

Request for Quotation: FDA_ 1255491

Posted Date: August 25, 2022

Response Date: September 1, 2022, 10:00 a.m. Eastern Time.

Interested parties may identify in writing their interest and capability to respond by no later than September 1, 2022, 10:00 a.m. Eastern Time. Please email responses to Elena Tatarov at Elena.Tatarov@fda.hhs.gov.

Indicate company's SAM.gov Unique Entity ID on the quote. The subject line shall read: *FDA_ 1255491 – Vapodest Kjeldahl Distillation and Titration system*

This announcement constitutes the only solicitation; quotes are being requested and a written solicitation will not be issued. This requirement is being issued in conjunction with FAR Part 13 Simplified Acquisition Procedures. This solicitation is issued as a Request for Quote (RFQ).

NAICS Code: 334516

Notice of Intent to Sole Source: The proposed contract action is for supplies for which the Government is soliciting, only YSI Incorporated, under authority of FAR 6.302-1.

This notice of intent is not a request for competitive proposals. However, the Government will consider all proposals received prior to the closing date and time of this solicitation.

Line Item Structure: The following is a contract line item number(s), quantities, and units of measure, (including option(s), if applicable):

Line Item 0001 – *(1) One Vapodest Kjeldahl Distillation and Titration system*

1. **Background**

The U.S. FDA Southeast Food and Feed Laboratory (SFFL) Nutrition Analysis Branch (NAB) need to replace existing Kjeldahl Distillation/Titration system used for analysis of Infant formula, medical foods and other routine protein sample analysis. The systems in use need to maintain cGMP/cGLP, ISO/IEC 17025-2017, ISO 9001:2008, and 21 CFR 11 standards for use as analytical equipment under the current accreditation. The systems is used to screen and analyze Infant formula, medical foods and other product samples using specific protocols and methods established by USP, internal FDA, AOAC and LIB methods.

As an Infant Formula and Medical Foods Nutrition Analytical Branch (NAB) laboratory, the laboratory uses Kjeldahl distillation and titration technology to analyze sample for protein. The FDA needs to update NAB's existing Kjeldahl distillation and titration system with modern protein analysis capabilities in preparation for our move to a new Atlanta location. Specifically, replacing the older Kjeldahl distillation and titration systems with a new system.

The new Kjeldahl distillation and titration system can save time and resources while increasing the reproducibility of protein analysis results, faster analyses, and sophisticated data analysis and reporting meeting all quality standards, while achieving lower cost operations, with fast analysis and reporting, and electrical demand.

Requirements

The Contractor shall provide all resources necessary to accomplish the tasks and deliverables described in this Statement of Work (SOW). The contractor shall provide one (1) Vapodest Kjeldahl Distillation and Titration system with improved capabilities shall meet all quality standards and efficiencies.

- a. The Kjeldahl Distillation and Titration system shall comply with the following requirements:
 - i. ISO/IEC 17025-2022 <https://www.iso.org/standard/39883.html>,
<https://www.iso.org/standard/66912.html>
 - ii. ISO 9001:2008 <https://www.iso.org/standard/46486.html>
 - iii. 21 CFR Part 11 Compliance
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm>
 - iv. USP, cGMP/cGLP
<https://login.usp.org/cas/login?service=http%3A%2F%2Fonline.uspnf.com%2Fcas%2Flogin>
 - a. Variable steam power = 10 – 100%
 - b. Size of the Display: 7" feet, 480 – 800 pixel, touchscreen
 - c. Stand-By-Mode
 - d. Distillation time/sample: approx. 3-5 min.
 - e. Recovery: > 99.5%
 - f. Reproducibility: +/- 1%
 - g. Detection Limit: 0.1 mg N absolute
 - h. Safety Door
 - i. Tubes 250/300 ml volume
 - j. Can use distillation tubes, Kjeldahl flasks
 - k. Connection to level control
 - l. Cooling water pressure: 1-6 bar
 - m. Nominal voltage: 230 V, 50 Hz
 - n. Nominal wattage: 2200 W

- o. Pre-defined methods
- p. Pump calibration
- q. Model with external titrator
- r. Model prepared with connection to external titrator
- s. Programmable, automatic addition of NaOH, H₂O and H₃BO₃
- t. Programmable distillation and reaction times
- u. Programmable steam power, 10 to 100% with steam soft start
- v. Programmable suction of sample residue
- w. Back lit glass components and easy clean surfaces
- x. Inline connection for an optional titrator features
- y. Automatic endpoint titration
- z. Display of consumed titration solution
- aa. Display of pH value and data export
- bb. Programmable addition of chemicals
- cc. Programmable distillation time
- dd. Steam power and "Soft Start" to save numerous manual steps
- ee. Intuitive, guided navigation via touchscreen
- ff. Method Library that saves you time and rules out input data errors
- gg. An illuminated chamber to let you keep everything in view
- hh. A self-diagnosis feature that detects errors early and switches to safe mode automatically
- ii. Design protection against unintentional contact with hazardous substances
- jj. Individually configurable user rights
- kk. Automatic logs all work steps
- ll. Tamper-proof data storage
- mm. Dimensions (W x D x H) 527 x 390 x 697 mm
- nn. Weight 35 - 40 kg
- oo. Installation
- pp. Warranties
- qq. Training for 3-5 users

The contractor shall ensure the following:

- Provide a minimum of a one-year manufacturing warranty for all manufactured equipment and parts. The warranty shall be included with the equipment and not separately priced. The warranty shall include at a minimum: coverage on all non-consumable items and parts supplied including base instrument, factory-certified replacement parts, engineer labor and travel costs. Any equipment repair and maintenance work shall be performed by an OEM-trained engineer. This factory-trained engineer shall have (verified by the OEM) the following: 1) access to OEM factory telephone support; 2) access to the most current OEM factory training for both hardware and software components; and 3) access to all current OEM factory parts, not build-to-order parts. The OEM-trained service engineer shall not use

salvaged parts from other instruments for performing maintenance and repairs. All parts used in PM and repairs must be guaranteed, factory-tested, OEM quality parts.

- Instrument operators shall have access to a technical representative call center at no additional charge, for technical assistance and troubleshooting, which is staffed by senior engineers to provide a high level of expertise for troubleshooting the instrument.
- Provide training and validation of the equipment and software on site at the time of installation. Sufficient familiarization training for 3-5 users per delivery onsite location shall be provided, such that operators may independently operate the instrument and with increased familiarity and proficiency. The training shall include manuals and any consumables to be used during training.
- Provide installation qualification with an employee who can provide proof of installation qualification/Operation qualification (IQ/OQ) certification. The qualification and verification report shall include the standard operating procedures and the allowed manufacturer limits for the instrument. A copy of the calibration report and the qualification and verification report(s) shall be reviewed and approved by an FDA representative before installation of the equipment and execution of protocols.
- Equipment shall be newly manufactured, not used, refurbished, or previously used for demonstration.
- Inside delivery, disposing pallets, boxes, and any associated garbage, and unpacking the equipment and inventory of parts with a lab representative.

Documentation Requirements

- Installation and Operational Qualification Documentation
- Certificates of Familiarization Training
- Instrument Manuals

Records and Reports

The Contractor shall, commensurate with the completion of each service call (inclusive of warranty service), provide the end-user of the equipment with a copy of a field service report/ticket identifying the equipment name, manufacturer, model number, and serial number of the equipment being serviced/repared and detailing the reason for the service call, a detailed description of the work performed, the test instruments or other equipment used to affect the repair or otherwise perform the service, the name(s) and contract information of the technician who performed the repair/service, and for information purposes, the on-site hours expended, and parts/components replaced.

Deliverable Table/Period of Performance:

| Deliverable | Quantity | Due Date |
|--|---------------------------|------------------------------------|
| Vapodest Kjeldahl Distillation and Titration system, firmware and drivers, package (Atlanta, GA) | 1 | Within 60 days after date of award |
| Installation and Operation Qualification documentation (Atlanta, GA) | 1 | Within 60 days after date of award |
| Certificates of Familiarization Training (Atlanta, GA) | 3-5 users at one location | Within 60 days after date of award |
| Instrument User Manuals (Atlanta, GA) | 1 | Within 60 days after date of award |

Training

Familiarization training shall be provided to 3-5 employees by the manufacturer in terms of operation, etc. Instrument user manuals shall be available during training. The contractor/manufacturer shall be available to provide any troubleshooting and answer operation/troubleshooting questions as part of the service provided after installation.

Role-based Training. All employees (and/or any subcontractor) with significant security responsibilities (as determined by the program manager) must complete role-based training annually commensurate with their role and responsibilities in accordance with HHS and FDA policy and FDA Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Standard Operating Procedures (SOP).

Training Records. The employer (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS and FDA policy. A copy of the training records shall be provided to the COR within 30 days after contract award and annually thereafter or upon request.

Place of Performance

Food and Drug
Administration Food and
Feed Laboratory
Nutrition Analysis Branch
60 8th Street N.E
Atlanta, GA 30309

FOB destination

POC: To be identified at time of award

Contractor shall call the Government POC at least 48 hours prior to delivery. Unless otherwise specified, deliveries shall be made to the Delivery Point specified above, Monday through Friday (excluding Federal Holidays see below between the hours of 8:00 a.m. and 4:00 p.m. in accordance with the delivery location time zone (Eastern Time, Central Time, or Pacific Time). Supplies or services scheduled for delivery on a Federal holiday shall be made the next business day. Delivery shall be inside the facility.

Government Holidays

Workplace is not available on the Government Holidays stated below, or as prescribed by an Executive Order (EO) due to inclement weather.

| | |
|----------------------------------|-----------------------------|
| January (New Year's Day) | September (Labor Day) |
| January (Martin Luther King Day) | October (Columbus Day) |
| February (President's Day) | November (Veterans Day) |
| May (Memorial Day) | November (Thanksgiving Day) |
| June (Juneteenth) | December (Christmas Day) |
| July (Independence Day) | |

Period of Performance:

The Period of Performance begins the date of contract award execution and continues for one year (or longer depending on how long the OEM offered warranty period is) from the date of formal government acceptance. Instrument to be delivered no later than 60 days after date of award.

Type of Contract: Firm-Fixed-Price (FFP); The Government anticipates issuing a firm fixed-price purchase order.

Set Aside: N/A

FDA Electronic Invoicing and Payment Requirements - Invoice Processing Platform (IPP) (Jan 2022)

(a) All Invoice submissions for goods and or services must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).

<http://www.ipp.gov/contractors/index.htm>

(b) Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in in FAR 32.905(b), "Content of Invoices" and the

applicable Payment clause included in this contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is: <https://www.ipp.gov>.

(c) -----

(1) The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.

(2) Registration emails are sent via email from ipp.noreply@mail.eroctwai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

(3) The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.

(4) If your company is already registered to use IPP, you will not be required to re-register.

(5) If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

(d) Invoices that include time and materials or labor hours Line Items must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

(e) Invoices that include cost-reimbursement Line Items must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts.

(1) At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category.

- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirect)- show rate, base and total amount.

- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant.
- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed.
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor.
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

(f) Contractor is required to attach an invoice log addendum to each invoice which shall include, at a minimum, the following information for contract administration and reconciliation purposes:

- (1) list of all invoices submitted to date under the subject award, including the following:
- invoice number, amount, & date submitted
 - corresponding payment amount & date received
 - total amount of all payments received to date under the subject contract or order
 - and, for definitized contracts or orders only, total estimated amounts yet to be invoiced for the current, active period of performance.

(g) Payment of invoices will be made based upon acceptance by the Government of the entire task or the tangible product deliverable(s) invoiced. Payments shall be based on the Government certifying that satisfactory services were provided, and the Contractor has certified that labor charges are accurate.

(h) If the services are rejected for failure to conform to the technical requirements of the task order, or any other contractually legitimate reason, the Contractor shall not be paid, or shall be paid an amount negotiated by the CO.

(i) Payment to the Contractor will not be made for temporary work stoppage due to circumstances beyond the control of U.S. Food and Drug Administration such as acts of God, inclement weather, power outages, and results thereof, or temporary closings of facilities at which Contractor personnel are performing. This may, however, be justification for excusable delays.

(j) The Contractor agrees that the submission of an invoice to the Government for payment is a certification that the services for which the Government is being billed, have been delivered in accordance with the hours shown on the invoices, and the services are of the quality required for timely and successful completion of the effort.

(k) Questions regarding invoice payments that cannot be resolved by the IPP Helpdesk should be directed to the FDA Employee Resource and Information Center (ERIC) Helpdesk at 301-827-ERIC (3742) or toll-free 866-807-ERIC (3742); or, by email at ERIC@fda.hhs.gov. Refer to the Call-in menu options and follow the phone prompts to dial the option that corresponds to the service that's needed. All ERIC Service Now Tickets will either be responded to or resolved within 48 hours (2 business days) of being received. When emailing, please be sure to include the contract number, invoice number and date of invoice, as well as your name, phone number, and a detailed description of the issue.

(END OF CLAUSE)

FAR / HHSAR Clauses:

I. The provision at 52.212-1, Instructions to Offerors – Commercial DEVIATION 2018-O0018, applies to this acquisition. The following addenda have been attached to this provision:

In addition to the requirements set for the in FAR 52.212-1, all offers responding to this solicitation must provide their business size in relation to the NAICS code contained in this solicitation and shall identify any socioeconomic categories to which they belong.

II. Evaluation Criteria - The specific evaluation criteria to be used are as follows: Lowest price technically acceptable (LPTA).

III. Offerors shall include a completed copy of the provision at FAR 52.212-3 (with its Alternate I), Offeror Representations with its offer.

IV. The clause at 52.212-4, Contract Terms and Conditions - Commercial Items, applies to this acquisition. The following addenda have been attached to this clause – Not Applicable

V. The clause at 52.212-5, Contract Terms and Conditions Required to Implement Statutes or Executive Orders - Commercial Items applies to this acquisition. The following additional FAR clauses cited in this clause are applicable:

52.204-10, Reporting Executive Compensation and First-Tier Subcontract Awards (Oct 2018)

52.209-6, Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment. (Oct 2015)

52.219-28, Post Award Small Business Program Representation (Nov 2020)

52.222-3, Convict Labor (June 2003)

52.222-19, Child Labor-Cooperation with Authorities and Remedies (Jan 2020)

52.222-21, Prohibition of Segregated Facilities (Apr 2015)

52.222-26, Equal Opportunity (Sept 2016)

52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020)

52.222-50, Combating Trafficking in Persons (Oct 2020)

52.223-18, Encouraging Contractor Policies to Ban Text Messaging While Driving (Jun 2020)

52.225-13, Restrictions on Certain Foreign Purchases (June 2008)

52.232-33, Payment by Electronic Funds Transfer-System for Award Management (Oct 2018)

52.204-7 System for Award Management (Oct 2018)

52.204-13 System for Award Management Maintenance (Oct 2018)

52.204-16 Commercial and Government Entity Code Reporting (Aug 2020)

52.204-18 Commercial and Government Entity Code Maintenance (Aug 2020)

52.204-24 Representations Regarding Certain Telecommunications and Video Surveillance Services or Equipment (Aug 2019)

52.204-25 Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment

52.204-26 Covered Telecommunications Equipment or Services-Representation

52.211-6 Brand Name or Equal.(Aug 1999)

52.232-40 Providing Accelerated Payments to Small Business Subcontractors (Dec 2013)

352.239-73 Electronic and Information Technology Accessibility Notice (Dec 2015)

352.239-74 Electronic and Information Technology Accessibility (Dec 2015)

352.232-71 Electronic Submission of Payment Requests (FEB 2022)

(a) Definitions. As used in this clause—
Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), “Content of Invoices” and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or

successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(END OF CLAUSE)

VII. This acquisition is rated under the Defense Priorities and Allocations System (DPAS) as N/A

VIII. The following notes apply to this announcement: N/A

Section 508 Requirements

The following standards are applicable for this requirement:

- Must meet WCAG 2.0 A and AA
- E101.2 Equivalent Facilitation (Appendix A, Application and Scoping Requirements)
- E203 Access to Functionality (Appendix A, Application and Scoping Requirements)
- E204 Functional Performance Criteria (Appendix A, Application and Scoping Requirements)
- E205 Electronic Content (Appendix A, Application and Scoping Requirements)
- E208 Support Documentation and Services (Appendix A, Application and Scoping Requirements)
- Chapter 6 Support Documentation and Services (Appendix C, Functional Performance Criteria and Technical Requirements)
- 302 Functional Performance Criteria (Appendix C, Functional Performance Criteria and Technical Requirements)
- E206 Hardware (Appendix A, Application and Scoping Requirements)
- Chapter 4 Hardware (Appendix C, Functional Performance Criteria and Technical Requirements)

Electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at <https://www.hhs.gov/web/section-508/accessibility-checklists/index.html>, or from the Section 508 Coordinator listed at <https://www.hhs.gov/web/section-508/additional-resources/section-508-contacts/index.html>. Materials that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Representative.

Instructions to Offeror for Proposal Submission

FAR 52.212-1 Instructions to Offerors—Commercial Items (Jun 2020)

PROPOSAL SUBMISSION FORMAT:

The solicitation does not commit the Government to pay any cost for the preparation and submission of a quote or proposal. It is also advised that the Contracting Officer (CO) is the only individual who can legally commit and obligate the Government to the expenditure of public funds in connection with the proposed acquisition.

QUOTES DUE: All quotes are due, electronically via email to Elena.Tatarov@fda.hhs.gov for the RFQ no later than September 1, 10:00 a.m. Eastern Time. Late submissions may not be evaluated.

The subject line shall read: *FDA_ 1255491* – Vapodest Kjeldahl Distillation and Titration system.

The offeror or applicant shall submit all electronic documents for Microsoft Office suite products without the use of “macros”. When submitting proposals via email, DO NOT include .exe, .mso, or any other executable file types that could potentially trigger email security protections (i.e., email blocks, quarantine). If the offeror or applicant submits documents that contain macros, macro referenced files, and/or executable files, the Government will not be able to view or open such documents and the submission will be considered non-responsive to the solicitation. No additional time will be given to an offeror or applicant to correct the document submission and the Government will not inform the offeror or applicant that their submission is non-responsive prior to award. It is the offerors or applicant’s responsibility to ensure all electronic documents are submitted without the use of macros.

Basis for Award/Evaluation Criteria

The Government shall award a firm fixed price contract resulting from this solicitation to the responsible Quoter whose price is deemed fair and reasonable. Quoters' initial quote should contain the Quoters’ best terms from a price standpoint. The Government requests the Contractor to provide discounts off their established pricing for each line item. The Government reserves the right to conduct discussions if later determined by the Contracting Officer to be necessary.