

LIMITED SOURCES JUSTIFICATION

ORDER >\$150,000

FAR PART 8.405-6

Acquisition Plan Action ID: VA244-17-AP-5927, 646-18-1-080-0001

This acquisition is conducted under the authority of the Multiple Award Schedule Program. The material or service listed in part 3 below is sole source, therefore, consideration of the number of contractors required by FAR Subpart 8.4 – Federal Supply Schedules, is precluded for the reasons indicated below.

Restricted to the following source:

Manufacturer/Contractor: Immucor, Inc (Immucor)

Manufacturer/Contractor POC & phone number: Glennoris Riley, 770.441.5303, griley@immucor.com

Mfgr/Contractor Address: 3130 Gateway Drive, Norcross, GA 30071

Dealer/Rep address/phone number: 855.466.8267

☒ The requested material or service represents the minimum requirements of the Government.

(1) AGENCY AND CONTRACTING ACTIVITY:

Department of Veterans Affairs

Network Contracting Office 4 (NCO4)

1400 Blackhorse Hill Road (90C)

Coatesville, PA 19320

VISN:

(4), VA Pittsburgh Healthcare System

(VAPHS), Pittsburgh, PA.

(2) NATURE AND/OR DESCRIPTION OF ACTION BEING APPROVED:

The VAPHS' Pathology & Laboratory Medicine Service (P&LM) Blood Bank/Hematology section is requesting award of a delivery order on a limited source basis to Immucor, Inc under their FSC Group 65, Part VII, Invitro Diagnostics Substances, Reagents, Test Kits and Sets FSS V797D-70110, and SIN 555-1.

(3) (a) A DESCRIPTION OF THE SUPPLIES OR SERVICES REQUIRED TO MEET THE AGENCY'S NEED:

A blood transfusion is a routine medical procedure that can be lifesaving. During a blood transfusion, donated blood is added to the patient's blood. A blood transfusion may also be done to supplement various components of the patient's blood with donated blood products. Before blood or blood products can be released for infusion, compatibility testing must be completed in the Blood Bank. There is a need for Immucor reagents/supplies to be used for the monitoring of precision, quality and accuracy of Blood Bank testing. All materials must be FDA approved for Immunohematology testing using the manual tube testing method and the Immucor Echo automated method. All materials must be interchangeable between the manual tube testing method and the automated Immucor Echo testing method. Quality control materials, screening panels, antibody panels, etc. must detect the presence of all major antigens. Materials must have published expected antigen positivity/negativity for manual tube testing method and the Immucor Echo automated method. See attached contract line item listing

with all reagents required including quantities and unit pricing in accordance with Immucor's FSS price list.

(b) ESTIMATED DOLLAR VALUE: \$168,058.27

(c) REQUIRED DELIVERY DATE: Phased delivery from 10/1/2017 – 09/30/2018.

(4) IDENTIFICATION OF THE JUSTIFICATION RATIONALE (SEE FAR 8.405-6), AND IF APPLICABLE, A DEMONSTRATION OF THE PROPOSED CONTRACTOR'S UNIQUE QUALIFICATIONS TO PROVIDE THE REQUIRED SUPPLY OR SERVICE.

☒ Specific characteristics of the material or service that limit the availability to a sole source (unique features, function of the item, etc.):

Blood Bank reagents are required for use in Transfusion Service for patient testing. These reagents are used for ABO/ Rh typing, Antibody Screen, Antibody Identification, Direct Antiglobulin Testing and Crossmatching of blood. All reagents must be FDA approved for patient testing. The standard operating procedures for testing in the Blood Bank are all developed and written using these products. Currently, all Transfusion Service/ Blood Bank procedures are specifically written according to Immucor reagent use. Change of these reagents to another manufacturer would require P&LM to change their protocols and procedures. Not only would the procedures change, but a period of time would exist where P&LM would need to purchase not only the new products, but the existing Immucor reagents because accreditation standards require that the new testing material/reagents would have to be validated by the Blood Bank. Accreditation Standards for all accrediting bodies must be followed when changing reagents. These agencies include American Association of Blood Banks, College of American Pathologists, Joint Commission and the Food and Drug Administration.

☒ The material/service must be compatible in all aspects (form, fit and function) with existing systems presently installed/performing. Describe the equipment/function you have now and how the new item/service must coordinate, connect, or interface with the existing system.

All reagents must be interchangeable between the manual tube testing method and the automated Immucor Echo testing method. Only Immucor reagents are compatible with the Immucor automated testing instruments currently in use by the VAPHS P&LM.

(5) DESCRIBE WHY YOU BELIEVE THE ORDER REPRESENTS THE BEST VALUE CONSISTENT WITH FAR 8.4 TO AID THE CONTRACTING OFFICER IN MAKING THIS BEST VALUE DETERMINATION:

Award of the described delivery order to Immucor represents the best value to Government for the following reasons: (1) The price offered by Immucor for reagents has been determined fair and reasonable by a VA contracting officer at time of award of Immucor's FSS V797D-70110. (2) The reagents offered by Immucor are the most expedient means to avoid a testing backlog. (3) The reagents offered by Immucor are in wide use throughout the healthcare market place and are generally accepted to be accurate and reliable.

(6) DESCRIBE THE MARKET RESEARCH CONDUCTED AMONG SCHEDULE HOLDERS AND THE RESULTS OR A STATEMENT OF THE REASON MARKET RESEARCH WAS NOT CONDUCTED:

Market research was conducted among various FSS schedule holders and open mark vendors whom provide blood banks reagents of various types such as Bio-Rad Laboratories and Medion Diagnostics. Results of market research indicate that provision of blood bank reagents and supplies to perform compatibility and other hematological testing can only be provided by Immucor, as only Immucor reagents and supplies are compatible with the VAPHS' Immucor testing instruments. Also, currently all blood bank testing procedures are specifically written for Immucor reagent use.

(7) ANY OTHER FACTS SUPPORTING THE JUSTIFICATION:

N/A

(8) A STATEMENT OF THE ACTIONS, IF ANY, THE AGENCY MAY TAKE TO REMOVE OR OVERCOME ANY BARRIERS THAT LED TO THE RESTRICTED CONSIDERATION BEFORE ANY SUBSEQUENT ACQUISITION FOR THE SUPPLIES OR SERVICES IS MADE:

VAPHS P&LM will stay abreast of the latest FDA approved blood bank testing methodologies and products and conduct a competitive best value procurement at a time when it is deemed prudent to change their testing methodologies or otherwise consider use of blood bank reagents other than Immucor.

(9) REQUIREMENTS CERTIFICATION: I certify that the requirement outlined in this justification is a Bona Fide Need of the Department of Veterans Affairs and that the supporting data under my cognizance, which are included in the justification, are accurate and complete to the best of my knowledge. I understand that processing of this limited sources justification restricts consideration of Federal Supply Schedule contractors to fewer than the number required by FAR Subpart 8.4. *(This signature is the requestor's supervisor, fund control point official, chief of service or someone with responsibility and accountability.)*

SIGNATURE

Jason Tedrow

NAME

VA Pittsburgh Healthcare System

FACILITY

DATE

Medical Technologist

TITLE

Pathology & Laboratory Medicine

SERVICE LINE/SECTION

(10) APPROVALS IN ACCORDANCE WITH THE [VHAPM, Volume 6, Chapter VI: OFOC SOP](#):

a. **CONTRACTING OFFICER'S CERTIFICATION (required):** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

_____	09/21/2017
CONTRACTING OFFICER SIGNATURE	DATE
Matthew D. Parlett, Contracting Officer	NCO4, Clinical Support Services (Med 2)
NAME AND TITLE	FACILITY

b. **Director of Contracting/DESIGNEE:** I certify that the foregoing justification is accurate and complete to the best of my knowledge and belief.

_____	09/21/2017
SIGNATURE	DATE
Nancy L. Porter	
Branch Chief, NCO4, Clinical Support Services (Med 2)	

Contract Line Item Listing – Immucor, Inc, V797D-70110

CLIN	Description	Quantity	UoM	Unit Price	STOCK #
0001	CAPTURE R INDICATOR CELLS DELIVERY: 2 EVERY TWO WEEKS	52	EA	\$60.00	6428
0002	WBcorQC DELIVERY: 1 EVERY TWO WEEKS	26	EA	\$180.00	66090
0003	REF A1, B CELLS DELIVERY: 5 EVERY 2 WEEKS	130	EA	\$38.72	2345
0004	DAT POSITIVE CELLS DELIVERY: 1 EVERY 4 WEEKS	13	EA	\$64.00	66125
0005	CAPTURE LISS LAB WILL CALL WHEN NEEDED	36	EA	\$48.30	6420
0006	CMT PLATES LAB WILL CALL WHEN NEEDED	28	EA	\$170.00	89000
0007	CAPTURE READY SCREEN 3 DELIVERY: 13 EVERY 8 WEEKS	112	EA	\$400.00	66813
0008	CAPTURE EXTEND 1 DELIVERY: 2 EVERY 8 WEEKS	12	EA	\$85.00	6454
0009	CAPTURE EXTEND 2 DELIVERY: 2 EVERY 8 WEEKS	12	EA	\$85.00	6456
0010	CAPTURE READY ID DELIVERY: 1 EVERY 8 WEEKS	6	EA	\$375.00	66214
0011	CAPTURE SELECT DELIVERY: 1 EVERY 8 WEEKS	6	EA	\$251.41	6446
0012	PANOSCREEN I, II, III 3 X 10ml PER EACH DELIVERY: 2 BOXES EVERY 2 WEEKS	52	EA	\$104.06	2381
0013	COMPLEMENT COOMBS CONTROL (EC3b), 5ml EACH DELIVERY: 1 EVERY 4 WEEKS	13	EA	\$93.17	7930
0014	REFERENCE CELLS, A2 1X10ml PER EACH DELIVERY: 1 BOX EVERY 4 WEEKS	13	EA	\$37.51	2342
0015	CHECK CELLS WEAK 3X10ml DELIVER: 1 EVERY 2 WEEKS	26	EA	\$130.68	0002227
0016	CORQC QUALITY CONTROL OF ROUTINE REAGENTS DELIVER: 2 KITS EVERY MONTH	26	KT	\$104.06	2400
0017	PANEL 20, 20X3ml PER EACH DELIVER: 1 EVERY 3 WEEKS	18	EA	\$359.37	5020
0018	PANOCELL-10 DELIVER: 1 EVERY 4 WEEKS	13	EA	\$169.40	3032
0019	pHix BUFFER DELIVERY: 1 EVERY 4 WEEKS	13	BX	\$85.00	5070

0020	STIRBALLS DELIVERY: 1 EVERY 8 WEEKS	7	EA	\$12.08	6226
0021	ANTI-A (SERIES 1)-8 LAB WILL CALL WHEN NEEDED	18	EA	\$315.81	6400
0022	ANTI-B (SERIES 3) LAB WILL CALL WHEN NEEDED	15	EA	\$315.81	6406
0023	ANTI-D (SERIES 4) LAB WILL CALL WHEN NEEDED	15	EA	\$326.70	6412
0024	ANTI-D (SERIES 5) LAB WILL CALL WHEN NEEDED	15	EA	\$326.70	6414
0025	MONOCLONAL CONTROL LAB WILL CALL WHEN NEEDED	15	EA	\$158.00	66089
0026	SELF CHECK II, 3 X 5ml PER EACH DELIVERY: 2 EVERY MONTH	26	EA	\$272.25	56169
0027	REAGENT, SEROLOGY, ANTIBODY POTENTATING, 10 ML, GAMMA LO-ION, LOW IONIC STRENGTH ADDITIVE, 10 TEST/KIT LAB WILL CALL WHEN NEEDED	8	BX	\$76.23	0705410
0028	REAGENT, BLOOD BANK, ANTIBODY ENHANCEMENT, GAMMA PEG, 10 ML X 10 BOTTLES LAB WILL CALL WHEN NEEDED	8	PG	\$108.90	705010
0029	ANTI-HUMAN-SRUM-IgG-GREEN-10 x 10 ml LAB WILL CALL WHEN NEEDED	12	PG	\$163.35	0409210
0030	REAGENT, BLOOD BANK, ANTI-IGG/C3D, 10 ML, CLONE GAMMA003/GAMMA004/16HB, GREEN LAB WILL CALL WHEN NEEDED	2	PG	\$231.00	0409710
0031	REAGENT, BLOOD BANK, ANTI-HUMAN GLOBULIN TESTING, ANTI-C3B/C3D, 5 ML SOLUTION LAB WILL CALL WHEN NEEDED	5	EA	\$120.00	0004068
0032	RISE DELIVERY: 1 EVERY 4 MONTHS	4	EA	\$158.51	7999
0033	ANTI KELL LAB WILL CALL WHEN NEEDED	20	EA	\$94.38	66451
0034	ANTI M LAB WILL CALL WHEN NEEDED	5	EA	\$217.80	4802
0035	ANTI N LAB WILL CALL WHEN NEEDED	3	EA	\$228.69	4807
0036	ANTI C LAB WILL CALL WHEN NEEDED	20	EA	\$94.38	66421
0037	ANTI E LAB WILL CALL WHEN NEEDED	20	EA	\$94.38	66422

0038	ANTI <i>c</i> LAB WILL CALL WHEN NEEDED	20	EA	\$94.38	66425
0039	ANTI <i>e</i> LAB WILL CALL WHEN NEEDED	20	EA	\$173.36	66424
0040	ANTI <i>Fyb</i> LAB WILL CALL WHEN NEEDED	5	EA	\$410.00	7594
0041	ANTI <i>k</i> LAB WILL CALL WHEN NEEDED	3	EA	\$248.05	7537
0042	ANTI <i>Kpa</i> LAB WILL CALL WHEN NEEDED	2	EA	\$136.73	7540
0043	ANTI <i>Lea</i> LAB WILL CALL WHEN NEEDED	8	EA	\$525.00	4861
0044	ANTI <i>Leb</i> LAB WILL CALL WHEN NEEDED	4	EA	\$525.00	4864
0045	ANTI <i>P</i> LAB WILL CALL WHEN NEEDED	2	EA	\$600.00	4501
0046	GAMMA ELU-KIT LAB WILL CALL WHEN NEEDED	6	KT	\$145.20	7861
0047	SPECIMEN DILUENT LAB WILL CALL WHEN NEEDED	4	EA	\$134.00	60052
0048	ANTI <i>FYA</i> LAB WILL CALL WHEN NEEDED	10	EA	\$239.58	0004816
0049	ANTI <i>JKa</i> LAB WILL CALL WHEN NEEDED	10	EA	\$445.00	0004812
0050	ANTI <i>JKb</i> LAB WILL CALL WHEN NEEDED	10	EA	\$480.00	0004813
0051	ANTI <i>S</i> LAB WILL CALL WHEN NEEDED	3	EA	\$700.00	0004814
0052	ANTI <i>s</i> LAB WILL CALL WHEN NEEDED	3	EA	\$300.00	0004815