

This is a pre-solicitation notice for laboratory testing. The anticipated release date will be in 30 days.

SCOPE: The Clinical Laboratory of the Contractor is to provide pick-up of specimens from the Veterans Affairs Loma Linda Healthcare System (VALLHS), 11201 Benton Street, Loma Linda, CA 92357 and transportation of those specimens back to the Contractor for the purpose of performing analytical laboratory testing services. The Contractor shall work with VALLHS in the performance and results communication of six, non-routine, time sensitive tests, needed by VA clinicians to make treatment decisions for acutely ill VA patients.

The contract award will be for one the base year with the Government's option to extend the contract for four (4) additional one-year option periods.

DESCRIPTION OF SERVICE: The Contractor's Clinical Laboratory shall provide the following services:

1. Provide VA Loma Linda Healthcare System with client numbers and pre-printed test requisition forms
2. Pick-up of specimens from VA Loma Linda Healthcare System
3. Transportation of specimens back to the Contractor's Clinical Laboratory
4. Pre-analytic processing
5. Analysis of result
6. Reporting of analytic results by fax
7. Mailing a hard copy test result to the VA Loma Linda Healthcare System
8. Consultation regarding selection, collection, transportation and result interpretation

DESCRIPTION OF TEST:

1. *Tacrolimus* & 2. *Cyclosporine* are immunosuppressant (anti-rejection) drugs that our nephrologists administer to our VA kidney and pancreas transplant patients to reduce their natural immunities to minimize, or avoid, rejection of the organ transplant. While these drugs are administered for therapeutic reasons, they can have potentially toxic side effects and reduce the body's ability to fight infections. Therefore, our VA patients have their blood drawn frequently to monitor the levels in their blood.

3. Procalcitonin results are needed within a short turn-around-time (less than 24 hours) for the treatment of critically ill patients with possible sepsis, in order to direct their antibiotic treatment length.

4. *Flow Cytometry* of fine needle aspiration specimens and core needle biopsy specimens - fine needle aspirations are performed to obtain a diagnosis of lymphoma without doing a large, unnecessary surgery. Needle core biopsies are obtained of deep specimens that are not easily accessible by surgery, and are used to guide whether the patient shall need a large surgery or only chemotherapy/radiation. FNA and core needle biopsy specimens are by nature overall paucicellular compared to large excisions. Transporting these relatively paucicellular specimens for extended amounts of time causes the viability of the specimen to be insufficient for analysis once the specimen arrives at a distant laboratory. Therefore a short transport time is required. The Flow Cytometry reference laboratory shall be open Monday through Friday from 8:00 AM to 5:00 PM. Contractor shall provide rapid submission-to-processing time AND turn-around-time for specimens that are relatively paucicellular including fine needle aspiration (FNA) specimens and biopsies that consist of a few core needle biopsies. The Flow Cytometry testing shall be performed within four (4) hours of submission to reference laboratory courier.

5. *HLA* testing is used to determine whether or not a transfusion recipient requires HLA-matched platelets. Because this testing is used to determine if a transfusion recipient requires HLA-matched platelets or not, an extended turn-around-time shall directly affect patient care when a patient needs a platelet transfusion. Patients who have developed certain HLA antibodies often shall have little to no benefit from random donor platelets and often need HLA-matched platelets for optimal survival of the donor platelets in their circulation. This patient population also tends to have chronic thrombocytopenia (low platelet counts) with a high risk for bleeding unless they receive prophylactic transfusions of platelets. For this reason we require all testing results be provided from a single phlebotomy within 48-72 hours from draw. In addition, Contractor shall offer HLA PRA testing as an initial screen with the ability to reflex to HLA DNA Typing without requiring submission of new samples and allow VALLHS staff direct communication with the Contractor's HLA Laboratory staff to assist with answers to questions and other technical assistance.

6. *Core needle biopsies of kidney specimens* (technical and professional components) - patients who require core needle biopsy of their kidneys in order to direct patient care are typically quite ill. Therefore, rapid turn-around-time for the preliminary light microscopic findings is required to guide patient care. An integrated final report, produced by a renal pathologist that discusses the results of light, immunofluorescence, and electron microscopy findings is required to ultimately guide long-term patient care. This report shall be provided to VALLHS within two (2) weeks of submission to the reference laboratory. The staff renal pathologist at the Contractor reference laboratory shall be available Monday through Friday from 8:00 AM to 5:00 PM to provide clinical consultation to VALLHS staff nephrologists regarding submitted cases.