

JUSTIFICATION FOR SINGLE SOURCE AWARDS IAW FAR 13.106-1
(OVER MICRO-PURCHASE THRESHOLD(\$3K) BUT NOT EXCEEDING THE SAT (\$150K))

IAW [FAR13.104](#), COs must promote competition to the maximum extent practicable to obtain supplies and services from the source whose offer is the most advantageous to the Government, considering the administrative cost of the purchase. When competition is not practicable, IAW [FAR13.106-1\(b\)](#), COs solicit from a single source for purchases not exceeding the simplified acquisition threshold. COs may solicit from one source if the CO 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). IAW [FAR13.106-3\(b\)\(3\)](#), COs are required to include additional statements ***explaining the absence of competition*** (see [13.106-1](#) for brand name purchases) if only one source is solicited and the acquisition does not exceed the simplified acquisition threshold (does not apply to an acquisition of utility services available from only one source) or supporting the award decision if other than price-related factors were considered in selecting the supplier. This template when completed can be used to document single source awards IAW [FAR13.106-3\(b\)\(3\)](#). Note: Statements such as "only known source" or "only source which can meet the required delivery date" are inadequate to support a sole source purchase.

1. PURCHASE REQUEST OR REQUISITION NUMBER:
528-16-1-4307-0022

**1A. PROJECT/TASK
NUMBER**
N/A

1B. ESTIMATED AMOUNT:
Buffalo: [REDACTED]

2. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES REQUIRED AND THE INTENDED USE:

Award of a firm fixed price purchase order for the procurement of Genexpert test kits for the Buffalo VA Medical Center for the period of 10/26/2015 – 12/31/2015 while a base plus four option year IDIQ is being completed.

These tests kits will be used to detect Influenza A&B in nasopharyngeal samples, C. difficile toxin in stool samples, MRSA/SA in blood cultures and wound samples and BCR-ABL in blood samples. The Buffalo VA Medical Center currently owns the Cepheid GenXpert instruments and it is already in house.

3. UNIQUE CHARACTERISTICS THAT LIMIT AVAILABILITY TO ONLY ONE SOURCE, WITH THE REASON NO OTHER SUPPLIES OR SERVICES CAN BE USED:

Cepheid is the only responsible source for the proprietary test kits required to perform highly specialized molecular testing on the state-of-the-art Cepheid GeneXpert instrument which is owned by the Buffalo VA Medical Center. The molecular testing performed using this instrumentation/test kits provides for timely, sensitive and specific test results that can be used for the real time management of patients.

4. REASON THAT SUGGESTED SOURCE IS THE ONLY SOURCE, WHICH CAN PROVIDE THE SUPPLIES OR SERVICES:

Discussions with the vendor indicated that they are the manufacturer and sole distributor of these products. The vendor confirmed they only market this system in the United States through direct sales organization.

Market research on FBO has also shown that other VA Medical Centers, including VISN 2 Medical Centers,

the Cleveland VA Medical Center and the West Palm Beach VA Medical Center as well as the Walter Reed National Military Medical Center, have sole sourced the requested products from Cepheid, Inc. in the past.

5. DESCRIPTION OF MARKET RESEARCH CONDUCTED AND RESULTS OR STATEMENT WHY IT WAS NOT CONDUCTED:

The overall North American Industry Classification System (NAICS) code was determined to be 325413 (In-Vitro Diagnostic Substance Manufacturing); with the small business size standard of 500 employees.

A search on Vetbiz using the NAICS code 325413 – In-Vitro Diagnostic Substance Manufacturing indicated that there are four SDVOSB's that are registered with that NAICS code on Vetbiz.

A search on SBA Dynamic Search Tool using the NAICS code 325413 – In-Vitro Diagnostic Substance Manufacturing indicated that there are three hundred sixty five small business vendors that are registered with that NAICS code.

A sources sought notice was posted on FBO (4/7/2015 – 4/14/2015). The sources sought notice was posted to seek alternative vendor's solutions to the government's need for brand name or equal reagent test kits to be used in Cepheid Genexpert instrument systems. One response was received, which was from the requested vendor, Cepheid (large business). That the requested items are open market. No other vendor's responded to the sources sought notice. The vendor also confirmed that only Cepheid test kits can be used on these instrument systems and these test kits cannot be used on any other brand of instrumentation.

Discussions with the vendor indicated that they are the only source of this product. The vendor confirmed they only market this system in the United States through direct sales. The vendor further confirmed that only their products can be utilized in their analyzers.

Market research on FBO has also shown that other VA Medical Centers, including VISN 2 Medical Centers, the Cleveland VA Medical Center and the West Palm Beach VA Medical Center as well as the Walter Reed National Military Medical Center, have sole sourced the requested products from Cepheid, Inc. in the past.

Finally, a review on FPDS showed that 258 awards were made to Cepheid in Fiscal Year 2015. A sample of 10 was surveyed and all acquisitions were determined to be procured as Sole Source or if full and open competition was used, only one quote was received in response to their solicitation.

The extensive market research conducted concluded that only one source was available to provide the Cepheid reagent test kits.

6. a. Contracting Officer's Certification: *Purchase is approved in accordance with FAR13.106-1(b). I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.*

Allison Dubin
Contracting Officer
VISN 2 NCA

Date