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| **AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT** | | | | | | | | | | 1. CONTRACT ID CODE | | | PAGES OF PAGES | | | |
| 1 | | 9 | |
| 2. AMENDMENT/MODIFICATION NO.  **Mass Modification 0003** | | | | 3. EFFECTIVE DATE | | | 4. REQUISITION/PURCHASE REQ. NO. | | | | 5. PROJECT NO. *(If applicable)* | | | | | |
| 6. ISSUED BY: | | CODE: | | | 003B6B | | 7. ADMINISTERED BY *(If other than Item 6)* | | | | | CODE: | | 003B6B | | |
| Department of Veterans Affairs  National Acquisition Center  P.O. Box 76, Bldg. 37  Hines, IL 60141 | | | | | | Department of Veterans Affairs  National Acquisition Center  P.O. Box 76, Bldg. 37  Hines, IL 60141 | | | | | | | | | |
| 8. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)* | | | | | | | | (X) | 9A. AMENDMENT OF SOLICITATION NUMBER | | | | | | | |
|
| 9B. DATED *(SEE ITEM 11)* | | | | | | | |
|
| X | 10A. MODIFICATION OF CONTRACT/ORDER NUMBER | | | | | | | |
| 10B. DATED *(SEE ITEM 13)* | | | | | | | |
| CODE | | | FACILITY CODE | | | | |
| 11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS | | | | | | | | | | | | | | | | |
| The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers  is extended  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     copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted;  or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT 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 letter or electronic communication, provided each letter or electronic communication 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.** | | | | | | | | | | | | | | | | |
| (x) | 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). | | | | | | | | | | | | | | | |
| X | C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:  52.212-4(c) Contract Terms and Conditions - Commercial Items (Changes) | | | | | | | | | | | | | | | |
|  | 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. | | | | | | | | | | | | | | | | |

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| 14. DESCRIPTION OF AMENDMENT/MODIFICATION (*Organized by UCF section headings, including solicitation/contract subject matter where feasible.)*  **REVISION OF GENERAL DEFINITIONS AND STATEMENT OF WORK**  This modification is issued to incorporate the attached, revised General Definitions and Statement of Work into the above-referenced contract pursuant to an amendment issued under 66 III solicitation RFP-797-FSS-03-0001-R1. |
| 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. |

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| --- | --- | --- | --- | --- | --- |
| 15A. NAME AND TITLE OF SIGNER *(Type or print)* | | 16A. NAME AND TITLE OF CONTRACTING OFFICER *(Type or print)* | | | |
| 15B. CONTRACTOR/OFFEROR  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(Signature of person authorized to sign)* | 15C. DATE SIGNED | | 16B. UNITED STATES OF AMERICA  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  *(Signature of Contracting Officer)* | | 16C. DATE SIGNED |
| EXCEPTION TO SF 30 | | | | STANDARD FORM 30 (REV. 11/2016) | |
| APPROVED BY OIRM 11-84 | | | | Prescribed by GSA FAR (48 CFR) 53.243 | |

**GENERAL DEFINITIONS**

**Cost Per Reportable Result (CPRR)**

Contractors are required to provide and customers will be billed a price for each reportable patient result generated on its equipment by an approved method of testing. The per reportable result price shall include costs covering all of the following:

**(a)** Equipment use.

**(b)** All reagents, standards, quality control material, 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 does not include those items approved for exclusion by the Government such as printer paper, labels etc. This per patient reportable result price will also encompass all costs associated with dilution, repeat and confirmatory testing required to produce a single patient reportable result. It will also include the material to perform as well as all other costs associated with quality control, calibration and validation testing that is prescribed by the Clinical Laboratory Standards Institute (CLSI).

**(c)** All necessary maintenance to keep the equipment in good operating condition and in compliance with the performance characteristics as approved by the Food and Drug Administration (FDA). This element includes both preventive maintenance and emergency repairs.

**(d)** Training for Government personnel.

The price for each reportable test is calculated by multiplying the individual cost per reportable test by the number of reportable tests generated by the testing analyzer.

**Cost Per Test (CPT)**

Contractors are required to provide and customers will be billed a price for each test that is performed on its equipment by an approved method of testing. The per test price shall include costs covering all of the following:

**(a)** Equipment use.

**(b)** All reagents, standards, quality control material, 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.

**(c)** All necessary maintenance to keep the equipment in good operating condition and in compliance with the performance characteristics as approved by the Food and Drug Administration (FDA). This element includes both preventive maintenance and emergency repairs.

**(d)** Training for Government personnel. The price for each test is calculated by multiplying the individual cost per test by the number of tests generated by the testing analyzer.

**Clinical Laboratory Analyzers and Equipment**

Clinical Laboratory Analyzer and Equipment (herein referred to as equipment) include~~s~~ any equipment approved by the Food and Drug Administration to perform and report clinical laboratory tests for the purposes of the diagnosis, treatment or monitoring of medical patients.

**Acceptable CPRR/CPT Pricing Model**

1. Per reportable result or per test fixed pricing approaches include, but are not limited to, the following two models:
2. Matrices of all net prices inclusive of subject fixed and variable costs as indicated in the above definitions.
3. Pricing of subject fixed and variable costs broken down individually and subject to an acceptable calculation that would be applied, resulting in the net fixed price consistent with the requirement of the solicitation.
4. Cost Per Kit Pricing is not accepted under the Cost Per Test/Cost Per Reportable Schedule 66 III.
5. All calculations and offered pricing shall be based upon a five (5) year period of performance.
6. Contractor shall provide a pricelist of reagents, controls, and consumables which provides the unit prices used in the determination of offered CPT/CPRR prices.
7. Pursuant to the Price Reductions clause, the contractor shall provide a list which includes the proposed tracking customer and the tracking customer’s price for offered equipment, reagents, controls, and consumables.

**STATEMENT OF WORK**

**CLINICAL LABORATORY ANALYZERS**

* The Government will award multiple award indefinite delivery, indefinite quantity contracts for requirements as specified throughout this Request for Proposals (RFP).
* The contractor shall furnish clinical laboratory analysis equipment, reagents, supplies, service and training to perform and report clinical laboratory tests in accordance with the General Definitions section of this solicitation.
* Contractors are required to provide delivery, installation and removal of equipment at no additional charge.
* Contractors are required to provide a price for each patient reportable result and/or test performed on its equipment in accordance with the CPRR and CPT definitions provided in the General Definitions section of this solicitation.

**I. EQUIPMENT CAPABILITIES**

Each model of clinical laboratory analyzer offered under this RFP shall comply with all general requirements stated herein.

As part of their offer, each contractor must submit technical data or descriptive literature to ascertain that the equipment offered meets the requirements outlined below.

By signing this offer the contractor is certifying that the equipment will regularly function without excessive malfunctions, breakdowns, or service calls. A high incidence of such problems with any equipment/model supplied may indicate probable non-compliance with the terms of this contract and will entitle the Government to its replacement with other model(s) that can produce the required minimum number of sample results per hour in a manner that is satisfactory to the user. See paragraph III (D) of this statement of work for replacement policy.

**A. GENERAL REQUIREMENTS (Applicable for all equipment)**

1. Equipment must be approved by the Food and Drug Administration.
2. The testing analyzers will be capable of generating a report of the actual number of tests ran (daily, weekly, and/or monthly) and used to perform reconciliations and calculate the price for each test and/or reportable test.
3. Contractors are required to have at least two years corporate experience in providing products and services relative to this solicitation in order to qualify for an award. (See Exhibit 2 Technical Proposal - Instructions, Sub-Factor A)
4. The contractor shall provide new state-of-the-art equipment that is in current production as of the date the offer is submitted.
5. For purposes of this solicitation, "current production" shall mean that the clinical laboratory analyzer model is being manufactured as new equipment. Discontinued models that are only being made available as remanufactured equipment are not acceptable.
6. The offered model will be made available in the same condition of production (as newly manufactured and remanufactured state-of-the-art equipment) as offered for a period of at least one (1) year after the date of contract award.
7. Remanufactured state-of-the-art equipment may be offered as a substitute for new equipment. However, this type of equipment must be accepted by the ordering facility. All remanufactured equipment must be in current production and fully supported by the manufacturer. It also must be inspected and tested to "new machine" standards. The contractor shall furnish a certified copy of the inspection and test reports.
8. The contractor will notify the Contracting Officer, within 30 days, of equipment that is no longer in production or no longer supported by the contractor. Such equipment will be replaced at the customer’s request.
9. The contractor shall provide, without additional charge to the Government, all enhancements to the technology such as device corrections and/or upgrades to the equipment hardware and operating system software that are offered at no expense to other commercial customers.
10. These enhancements to the contractor's equipment shall be delivered to the Government site and installed within sixty (60) days of their issuance or date of first commercial availability.
11. Any upgrade that is supplemental and retrofitted to the initial contracted features of the model (e.g. connection with another piece of equipment, new specimen tracking system, new module that adds new tests and or different methodologies to their instrument, expansion of their reagent storage capabilities, etc.) AND is being marketed to their commercial customers at a cost, would not be included in the contracted cost of the equipment.
12. The Contractor may request a contract modification to add equipment by submitting a request to the Contracting Officer for approval. See clause **552.238-81 Modification (Federal Supply Schedule) located in solicitation amendment A00007.**
13. The Contractor shall provide all commercial documentation necessary for the successful operation of the equipment, e.g. operator's manual, procedures for regulatory compliance, etc. Electronic formats (e.g. on a CD) are acceptable.
14. The offered clinical laboratory analyzer software shall have the immediate capability to interface with the Veterans Health Information Systems and Technology Architecture (VistA) (VA laboratory information system). The Contractor shall supply the required hardware and software necessary to successfully complete the connection.

**B. SPECIFIC REQUIREMENTS**

Offered model (s) of testing analyzers and equipment shall be capable of producing or assist in the production of accurate and reproducible assays on biological and other specimens by established in vitro diagnostic methods. Model (s) will provide an accurate specimen test result in accordance with the manufacturer’s stated specifications without excessive malfunctions, breakdowns, or service calls. The testing analyzers will be capable of reporting the actual number of tests ran (daily, weekly, and/or monthly) used to perform reconciliations and calculate cost for each test and/or reportable test.

1. High Maintenance/Complexity Clinical Laboratory Analyzers Instrumentation whose operation typically requires formal operator training and extensive maintenance.
2. Low Maintenance/Complexity Clinical Laboratory Analyzers Instrumentation whose operation and maintenance **may not** require formal operator training and extensive maintenance.

**C. EQUIPMENT IDENTIFICATION**

Each piece of equipment shall have the manufacturer's serial number permanently and legibly stamped or affixed on a major component in a readily accessible location. In addition, each laboratory analyzer shall be permanently and legibly marked in a conspicuous location with the manufacturer's name or trademark and model number.

**II. INVENTORY CONTROL REAGENTS, SUPPLIES AND DISPOSABLES**

All consumable supplies (reagents, standards, quality control material, disposables, etc.) required for the proper operation of the contractor's equipment and necessary to perform tests on the equipment provided shall be included and shall be furnished by the contractor for each clinical laboratory analyzer model.

All reagents, standards, and quality control material must be approved by the FDA for use on the offered equipment. They must be of the highest quality and meet the performance characteristics for accuracy and precision as defined by the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and the Clinical Laboratory Standards Institute. Performance characteristics must meet the standards for acceptance as defined in Section VIII.

The contractor shall insure the availability and deliver a sufficient inventory of reagents, standards, quality control material, disposable supplies and any other material required to properly perform tests on the offered equipment.  The contractor shall allow the Government facility to place an order based on their expected inventory needs as indicated in their delivery order and/or based upon adjustments made during quarterly reconciliations. At a mutually agreed upon date during the contract year, the customer will provide the contractor the annual test volumes of the individual tests upon which the Cost Per Test or Cost Per Reportable contract is awarded. Adjustments to the delivery order, based upon reconciliations, will be of mutual consent.

1. **DELIVERY OF SUPPLIES**

On or about the first day of each month or as negotiated with the ordering facility, the contractor will insure that each site is furnished with sufficient consumable supplies to produce a volume of tests equal to that stated in the Delivery Order.

**B**. **SPECIAL HANDLING FOR EMERGENCY ORDERS OF SUPPLIES**

In the event that the consumables 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 shall deliver the consumable supplies within a period of twenty-four hours after receipt of the verbal order for priority delivery from the Government activity. If either circumstance has occurred, the contractor will 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 until the original order is delivered. If additional requests for emergency supply delivery are required by the Government, they will be honored by the contractor until the arrival at the Government site of the monthly standing order/routine supplies delivery. Failure to reserve adequate inventory will result in default.

**III. MAINTENANCE**

**A. GENERAL PROVISIONS**

1. The contractor shall provide maintenance (labor and parts) to keep the equipment in good operating condition.
2. The Contractor shall be subject to all Government security regulations.
3. The Government shall provide the contractor access to the equipment for servicing.
4. Contractor will provide regular, scheduled preventive maintenance to assure the continued reliable operation of the equipment. These preventive maintenance visits shall be of a frequency that conforms to the manufacturer's operation and maintenance instructions for the supported equipment. However, if the scheduled maintenance service for commercial customers exceeds the manufacturer’s operation and maintenance instructions, the same shall be provided to the Government for the same model of clinical laboratory equipment.

**5.** The Government agrees to maintain the equipment according to manufacturer's specifications.

**B. EMERGENCY REPAIR**

System failure downtime is that period of time when either the clinical analyzer or a component piece in the system is inoperable and is not capable of generating reportable test results.

Emergency repairs shall be performed after notification that the equipment is inoperative.

The contractor shall provide the Government with a designated point of contact for emergency equipment repair and shall make arrangements to enable his maintenance representative to receive such notification.

The contractor must be capable of performing emergency repair service 24 hours per day, 7 days per week (except when the ordering facilities elects reduced service at contract agreed reduction offered under Attachment 3c of Exhibit 3 of this solicitation). The contractor must respond within a mutually acceptable time frame that is negotiated between the contractor and the Government facility. The contractor will provide all parts and labor needed to repair the malfunction. Travel, per diem and other expenses associated with the repair will be borne by the contractor.

The contractor shall furnish a malfunction incident report to the Government 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(s) of equipment; (d) time spent for repair; (e) description of malfunction and repair; and (f) evidence that the repair is successful, e.g. documentation of a sample run of quality control verifying acceptable performance.

**C. MAINTENANCE CREDIT FOR EQUIPMENT MALFUNCTION**

If the equipment remains inoperative due to a malfunction through no fault or negligence of the Government for a total of more than twenty-four hours, the contractor shall be assessed damages which will be applied to the invoice in the form of a credit or deduction, at the prorated rate of 1/30 of the preceding average 3 month cost-per-reportable/test billings times the total number of days certified as downtime. In the event that there is no history of cost-per-test/reportable billings then the estimated volumes that were established and agreed to in the contract document (e.g. blanket purchase agreement or order placed against the contract) will be used.

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 equipment is returned in good operating order. However, if the delivery/task order provides for emergency repair during normal business hours in lieu of twenty-four hour service, the non-contracted maintenance (Emergency Repairs) days will not be included in the downtime calculation.

**D. REPLACEMENT LABORATORY EQUIPMENT**

During the contract period, should the repair record of any laboratory equipment reflect a downtime of 10% or more of the normal working days in one calendar month, a determination may be made by the designated representative of the Government to replace the initial laboratory equipment with new equipment.

The contractor shall remove the equipment at the expiration of the term of the multi-year pricing arrangement (may encompass performance under previous or ensuing contracts) unless the Government opts to retain the equipment at the reduced contract price.

**IV. TRAINING AND TECHNICAL SERVICE**

The contractor, without additional charge to the Government, shall provide initial training for two operating personnel at the time of installation of the contractor's equipment. Annually, the Government may appoint a replacement person to receive contractor provided training, without additional charge to the Government.

The method and scope of training must be consistent with, and no less than, the method of training offered to other commercial customers. This may include travel of Government personnel to the manufacturer’s training facility.

The contractor shall provide, as indicated, supplemental operating training to the Government personnel, without additional charge to the Government, upon installation of any upgrade in equipment hardware or operating system software connected with the operation of an instrument already furnished under this contract.

At the Government's request, the contractor shall furnish training for additional personnel. The expenses associated with the training of additional personnel shall be borne by the Government as set forth in Exhibit 3, Attachment 3c.

The contractor, at its discretion, may make additional training available at its facility on terms and conditions mutually agreed upon by the agency and the contractor.

**V. SITE PREPARATION**

1. Site specifications will be ascertained through analysis of the published requirements in the manufacturer's literature.
2. The Government shall prepare the site at its own expense and in accordance with the specifications furnished by the contractor. Expenditures associated with required infrastructure changes that are deemed excessive by the Government may preclude award of the BPA to the Contractor.
3. The contractor shall inspect the site on the date and time acceptable to using activity. The contractor shall report to the Government the inspection dates, any rejections, the reasons therefore, and the final inspection and acceptance results. The results will be utilized to assure that the equipment would be in the appropriate environment for optimum use.
4. Any alterations or modification in site preparation that are attributable to incomplete or erroneous specifications provided by the contractor and would involve additional expense to the Government shall be made at the expense of the contractor.
5. Any such site alterations or modifications as specified in Subparagraph d. above which cause a delay in the installation date will also result in liquidated damages for equipment as specified in Paragraph III. (C) of this Statement of Work.

**VI. DELIVERY AND INSTALLATION**

By a mutually agreed upon date, the contractor's representative shall satisfactorily perform (and complete) the installation/setup of the analyzer. Installation is required by a mutually agreed upon date after site preparation has been completed (in conformance with Paragraph V of this Statement of Work) and mutual agreement has been reached as to site preparation acceptability.

Installation by the contractor's representative(s) shall be complete, and in accordance with the manufacturer’s installation and operation manuals/instructions, and shall include, as a minimum:

1. Unpacking the analyzer from the shipping crate and removal of all packing and shipping material(s);
2. Taking system component (and accessories) inventory, and performing inspection to insure that all required analyzer components are present, in working order, and undamaged;
3. Assembling the analyzer into its normal operational configuration; this includes making any required connections for electrical power, drain or vent lines, gas/compressed air, etc. and software installation (loading into computer based/controlled analyzers any operating/configuration software);
4. Performing a complete system operation check (including all system diagnostics, standardization/calibration of the analyzer, making any required electrical or mechanical adjustments, and if requested by the customer, performance of a trial sample run to verify quality control and/or system performance;
5. Providing the operator training for two Government personnel (as specified in paragraph V. Training and Technical Service of this contract).

Upon completion, the contractor's representative shall provide the Government with:

1. A certified copy verifying the analyzer's operation performance (the level of performance must be within the manufacturer's specifications for a new analyzer);
2. All required operating manuals, etc. (as specified in the General Requirements section of this contract); and
3. A telephone number for the contractor's technical support/assistance department for the supported analyzer.
4. **OWNERSHIP OF EQUIPMENT**

Title to equipment provided under this contract shall remain with the contractor. All accessories (unused consumable, etc.) furnished by the contractor shall accompany the equipment when returned to the contractor.

The contractor will remove equipment upon expiration of order(s), replacement of equipment per paragraph IV.D. of this Statement of Work, or notice of termination of the order or contract. The contractor will disconnect the analyzer (gas, water, air, etc.), and will be responsible for all packing and shipping required to remove the analyzer within seven (7) calendar days.

**VIII. STANDARD OF PERFORMANCE FOR ACCEPTANCE**

This section establishes a standard of performance which must be met before any equipment listed on the purchase order is accepted by the Government. This also covers any replacement, substitute equipment and equipment, which is added, or field modified, after a system has completed a successful performance period.

The performance period shall begin on the installation date and shall end when the equipment has met the standard of performance for a period of thirty consecutive calendar days by operating in conformance with the contractor's technical specification or as quoted in any proposal at an effectiveness level of 90% or more. The contractor shall be notified when the standard of performance has been completed and performance met.

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

If the equipment fails to meet the standard of performance after ninety (90) calendar days from the installation date, the Government may, at its option, request a replacement or terminate the order in accordance with the provisions of FAR 52.212-4 (m) entitled "Termination for cause". The contractor will receive payment for tests actually performed by the Government that would appropriately be invoiced under normal operational conditions during the 90 day acceptance period.

Operational use time for performance testing for a system is defined as the accumulated time during which the equipment is successfully issuing reportable test results.

Operations use time and downtime shall be measured in hours and whole minutes.

During the performance period for a system a minimum of 100 hours of operational use time with productive or simulated work will 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.

The Government shall maintain appropriate daily records to satisfy the requirements of this paragraph and shall notify the contractor in writing of the date of the first day of the successful performance period.