



JUSTIFICATION FOR SOLE SOURCE PROCUREMENT (OPEN MARKET OR GSA) UNDER \$250,000

Sole source acquisitions may be used on a limited basis and only when the Contracting Officer's Representative (COR)/Program Official has provided sufficient justification and the Contracting Officer has determined that the circumstances warrant such action. The content for a justification must contain detailed facts and rationale to justify the sole source acquisition. Soliciting from a single source must be done in accordance with FAR 13.106-1(b) or 8.405-6. At a minimum, the following information must be included:

Identification of Program Office, Contracting Activity, and Proposed Requirement, Justification and Program Office Certification:

A. Program Office:

NCEZID/DVBD/BDB
Fort Collins
P02
Centers for Disease Control and Prevention
Fort Collins, CO 80521

B. Contracting Activity:

Centers for Disease Control and Prevention
Office of Financial Resources
Acquisition Branch [Click here to enter text.](#)

C. Identification of Requirement:

1. Nature of Action to be Approved by Contracting Officer:

- a. Sole source acquisition of: Large volume serum samples from patients with well-characterized *Borrelia miyamotoi* disease to enhance the CDC serum repository
- b. Procurement Request (PR) Number (if available): 00HCVLJC-2023-77631

2. Proposed Vendor and Estimated Procurement Amount (if available):

- a. Proposed Vendor: The Massachusetts General Hospital, 55 Fruit St, Boston, MA 02114
- b. Estimated Procurement Amount: \$134,232.40

3. Is the requirement on GSA Schedule? Yes No

If yes, provide schedule number: [Click here to enter text.](#)

D. Justification:

1. The justification for this non-competitive action is: **(NOTE: Must select only ONE of the listed justifications for other than full and open competition and fully support the justification in the following paragraphs. Please delete this note prior to submitting the justification.)**

In accordance with FAR 13.106-1(b)(1), “only one source [is] reasonably available” which states that, “For purchases not exceeding the simplified acquisition threshold. (i) Contracting officers may solicit from one source if the contracting officer determines that the circumstances of the contract action deem only one source reasonably available (e.g., urgency, exclusive licensing agreements, brand-name or industrial mobilization). (ii) Where a single source is identified to provide a portion of a purchase because that portion of the purchase specifies a particular brand-name item, the documentation in paragraph (b)(1)(i) of this section only applies to the portion of the purchase requiring brand-name item. The documentation should state it is covering only the portion of the acquisition which is brand- name.”

- Urgency
 Exclusive licensing agreements/Proprietary data
 Brand name required
 Industrial mobilization
 Other (e.g., compatibility, space issues, continuity, compatibility, etc.)

In accordance with FAR 8.405-6 “Limiting Sources” which states that, “the only circumstances that may justify the action are – (A) An urgent and compelling need exists, and following the procedures would result in unacceptable delays; (B) Only one source is capable of providing the supplies or services required at the level of quality required because the supplies or services are unique or highly specialized; or (C) In the interest of economy and efficiency, the new work is a logical follow-up to an original Federal Supply Schedule order provided that the original order was placed in accordance with the applicable Federal Supply Schedule ordering procedures. The original BPA must not have been previously issued under sole-source or limited-sources procedures.”

- Urgency
 Only One Source
 Logical Follow Up
 Brand name required

2. Other facts supporting sole source procurement:

- a. What can this product/service do that other products/services cannot do?

The CDC serum repository for Lyme disease and other tickborne infections is an existing repository of serum samples from patients at various stages of Lyme disease, healthy individuals and patients with other diseases. These serum samples are made available as with accompanying clinical and laboratory testing results to Lyme disease serological test users and researchers to support the development and FDA clearance of improved tests. Collection of serum samples from well-characterized patients with *Borrelia miyamotoi* disease and other tickborne illness (anaplasmosis, babesiosis as well as Lyme disease) is critical for maintaining the longevity of the repository for test developers. Consistency of serum sample collection is essential for assuring the integrity and quality of the CDC Lyme serum repository. Analogous performance of the collected serum samples is critical as these samples are used nationwide to assess Lyme disease test performance as well as *B. miyamotoi* disease test performance. Collection of serum from the same well-

characterized patient population using the same patient enrollment criteria and laboratory testing methods to confirm patients with B. miyamotoi disease is therefore required. Massachusetts General Hospital is the only vendor that can provide the required serum samples that meet the above requirements of the CDC Lyme serum repository.

- b. What other products/services were considered and why did they not meet the need? No other products were considered. Collection of serum from the same well-characterized patient population, maintenance of the same patient enrollment criteria and use of the laboratory testing methods can only be provided by Massachusetts General Hospital.

- 3. Program Office efforts to seek potential offerors:
Market research was not conducted. Consistency of serum sample collection is essential for assuring the integrity and quality of the CDC Lyme serum repository, including assuring analogous performance of the collected serum samples. Collection of serum from the same well-characterized patient population using the same patient enrollment criteria and laboratory testing methods to confirm patients with B. miyamotoi disease can only be provided by Massachusetts General Hospital.

E. Program Office Certification:

I have reviewed this sole source justification and certify the justification is true and accurate to the best of my knowledge and adequate to support other than full and open competition.

Center/Institute/Office COR/Program Official Name/Title: Amy Ullmann, PHA

_____ Center/Institute/Office COR/Program Official Signature:

Certification Date: 11/19/2023

F. Contracting Office Certification:

I have fully relied on the information provided herein and hereby certify that this justification is accurate and complete to the best of my knowledge and belief:

Contracting Officer Name: [Click here to enter text.](#)

_____ Contracting Officer Signature:

Certification Date: [Click here to enter a date.](#)