will contact the main laboratory to have an escort come down to receive them. All contracting personnel shall be escorted at all times and shall not be permitted on premises without an escort. SYMPLR© access will not be paid for by the government and access is by individual not by company.

2.8. Contractor maintenance personnel shall check in with Medical Maintenance. Medical Maintenance will issue a temporary badge and check them in. The Contractor will then be escorted by medical maintenance to the lab or medical maintenance will contact the main lab for the escort. At no time will Contractor Maintenance Personnel be without an escort in the WBAMC facility.

2.9. WBAMC Contractor Maintenance policy may change to the SYMPLR© system for login. The COR will notify the Contractor when and if this happens. SYMPLR© access will not be paid for by the government and access is by individual not by company.

2.10. The Contractor shall notify its employees of the United States Government's zero-tolerance policy described in paragraph (b) of FAR clause 52.222-50 "Combating Trafficking in Persons" and the actions that will be taken against employees for violations of this policy.

### **3. SAFETY DATA SHEETS (SDS)**

3.1. The Contractor shall provide safety data sheets (SDS) for each item delivered under this contract that is considered to be HAZARDOUS MATERIAL by the COR. The SDS shall contain information on the hazards associated with each specific chemical or material. The SDS shall be printed in the English language and shall contain as a minimum the following information: identification of the specific hazard, the required practice for the safe use of the product, first aid procedures, and what to do in the event of a spill or other mishap or accident.

### **4. INFORMATION SECURITY / CYBER LOGISTICS**

#### **4.1. Telecommunication**

4.1.1. All Contractor systems that communicate with Department of Defense (DoD) systems shall interconnect through the established Military Healthcare System (MHS) Virtual Private Network (VPN) Business to Business (B2B) gateway. For all Web applications, Contractors shall connect to a Defense Information Systems Agency (DISA)-established Web Demilitarize Zone (DMZ). All software must be approved through the DHA Software and Application Certification Assessment. Submission of DHA Application Request Worksheet must be completed within the six (6) months of contract award.

4.1.2. The Contractor shall follow Army Regulation 25-1, "Army Knowledge Management and Information Technology, AR 25-2, "Cybersecurity," and DoD 6025.18-R, DoD Health Information Privacy Regulation.

4.1.3. In accordance with contract requirements, Contractors shall connect to the B2B gateway via a Contractor procured Internet Service Provider (ISP) connection. The Contractor shall assume all responsibility for establishing and maintaining their connectivity to the B2B gateway. This shall include acquiring and maintaining the circuit to the B2B gateway and acquiring a Virtual Private Network (VPN) device compatible with the MHS VPN device.

4.1.4. The Contractor shall comply with DoD guidance regarding allowable ports, protocols and risk mitigation strategies and will provide, maintain and configure VPN concentrator that complies with DoD security standards.

4.1.5. All costs for VPN hardware and software shall be borne by the Contractor.

4.1.6. The Contractor shall initiate, maintain, and document personnel security investigations appropriate to the Business Associate Representative's responsibilities and required access to MEDCOM Sensitive Information (SI) as determined by the site Chief Information Officer.

4.1.7. The Contractor shall validate that systems authenticate users through the use of the Common Access Card (CAC) or CAC alternative as a part of a two-factor authentication mechanism on the business partner side of the VPN. The Contractor shall also identify the exact location from which remote operational control will take place from, the encryption that will be used, and how the vendor's technical users will maintain secure login.

#### 4.2. Risk Management Framework (RMF) Implementation Plan.

4.2.1. The Contractor shall provide information for the Risk Assessment Analysis to the government for all networking IT applicability.

4.2.2. Contractors shall only offer items, which already have an Authorization to Operate (ATO) or Authorization to Operate – Conditional (ATO-C). Vendors with an ATO-C must complete the full ATO process within 6-months of award of the contract.

4.2.3. Any offered system must meet DoD Cybersecurity/Risk Management Framework (RMF) and the attached Service Information Assurance (IA) requirements. Vendors are required to provide a statement with their quote that they agree to the Service Cybersecurity/IA Requirements, HIPAA requirements and B2B requirements that are attached to this RFO.

4.2.4. Contractors are required to provide a completed Joint Medical Device Risk Assessment Questionnaire (v1.1) for the offered system along with their offer. These should be provided by DHA Cyber Logistics or local IMD.

4.2.5. RMF shall be evaluated as part of the System Capability Factor. Contractors shall meet all the below RMF minimum requirements along with any additional RMF requirements listed/attached to the RFO. Contractors may be assigned strengths if they exceed any RMF minimum requirement and/or meet any RMF objective. Additionally, weaknesses may be assigned based on the vendor's responses in the Joint Medical Device Risk Assessment Questionnaire (v1.1). RMF weaknesses may include; but are not limited to; deficiencies in architecture or software versions, other services having cancelled RMF efforts due to vendor non-responses or inability to get an RMF ATO, system having received a DATO from any service, and deficiencies that cannot be mitigated/accepted.

4.2.6. Submitting a quote for any requirement under this initiative constitutes full agreement to all specific Service IA requirements and the attached IA document.

4.2.7. Failure to agree to the attached Service IA requirements and to provide a completed Joint Medical Device Risk Assessment Questionnaire shall result in rejection of the vendors quote. Failing to disclose that a system cannot meet IA requirements, failure to meet certification timeframes or failure to receive ATO may result in termination for cause in accordance with FAR 52.212-4(m).

#### 4.2.8. Establishing Interface.

(a) The system shall bi-directionally interface with Military Healthcare System (MHS) Genesis and the laboratory information system (LIS), as specified in the SOW.

(b) The system shall have the ability to receive HL7 order messages (ORM) and information from the LIS and provide DICOM Modality Worklist to the modalities.

(c) If the Contractor is not already approved to connect to MHS Genesis bi-directionally, the Contractor shall agree to complete any bi-directional interface integration at no additional cost to the government. Interface integration shall be completed prior to final acceptance of the system.

#### 4.3. Security Clearances.

4.3.1. Personnel to be assigned to an Automated Data Processing (ADP)/IT position must undergo a successful security screening before being provided access to DoD information technology resources. Prior to an employee being granted interim access to DoD sensitive information, MAMC must receive notification that the Office of Personnel Management (OPM) has scheduled the employee's investigation. This requirement shall (must) be met by Contractors, subcontractors and other who have access to information systems containing information protected by the Privacy Act of 1974 and protected health information under HIPAA. Background checks are required for all ADP/IT personnel who receive, store, display, or transit sensitive information. Employees shall (must) have at a minimum an ADP Sensitivity Designation of Level II to access the DoD Network.

4.3.2. All Contractors that use the DoD gateways to access government systems shall submit a DISA Form 41 or equivalent in accordance with COR guidance. In addition, Form 41s are required for each system administrator responsible for each host-to-host interface. Contractors shall complete and submit to TMA one Form 41 for their organization, attached to which shall be a listing of those individuals for whom background checks have been completed, submitted to the OPM, and acknowledgements have been received from OPM that the applications are complete and are pending action by OPM. The request must clearly delineate the ports and protocols used for each Internet Protocol (IP) address. The Contractor shall complete the form and submit to the Government for final processing.

4.3.3. All costs for the Contractors employee background investigations are the responsibility of the Contractor, unless the investigation is completed by the government, which would be at no cost to the Contractor.

4.3.4. The terms and conditions of this clause shall be completed no later than three (3) months post award.

#### 4.4. Business to Business Gateway (B2B) Partners and Third Party Vendors.

4.4.1. General Security Requirements. The Contractor shall establish appropriate administrative, technical, and physical safeguards to protect any and all government data, to ensure the confidentiality, integrity, and availability of government data. As a minimum, this shall include provisions for personnel security, electronic security and physical security as listed in the sections that follow.

#### 4.4.2. Personnel Security.

4.4.2.1. The Contractor shall comply with the following:

- DoD Directive 8500.01, "Cybersecurity
- DoD Directive 5400.11, "DoD Privacy Program"
- DoD 6025.18-R, "DoD Health Information Privacy Regulation"
- DoD 5200.2-R, "Personnel Security Program Requirements"
- Local regulations as deemed appropriate by the Information Assurance Officer
- AR 25-1, "Army Knowledge Management and Information Technology"
- AR 25-2 "Cybersecurity"
- AR 525-13 Antiterrorism
- AR 530-1 Operations Security (OPSEC)
- DOD Instruction 8510.01 Risk Management Framework (RMF) for DoD Information Technology (IT)

4.4.2.2. Contractor responsibilities for ensuring personnel security include, but are not limited to, meeting the following requirements:

4.4.2.2.1. Follow the DoD guidelines for submittal of Automated Data Processor/Information Technology (ADP/IT) background investigations and ensure all Contractor personnel are designated as ADP/IT-I, ADP/IT-II, or ADP/IT-III where their duties meet the criteria of the position sensitivity designations outlined in AR25-2.

4.4.2.2.2. Initiate, maintain, and document personnel security investigations appropriate to the individual's responsibilities and required access to Information Systems within the logical boundaries of the facility local area network (LAN).

4.4.2.2.3. Immediately report to the MTFs Security Office and deny access to any automated information system (AIS), network, or information if a Contractor employee filling a sensitive position receives an unfavorable adjudication, if information that would result in an unfavorable adjudication becomes available, or if directed to do so by the appropriate government representative for any reason.

4.4.2.2.4. Ensure that all Contractor personnel receive information assurance (IA) training before being granted access to DoD AISs/networks and information.

4.4.2.3. AT Level 1 Training. All Contractor employees, to include subcontractor employees, requiring access Army installations, facilities, and controlled access areas shall complete AT Level 1 training within 30 calendar days after contract start date or effective date of incorporation of this requirement into the contract, whichever is applicable. The Contractor shall submit certificates of completion for each affected Contractor employee and subcontractor employee, to the COR, or to the Contracting Officer, if a COR is not assigned, within 10 days after completion of training by all employees and subcontractor personnel. AT Level 1 Awareness Training is available at the following website: <https://atlevel1.dtic.mil/at>.

4.4.2.4. Access and General Protection/Security Policy and Procedures. Contractor and all associated subcontractors employees shall comply with applicable installation, facility, and area commander installation/facility access and local security policies and procedures (provided by government representative). The Contractor shall also provide all information required for background checks to meet installation access requirements to be accomplished by installation Provost Marshall Office, Director of Emergency Services or Security Office. Contractor workforce shall comply with all personal identity verification requirements as direct by DOD, HQDA, and or local policy. In addition to the changes otherwise authorized by the changes clause of this contract, should the Force Protection Condition (FPCON) at any individual facility or installation change, the government may require changes in contractor security matters or processes.

4.4.2.5. OPSEC Training. Per AR 530-1, Operations Security, new Contractor employees shall complete Level 1 OPSEC training within 30 calendar days of their reporting for duty. All Contractor employees shall complete annual OPSEC awareness training.

## 5. BILLING AND PAYMENTS.

5.1. Payment will be made by Defense Finance and Accounting Service, (DFAS Indianapolis), Indianapolis, IN (address in Block 18a), after receipt of services. Contractor submits their 2-n-1 invoice in the Wide Area Workflow (WAWF) system for payment. The Contracting Officer's Representative (COR) shall verify for acceptance to be submit to DFAS Indianapolis. Government payment will only be authorized for services actually rendered. Advance payments under this contract are not authorized.

5.2. The Contractor shall provide a reagent list with each fixed price for the appropriate test upon award of the contract to the COR. This will be the firm, fixed-price for the entire term of the contract to include option years.

5.3. WBAMC COR will submit this document for billing to the Contractor on the 1<sup>st</sup> of each month for the previous month. The Contractor shall supply the POC for who will receive these for billing.

5.4. The Contractor shall bill in WAWF within 30 days of receiving the billing statement.

5.5. The Contractor shall attach an itemized invoicing in order for invoices to be paid.

5.6. The Contractor shall submit monthly, in arrears, itemized invoices in accordance with DFARS 252.232-7003, for services rendered under this contract. Information regarding IRAPT is available on the Internet at <https://wawf.eb.mil/>.

## **6. APPLICABLE TECHNICAL ORDERS, SPECIFICATIONS, REGULATIONS, AND MANUALS**

6.1. General. Applicable documents - The latest practicable local (Texas) and national (US) technical regulations are applicable for the manufacturing of the system. In case of differences between local and national regulations, the regulations containing the most stringent requirements shall govern. Contractor will comply with all U.S. laws pertaining to medical equipment. Contractor will also comply with all Department of Defense (DOD), Department of Army (DA), US Army Medical Command (USAMEDCOM), Central Regions Medical Command and William Beaumont Army Medical Center regulations and policies pertaining to medical equipment. Current issues of many DA publications can be accessed at <http://www.usapa.army.mil/gils>. Current issues of many forms can be accessed at <http://www.usapa.army.mil/forms>. Publications and forms not on the internet can be obtained from the MTF. These regulations include, but are not limited to, the following:

6.2. The Publications have been coded as mandatory or advisory. The Contractor is obligated to follow those coded as mandatory only to the extent that they apply to this contract. Supplements, amendments, or changes to these mandatory publications may be issued during the life of the contract. Advisory publications may be used for information and guidance but are not binding for compliance.

6.3. Publications - Mandatory:

Public Law 91-596 29 Dec 70 Occupational Safety and Health Administration

Public Law 104-191 (Aug 1996) Health Insurance Portability and Accountability Act of 1996

Current Edition Joint Commission for Accreditation of Healthcare Organizations (JCAHO)

### Manual

AR 40-1 Composition, Mission, and Functions of the Army Medical Department

AR 40-2 Army Medical Treatment Facilities and General Administration

AR 40-4 Army Medical Department Facilities/Activities

AR 40-68 Quality Assurance Administration

AR 340-21 The Army Privacy Program (05 Jul 85)

AR 380-19 Information Systems Security

AR 380-76 The Department of the Army Personnel Security Program

AFIP PAMPHLET 40-24; Clinical Laboratory Improvement Program (CLIP) policy mandated by DODI 6440.2

NFPA 99, Chapter 7.7.3.2. Advisory

AR 310-25 Dictionary of United States Army Terms

MEDCOM Pam 25-31 Index of Command Administrative Publications (15 AUG 01)

## **7. ADMINISTRATIVE**

7.1. Reports. The Contractor shall submit reports to the COR or Contracting Officer as requested for use in monitoring Contractor performance. The Contractor shall provide the balance of the required information to the clinical engineering manager no later than 48 hours after services are completed."

7.2. Safety. The Contractor shall ensure its personnel comply with all installation and MTF safety regulations. Such regulations include, but are not limited to, general safety, fire prevention, and waste disposal. Copies of these regulations are on file in the medical activity safety office or may be obtained through the COR. The use of cellular phones and 2-way radios is expressly forbidden in all Medical Treatment Facilities and Health Clinics. "The government and the contractor's service representative will exchange hazard communication information before the



commencement of any repair." "When required, the contractor's service representative will comply with the Office of Safety and Health Administration (OSHA) lockout/tag-out standards while performing sustainment on MD/MDS."

## **8. CONTRACTOR CONDUCT**

8.1. The Contractor is responsible for the conduct of its employees. All services shall be provided in accordance with established standards, principles, and ethics of the profession and applicable professional specialty organizations, and shall ensure the highest regard to patient dignity.

8.2. The Contractor shall ensure that its personnel comply with MTF policies regarding personal appearance and conduct.

8.3. Inquiries. Contractor shall ensure that its personnel do not respond to any media inquiries. Any inquiries from the media shall be immediately relayed to the COR, who will relay them to the MTF Commander. There shall be no interviews, comments, or any other response without the knowledge and approval of the MTF Commander. Other than routine inquiries from external agencies, all other inquiries and complaints shall be brought to the attention of the Government.

8.4. Smoking. The Contractor shall ensure its personnel shall comply with the MTF smoking policy.

8.5. Complaints. Complaints will be validated by the COR and be reported in writing to the Contracting Officer and the Contractor for action, if it constitutes a failure to perform, as determined by the Government. The Contractor shall have no more than one substantiated complaint for each period of performance.

8.6. Contractor Representation. The Contractor shall designate a Contract Officer Technical Representative (COTR) for the contract. The COTR shall be the only authorized representative of contractor authorized to discuss with the COR, any and all sustainment services required by the contract and ensure response to requests for performance of the contract. The COTR shall have the authority to make decision for the Contractor. The Contracting Officer or the COR shall be notified promptly whenever the POC changes. COTR shall be submitted no later than 10 days after award of contract, and shall include as a minimum name, title, and telephone number.

8.7. Impaired Personnel. At any time during the performance of this contract, the Contracting Officer may direct the contractor to immediately remove any contract personnel whose actions or impaired state raises reasonable suspicion that clear and present danger of physical harm exists to a patient, other contract personnel, government personnel, or to the impaired individual. This provision will be used in emergency situations only and not for the purpose of bringing performance issues or other non-urgent concerns to the attention of the contractor.

8.8. Sexual Harassment/Assault Response And Prevention. The contractor shall comply with OTSG/MEDCOM Policy Memo 13-062, Policy for Reporting Incidents of Sexual Assault and Sexual Harassment under the Sexual Assault Prevention and Response Program (SHARP), 12 Nov 2013. The SHARP reporting requirements apply only to knowledge obtained by contractor personnel while performing services under this contract.

The Contractor shall require all Contract Service Providers (CSP) with knowledge of an incident of sexual assault occurring on a Government facility, to include a Government leased facility, where the contractor is providing services under this contract, to report the incident to the contractor who shall immediately (within 24 hours) report the incident in writing to the government's COR. All incidents shall be reported whether they involve contractor personnel or Government personnel, or other individuals.

## **9. CONTRACTOR**

9.1. The Contractor shall provide each employee an identification badge which shall be displayed on their outer garment at all times when responding to a service call at IACH. The badge shall include, at a minimum, the employee's name, current picture, Company name, and job title.

9.2. Other than validation kits and certain other materials as described in the instructions for use provided by Contractor, all materials, other than those materials specified as government-furnished, required in the performance of this contract shall be furnished by the Contractor.

9.3. Availability of manufacturer's service literature needed in the performance of the contract will be Contractor's responsibility and will remain Contractor-owned at termination of the contract. The Contractor shall obtain the currently available literature of the original equipment manufacturer (OEM).

9.4. MD/MDS sustainment performance under the contract includes the unlimited replacement of defective parts in accordance with the terms of Contractor's Standard Limited Warranty or Extended Warranty, if applicable.

9.5. Contractor shall notify the COR when replacement parts needed to complete service are not available.

9.6. The government is not responsible for any damages or loss of Contractor supplies, materials, or equipment nor is the government responsible for any damages or loss of the Contractor employees' personal belongings, due to fire, theft, accidents or other causes.

9.7. The Contractor shall report immediately to the government point of contact (POC), or the Chief of Equipment Management Branch (EMB), all accidents which may arise out of or in connection with the performance of services required within the scope of this contract.

## **10. SERVICE**

10.1. Contractor employees shall check-in at WBAMC Clinical Engineering Branch, to check in with the COR, ACOR, OIC, NCOIC, or EMB Supervisor before proceeding to complete sustainment services.

10.2. Persons Authorized to Make Calls. Only those people listed below and the Contracting Officer are authorized to give the Contractor instructions, place service calls, or request updates status. The Government representative will call and leave their name and number. The Contractor will return the call or come directly to the Medical Maintenance Branch to verify instructions prior to initiating any action.

Primary POC Ms. Natalia Quintero

Alternate POC Ms. Magaly Segovia

10.3. Contracting Officer's Representative (COR). The Contracting Officer will designate a primary point of contact in which the Contractor will receive guidance.

10.4. Any service performed without the prior approval of one of the individuals above shall be at no cost to the government.

10.5. Service Reports.

10.5.1.1. Upon completion of services by the Contractor's service representative, a written service report shall be provided to the clinical engineering staff. In the event all information is not available to the Contractor's service representative when services are performed, the initial service report shall include all available information. This report is initiated by the Contractor at the completion of each service and at the minimum will include:

Contract number, Contractor's name, COTR's name (full printed and signed name), Equipment Control Number and serial number of MD/MDS being sustained.

10.5.1.2. The time required to complete the work, price of labor (hourly rate), and a list of parts replaced with part numbers and list prices for each part used. Hours are in tenths and rounded up to the nearest tenth of an hour.

10.5.1.3. After performing Calibration/Verification/Certification services, the Contract Officer Technical Representative (COTR) will affix and/or update DD Form 2163 (Medical Equipment Verification/Certification) in accordance with the instructions provided in TB 38-750-2, or by the clinical engineering activity's internal SOP.

## **11. OTHER REQUIRED TASKS**

11.1. Contractor's service representative shall report to the Clinical Engineering Branch and sign-in the Contractor's Log by indicating company name, individuals name, time of arrival, and destination. When departing WBAMC, the COTR must report back to Clinical Engineering and provide the service report as required if available.

11.2. The performance of all services shall meet or exceed the specifications of the original equipment manufacturer.

11.3. The Contractor is not responsible for the sustainment of MD/MDS listed when damage resulted from acts of God, or government neglect/misuse/abuse, or when services were conducted by personnel other than the COTR.

11.4. Delays caused by government will not be counted as Contractor "down time" for the purpose of this requirement.

11.5. Contractor shall use only OEM new or OEM refurbished repair parts, as approved by the Clinical Engineering Branch to ensure proper and safe operation of the MD/MDS. The Contractor shall provide technical assistance and shall furnish all software upgrades issued by the MD/MDS manufacturer.

11.6. The Contractor shall comply with applicable federal, state, and local laws and regulations.

11.7. If a malfunction exists with the Contractor maintained equipment or the government's utilities (i.e., water, air, electricity), the COTR will be notified. The COTR and the government's maintenance representative will test the utilities and determine whether the utilities or the MD/MDS failed. If it is determined that the MD/MDS failed, the COTR shall perform sustainment services immediately.

11.8. Contractor personnel shall leave job site in the same condition as found upon arrival.

## **12. REPLACEMENT PARTS**

12.1. The Contractor shall have and maintain an adequate inventory of repair parts to service the MD/MDS listed herein and as may be needed in the performance of this contract. The Contractor shall maintain a backup inventory

of spare parts so that any spare parts can be delivered to the site within the time frames established, if the spare part is not available from the local contractor inventory.

12.2. Parts which have been replaced with Contractor furnished parts shall become the property of the Contractor. Parts once placed in a system or sub-system becomes the property of the Government.

12.3. The Contractor shall replace all worn, failed, or defective parts at no additional cost to the Government.

**13. APPLICABLE FORMS AND PUBLICATIONS:** Publications documents and forms applicable to this PWS are listed below. The Contractor shall use reasonable efforts to comply with these directives. Supplements or amendments may be issued during the life of the contract and will be considered to be in full force and effective immediately upon receipt by the Contractor. If compliance with such supplements and amendments changes the contract cost, scope or purpose, it shall be a change within the meaning of the "Changes" clauses of the contract.

13.1. FORMS. The forms listed below will be provided to the Contractor by the Government for use in the performance of this contract.

DD Form 2163, Medical Equipment Verification/Certification.

13.2. PUBLICATIONS. Army publications shall be made available to the Contractor during the period of the contract. These publications are located in the Clinical Engineering Branch, IACH.

AR 40-5 Preventive Medicine AR 40-61, Medical Logistics Policies and Procedures SB 8-75-11 Augments AR 40-61

TB MED 7, Maintenance Expenditure Limits for Medical Equipment TB MED 750-1, Operating Guide for Medical Equipment Maintenance FR MEDDAC 750-1

13.3. OTHER PUBLICATIONS - The following publications will be acquired by the Contractor for his use at his own expense. These publications are other than Army publications which establish guidelines for administering adequate healthcare services. When a conflict between these publications and Army publications arises, the publication which is more restrictive will be followed.

Joint Commission Manual (Current edition) National Fire Protection Association (NFPA) 99, Health Facilities Handbook, (Current edition). National Fire Protection Association (NFPA) 101, Life Safety Code, (Current edition).

**14. PERFORMANCE MEASUREMENT REQUIREMENT SUMMARY.** The following performance objectives and measures will be used to evaluate Contractor performance and compliance under the contract. This information will be used to prepare annual past performance evaluations. See Exhibit 1, Quality Assurance Surveillance Plan (QASP), for additional details.

PERFORMANCE REQUIREMENT	PERFORMANCE STANDARD	PERFORMANCE LEVEL	SURVEILLANCE METHOD
1. Contractor shall provide telephone support 24 hours per day, 7 days per week. SOW Para 1.6	Provides telephone support 24 x 7 as required.	Meets - 100% based on the number of calls placed each month.	Continuous monitoring. Technical Evaluator Monitors
2. Module Replacement for defective/broken modules will be completed within 48hr. of defective unit being identified. SOW Para 12	Verified broken by technical support; 48hr starts from when tech support says unrepairable onsite.	Meets – 100% *weekends and holidays it is understandable delay may occur to initiate repair	Continuous monitoring. Technical Evaluator Monitors
3. The Contractor delivers reagents within one (1) week after delivery is requested. SOW Para 1.4	Agents delivered as required.	Meets – 100% based on the number of reagents delivered each month	Review of delivery documents. Technical Evaluator Monitors
4. Packaging and temperature control requirements for all Reagents and Supplies. SOW Para 1.5	Meets packaging and temperature controls as required.	Meets – 100% based on Each shipment of supplies and reagents.	Inspection upon receipt. Technical Evaluator and COR
5. Analyzer Operational up-time	Analyzer must be operational 24/7 to support patient testing	Meets – 100%	Technical Evaluator and COR monitors

6. Quality Control	Performed by the technologist, QA must perform within historical records established and be within federal and manufacturer limits. QC discrepancies / problems will be handled by the vendor and may result in refund or additional kits to replace those used	Meets – 100%	Technical Evaluator
7. Installation and movement of equipment	Installation is not performed properly or relocation/movement of equipment causes the equipment to not be within standards for testing at WBAMC, the Vendor is responsible for replacing the equipment and meeting the standard of the contract	Meets – 100%	Technical Evaluator and COR
8. Training	Vendor will supply the necessary off site training slots per year at no cost to the government for all sites identified in the contract. Vendor will also supply onsite training and provider education as necessary at no additional cost to the government	Meets – 100%	Technical Evaluator
9. WAWF/Payment	Vendor must submit payment request within 30 days of receiving order at WBAMC. Vendor must submit itemized invoice to accompany the request for payment	Meets – 100%	COR
10. OTSG/MEDCOM Policy Memo 13-062.	Policy for Reporting Incidents of Sexual Assault and Sexual Harassment under the Sexual Assault Prevention and Response Program (SHARP)	100% compliance.	COR documentation and program review. Any non-compliance must be brought to the immediate attention of the KO.
11. Sexual Assault and/or Sexual Harassment Reporting	Within 24 hours of incident	100% compliance.	COR Documentation. Any non-compliance must be brought to the immediate attention of KO.

(End of PD)

(End of Summary of Changes)