

STATEMENT OF WORK

VA Central California Health Care System (VACCHCS) - Fresno

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) **(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
 - 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. Certifications

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.

C. Donor Requirements

1. The contractor shall maintain readily available blood donor lists including names, addresses and a unique identifier for each donor that is not linked to their social security number. Such lists shall indicate whether, and on what date, blood of a particular donor was furnished to the VA.
2. Donor selection shall be in accordance with criteria established by the FDA and/or the AABB.
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).

D. Expiration Dates

1. The contractor shall supply blood and blood components in accordance with the expiration dates specified in the AABB Standards.
2. The contractor shall supply Red blood cell products not over 15 days from the date of collection.
3. The contractor shall return for full credit any Red blood cell products that exceed 15 days from the date of collection.

E. Blood Products

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.
2. The contractor shall supply whole blood, red blood cells and components 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, signed by the veteran’s physician.

F. Special Donations

1. Contractor shall not require pre-payment of blood processing & handling surcharges from autologous or designated blood donors for VA.
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.
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. The contractor shall ship blood components at no additional expense to the VA. These units shall be shipped to VA when received.

G. 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 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.

H. Description of the required services

1. Screening for negative blood per antigen - Testing donor units for RBC antigens and select units negative for a given antigen.
2. Irradiate units - Treat units with gamma irradiation to prevent lymphocyte proliferation.
3. Screening for CMV negative blood - Testing units for antibody to cytomegalovirus and select negative units.

4. Freezing and storing autologous - Freeze blood donated by the patient for his or her own use and store it until needed.
5. Thawing and deglycerolizing autologous blood - Thaw and wash frozen blood.
6. Plateletpheresis, crossmatched - Compatibility test between recipient serum and donor platelets.
7. Crossmatched Platelet Donor Recruitment - Recruit a donor known from previous testing to be compatible with a recipient.
8. 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.

I. Delivery of Orders

Supplies and services to be delivered at VA Medical Center, Building 1, Second Floor, Room W215, 2615 E. Clinton Ave, Fresno, CA 93703. 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-----Four (4) hours

J. Distance and Impediments for deliveries during disasters or traffic congestion

Due to the important nature of STAT or emergency delivery requests for blood and blood products, the distribution center must be located within a reasonable distance to provide the orders within the specified time frames listed in Section I. Factors considered for a reasonable distance include, but are not limited to route and normal traffic patterns.

SCHEDULE B – BLOOD, BLOOD COMPONENTS AND SERVICES

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

SCHEDULE C – INFORMATION SECURITY