

PERFORMANCE WORK STATEMENT

BLOOD TESTING SERVICES & PRODUCTS

BLOOD SOURCE FY 09

(10536 Peter A McCuen Blvd Mather, CA 95655-4128)

- 1.1 **SCOPE OF WORK.** The Contractor shall provide blood testing services and products as required for Government beneficiaries at Travis Air Force Base (AFB), hereafter referred to as David Grant USAF Medical Blood Bank Services for a period of one year. The Contractor shall arrange transportation of blood and/or components and services (special testing for blood products as required) that have been tested as required by the Food and Drug Administration (FDA), as well as tests currently performed under Investigational New Drug (IND) protocols as mandated by the Air Force Blood Program Office. Performance shall be according to this statement of work (SOW), professional standards of the American Association of Blood Banks (AABB), and FDA guidelines and regulations (CFR Title 21 Parts 600-799).
- 1.2 **POINT OF CONTACT.** All information regarding testing will be coordinated with the Chief of the David Grant USAF Medical Blood Bank Services element.
- 1.3 **AVAILABILITY.** Products or services shall be available for acquisition 24 hours a day, 365 days a year.
 - 1.3.1 **HOURS OF PERFORMANCE.** Products or services shall be delivered within 1 hour for STAT request and within 24 to 48 hours for routine request.
 - 1.3.2 **GOVERNMENT PROVIDED DUTY SCHEDULES:** The processing schedule for the contract period will be Monday through Sunday to include federal holidays described below. Schedule is subject to change with prior notification.
 - 1.3.3 **FEDERAL HOLIDAYS.** The Contractor is required to provide routine services on the following federal holidays or observed holidays: New Year's Day, Martin Luther King Jr's Birthday, Presidents Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day.
- 1.4 **CONTINUITY OF SERVICES.** Failure to provide service may subject the contractor to reimbursement of any additional cost incurred by the government. In the event blood testing services cannot be performed, the Contractor must promptly notify the Blood Bank Element Chief. The David Grant USAF Medical Blood Bank Services retains the right to seek these services elsewhere should services not provided by the Contractor.

- 1.5 PERFORMANCE OF SERVICES DURING CRISIS DECLARED BY THE NATIONAL COMMAND AUTHORITY OR OVERSEAS COMBATANT COMMANDER.** David Grant USAF Medical Blood Bank Services is required to meet readiness requirements during war or peacetime crisis in accordance with DoDI 3020.37. The Contractor shall be required to provide additional blood testing services to the David Grant USAF Medical Blood Bank Services during war or peacetime crisis. Contractor shall be required to test up to 100 donor samples per day while continuing to meet all requirements as outlined in this performance work statement. The Contractor will be notified by phone when a crisis is declared.
- 1.6 ENGLISH LANGUAGE REQUIREMENT.** Reports or reference laboratory testing data shall be submitted in English.
- 1.7 BOARD CERTIFICATION.** The testing site shall meet or exceed all FDA current Good Manufacturing Practice guidelines and be in good standing with the FDA.
- 1.7.1 LICENSURE/REGISTRATION.** The Contractor shall be, and shall remain, licensed by the FDA and the state in which they are located (if required by state law) and shall be accredited by the AABB to operate as a blood center.
- 1.7.2 CREDENTIALS.** The Contractor is responsible for ensuring personnel performing testing possess required credentials commensurate with testing difficulty in compliance with the Clinical Laboratory Improvement Act of 1988 (CLIA).
- 1.8 MEDICAL QUALITY IMPROVEMENT/RISK MANAGEMENT (QARM).** The Government will evaluate the Contractor's professional, as differentiated from administrative, performance under this contract using the FDA Code of Federal Regulations (CFR) Parts 200-299, Current Good Manufacturing Practices.
- 1.9 RECORDS.** The Contractor shall create and maintain Government-owned / contractor-held records, regardless of media, in accordance with (IAW) AFI 33-119. Electronic Mail (E-Mail) Management and Use, paragraph 8; AFI 33-202, Computer Security, paragraphs 3.5.1 and 3.6.1; AFI 33-322, Records Management Program, paragraph 7, 8,9,10 and supplements; AFMAN 37-123, Management of Records. Chapter 2 – 6, paragraphs 7.10 – 7.29. Segregate the governing-owned records from the company-owned records. Background electronic data and records specified for delivery to the contracting agency must be accompanied by sufficient technical documentation to permit the Air Force to use the data. Upon completion of the contract, all government-owned / contractor-held records (regardless of media) received, created, maintained, or provided by the government and/or generated for the government in the performance of this statement of work shall be turned over to the government. In the event of default or non-performance, the government will have access to all records in order to ensure mission support is not interrupted.

1.10 **FOR OFFICIAL USE ONLY.** The contractor shall create and maintain FOUO material IAW DoD 5400-7, R, DoD Freedom of Information Act Program, Chapter 4, AFI 33-129, Transmission of Information via the Internet, paragraphs 7.4, 8.23, 16 and 17; and AFI 33-201, Communications Security (COMSEC), Table 1. Mark all documents meeting the requirements identified in DoD Regulation 5400.7/Air Force Supplement, paragraphs C3.2.1.2 thru C3.2.1.9 as "For Official Use Only" IAW instructions identified in paragraph C4.2.1. Safeguard all sensitive data IAW DoD Regulation 5400.7/Air Force Supplement, paragraph C4.4. When documents containing FOUO material are authorized for destruction, shred the records so that the pieces cannot be reconstructed. Degauss or overwrite magnetic tapes or other magnetic media.

1.10.1 **PATIENT LISTS.** Patient lists, no matter how developed, shall be treated as privileged information. Add the following to the bottom of all patient lists: "**FOR OFFICIAL USE ONLY.** This document contains information exempt from mandatory disclosure under the Freedom of Information Act (FOIA), Title 5 U.S.C 552(b) (2) High and (b) (6) apply." Lists and/or names of patients shall not be disclosed or revealed in any way for any use outside the MTF without prior written permission by the Chief of Hospital Services. (See Attached HIPPA document)

1.11 **PRIVACY ACT PROGRAM.** The contractor shall create and maintain Privacy Act data IAW AFI 33-129, Transmission of Information Via the Internet, paragraphs 7.4, 8.2.3, 16 and 17 and supplements; AFI 33-201, Communications Security (COMSEC), Table 1; AFI 33-332, Air Force Privacy Act Program, paragraphs 1.4.7, 1.4.8, 3:3.3, Chapter 7, Chapter 9, Chapter 10 and supplements and Privacy Act systems of records notice(s), which are posted on the internet at (<http://www.defenselink.mil/privacy/notices/usaf>). The contractor shall not create or maintain a Privacy Act system of records prior to public notice. If the contractor receives a Privacy Act request, the contractor shall be responsible for searching for the records and providing those records to the government official who, as authorized official, will make the decision on releasing government records.

1.11.1 **RELEASE OF MEDICAL INFORMATION.** The Contractor shall release medical information obtained during the course of this contract to MTF staff involved in the care and treatment of that individual patient only.

1.12 **DOD FREEDOM OF INFORMATION ACT (FOIA) PROGRAM.** If the contractor receives a FOIA request the contractor shall immediately hand-carry it to the base FOIA manager for processing. The FOIA manager will task a government official. When tasked, the Contractor shall be responsible for searching for the records and providing those records to a government official who, as the authorized official, will make the decision on releasing government records.

1.13 **FUNCTIONAL REQUESTS.** A written request for DoD records that does not cite either the FOIA or Privacy Act may be received from any person (including a member of the public), or organization, or a business. The contractor shall be responsible for searching for the records and providing those records to a government official who, as the authorized official, will make the decision on releasing government records.

2.1 DAVID GRANT USAF MEDICAL BLOOD BANK SERVICES' RESPONSIBILITIES.

2.1.1 The David Grant USAF Medical Blood Bank Services element will remain licensed, registered and/or accredited by the FDA, AABB and other regulatory agencies as required.

2.1.2 The David Grant USAF Medical Blood Bank Services element will purchase and validate shipping containers for use in transporting samples to the Contractor's facility for testing purposes.

2.1.3 The David Grant USAF Medical Blood Bank Services element will agree to follow approved Investigational New Drug (IND) protocols established by the Contractor for testing of blood donor samples.

2.1.4 The David Grant USAF Medical Blood Bank Services element agrees to collect and process samples for testing in accordance with Contractor established protocols.

3.1 **CONTRACTOR FURNISHED ITEMS AND SERVICES.** Except for those items or services specifically stated to be Government furnished, the Contractor shall furnish everything required to perform this contract in accordance with all of its terms.

4.1 **NATURAL DISASTER/CRISIS.** In the event of a natural disaster or crisis, Contractor shall be required to serve as an alternative testing site for allogeneic donor blood. Contractor agrees to provide those tests that are required by the FDA, AABB, and the Air Force Blood Program to include nucleic acid testing and test which may be under an IND protocol.

4.1.1 The Contractor shall perform procedures compatible with the Air Force Blood Program's FDA requirements. New medical procedures/services shall not be introduced without prior recommendation to, and approval of the medical facility's Commander or authorized representative. If the scope of the contract is changed by new medical procedures/services, the Contracting Office prior to implementation will incorporate the changes into the contract.

4.1.2 Procedures for donor specimen testing shall include but may not be limited to:

- a. HbsAg by EIA
 - b. Anti-HIV 1,2 by EIA
 - c. Anti-HTLV 1,2 by EIA
 - d. Anti-HCV third generation (3.0) by EIA
 - e. Anti-HBc (Core) by EIA
 - f. STS: Automated MHATP or FDA approved method for donor samples
 - g. Antibody Screen
 - h. ABO/Rh Typing
 - i. HIV 1 Antigen
 - j. CMV (when requested)
 - k. HIV and HCV by Nucleic Acid Testing (FDA approved NAT)
 - l. FDA approved confirmatory test for repeat reactive viral markers
- 4.1.3 The Contractor shall arrange for transportation of samples. The Contractor shall also arrange for return of shipping containers to the David Grant USAF Medical Blood Bank Services. If transportation of shipped samples for testing is by Air delivery, Contractor must have a mechanism in place to ensure testing is completed and delivered in accordance with the timeline listed in this PWS should air traffic be grounded due to crisis.
- 4.1.4 Confirmation tests performed on a routine schedule will be included as part of the services.
- 4.1.5 There shall be a mechanism, between specified or appropriate divisions or departments of the Contractor's testing center and the David Grant USAF Medical Blood Bank Services element, for transmission of results of all testing within 48 hours of receipt by the Contractor.
- 4.1.6 A list of all initial or repeat reactive units shall be faxed or electronically transmitted daily to the David Grant USAF Medical Blood Bank Services element by unit number and by test immediately after review and validation. Initially reactive units are repeat tested on the next testing day. Repeatedly reactive units will undergo confirmatory testing provided by the Contractor in accordance with this statement of works

- 4.1.7 The identification number used on samples must identify the David Grant USAF Medical Blood Bank Services and be different from the testing center's numbering sequence. The Contractor must be able to utilize the David Grant USAF Medical Blood Bank Services' numbering sequence. In addition, barcode labels will be used on each specimen tube. Donor information will not be provided to the blood center unless an individual is enrolled in Phase II of the IND study with a completed Informed Consent Document (ICD) in accordance with Collection Center's local IRB guidelines.
- 4.2 **AUTOLOGOUS (Self) DONATIONS.** The contractor shall provide testing services for Autologous (Self) donations. These donations can be performed at any of the contractor donation facilities and must be coordinated with the David Grant USAF Medical Blood Bank Services' element.
- 4.3 **REFERENCE LAB.** The Contractor shall serve as a Reference Lab with the ability to provide a wide range of reference lab services, including but not limited to:
- a. Serologic Work-ups.
 - b. Antigen Screens.
 - c. Compatibility Testing.
- 4.4 **SPECIFIC PRODUCTS FOR WHICH THE CONTRACTOR SHALL BE RESPONSIBLE.** Contractor shall provide blood products to include whole blood, packed red blood cells, platelets, fresh frozen plasma, and cryoprecipitate AHF. Contractor shall have the means to provide products that are irradiated, leukocyte reduced, pooled, washed, obtained by aphaeresis, antigen specific or a combination of the characteristics listed upon request by the David Grant USAF Medical Blood Bank Services element.
- 4.5 **FDA MANDATES/INDUSTRY STANDARD CHANGES.** In the event the FDA mandates, or industry standards require, additional testing or other processes relative to the collection and provision of blood products, necessitates and increase in test or processing cost, an equitable adjustment will be negotiated between the Contractor and the Contracting Officer prior to implementation.
- 4.6 **DOCUMENTATION.** Upon written request, and as required by Section 952 of U.S. Public Law 96-499 and the FDA CFR Parts 600-799, the Contractor shall make available to the Blood Bank Element Chief, the Food and Drug Administration, or any of their duly authorized representatives, any and all documents and records. This will occur if required by the cited law and regulations and provided that the request for access complies with the procedural requirements of those regulations.
- 4.7 **COMMUNICATION.** The Contractor shall ensure service providers under his/her supervision maintain open and professional communication with members of the MTF. Complaints validated by the Functional Commander shall be reported in writing to the contract administrator and the Contractor for action. Failure of the

Contractor to correct the validated complaints raised by the Functional Commander will be considered a failure to perform.

4.8 PERFORMANCE EVALUATION MEETINGS. The Contracting Office may require the Contractor of his representative to meet with the Contracting Office administrator or other government personnel as often as deemed necessary. The Contractor may request a meeting with the Contracting Office when he deems such necessary. Meetings will be documented in the contract file with written minutes signed by the contract manager and the Contracting Office, or contract administrator. Should the Contractor not concur with the minutes, such nonconcurrency shall be provided in writing to the Contracting Office within 10 (ten) calendar days of receipt of the minutes.

4.9 PRIVACY AND SECURITY OF PROTECTED HEALTH INFORMATION

(a) *Definitions.* As used in this clause:

Individual has the same meaning as the term "individual" in 45 CFR 164.501 and 164.103 and shall include a person who qualifies as a personal representative in accordance with 45 CFR 164.502(g).

Privacy Rule means the Standards for Privacy of Individually Identifiable Health Information at 45 CFR part 160 and part 164, subparts A and E.

Protected Health Information has the same meaning as the term "protected health information" in 45 CFR 164.501, limited to the information created or received by The Contractor from or on behalf of The Government. *Required by Law* has the same meaning as the term "required by law" in 45 CFR 164.501 and 164.103. *Secretary* means the Secretary of the Department of Health and Human Services or his/her designee. *Security Rule* means the Health Insurance Reform: Security Standards at 45 CFR part 160, 162 and part 164, subpart C. Terms used, but not otherwise defined, in this Agreement shall have the same meaning as those terms in 45 CFR 160.103, 164.501 and 164.304.

(b) The Contractor agrees to not use or further disclose Protected Health Information other than as permitted or required by the Contract or as Required by Law.

(c) The Contractor agrees to use appropriate safeguards to prevent use or disclosure of the Protected Health Information other than as provided for by this Contract.

(d) The Contractor agrees to use administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic protected health information that it creates, receives, maintains, or transmits in the execution of this Contract.

(e) The Contractor agrees to mitigate, to the extent practicable, any harmful effect that is known to the Contractor of a use or disclosure of Protected Health Information by the Contractor in violation of the requirements of this Contract.

(f) The Contractor agrees to report to the Government any security incident involving protected health information of which it becomes aware.

(g) The Contractor agrees to report to the Government any use or disclosure of the Protected Health Information not provided for by this Contract.

(h) The Contractor agrees to ensure that any agent, including a subcontractor, to whom it provides Protected Health Information received from, or created or received by the Contractor on behalf of the Government agrees to the same restrictions and conditions that apply through this Contract to the Contractor with respect to such information.

(i) The Contractor agrees to ensure that any agent, including a subcontractor, to whom it provides electronic Protected Health Information, agrees to implement reasonable and appropriate safeguards to protect it

(j) The Contractor agrees to provide access, at the request of the Government, and in the time and manner designated by the Government to Protected Health Information in a Designated Record Set, to the Government or, as directed by the Government, to an Individual in order to meet the requirements under 45 CFR 164.524.

(k) The Contractor agrees to make any amendment(s) to Protected Health Information in a Designated Record Set that the Government directs or agrees to pursuant to 45 CFR 164.526 at the request of the Government or an Individual, and in the time and manner designated by the Government.

(l) The Contractor agrees to make internal practices, books, and records relating to the use and disclosure of Protected Health Information received from, or created or received by the Contractor on behalf of, the Government, available to the Government, or at the request of the Government to the Secretary, in a time and manner designated by the Government or the Secretary, for purposes of the Secretary determining the Government's compliance with the Privacy Rule.

(m) The Contractor agrees to document such disclosures of Protected Health Information and information related to such disclosures as would be required for the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

(n) The Contractor agrees to provide to the Government or an Individual, in time and manner designated by the Government, information collected in accordance with this Clause of the Contract, to permit the Government to respond to a request by an Individual for an accounting of disclosures of Protected Health Information in accordance with 45 CFR 164.528.

General Use and Disclosure Provisions, Except as otherwise limited in this Agreement, the Contractor may use or disclose Protected Health Information on behalf of, or to provide services to, the Government for the following purposes, if such use or disclosure of Protected Health Information would not violate the Privacy Rule, the Security Rule or the Department of Defense Health Information Privacy Regulation if done by the Government: [List Purposes].

Specific Use and Disclosure Provisions.

(a) Except as otherwise limited in this Agreement, the Contractor may use Protected Health Information for the proper management and administration of the Contractor or to carry out the legal responsibilities of the Contractor.

(b) Except as otherwise limited in this Agreement, the Contractor may disclose Protected Health Information for the proper management and administration of the Contractor,

provided that disclosures are required by law, or the Contractor obtains reasonable assurances from the person to whom the information is disclosed that it will remain confidential and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person, and the person notifies the Contractor of any instances of which it is aware in which the confidentiality of the information has been breached.

(c) Except as otherwise limited in this Agreement, the Contractor may use Protected Health Information to provide Data Aggregation services to the Government as permitted by 45 CFR 164.504(e)(2)(i)(B).

(d) Contractor may use Protected Health Information to report violations of law to appropriate Federal and State authorities, consistent with 45 CFR 164.502(j)(1).

Obligations of the Government-Provisions for the Government to Inform the Contractor of Privacy Practices and Restrictions.

(a) Upon request the Government shall provide the Contractor with the notice of privacy practices that the Government produces in accordance with 45 CFR 164.520, as well as any changes to such notice.

(b) The Government shall provide the Contractor with any changes in, or revocation of, permission by Individual to use or disclose Protected Health Information, if such changes affect the Contractor's permitted or required uses and disclosures.

(c) The Government shall notify the Contractor of any restriction to the use or disclosure of Protected Health Information that the Government has agreed to in accordance with 45 CFR 164.522. Permissible Requests by the Government-The Government shall not request the Contractor to use or disclose Protected Health Information in any manner that would not be permissible under the Privacy Rule if done by the Government, except for providing Data Aggregation services to the Government and for management and administrative activities of the Contractor as otherwise permitted by this clause.

Termination

(a) Termination. A breach by the Contractor of this clause, may subject the Contractor to termination under any applicable default or termination provision of this Contract.

(b) Effect of Termination.

(1) If this contract has records management requirements, the records subject to the Clause should be handled in accordance with the records management requirements. Upon termination of this Contract, for any reason, the Contractor shall return or destroy all Protected Health Information received from the Government, or created or received by the Contractor on behalf of the Government. This provision shall apply to Protected Health Information that is in the possession of subcontractors or agents of the Contractor. The Contractor shall retain no copies of the Protected Health Information.

Miscellaneous

(a) Regulatory References. A reference in this Clause to a section in the Privacy Rule or Security Rule means the section as in effect or as amended, and for which compliance is required.

(b) Survival. The respective rights and obligations of Business Associate under the "Effect of Termination" provision of this Clause shall survive the termination of this Contract.

(c) Interpretation. Any ambiguity in this Clause shall be resolved in favor of a meaning that permits the Government to comply with the Privacy Rule or Security Rule.