STATEMENT OF NEED (SON)

1.0 TITLE

LP Flow Cytometry BD FACSLyric Upgrade Kit (10- to 12-color)

2.0 BACKGROUND

a. **Federal agency and contracting activity.** HHS/NIH/NCI
b. **Sponsoring organization.** CCR/Laboratory of Pathology
c. **Project Officer information.**

- **Project Officer name.** **Catharine McCoy**
- **Mailing address.** NIH/NCI/LP Flow Cytometry Lab
BLDG 10/Rm 3S240
10 Center Drive
Bethesda, MD 20892
- **E-mail address.** mccoyca@mail.nih.gov
- **Telephone number.** **301-480-8078**

d. This acquisition is being pursued to upgrade existing Government-owned BD FACSLyric 10-color Flow Cytometer to a 12-color Flow Cytometer to meet expanding multi-immunophenotypic needs of the clinical protocol patient services provided by the Clinical Flow Cytometry clinical service in the Laboratory of Pathology, CCR, NCI.

The mission of the Laboratory of Pathology (LP) Department is to investigate the biology and genetics of cancer and other diseases, develop and apply leading edge technologies to diagnostic pathology, and provide collaborative support for clinical research protocols.

The existing Government-owned BD FACSLyric Flow Cytometer system was purchased in 2019 as a 10-color instrument because the more costly 12-color system provided little added benefit due to the limited availability of 12-color products on the market. However, as the availability of commercial, off-the-shelf products has expanded into the 12-color range and the advent of novel immunotherapeutic regimens has increased the need for multi-dimensional immunophenotyping, the existing 10-color system must be expanded to meet the needs of clinical protocol patient specimens with increasingly complex antigenic signatures resulting from the impact of new protocols.

Acquisition of a new BD FACSLyric Upgrade kit, rather than purchase of a new 12-color flow cytometer system, is a fiscally responsible option for extending the capabilities of existing Government-owned equipment from a 10-color system to a

12-color system to meet the expanding needs of clinical protocol patient testing support.

The Upgrade Kit provides two novel fluorescent parameter capabilities via new photomultiplier tubes (PMTs), one each of BD Horizon™ BV711 and BD Horizon™ BV786 to convert the existing 10-color configuration (4-3-3) of the Class I solid state 3-laser system (488 nm, 640 nm, 405 nm) to a new 12-color configuration (4-3-5) to provide exponential expansion of population comparisons and subtle distinction between populations undergoing novel therapeutic regimens. This increased ability to identify abnormal vs. normal cells allows more reproducible and robust identification of individual populations with predefined groups of abnormal samples to quickly determine possible disease types.

These key features are vital advances in the field of flow cytometry and are needed to provide the Government with the best ongoing analysis of clinical protocol patient specimens for detection of trends and comparison of subtle therapeutic changes at a time when immunotherapy creates ever increasing complexity in patient presentation.

3.0 TYPE OF ORDER

This is a Firm Fixed-Price Purchase Order.

4.0 SPECIAL ORDER REQUIREMENTS

4.1 PRODUCT FEATURES/SALIENT CHARACTERISTICS

The following advanced flow cytometry analysis features/characteristics are required for this requirement:

a. Proprietary Fit: Only proposed Upgrade Kit components (part no. 662858), provided by the original manufacturer Becton, Dickinson and Company, will fit the sockets built into the existing Government-owned equipment, model FACSLyric Flow Cytometer, SN Z662878000154. No other manufacturers' kit or third party PMT components will fit the PMT outlets to convert the 3-laser, FACSLyric 10-color (4-3-3) configuration to a 12-color (4-3-5) configuration.
b. Manufacturer's recommendations: Only the proposed Upgrade Kit (part no. 662858 supplied by the original BD FACSLyric manufacturer) is recommended by the manufacturer to maintain clinical patient certification e.g. JCAHO, CLIA, CAP.
c. Manufacturer-trained personnel: Only BD-trained engineers with 2-years' experience on BD FACSLyric flow cytometers are qualified for installation/alignment/testing and customer service support of the Upgrade Kit.

d. Brand new condition: Upgrade Kit (Becton, Dickinson and Company, manufacturer part no. 662858). Kit or components in used, refurbished, resealed or unsealed condition are unacceptable.

e. Upgrade Kit must include two (2) new photomultiplier tubes (PMTs) specifically, one each of BD Horizon™ BV711 and BD Horizon™ BV786 to convert the existing 10-color configuration (4-3-3) of the Class I solid state 3-laser system (488 nm, 640 nm, 405 nm) to a new 12-color configuration (4-3-5).

f. All parts will be manufacturer-recommended to maintain clinical patient testing compliance requirements after the upgrade kit installation e.g. JCAHO, CLIA, CAP certifications.

   Example: Installation of a third-party kit or components is not acceptable without written recommendation of each installed alternate component by Becton, Dickinson and Company.

g. Installation, alignment and testing of all kit components by BD-trained engineers with manufacturer-training and at least 2 years' experience with BD FACSLyric 3-laser flow cytometers (4-3-3 and 4-3-5 configurations), according to recommendations by the original manufacturer (Becton, Dickinson and Company).

4.2 DELIVERY / INSTALLATION

One (1) Upgrade Kit, part #662858, with two (2) PMTs, specifically one each of BD Horizon™ BV711 and BD Horizon™ BV786 shall be delivered within 5 days of purchase order award along with detailed invoice (see 5.0 PAYMENT details, below) to:

Point of Contact: Dr. Hao-Wei Wang, Director
Phone: 301-480-8043

Delivery Address: NIH/NCI, Laboratory of Pathology
BLDG 10/RM 3S235F
9000 Rockville Pike
Bethesda, MD 20892

4.3 TRAINING

a. Installation by BD Bioscience engineers with manufacturer-training and at least 2 years' experience with BD FACSLyric 3-laser flow cytometers (4-3-3 and 4-3-5 configurations).

b. Customer support will be provided by BD Bioscience-trained personnel via customer service calls as needed. Upgrade will not require additional onsite customer training.

5.0 PAYMENT

Payment shall be made immediately upon delivery and satisfactory installation and performance testing of each Upgrade Kit component (both PMTs). Payment authorization requires submission and approval of invoices to the COR and NIH OFM, in accordance with the payment provisions listed below:

The following clause is applicable to all Purchase Orders, Task or Delivery Orders, and Blanket Purchase Agreement (BPA) Calls: PROMPT PAYMENT (JUL 2013) FAR 52.232-25. Highlights of this clause and NIH implementation requirements follow:

STATEMENT OF NEED (SON)

I INVOICE REQUIREMENTS

A. An invoice is the Contractor's bill or written request for payment under the contract for supplies delivered or services performed. A proper invoice is an "Original" which must include the items listed in subdivisions 1 through 12, below, in addition to the requirements of FAR 32.9. If the invoice does not comply with these requirements, the Contractor will be notified of the defect within 7 days after the date the designated billing office received the invoice (3 days for meat, meat food products, or fish, and 5 days for perishable agricultural commodities, dairy products, edible fats or oils) with a statement of the reasons why it is not a proper invoice. (See exceptions under II., below.) Untimely notification will be taken into account in the computation of any interest penalty owed the Contractor.

1. Vendor/Contractor: Name, Address, Point of Contact for the invoice (Name, title, telephone number, e-mail and mailing address of point of contact).
2. Remit-to address (Name and complete mailing address to send payment).
3. Remittance name must match exactly with name on original order/contract. If the Remittance name differs from the Legal Business Name, then both names must appear on the invoice.
4. Invoice date.
5. Unique invoice #s for all invoices per vendor regardless of site.
6. NBS document number formats must be included for awards created in the NBS: Contract Number; Purchase Order Number; Task or Delivery Order Number and Source Award Number (e.g., Indefinite Delivery Contract number; General Services Administration number); or, BPA Call Number and BPA Parent Award Number.
7. Data Universal Numbering System (DUNS) or DUNS + 4 as registered in the Central Contractor Registration (CCR).
8. Federal Taxpayer Identification Number (TIN). In those exceptional cases where a contractor does not have a DUNS number or TIN, a Vendor Identification Number (VIN) must be referenced on the invoice. The VIN is the number that appears after the contractor's name on the face page of the award document.
9. Identify that payment is to be made using a three-way match.
10. Description of supplies/services that match the description on the award, by line billed.*
11. Freight or delivery charge must be billed as shown on the award. If it is included in the item price do not bill it separately. If identified in the award as a separate line item, it must be billed separately.
12. Quantity, Unit of Measure, Unit Price, Extended Price of supplies delivered or services performed, as applicable, and that match the line items specified in the award.*

* NOTE: If your invoice must differ from the line items on the award, please contact the Contracting Officer before submitting the invoice. A modification to the order or contract may be needed before the invoice can be submitted and paid.

B. Shipping costs will be reimbursed only if authorized by the Contract/Purchase Order. If authorized, shipping costs must be itemized. Where shipping costs exceed $100, the invoice must be supported by a bill of lading or a paid carrier's receipt.

C. Mail an original and 1 copy of the itemized invoice to:

National Institutes of Health
Office of Financial Management, Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

For inquiries regarding payment call: (301) 496-6088

In order to facilitate the prompt payment of invoices, it is recommended that the vendor submit a photocopy of the invoice to the "Consignee" designated for the acquisition in blocks 6A – 6E of the face page of the Order/Award document.

II. INVOICE PAYMENT

A. Except as indicated in paragraph B., below, the due date for making invoice payments by the designated payment office shall be the later of the following two events:

1. The 30th day after the designated billing office has received a proper invoice.
2. The 30th day after Government acceptance of supplies delivered or services performed.

B. The due date for making invoice payments for meat and meat food products, perishable agricultural commodities, dairy products, and edible fats or oils, shall be in accordance with the Prompt Payment Act, as amended.

III. INTEREST PENALTIES

A. An interest penalty shall be paid automatically, if payment is not made by the due date and the conditions listed below are met, if applicable.
1. A proper invoice was received by the designated billing office.
2. A receiving report or other Government documentation authorizing payment was processed and there was no disagreement over quantity, quality, or contractor compliance with a term or condition.
3. In the case of a final invoice for any balance of funds due the contractor for supplies delivered or services performed, the amount was not subject to further settlement actions between the Government and the Contractor.

B. Determination of interest and penalties due will be made in accordance with the provisions of the Prompt Payment Act, as amended, the Contract Disputes Act, and regulations issued by the Office of Management and Budget.

IV. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (DEC 2013)

a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the

applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

b) The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.