## DESCRIPTION OF INTENDED SINGLE SOURCE PURCHASE

(PUR 7776)

AGENCY: Department of Health

TITLE: Bio-Rad Laboratories Geenius<sup>TM</sup> System

Short description of the commodity or service desired: Assays and controls necessary to perform HIV-1/HIV-2

Supplemental differentiation testing

**CONTACT** 

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Internal tracking number, if any: EXP2421

11/24/21 @ 3:00 pm

Date posted: 10/28/21 @ 3:00 pm Last day for receipt of information: 11/18/21 @ 3:00 pm

This description of commodities or contractual services intended for purchase from a single source is posted in accordance with sections 120.57(3) and 287.057(3), Florida Statutes and will remain posted for a period of at least 15 business days.

<u>Commodity or Contractual Service Required</u> (commodity or United National Standard Products and Services Code (UNSPSC), manufacturer, model, and description, as appropriate):

12161500 Indicators and Reagents

41116000 Clinical and diagnostic analyzer reagents

41116100 Manual test kits and quality controls and calibrators and standards

Quantity or Term (as appropriate):

3 years

Requestor (division, bureau, office, individual, as appropriate):

Division of Disease Control and Health Protection (DCHP), Bureau of Public Health Laboratories (BPHL)

<u>Performance and/or Design Requirements</u> (e.g. intended use, function or application, compatibility, requirements; reference to policy, rule, statute or other act of the Legislature, etc., as appropriate):

The Department needs a system to perform HIV-1/HIV-2 Supplemental differentiation assay to confirm HIV infection in patients testing positive on an initial screen. The assay must be able to test whole blood, serum, plasma, and inhouse validated oral fluid to conform to the CDC 2014 HIV Diagnostic Algorithm guidelines. In accordance with Chapter 60A-1.045, Florida Administrative Code, the Florida Department of Health, BPHL, requests authorization to purchase, as a single source, the Bio-Rad Laboratories Geenius<sup>TM</sup> System assays and controls.

Intended Single Source:

**Bio-Rad Laboratories** 

**Estimated Dollar Amount:** 

\$413,832.00

<u>Justification for single source acquisition</u> (what is necessary and unique about the product, service or source; steps taken to confirm unavailability of competition, as appropriate):

- Bio-Rad Laboratories (manufacturer) is the sole distributor of the Geenius<sup>TM</sup> System.
- The Geenius<sup>™</sup> System is the only FDA approved HIV-1/HIV-2 differential assay currently on the U.S. market and has been validated in-house for the confirmation of HIV-1 Oral Fluid meeting the guidelines required.

Approved By (names & titles, as appropriate, e.g., requestor, requestor management, information systems, budget, purchasing):

Samantha Washington, Chief, Bureau of General Services

Prospective vendors are requested to provide information regarding their ability to supply the commodities or contractual services described. If it is determined in writing by the agency, after reviewing any information received from prospective vendors, that the commodities or contractual services are available only from a single source, the agency shall: provide notice of its intended decision to enter a single-source purchase contract in the manner specified in s.120.57(3), FS.