Notice of Intent to Certify Sole Source

To: Interested Parties

From: Stacy Baldwin Agency Procurement Officer

Date: May 15, 2017

Re: Sole Source Certification Number SS5097 for Bio-Plex Suspension Array System

Contact Email Address: solesource@umc.edu

Sole Source Certification Award Details

Regarding UMMC Sole Source Certification Number **SS5097** for **Bio-Plex Suspension Array System**, please be advised that UMMC intends to award the purchase of the Bio-Plex Suspension Array System to BioRad as the sole source provider of the Bio-Plex Suspension Array System.

UMMC issues this notice in accordance with Mississippi state law, policy, and procedures for sole source procurements.

Sole Source Criteria

- 1. Where the compatibility of equipment, accessories, or replacement parts is the paramount consideration (and manufacturer is the sole supplier).
- 2. Where a sole supplier's item is needed for trial use or testing.
- 3. Where a sole supplier's item is to be required when no other item will service the needs of UMMC.

Schedule

Task	Date
First Advertisement Date	May 15, 2017
Second Advertisement Date	May 22, 2017
Response Deadline from Objectors	May 30, 2017, at 3:00 p.m. Central
	Time
Notice of Award/No Award Posted	Not before June 30, 2017

Project Details

1. Describe the commodity that the agency is seeking to procure:

The department is seeking to procure a Bio-Plex Suspension Array System. This technology allows one to simultaneously measure up to 100 analytes in a single microplate well, using very small samples. The system delivers fast and cost-effective bioassay results on many assay formats including nucleic acid assays, receptor-ligand, assays, immunoassays, and enzymatic assays.

2. Explain why the commodity is the only one (1) that can meet the needs of the agency:

The Bio-Plex is a combination of the Luminex instrumentation technology in conjunction with the Bio-Plex Manager software that allows the user to operate the reader and the Bio-Rad Data Pro software that allows for analysis of data directly from the instrument. Luminex technology is currently the only available technology to perform these types of multiplex assays simultaneously and is only available from BioRad.

3. Explain why the source is the only person or entity that can provide the required commodity:

The BioPlex 200 instrument system with Bio-Plex Manager software, MVC plate and analysis software is only available through BioRad. This configuration is not available from any other distributor. See supporting letter from BioRad, Attachment A.

- **4.** Explain why the amount to be expended for the commodity is reasonable: The estimated amount to be expended is for the purchase of the Bio-Plex Suspension Array System is \$49,891.10. This amount is within the expected price range for these products.
- 5. Describe the efforts that the agency went through to obtain the best possible price for the commodity:

Through market intelligence, UMMC was able to negotiate best pricing for these products. All applicable discounts were explored and applied.

Submission Instructions and Format of Response from Objecting Parties

Interested parties who have reason to believe that the Bio-Plex Suspension Array System (hereafter, "Products") should not be certified as a sole source should provide information in the Vendor Form for the State to use in determining whether or not to proceed with awarding the sole source to BioRad. The Vendor Form may be found at http://www.dfa.state.ms.us/Purchasing/documents/ObjectiontoSoleSourceDetermination.pdf.

Objections must include the certification in Attachment B.

Comments will be accepted at any time prior to Tuesday, May 30 2017, at 3:00 p.m. (Central Time) to <u>solesource@umc.edu</u>. Responses may be delivered via email to <u>solesource@umc.edu</u>.

UMMC WILL NOT BE RESPONSIBLE FOR DELAYS IN THE DELIVERY OF RESPONSES. It is solely the responsibility of the Interested Parties that responses reach UMMC on time. Responses received after the deadline and responses that lack all required information will be rejected. UMMC reserves the right to inspect Interested Party's commodity for comparison purposes.

If you have any questions concerning the information above or if we can be of further assistance, please contact <u>solesource@umc.edu</u>.

Attachment A: Vendor Correspondence Attachment B: Objection Certification Attachment A



Sole Source Specifications for Bio-Plex Suspension Array System

Bio-Rad is the sole distributor of the Bio-Plex 200 instrument with Bio-Plex ManagerTM 6.1 software, Proprietary MCV plate, and Bio-Rad Data Pro analysis software included. The Bio-Plex System (catalog numbers 171-0002005 and 171-000201) is distinguished chiefly by the Bio-Plex ManagerTM 6.1 software used to operate the Bio-Plex reader and microplate platform, as well as the Bio-Plex Validation Kit (included with system). Bio-Rad Data Pro software is also included to combine multiple instrument runs and efficiently understand how the multiplex data correlated to the biological system investigated.

The following features are unique to Bio-Plex Manager system and are not available in competing packages:

UNIQUE SOFTWARE FEATURES

- Instrument control software with integrated data analysis package- Bio-Plex Manager[™] 6.1 software. No export to third party software necessary for data reduction.
- Data reduction package including automatic and simultaneous calculation of unknown sample concentrations, standard deviation and coefficient of variation percentage for duplicate samples, and recovery values for standard curves (assessment of "goodness of fit").
- Integrated data regression analysis including seamless implementation of StatLIA "weighted" 5 PL (parameter logistic) curve-fitting algorithm (exclusively licensed from Brendan Scientific).
- Full menu of additional regression methods including 4PL, cubic spline, linear, and point-topoint curve fitting.
- Real-time data acquisition permitting display of multiplex data as it is generated, including bead map, single parameter histogram, bead flow rate, and median fluorescence intensity values for all analytes in each well.
- Raw data is collected and displayed well by well rather than at the conclusion of the read, allowing for data recovery should an unexpected event occur.
- · Rerun/Recovery mode allows for complete rerun of all or a portion of samples.
- System monitoring of instrument functionality with error flags and available pause function
 enabling user intervention and troubleshooting in case of problems with low bead count,
 aggregated beads, classification efficiency, region selection, or platform temperature.
- Automation of commonly used functions such as start-up, calibration, washing, and shutdown.



- · "One-click" data export to Excel providing tab-delimited version of Bio-Plex generated data.
- Calibration, Validation and Instrument Operations Logs automatically generated, providing documentation of system maintenance, performance and operation, enabling enhanced troubleshooting.
- Calibration is available at optional "high PMT" setting for maximum system sensitivity.
- Validation Report feature for generating hard copy quality control and IQ/OQ (installation qualification/operational qualification) documentation.
- Grouping function simplifies analysis of data for which standards are not available, e.g., nucleic acid-based bead assays, providing automated ratiometric data output.

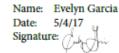
ADDITIONAL UNIQUE FEATURES

 Bio-Plex Validation Kit provides formal IQ/OQ (installation qualification/operational qualification) of instrument performance.

The Validation Kit consists of proprietary beads, procedures and a list of specifications developed by Bio-Rad to verify system parameters that can affect assay performance.

The kit checks optical alignment, fluidics carryover, accuracy, slope, linearity, sensitivity and dynamic range of the reporter laser, as well as classification efficiency and doublet discrimination.

- Proprietary MCV plate (included with Bio-Plex system) enables automated start-up, shutdown, calibration and validation functions. The onboard reagent reservoirs allow users to run maintenance, calibration and validation protocols unattended.
- Inclusion of Bio-Rad Data Pro Software: Effortlessly organize large volumes of multiplex data: Automate calculations with simple conservative statistics and select subgroups. Quickly view results in a finished state with little input and no need to perform extensive auditing of data. Change automated calculations to test new hypotheses or account for new insights with ease. Visualize results- Quickly present results in a manner relevant to research being undertaken and instantly update graphs when new comparisons are desired or different analysis options applied. Easily create graphs without the need to copy and paste to Excel.
- Bio-Rad Labs is the only vendor permitted or qualified to perform service on the Bio-Plex System; only Bio-Plex Systems can be serviced by Bio-Rad Field Service Engineers.
- · All Bio-Plex Systems are installed by Field Service Engineers free of charge.
- Bio-Plex System technical phone and field applications support is supplied directly by Bio-Rad Labs.
- Bio-Plex training will be provided by a Field Application Specialist free of charge.



SUBMITTED IN RESPONSE TO Sole Source Certification No. SS5097 Accepted until May 30, 2017, at 3:00 p.m.

I certify that the information contained in this objection is true and accurate to the best of my knowledge. I understand that UMMC will investigate all statements made in this objection and that any false or misleading information provided may result in adverse action.

> Objector Name Objector's title

Date