

DEPARTMENT OF VETERANS AFFAIRS

**Justification and Approval (J&A)
For
Other Than Full and Open Competition (>SAT)**

Acquisition Plan Action ID: _ 36C263-25-AP-0792

- Contracting Activity:** Department of Veterans Affairs, VISN 23 Biomedical Engineering, "Justification for Other Than Full and Open Competition" 499-25-2-6765-0031
- Nature and/or Description of the Action Being Processed:** This will be a fixed price contract. This is a new PO for annual maintenance and support renewal of the Cepheid laboratory instruments in VISN 23. This is required to ensure proper instrument functionality, accuracy, and uptime of the included lab equipment. The current 2237 number is 499-25-2-6765-0031.
- Description of Supplies/Services Required to Meet the Agency's Needs:** Service contract for the Cepheid Laboratory instruments in VISN 23. The following equipment should be included:

Serial Number	Model	VAMC	Location
110020218	GX 16-12	Black Hills	Fort Meade
839276	GX 16-16	Black Hills	Fort Meade
110020163	GX 4-4	Black Hills	Hot Springs
839228	GX 4-4	Black Hills	Hot Springs
110020205	GX 16-16	Central Iowa	Main Facility
840426	GX 16-18	Central Iowa	Main Facility
110020206	GX 16-16	Fargo	Main Facility
810071	GX 16-16	Iowa City	Main Facility
839290	GX 16-16	Iowa City	Main Facility
110020853	Infinity 48-40	Minneapolis	Main Facility
110003290	GX 16-16	Minneapolis	Main Facility
120000054	GX 16-16	NWI	Main Facility
110003276	GX 16-16	Sioux Fall	Main Facility
839300	GX 16-16	St. Cloud	Main Facility
839353	Xpress 4X4	Central Iowa	Fort Dodge
839455	Xpress 4X4	Central Iowa	Mason City

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839449	Xpress 4X4	Central Iowa	Marshall Town
839503	Xpress 4X4	Central Iowa	South Side
839506	Xpress 4X4	Central Iowa	Knoxville
110011412	Xpress 4X4	Central Iowa	Carroll
840117	Xpress 4X4	NWI	Main Facility
840171	Xpress 4X4	NWI	Main Facility
838461	Xpress 4X4	Minneapolis	Albert Lea
839548	Xpress 4X4	Minneapolis	Chippewa Valley
840962	Xpress 4X4	Minneapolis	Hayward
840963	Xpress 4X4	Minneapolis	Hibbing
838367	Xpress 4X4	Minneapolis	Lyle C
839545	Xpress 4X4	Minneapolis	Maplewood
839546	Xpress 4X4	Minneapolis	Northwest Metro
838404	Xpress 4X4	Minneapolis	Rice Lake
838338	Xpress 4X4	Minneapolis	Rochester
839547	Xpress 4X4	Minneapolis	Shakopee
838463	Xpress 4X4	Minneapolis	Twin Ports
845144	Xpress 4x2	Minneapolis	St. James
841247	Xpress 4X4	Iowa City	CR
840967	Xpress 4X4	Iowa City	DEC
840923	Xpress 4X4	Iowa City	DUB
841734	Xpress 4X4	Iowa City	GAL
840966	Xpress 4X4	Iowa City	IC
841732	Xpress 4X4	Iowa City	OTT
840964	Xpress 4X4	Iowa City	QC
841738	Xpress 4X4	Iowa City	QNC
841733	Xpress 4X4	Iowa City	STER
841736	Xpress 4x4	Iowa City	WLOO

Services to be provided:

- 1) The contractor will provide unlimited 24/7 technical phone support
- 2) The contractor will provide 2 day on-site response
- 3) The contractor will provide next day system swap
- 4) The contractor will provide all labor, parts, and travel expenses to fully support and maintain the following inventory of Cepheid laboratory analyzers in VISN 23. "Fully support and maintain" is defined in the manufacturer user and service manuals of each laboratory analyzer. This includes 98%

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uptime guarantee for the Xpert devices and all software upgrades. This also includes 1 annual preventative maintenance check for all devices.

Estimated Cost: \$439,785.00 for 1 year. This is a request for a 1 year contract.

4. **Statutory Authority Permitting Other than Full and Open Competition:**

- ☒ (X) (1) Only One Responsible Source and No Other Supplies or Services Will Satisfy Agency Requirements per 41 USC §3304(a)(1) as implemented by FAR 6.302-1;
- ☐ () (2) Unusual and Compelling Urgency per 41 USC §3304(a)(2) as implemented by FAR 6.302-2;
- ☐ () (3) Industrial Mobilization, Engineering, Developmental or Research Capability or Expert Services per 41 USC §3304(a)(3) as implemented by FAR 6.302-3;
- ☐ () (4) International Agreement per 41 USC §3304(a)(4) as implemented by FAR 6.302-4
- ☐ () (5) Authorized or Required by Statute per 41 USC §3304(a)(5) as implemented by FAR 6.302-5;
- ☐ () (6) National Security per 41 USC §3304(a)(6) as implemented by FAR 6.302-6;
- ☐ () (7) Public Interest per 41 USC §3304(a)(7) as implemented by FAR 6.302-7;

5. **Demonstration that the Contractor's Unique Qualifications or Nature of the Acquisition Requires the Use of the Authority Cited Above (applicability of authority):**

Cepheid is the manufacturer of the Cepheid laboratory instruments and has stated that they are the only authorized provider of service for these instruments in the US. Only authorized and trained parties should service this medical laboratory equipment or risk comprising the devices safety and accuracy.

6. **Description of Efforts Made to ensure that offers are solicited from as many potential sources as deemed practicable:**

Market research was conducted. No other vendor was identified meeting the specific requirements. An intent to sole source was published to SAM Contract Opportunities from 12/20/24-12/27/24. There were no responses received.

7. **Determination by the CO that the Anticipated Cost to the Government will be Fair and Reasonable:**

The Contracting Officer will make a fair and reasonable determination by using one of the following methods:

1. Comparison of previously proposed prices and previous Government and commercial contract prices with current proposed prices for like items. The procurement history for this service is extensive and comparing the proposed pricing to previous pricing will provide the best value to the VA.

8. Description of the Market Research Conducted and the Results, or a Statement of the Reasons Market Research Was Not Conducted:

Market research was conducted. No other vendor was identified meeting the specific requirements. An intent to sole source was published to SAM Contract Opportunities from — 12/20/24-12/27/24. There were no responses received.

9. Any Other Facts Supporting the Use of Other than Full and Open Competition:

This is medical laboratory equipment utilized in VISN 23 that must be serviced by parties authorized by the original equipment manufacturer only.

10. Listing of Sources that Expressed, in Writing, an Interest in the Acquisition:

Cepheid
904 Caribbean DR
Sunnyvale, California
94089-1189, United States

11. A Statement of the Actions, if any, the Agency May Take to Remove or Overcome any Barriers to Competition before Making subsequent acquisitions for the supplies or services required: None, there are no other vendors that can have the training, expertise, or authorization to service this equipment.

12. Requirements Certification: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge and belief.

KAYLA SHUTE

Digitally signed by KAYLA
SHUTE
Date: 2024.12.30 14:11:18
-06'00'

Kayla Shute
Biomedical Engineer
VISN 23 Midwest Healthcare Network

13. Approvals in accordance with the [VHAPM Part 806.3 OFOC SOP](#):

- a. **Contracting Officer Certification (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

Joshua Imdacha
Contracting Officer
Network Contracting Office (NCO) 23

Date

- b. **One Level Above the Contracting Officer (Required over SAT but not exceeding \$750K):** I certify the justification meets requirements for other than full and open competition.

Chara Collins
Branch Chief
Network Contracting Office (NCO) 23

Date