

**DESCRIPTIONS/SPECIFICATIONS/WORK STATEMENT**  
**VA Palo Alto Health Care System (VAPAHCS)**

**A.1 Contract Requirements**

A.1.1 Contractor shall provide blood, blood components, and services described in Schedule B to the VA Palo Alto Health Care System Palo Alto and Livermore divisions.

A.1.2 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) (**available from the AABB website: <http://www.aabb.org/content>**). 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, West Nile Virus
- b. ALT and HIV P24 optional

A.1.3 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.

A.1.4 All blood supplied shall be visually free of hemolysis, excessive chyle and clots.

**A.2 Certifications**

A.2.1 The contractor shall supply 100% “volunteer donor” blood in accordance with FDA rules and regulations effective May 15, 1978 or latest 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.

### **A.3 Donor Requirements**

A.3.1 The contractor 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 the VA .

A.3.2 Donor selection shall be in accordance with criteria established by the FDA and/or the AABB.

A.3.3 Immediately after collection, 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).

### **A.4 Expiration Dates**

A.4.1 The contractor shall supply blood and blood components in accordance with the expiration dates specified in the AABB Standards.

A.4.2 The contractor shall supply Red blood cell products not over 15 days from the date of collection.

A.4.3 The contractor shall return for full credit any Red blood cell products that exceed 15 days from the date of collection.

### **A.5 Blood Products**

A.5.1 The contractor shall furnish blood labeled as 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) days before date on which purchase order is filled. Types such as AB Rh positive, B. Rh negative and AB Rh negative will be supplied 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.

A.5.2 The contractor shall supply whole blood, red blood cells and components in standard collection containers, with appropriate samples for laboratory work.

A.5.3 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.

A.5.4 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, signed by the veteran’s physician.

## **A.6 Special Donations**

A.6.1 Contractor shall not require pre-payment of blood processing & handling surcharges from autologous or designated blood donors for VA.

A.6.2 The contractor shall direct autologous or designated blood donors for VA patients to a facility as decided by VA and the blood center after coordination with COR.

A.6.3 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.

A.6.4 Shipping fees of blood components shall be incurred by the blood center. The contractor shall ship blood components at no additional expense to the VA. These units shall be shipped to VA when received.

## **A.7 Hospital Notification**

A.7.1 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 Dept. of Veterans Affairs 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.

## **A.8 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 mass - Samples to identify antibodies when detected by antibodies screening.

### **Delivery of Orders**

#### **VA Palo Alto Health Care System (VAPAHCS)**

Supplies and services to be delivered to the specified VA Palo Alto Health Care System site:

Blood Bank, Building 100, 4<sup>th</sup> Floor, Room F4-140  
 Pathology & Laboratory Medicine Service  
 VA Palo Alto 3801 Miranda Ave.  
 Palo Alto, CA 94304

Laboratory, Building 62, 2<sup>nd</sup> Floor Room 220  
 Pathology & Laboratory Medicine  
 VAPAHCS-Livermore Division  
 4951 Arroyo Road  
 Livermore, CA 94550

Delivery orders may be placed by phone, fax, or online. The type of delivery order will be specified when the order is placed and the Contractor shall deliver within the following times. The time begins when the authorized official places the delivery order.

STAT/Emergency-----	One (1) hour
ASAP-----	Two (2) hours
Stock-Palo Alto-----	Six (6) hours with two (2) deliveries per day
Stock-Livermore-----	Non-applicable, pre-scheduled

### **Distance and Impediments for deliveries during disasters or traffic congestion**

Due to this important nature of STAT or emergency delivery requests for blood and blood products at the Palo Alto Division, the courier cannot be required to cross a bridge, such as the Bay Bridge, Golden Gate Bridge, or the San Mateo Bridge (disaster preparedness and past experience). The Palo Alto Division of VAPAHCS provides a high level of ER services, large number of cardiac surgeries, supports Hematology/Oncology/Transplant patients and has a need

for expedient emergency delivery.

The Livermore Division of VAPAHCS provides pre-scheduled transfusion services on specific days for Hematology Clinic patients, so distance is not critical. There is no ER or surgeries performed at Livermore Division.

Both divisions must receive blood units from the same supplier.

### **Frequency of Deliveries**

Palo Alto requires two (2) stock deliveries per weekday and one (1) stock delivery each Sunday. The first stock delivery is made before Noon, the second stock delivery between before 6:00 pm.

Livermore transfusions are infrequent and pre-scheduled. Orders will be placed for a routine stock delivery by a specific date.

### **Transportation Charges for STAT Orders:**

STAT and special delivery charges will be from point of origin, which is the Blood Centers to the requesting VA. Routine delivery charges will not be incurred as a separate charge.

**Return of Blood:** The Blood Center will accept the return of units under the following conditions:

- a. Proper temperature requirements have been maintained
- b. The integrity of the unit container has been maintained and the label has not been defaced
- c. At least two cross-match segments remain, unless the blood center laboratory has approved use of the last cross match segment

### **Reference Services**

- a. STAT reference specimens shall be picked up and delivered within two (2) hours from the time the order was placed
- b. STAT reference lab specimens shall have a progress report by the end of a work shift eight (8) hours from the time specimen arrives.
- c. All results are to be initially reported to VA by telephone and a preliminary test report by fax. The final test report will be sent within five (5) working days after the preliminary report.
- d. HLA and transplant reference specimens will be sent via the VA courier service on a routine route basis. Results will be sent back to the VA Palo Alto Blood Bank via fax or mail when testing is completed.
- e. Specimens sent to another laboratory for additional or specialty testing will be pre-approved by VAPAHCS Contact Officer's Representative and the VA Supervisor, Transfusion Services. Charges will be included on the Contractor's monthly invoice after testing is complete.

## **SCHEDULE B – BLOOD, BLOOD COMPONENTS AND SERVICES**

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

## **SCHEDULE C – INFORMATION SECURITY**