STATEMENT OF WORK

VA Sierra Nevada Health Care System (VASNHCS) - Reno

A. Contract Requirements

1. Contractor shall provide blood, blood components, and services described in Schedule B to the VACCHCS-Fresno (2615 E. Clinton Ave, Fresno, CA 93703).

2. Blood shall be typed for ABO and Rh antigens in accordance with methods recommended in the current edition of Standards for Blood Banks and Transfusion Services and the Technical Manual of the American Association of Blood Banks (AABB). Contractor shall provide services and products in accordance with the regulations and requirements of the Food and Drug Administration (FDA), the laws and regulations of the State of California and the Standards of the American Association of Blood bank. A sample of blood from each donation shall be tested for syphilis. Whole blood and/or components (non-autologous) shall not be used for transfusion unless the test is non-reactive. In addition, only blood testing negative for antibody to human immunodeficiency virus (HIV), for hepatitis B surface antigen (HBsAg), for anti-hepatitis B core antigen (Anti-HBc), for hepatitis C virus (anti-HCV), and for human T cell leukemia virus (anti-HTLV) shall be used for transfusion. Blood and components shall not be used for transfusion if the results are outside established limits. Testing must also include the following:

    a. Nucleic Acid Test (NAT) for HIV and HCV RNA
    b. ALT and HIV P24 optional

3. All blood shall be collected in a closed system under aseptic conditions, processed in appropriate solutions and the container so labeled. The label shall indicate the expiration date of the contents from the date of collection of the source blood. Source blood collected and stored with anticoagulant of CPD has a shelf life of 21 days, CPDA-1 35 days and ADSOL 42 days. This is with in guidelines of blood container manufactures, Food and Drug Administration (FDA) and AABB regulations.

4. All blood supplied shall be visually free of hemolysis, excessive chyle and clots.

B. Availability of Products

1. Contractor shall be responsible for ensuring the delivery of blood and blood products are delivered within the time frame specified.

2. In the event the Contractor is unable to meet the product demand, and to ensure patient care is not jeopardized, VA reserves the right to go to a secondary supplier. In such cases, the Contractor shall be responsible for payment on any difference in price.

C. Contractor's Qualifications

1. Offers shall be considered only from offerors whose blood bank is currently registered and/or licensed with the Food and Drug Administration (FDA), Department of Health and Human Services pursuant to Section 510 of the Federal Food, Drug and Cosmetic Act, as amended, 21 USC Section 260.

2. Prior to award the offeror shall submit proof that he holds an unrevoked U.S. License that is issued by the Director, Bureau of Biologics, FDA under Section 351 of the Public Health Service Act, as amended, 42 USC Section 262, as a source of supply for whole blood.

3. If interstate shipment of blood or blood component is involved, the offeror shall submit with the bid a statement that such approval has been authorized under Public Health Service Act 351, as amended, 42 USC Section 262.

4. Current CLIA and AABB Certification, and State of Nevada License are required.

D. Certifications

1. The offeror certifies that he/she shall comply with the requirements outlined below with respect to donors, containers, delivery, etc.

2. Offeror shall be from a blood bank that is able to provide VA with 100% "volunteer donor" blood in accordance with FDA rules and regulations effective May 15, 1978 or later revision. Definition of a "volunteer donor"-- A volunteer donor is a person who does not receive monetary payment for blood donation. Benefits, such as monetary times off from work, membership in blood assurance programs and cancellations on non-replacement fees that are not readily convertible to cash, do not constitute monetary payment.

E. Donor Requirements

1. The offeror shall maintain readily available blood donor lists including names, addresses and Social Security number. Such lists shall indicate whether, and on what date, blood of a particular donor was furnished to Veterans Affairs under this contract.

2. Donor selection shall be in accordance with criteria established by the FDA and/or the AABB.

3. Immediately after bleeding, the blood shall be stored in accordance with criteria established by the Food and Drug Administration (FDA) and/or American Association of Blood Banks (AABB).

F. Expiration Dates

1. Blood and blood components supplied by the contractor shall not exceed the expiration dates specified in the AABB Standards.

2. Red blood cell products shall be supplied as fresh as possible, preferably not over 15 days old.

3. Whole blood shall be supplied as fresh as possible, not to exceed 14 days old. If units are supplied greater than 14 days old, they may be returned for full credit.

G. Blood Products

1. Blood shall be furnished labeled as to A, B, O and Rh type. Type A Rh negative and O. Rh negative must have been drawn from donor not more than five (5) day before date on which purchase order is filled. Types such as AB Rh positive, B. Rh negative and AB Rh negative will be supplied as fresh as possible but not over fifteen (15) days old. These time limits may be adjusted if a system for exchange on credit is provided which minimizes or precludes losses due to outdating.

2. Whole blood, red blood cells and components shall be supplied in standard collection containers, with appropriate samples for laboratory work.

3. The following tests shall be completed by Contractor prior to delivery:

    a. ABO Grouping
    b. RHo(D) -- Testing
    c. Syphilis --- Testing
    d. Irregular Red Blood Cell Antibody Detection
    e. Hepatitis B Surface Antigen (HBsAg)
    f. HCV Antibody
    g. HIV Antigen and Antibody
    h. Hepatitis B Core Antibody
    i. HTLV Antibody
    j. Nucleic Acid Test for HCV and HIV RNA
    k. Other tests as may be included for licensure by the Office of Biologics/Food and Drug Administration.

4. Other than in the case of emergency, the above work shall be completed on all blood and its components prior to shipment. In such emergencies, products may be released with a “statement of justifications for request of incompletely tested blood components."

H. Special Donations

1. Contractor shall not require pre-payment of blood processing & handling surcharges from

autologous or designated blood donors for VA.

2. Autologous or designated blood donors for VA patients shall be directed to a facility as decided by VA and the blood center.

3. In the event a facility for autologous or designated blood donors for VA patient is not feasible for the donor, a community blood center may be used.

4. Shipping fees of blood components shall be incurred by the blood center. These units shall be shipped to VA when received.

I. Hospital Notification

1. If it is determined by the Contractor that a blood component potentially infectious with HIV, HCV, or HTLV I/II may have been provided to Veterans Administration Health Care Systems, contractor shall notify the VA. This notification process will comply with the requirements as defined by the U.S. Food and Drug Administration. Where required or allowed by law, notification to the VA Health Care Systems may be provided through a State Department of Health or similar governmental agency.

J. Description of the required services

a. Screening for negative blood per antigen - Testing donor units for RBC antigens and select units negative for a given antigen.

b. Irradiate units - Treat units with gamma irradiation to prevent lymphocyte proliferation.

c. Screening for CMV negative blood - Testing units for antibody to cytomegalovirus and select negative units.

d. Freezing and storing autologous - Freeze blood donated by the patient for his or her own use and store it until needed.

e. Thawing and deglycerolizing autologous blood - Thaw and wash frozen blood.

f. Plateletpheresis, crossmatched - Compatibility test between recipient serum and donor platelets.

g. Crossmatched Platelet Donor Recruitment - Recruit a donor known from previous testing to be compatible with a recipient.

h. Antibody Identification, enzyme panel, select cell panel, absorption/elution with panel, inhibition panel, chloroquine treatment, extended phenotype and phenotyping, genotyping whole blood or red cell Maa - Samples to identify antibodies when detected by antibodies screening.

K. Delivery

1. The Contractor shall furnish blood and blood components to VISN 21 VASNHCS Pathology and Laboratory Medicine Service Blood Bank located at VA Sierra Nevada Health Care System, 975 Kirman Avenue, Building 1, room C2309, Reno, NV 89502. Access is limited to the Emergency Department entrance from 8:00 pm to 6:00 am Monday through Friday, weekends, and Holidays.

2. Delivery Instructions: Delivery orders will be placed by phone/contractors web site (if available). Routine requests for stock supplies delivery and patient sample testing pick up shall be twenty-four hours per days, seven days per week. Urgent product orders and urgent testing requests will be clearly communicated to the Contractor.

L. Reference Laboratory Testing

1. The following patient or donor specialty testing is required including acceptable test turn-around times (TAT). If testing cannot be completed within the proscribed times the Contractor must notify the VASNHCS Clinical Laboratory Blood Bank, 775-784-3954 with the anticipated result availability time frame to allow for alternative patient testing.

Red cell testing (TAT)

a. ABO discrepancy (Routine=1 day, STAT=8 hours)
b. Antibody ID (Routine=1 day, STAT=8 hours)
c. Cold Agglutinin screen and titer (Routine=1 day, STAT=8 hours)
d. DAT (Routine=1 day, STAT=8 hours)
e. D(rH) discreptancy resolution (Routine=1 day, STAT=8 hours; longer if complicated)
f. Donath-Lansteiner testing (Routine=1-4 days)
g. Elution (Routine=1 day, STAT=8 hours)
h. Extended phenotyping (serological) (Routine=7-10 days, STAT=8 hours)
i. Red cell genotyping – rHD (Routine=7-10 days)
j. Thermal amplitude (Routine=1 day, STAT=8 hours)
k. Transfusion reaction investigation (Routine=1 day, STAT=8 hours)
l. Molecular testing (Routine=7-10 days)

Platelet testing (TAT)

a. Platelet antibody screen (Routine=1-4 days)
b. Platelet crossmatch: CMV negative, Irradiated (Routine=1-2 days, ASAP=1 days, STAT=8 hours)
c. Platelet refractory panel: Platelet crossmatch; platelet antibody screen; HLA A,B (IR); HLA matched donor search (Routine=2-3 days, STAT=1 day)
d. HLA class I antibody screen/ID, if positive (Routine=7-10 days)
e. HLA A,B (IR) typing (Routine=2-3 days, STAT=1 day)
f. Platelet genotyping (Routine=7-10 days)
g. HLA match/compatibility donor search (Routine=2-3 days, STAT=1 day)

M. Invoice Payment

1. All payments made under this contract will be made bi-monthly in arrears. No advance payments will be authorized. Invoices may include additional charges for extra services provided by the Contractor if notification and schedule of fees are provided to the VA.

2. The following address should be used in submitting your invoices:

   VA Sierra Nevada Health Care System
   P&LMS 113
   975 Kirman Avenue
   Reno, NV 89502

N. Modification

1. Any modification to the contract shall be in writing. The modification will be prepared by VA Contracting Officer prior to becoming effective.

O. Designation of Contracting Officer's Technical Representative (COR)

1. A Technical Representative of the Contracting Officer (COR) will be designated to represent the Contracting Officer in furnishing technical guidance and advice under this contract. The foregoing is not to be construed as authorization to interpret or furnish advice and information to Contractor relative to the financial or legal aspects of the contract. Those matters are the responsibility of the Contracting Officer and shall not be delegated.

P. SECURITY

1. Antigen and HLA testing do involve Patient Identification Information (PII). The vendor is responsible to meet HIPPA and ensure PII remains confidential and secure. Testing results will be securely delivered via US Postal Service or faxed to the secure Clinical Laboratory fax.

2. A prohibition on unauthorized disclosure: "Information made available to the contractor or subcontractor by VA for the performance or administration of this contract or information developed by the contractor in performance or administration of the contract shall be used only for those purposes and shall not be used in any other way without the prior written agreement of the VA." See VA Handbook 6500.6, Appendix C, paragraph 3.a.

3. A requirement for data breach notification: Upon discovery of any known or suspected security/privacy incidents, or any unauthorized disclosure of sensitive information, including that contained in system(s) to which the contractor/subcontractor has access, the contractor/subcontractor shall immediately

and simultaneously notify the COIR, the designated ISO, and Privacy Officer for the contract. The term 'security incident' means an event that has, or could have, resulted in unauthorized access to, loss or damage to VA assets, or sensitive information, or an action that breaches VA security procedures. See VA Handbook 6500.6, Appendix C, paragraph 6.a.

4. A requirement to pay liquidated damages in the event of a data breach: "In the event of a data breach or privacy incident involving any SPI the contractor processes or maintains under this contract, the contractor shall be liable to VA for liquidated damages for a specified amount per affected individual to cover the cost of providing credit protection services to those individuals." See VA Handbook 6500.6, Appendix C, paragraph 7.a., 7.d,

5. A requirement for annual security/privacy awareness training:' Before being granted access to VA information or information systems, all contractor employees and subcontractor employees requiring such access shall complete on an annual basis either: (i) the VA security/privacy awareness training (contains VA's security/privacy requirements) within 1 week of the initiation of the contract, or (H) security awareness training provided or arranged by the contractor that conforms to VA's security/privacy requirements as delineated in the hard copy of the VA security awareness training provided to the contractor. If the contractor provides their own training that conforms to VA's requirements, they will provide the COTR or CO, a yearly report (due annually on the date of the contract initiation) stating that all applicable employees involved in VA's contract have received their annual security/privacy training that meets VA's requirements and the total number of employees trained. See VA Handbook 6500.6, Appendix C, paragraph 9.

Q. Blood, Blood Components and Services

1. Please reference Attachment 1 – Price-Cost Schedule for Estimated Usage