Pre-Solicitation HT941026Q2004 Questions and Answers

1) **Proposal due date clarification.** The RFQ states quotations are due "no later than 1:00 p.m. Pacific on Monday April 30, 2026." Since April 30, 2026 falls on a Thursday, please confirm the correct quotation due date and time.

   ANSWER: Please see amendment, extending the quotation due date and time.

2) **Option period date clarification.** In Attachment 3, please confirm the correct dates for all option periods, especially Option Period 4, which appears duplicated in the file set summary and may contain a date error.

   ANSWER: Attachment 3 Quote Sheet has been updated and corrected dates for Option Period(s).

3) **Site start-date clarification.** For sites showing alternate or TBD start dates, such as Madigan and Nellis, please confirm the final anticipated delivery/ transition start date for each location. Also please confirm the entries for Naval Medical Center San Diego and Tripler, which appear to list the same date twice with "TBD." (Excel attachment review)

   ANSWER: Each addition of new site on contract can be listed as a new CLIN line per OPY. The goal is to have all MTFs transitioned by 1 October 2027. Attachment 3 Quote Sheet has been updated to reflect "0" quantities for tests for MTFs that are estimated to transition after the base period.

4) **Quality Control Testing.** Will testing be performed for all assays every day, three times per day? If not, can you provide the details of how QC testing will be performed?

   ANSWER: PT, PTT, Fibrinogen, D-Dimer, and Xa (UFH) are being run every 8 hours. Factor Assay, LAC, and mixing studies are performed once a week. LMWH is good for 24 hours; run QC when patient encountered.

5) **CPR vs. By the Box.** Although PT/PTT and Fibrinogen are generally CPR is it permissible for a vendor to propose By the Box pricing for lower volume test such as D-Dimer and specialty tests?

   ANSWER: Vendor will have to perform site-specific assessment of operations/ workflow, test menu, and workload to optimize CPRR via the By the Box. This strategy is best applied billing CPRR monthly based on max monthly budget (CLIN line (site) of QTY=12 representing each month in FY), then vendor bill according to CPRR.

6) **Specialty Testing.** Can you provide details of how specialty testing is being performed?
   a) Specifically Madigan, Tripler & San Diego: Are these tests run as batch or on-demand as they come in the lab? This will make a difference on how this test will be quoted.
   b) For the Heparin assay, can you provide a break down of the sites running Unfractionated, Lower Molecular Weight (LMW), Apixaban and Rivaroxaban?
   c) Are any sites currently performing or sending out Heparin Induced thrombocytopenia (HIT) testing? If so, can this be included?

   ANSWER: Factor assays, mixing studies, and LAC are run once a week if any. LMWH is run when patient encountered. UFH is run everyday. Madigan AMC

does not run Apixaban and Rivaroxaban specific tests. Madigan AMC receives HIT testing from DMIS 0125 (MAMC), 0108, and 0053; we send out if any to LabCorp.

7) **Mandatory versus preferred requirements.** Please identify which site-specific requirements are mandatory minimum requirements and which are preferences, especially where the SOW uses terms like "preference will be for bench top" rather than a strict shall statement.

   ANSWER: Refer to space requirements and analyzer requirements in SOW. Coagulation SOW – Enclosure A Site Specific Information spreadsheet has been updated.

8) **Aptio Line compatibility at Nellis.** Is "Connection compatibility with the Aptio Line" at Nellis AFB a mandatory requirement for acceptability, or will alternate interface/connectivity approaches be considered if they fully meet workflow and reporting needs?
   a) Also, being that the test volume is lower than other sites without automation is this an award requirement?

   ANSWER: No, connection compatibility can be adjusted per awardee.

9) **Current incumbent transition assumptions.** Please confirm whether the Government expects a phased transition by site aligned to current contract end dates, and whether those incumbent contract end dates can be provided for planning purposes, given the SOW states deliveries are anticipated to begin and end off the current contracts and all sites must be live by 10/01/2027.

   ANSWER: Each addition of new site on contract can be listed as a new CLIN line per OPY. The goal is to have all MTFs transitioned by 1 October 2027. Attachment 3, Quote Sheet has been updated to reflect "0" quantities for tests for MTFs that are estimated to transition after the base period.

10) **All sites live by 10/01/2027.** Please confirm whether the 10/01/2027 live-date is a hard performance deadline for every MTF regardless of each site's individual transition schedule, and whether liquidated or other remedies apply if delays are caused by Government coordination, access, or interface dependencies.

    ANSWER: Each addition of new site on contract can be listed as a new CLIN line per OPY. The goal is to have all MTFs transitioned by 1 October 2027. Attachment 3, Quote Sheet has been updated to reflect "0" quantities for tests for MTFs that are estimated to transition after the base period.

<u>Technical and compliance questions</u>

8. **Size Requirements** Are the size requirements based on current instrument dimensions or size requirements available?

   ANSWER: Refer to space requirements and analyzer requirements in SOW. Coagulation SOW – Enclosure A Site Specific Information spreadsheet has been updated to reflect (estimated) maximum allowable space available.

   Will a Vendor be ruled out by exceeding these size requirements?

   ANSWER: Yes, depends on vendors' initiative to visit sites to measure workspace and requirement for redundancy of instrumentation.

9. **Technical Submission Form scoring.** Will the Government evaluate Attachment 2 strictly on pass/fail compliance to each minimum item, or will narrative strength and technical discrimination also affect the Technical rating?

   ANSWER: No. Narrative strength and technical discrimination will be considered.

10. **Multiple analyzer solutions.** The Technical Submission Form states that where multiple analyzers are proposed, all analyzers shall be of the same volume and speed rating. Please confirm whether this prohibits mixed-platform solutions across different sites or only within a single site configuration.

    ANSWER: Site-dependent discretion.

11. **Surge capacity requirement.** The Technical Submission Form requires capacity to support a surge of up to 50% in volume. Please confirm whether that surge requirement applies at each individual site, across the aggregate contract volume, or only at selected high-volume sites.

    ANSWER: See CSS Coagulation – Attachment 1 SOW paragraph 2.1.8. Surge of up to 50% in volume applies to the scope of this contract award (i.e., accumulative across all MTFs).

12. **Lot-to-lot support requirement.** Please confirm which sites require onsite vendor support for lot-to-lot studies and regression reports at implementation and thereafter, since the site attachment specifically mentions Naval MCSD and asks other sites whether they also require onsite support. (Site-specific attachment review)

    ANSWER: Recommend vendor performs lot sequestration for the year for each site.

    Contracting needs to confirm. Some sites said "NO" to "lot to lot".

<u>Cybersecurity / RMF questions</u>

13. **MDERA submission scope.** The CyberLOG/ICS MDERA states that any third-party components must be listed and included in the tables or have their own MDERA completed. Please confirm whether a separate MDERA is required for every third-party component, or whether those components may be addressed within a single consolidated MDERA package.

    ANSWER: Depends on what is already established for those devices/ instruments. MDIO question specific.

14. **Cloud component treatment.** If an offered system includes cloud-connected functionality that is not required for core clinical operation, should that be included in the MDERA and evaluated as part of the offered solution, or may the vendor propose the system without cloud-enabled features?

    ANSWER: Do not want anything outside the network. Cloud will require FEDRAMP (Federal Risk and Authorization Management Program) approved; cost born by the vendor.

15. **Country-of-origin disclosure.** Please confirm the level of detail expected for country-of-origin reporting for hardware, firmware, operating systems, and third-party software components under the MDERA.

ANSWER: Must make sure system is within standards for federal government regulations, NIST, STIG, HIPAA, cybersecurity, and etc.
The expected level of detail for Country of Origin (CoO) reporting under such a framework is driven by cybersecurity concerns and regulations designed to protect against vulnerabilities introduced by foreign adversaries. The goal is to create transparency throughout the entire supply chain.
Here is a breakdown of the expected level of detail for Country of Origin reporting for each of the components you listed:
Hardware
This is the most straightforward category for CoO reporting. The expectation is to identify the physical manufacturing location of the components.

- Final Assembly: The country where the medical device is fully assembled.
- Critical Components: The country of manufacture for key hardware components. This includes, but is not limited to:
  - Processors (CPUs, GPUs)
  - Memory chips (RAM)
  - Storage devices (hard drives, solid-state drives)
  - Network interface cards (NICs)
  - Power supplies

- Rationale: The focus is on identifying and mitigating risks associated with components sourced from countries that may pose a national security risk.
  Firmware and Operating Systems
  For firmware and operating systems, the "Country of Origin" is less about physical manufacturing and more about the origin of the intellectual property and the location of the development teams.
- Vendor's Nationality: The country where the vendor company is incorporated and has its headquarters.
- Location of Development: The primary location(s) where the software was developed, coded, and tested.
- Foreign Ownership and Influence: Any known ownership, control, or influence by a foreign entity, especially a foreign government. This is a critical element of SCRM.
- Rationale: This information helps to assess the risk of backdoors, malicious code, or other vulnerabilities being introduced during the development process. Concerns about vendors from certain countries, such as those highlighted in the National Defense Authorization Act (NDAA), would be addressed here.
  Third-Party Software Components
  This is the most granular and often the most challenging aspect of CoO reporting. The industry is moving towards the use of a Software Bill of Materials (SBOM) to provide this level of detail. An SBOM is a formal record containing the details and supply chain relationships of various components used in building software.
  For each component listed in the SBOM, the expected level of detail for CoO reporting would be similar to that for firmware and operating systems:
- Component Vendor's Nationality: The country of origin for the vendor of each third-party library or software component.
- Development Location: The primary location where the component was developed.
- Open-Source Software: For open-source components, the reporting should, at a minimum, identify the open-source license and the location of the primary development community, if known.
- Rationale: Modern software is assembled from numerous third-party and open-source components. A vulnerability in any one of these components

can create a risk for the entire system. Understanding the origin of these components is essential for a comprehensive risk assessment.
In summary, the level of detail expected for Country of Origin reporting under a Medical Device Equipment Risk Assessment (MDERA) is comprehensive and multi-layered. It extends beyond the physical manufacturing location to include the origin of the intellectual property, the location of development, and a detailed accounting of all third-party software components through a Software Bill of Materials. This level of transparency is becoming a standard expectation for ensuring the security and integrity of critical systems like medical devices.

Pricing and contractual questions

16. **Pricing list format.** The RFQ requires Attachment 3 plus a separate pricing list for CPRR reagents, controls, and consumables. Please confirm whether the separate pricing list may be in vendor format, and whether it must map by site, by analyte, or by reportable result.

    ANSWER: Vendor will have to perform site-specific assessment of operations/ workflow, test menu, and workload to optimize CPRR via the By the Box. This strategy is best applied billing CPRR monthly based on max monthly budget (CLIN line (site) of QTY=12 representing each month in FY), then vendor bill according to CPRR. Attachment 3 Quote Sheet has been updated and corrected dates for Option Period(s).

17. **Completeness of pricing.** Please confirm whether all ancillary equipment, interface hardware/software, middleware, UPS units, training, implementation, travel, service, QC, calibration, lot-to-lot support, and consumables must be fully included in the CPRR/quoted pricing unless expressly identified elsewhere.

    ANSWER: Yes, confirmed. Attachment 3 Quote Sheet has been updated and corrected dates for Option Period(s).

18. **New technology during contract term.** The SOW permits the contractor to propose new technology during the contract if the global CPRR price and DHA ATO status remain unchanged. Please confirm the process for submitting such upgrades and whether the Government anticipates evaluating equivalent successor models during performance.

    ANSWER: Quote (non-binding) may be submitted to Contracting Officer for review. Only the Contracting Officer will determine need for contract modification.

Evaluation and award questions

19. **Information Assurance rating implications.** Please confirm whether an Information Assurance rating of "Unacceptable" makes a quote ineligible regardless of the merits of the Technical and Price factors.

    ANSWER: Yes, Information Assurance rating of "Unacceptable" will make a quote ineligible.

20. **Award without discussions.** Since the Government intends to award without discussions, please confirm whether vendors may submit limited assumptions or exceptions, or whether any exception to a requirement will render the quotation non-compliant.

ANSWER: Assumptions and exceptions are based on capability requirements, which will be reviewed in a site-dependent manner to enable optimum performance. Assumptions can be input in Attachment 2 Technical Submission Form in Column E.

21. **Clarification of best value tradeoff.** Please confirm whether non-price factors, when combined, are significantly more important than price, and whether the Government intends to perform a tradeoff rather than a lowest-price technically acceptable approach.

    ANSWER: Contract award shall be made on a "Best Value Tradeoff" basis. See 52.212-2, EVALUATION—COMMERCIAL PRODUCTS AND COMMERCIAL SERVICES (DEVIATION 2025-O0038) (FEB 2026), (d) EVALUATION FACTORS FOR AWARD

22. Attachment 1 SOW and Attachment 2 Technical Submission Form Clarifications:

a. Page 1 of Attachment 1 SOW states "*The Contractor will be required to submit monthly reports for invoicing purposes showing actual test quantities performed by each site*." **In place of "*Contractor*", is this meant to instead state the "MTF", "Lab", or "Customer" will be required to submit monthly test quantities for monthly invoicing?**

ANSWER: No, the contractor will be required to submit monthly reports to ensure amounts per MTF are properly invoiced.

i. Or is it the desire of the government for the contractor to invoice the government a firm fixed monthly amount based solely on the volumes provided in the *Enclosure A Site Specific* document?

ANSWER: The contractor will be required to submit monthly reports to ensure amounts per MTF are properly invoiced.

b. Page 1 of Attachment 1 SOW states "*The Government will only pay for the actual test received. Invoiced quantities shall not exceed the annual quantities listed within the SOW, of the contract. The vendor will not be reimbursed for quantities that exceed the annual estimated volume.*" **Because vendors are unable to offer free testing for services provided, what is the resolution if the government performs and reports more tests than estimated in the Enclosure A SOW document?**

ANSWER: Workload (i.e., test quantities) are estimates. See CSS Coagulation – Attachment 1 SOW paragraph 2.1.8 and 2.1.9.

c. Page 4 of Attachment 1 SOW and Attachment 2 Row #38 under Technical Requirement qualifies only the first bullet point as "Preference will be". To allow low volume labs to obtain right-sized smaller analyzers which meet their space and volume requirements **please add "*Preference will be*" to the 2nd and 6th bullets also (dilutions and cap piercing).**

ANSWER: CSS Coagulation – Attachment 1 SOW and Attachment 2 Technical Submission Form have been updated.

d. Page 4 of Attachment 1 SOW and Attachment 2 Row #38 under Technical Requirement includes description "*(reagents good for at least one week on-board for PT/APTT/Fibrinogen/D-dimer)*". **Please remove this very specifically worded lockout specification for a single vendor that**

excludes all other vendors (4th bullet point). Although reagent shelf life and onboard stability is a feature to consider, vendors address this in different ways using various container sizes, ready to use reagents, and other features to maximize ease of use and minimize reagent change and waste.

ANSWER: Onboard stability is a feature that is being considered. If the vendor cannot meet the requirement in the SOW they are encouraged to provide an alternative means that minimizes waste and the frequency of repeat quality control testing. Provide comments in Column E of Attachment 2 Technical Submission Form.

e. An International Sensitivity Index (ISI) as close to 1.0 as possible is required to ensure the most sensitive and consistent PT/INR results possible (see below reference). **What ISI limits do DHA MTFs require for their PT/INR testing?**

ANSWER: An ISI of 1.0 or as close to 1.0 as possible. DHA MTFs generally accepts ISI values as provided by the manufacturer for each lot of PT reagent, with typical values ranging from 1.0 to 1.4. Some sites prefer ISI values as close to 1.0 as possible, while others report no strict lower or upper limits. Vendors should supply reagents with ISI values within this range and provide lot-specific ISI documentation.

f. Which MTFs, if any, use the "Activated Partial Thromboplastin Time (APTT)" test to monitor heparin levels in patients?

ANSWER: Coagulation SOW – Enclosure A Site Specific has been updated.

g. Page 7 of Attachment 1 SOW and Attachment 2 Row #86 Requests that "Delivery Information" be specified in the contract CLIN for each MTF. **Please clarify the location you'd like this information placed as the contract "CLIN" or other location to include this information could not be located. Additionally, Attachment 3 Quote sheet does not have a location specified to included Delivery Information.**

ANSWER: The delivery of the requirements described in this SOW shall be specified in the "Delivery Information" section of each contract line item number (CLIN) for each MTF, meaning, because not all MTFs will start on 1 October 2026, when the MTF does transition and delivery starts on this contract, the delivery information will then be populated in the CLIN for that particular MTF.

Each addition of new site on contract can be listed as a new CLIN line per OPY. The goal is to have all MTFs transitioned by 1 October 2027. Attachment 3, Quote Sheet has been updated to reflect "0" quantities for tests for MTFs that are estimated to transition after the base period.

23. <u>Attachment 3 Quote Sheet Clarifications:</u>

a. Is it the intention to have ALL tests quoted as a Cost Per Reportable Result as reflected in Attachment 3 or only the routinely ordered standard tests (PT/INR, APTT, Fibrinogen, and D-Dimer)?

ANSWER: ALL tests quoted as CPRR. Attachment 3 Quote Sheet has been updated and corrected dates for Option Period(s).

24. <u>Enclosure A Site-Specific Document Clarifications:</u>

a. Enclosure A Site-Specific document lists Madigan AMC, Nellis AFB, NMCSD, and Tripler AMC with a "Start Date" that includes "TBD". Additionally, Attachment 3 Quote Sheet lists total test counts implying all sites will go live on the same date. **To ensure all vendors can provide an accurate CPRR price, we ask that "TBD" be replaced with the intended start dates for the four listed sites? If truly unknown, will the awarded vendor be issued a modification to reflect the true start date and CPRR rate adjustment based on true start dates?**

ANSWER: A modification will be issued to reflect the start date and CPRR rate adjustment based on actual start dates. The goal is to have all MTFs transitioned by 1 October 2027. Attachment 3, Quote Sheet has been updated to reflect "0" quantities for tests for MTFs that are estimated to transition after the base period.

b. The "INR" test result listed in Row 13 of Attachment 3 and Column G of Enclosure A is typically reported in tandem with the Prothrombin Time (PT) result. Enclosure A only lists this test for one MTF at the same test volume as PT. **Please confirm if this is a duplicate column and can be removed or volumes added to the PT test numbers as necessary.**

ANSWER: (Duplicate) Annual test by MTF was updated; Attachment 3 Quote Sheet has been updated to reflect change.

c. Enclosure A references several vendor specific analyzer make, model and item numbers in the "Site Specific Information" tab. **To prevent potential vendor protests or suggestion there could be a vendor preference, we kindly ask that those references be removed.** (See cells E2, H2, D6, E6, and E10.)

ANSWER: References to specific analyzer make, model, and item numbers were provided for more accurate measurements and not to provide vendor preference. References have been removed from Coagulation SOW – Enclosure A Site Specific Information.

d. Which tests are performed in batches rather than routine?

ANSWER: Fort Irwin requires confirmation of annual test volumes for PT/INR, PTT, Fibrinogen, and D-Dimer. Other sites do not require volume confirmation for this test. Cogulation SOW – Enclosure A Site Specific Information has been updated.

i. If tests are performed in batches, what frequency is the QC performed?

ANSWER: Batch testing is performed at Madigan (Factor assays and Lupus Anticoagulant) and Tripler (Factor assays, AT III, vWF antigen). Other sites do not perform batch testing for coagulation assays. Cogulation SOW – Enclosure A Site Specific Information has been updated.

e. **What frequency and number of levels of QC are performed on Routine tests?** *(example: 3 levels once per day, 2 levels every 8 hours, or Only when ordered)*

ANSWER: Madigan performs batch QC weekly. Tripler performs QC prior to initial patient testing and if more than 8 hours have elapsed since the last acceptable QC result. Coagulation SOW – Enclosure A Site Specific Information has been updated.

25. Combined Synopsis Solicitation Document Questions:

a. "Evaluation Factor 4: Price" listed on page 6 states "*The Quoter shall submit a separate Pricing List of the CPRR reagents, controls, and consumables for the required testing*." **Is this to be a location to list all reagents, controls, and consumables included in the quoted CPRR, or is this to be items for purchase outside of the CPRR?**

ANSWER: A location to list all reagents, controls, consumables, etc.

Attachment 2 Technical Submission Form

26. Row 35. The Contractor shall provide a means of tracking reagent usage and reagent level detection via a metering capability or an alternative method, for informational use only, on the CPRR. These reports shall be provided to the Government. Please clarify what the vendor is required to provide. Will the vendor be required to provide a list of reagents and quantities used on a monthly/quarterly/yearly basis?

    ANSWER: The intent is for the contractor to provide a tracking system to be able to compare the number of reagents for a given test sent to an MTF with the quantity of reportable results for a given reagent. Basically, to show how much of the order did the MTF use.

27. Row 35. The Contractor shall provide a means of tracking reagent usage and reagent level detection via a metering capability or an alternative method, for informational use only, on the CPRR. These reports shall be provided to the Government. Please clarify what the vendor is required to provide. What does the government mean by "reagent level detection"? Typically, "reagent level detection" refers to an analyzers ability to determine, real-time, how much reagent is available on-board the analyzer.

    ANSWER: The intent of the tracking mechanism is for the contractor to provide a tracking system to be able to compare the number of reagents for a given test sent to an MTF with the quantity of reportable results for a given reagent. Basically, to show how much of the order did the MTF use.

28. Row 38. Automatic dilutions for clot based testing (at least PT/APTT). Clotting tests are not able to be diluted in the traditional way of adding a diluent to a patient specimen when the value is too high to read. Does the government mean that the analyzers will automatically extend the measurement time if the sample exceeds the pre-set upper limit?

    ANSWER: Yes, the analyzer will automatically extend the measurement time if the sample exceeds the pre-set upper limit.

29. Row 38. Shelf-life management of reagents (tracking on-board shelf-life) (reagents good for at least one week on-board for PT/APTT/Fibrinogen/D-dimer). This requirement is unduly restrictive. Only one vendor has onboard reagent stability for one week for PT/APTT.

    ANSWER: Concur, keep the following wording: Shelf-life management of reagents (tracking on-board shelf-life). Longer on-board stability is preferred.

    ANSWER to 22d: Onboard stability is a feature that is being considered. If the vendor cannot meet the requirement in the SOW they are encouraged to

provide an alternative means that minimizes waste and the frequency of repeat quality control testing. Provide comments in Column E of Attachment 2 Technical Submission Form.

Enclosure A Site-Specific information

30. Site Specific Information, Column E. Maximum Space Dimensions. Many of the sites list their current analyzers as the "maximum space dimensions". This makes the requirement unduly restrictive and misleading for the sites. Vendors are typically able to provide tables on wheels (that lock) at no additional charge to accommodate their analyzers. Please provide more generic dimension specifications such as "will fit on countertop, or "vendor will provide cart at no additional charge".

    ANSWER: Some sites do not have additional space for cart or table and or the site cannot perform facilities alterations while some sites can accommodate analyzers with varying space requirements. Vendors should reference the specific dimensions listed for each MTF to ensure compatibility. Vendors may provide comments to size/space availability in Colum E of the Attachment 2 Technical Submission Form.

1-Enclosure A Site Specific information & 2- Attachment 3 Quote Sheet

31. 1-Estimated Workload, Column G & 2- Coag Quote Sheet, Row 16. DIC Panel. INR is a calculation based on the Prothrombin (PT) test listed on Column B. Please consider removing Column G to avoid confusion.

    ANSWER: Attachment 3 Quote Sheet and Coagulation SOW – Enclosure A Site Specific Information has been updated to remove INR as a separate test.

32. 1-Estimated Workload, Column J & 2- Coag Quote Sheet, Row 13. INR. INR is a calculation based on the Prothrombin (PT) test listed on Column B. Please list what tests are included in a "DIC Panel".

    ANSWER: Attachment 3 Quote Sheet and Coagulation SOW – Enclosure A Site Specific Information has been updated to remove INR as a separate test.

33. 1-Estimated Workload, Column M & 2- Coag Quote Sheet, Row 19. Mixing Studies. Please specify which mixing studies are to be quoted. PT Mixing Studies or aPTT Mixing Studies?

    ANSWER: Madigan and San Diego require both PT and PTT mixing studies. Other sites do not require mixing studies for quoting.

    Conflicting information on DATA CALL – TAMC indicated 20 mixing studies but N/A on question of PT or aPTT. NMCSD indicated ZERO mixing studies but indicated PT and PTT on the question or PT or aPTT. THIRD DATA CALL sent out 4/30 due 4/30.