

**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/DHCPP/VSPB
Roybal campus
Building 15, Room SB 611, H18-SB
Centers for Disease Control and Prevention
Atlanta, GA 30333

B. Contracting Activity:

Centers for Disease Control and Prevention
Office of Financial Resources
Acquisition Branch 2920 Brandywine Rd Atlanta, GA 30341

C. Identification of Requirement:

1. Nature of Action to be Approved by Contracting Officer:
 - a. Sole source acquisition of: CLT ImmunoSpot S6 Universal M2 Analyzer
 - b. Procurement Request (PR) Number (if available): 63369
2. Proposed Vendor and Estimated Procurement Amount (if available):
 - a. Proposed Vendor: C.T.L. Analyzers, LLC
 - b. Estimated Procurement Amount: [REDACTED]
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:

- ☒ 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 laboratory response for Ebola entails measuring cell response to antigens. The most common method for monitoring lymphocyte responses is the ELISPOT (Enzyme-Linked ImmunoSpot) Assay. This model permits 5 color analysis, which can be upgraded up to 12 colors. It has powerful zoom lens optics which enable microscopic-range high-resolution and subcellular detail-oriented fluorescent analysis, while on the other end affording the flexibility to capture optimal images in the macroscopic domain, in any microtiter plate well format. It is suited to support a wide variety of microtiter plate-based assays that require analysis of colonies, foci, plaques or single cell. It's capable of high-throughput, handling up to 400 plates per run.

Product Specifications:

- Single-Color ELISPOT
- Double-Color Enzymatic ELISPOT
- Five-Color FluoroSpot, upgradable to 12 colors

- Five-Color Fluorescence BioSpot, upgradable to 12 colors
- FRNT / FRA
- PRNT / Viral Titer Assays
- Bacterial/Yeast/Viral Colony Counting
- Live/Dead/Apoptotic PBMC Counting
- Microscopic Fluorescent Cell Imaging, Five-Color (upgradable to 12 colors)
- Cell-mediated Cytotoxicity Assays, Five-Color (upgradable to 12 colors)
- Histology Slide Analysis
- Nucleic Acid and Protein Quantification
- ELISA Analysis
- Suited for Regulatory Compliance
- Suited for BSL-3/BSL-4

Well Formats

- 6/12/24/48/96/384/1536 & Terasaki (upgradeable to rapid 6/100mm Petri)

Advanced Components

- Precision stage (0.24 mm stepping)
- Digital area scan camera with image resolution of up to 25 Megapixels
- Computer Interface: USB 3.0
- Integrated Barcode Reader
- Optical Interface: Motorized zoom and focus
- Lighting Top: 114 LED Ring (rated for 100,000 operating hours)
- Lighting Bottom: High illumination, uniform luminescent flat light panel
- Lighting Fluorescence:
 - Long Life, Ultra-High Power BLUE LED
 - Long Life, Ultra-High Power GREEN LED
 - Long Life, Ultra-High Power VIOLET LED
 - Long Life, Ultra-High Power RED LED
 - Long Life, Ultra-High Power NIR LED (Upgradeable – requires NIR LED and additional dichroic mirrors)
- Excitation Filters: 405nm, 480 nm, 570nm, 630 nm, (Upgradeable – requires NIR LED and additional dichroic mirrors)

Emission Filters:

1. 440 nm: DAPI, Alexa Fluor® 405, Pacific Blue™, CF™ 405, Po-Pro™, Sytox™ Blue
2. 520 nm: FITC, AO, CFSC, Alexa Fluor® 488, GFP, sfGFP, Sytox™ Green, Yo-Pro™
3. 600 nm: PE, Cy3, TRITC, PI, Sytox™ Orange, dsRed, mRuby2
4. 625 nm: PI, mCherry, Alexa Fluor® 594
5. 690 nm: PE-Cy5, PerCP, PE-AF680, PERCP Cy 5.5, Cy5, Alexa Fluor® 647, APC
6. 800 nm: PE-Cy7, Qdot-800, APC-Cy7
7. Empty
8. Open for ELISPOT

Dimension

- Imaging Unit (H x W x D); (Weight): 73.1 cm x 56 cm x 56 cm; 52.16 kg
- Data Processing Unit (H x W x D); (Weight): 29 cm x 9 cm, 29 cm; 4.99 kg

- b. What other products/services were considered and why did they not meet the need?

A search identified two similar products: the AID iSpot Spectrum, and the Mabtech IRIS. While both machines are able to process ELISPOT plates, they do not meet our specific needs. The AID iSpot Spectrum does not meet our needs as they offer a narrow range of consumables, lacking critical reagents required for our established assays. The MabTech machine does not meet our needs as it is restricted to 4 colors and 96-well plates, and therefore doesn't have the required capacity. Furthermore, we have established protocols using a CTL machine and obtaining a different brand

would require us to repeat our validation and optimization efforts. The ability to withstand our BSL-3/BSL-4 decon treatment has been confirmed for the CTL machine, while that remains uncertain for the AID iSpot Spectrum, and the Mabtech IRIS.


3. Program Office efforts to seek potential offerors:

Internet searches, literature searches, consultation with other labs at CDC and partner labs of CDC, and vender shows.

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: NCEZID/DHCPP/VSPB/William Lonergan/CORII

William Lonergan - S  Digitally signed by William Lonergan -S
Date: 2022.02.07 12:19:13 -05'00'


Center/Institute/Office COR/Program Official Signature:

Certification Date: April 9, 2021

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.](#)

Cynthia L. Cason - S  Digitally signed by Cynthia L. Cason -S
Date: 2022.03.20 18:56:40 -04'00'

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