Pathology

SUNY DOWNSTATE MEDICAL CENTER
UNIVERSITY HOSPITAL OF BROOKLYN
POLICY AND PROCEDURE

Subject: GUIDELINES FOR SELECTING A REFERENCE LABORATORY	**No:** LAB- 47
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PURPOSE:

POLICY:

1. University Hospital of Brooklyn, Clinical Laboratory Services supports the diagnosis and management of its patients by referring laboratory tests that are not performed at UHB to NYS qualified laboratories.

2. Reference Laboratories are reviewed and approved by the Medical Staff prior to providing service to UHB patients.

3. Bid proposals will be evaluated for clinical testing of samples referred by UHB for a Reference Laboratory in accordance with the New York State procurement guidelines.

RESPONSIBILITIES:

Medical Staff, Laboratory.

SELECTION PROCEDURE:

A. Clinical Tests and Fees:

1. Contractor will provide the most current schedule of fees for all tests indicated. In addition, contractor will provide the principle, method, level of sensitivity and specificity, reference ranges analytic test range, action value, patient preparation, specimen collection, specimen handling for all tests.

2. Contractor will be required to comply with all Federal, State and New York City regulations and will provide its proposal evidence of licensure by Medicare, Medicaid, and the New York State Department of Health, Documentation of Proficiency Survey is required. Accordingly, the contractor is required to provide accreditation by

3. Contractor must supply with its proposal information detailing site where tests are performed, including methods, laboratory directorship, accreditation, and other pertinent

information and, when the test in question is sent to a laboratory other than the contracting laboratory. This information must appear on the "result" document.

4. Contractor must provide a performance guarantee policy by which it will issue credits for performance standards not met.

B. Quality Control:

1. Contractor will provide the most recent copy of its production schedule detailing assay set-ups (days per week, shift) minimum and maximum assay times.

2. Contractor will supply its most current copy of the laboratory's quality control and proficiency testing compendium and agree to on-site inspection both announced and unannounced.

3. Contractor must be able to perform 90% of its tests within its laboratory network.

4. Laboratory must have a Ph.D. or an M.D. heading each department and must supply the names and telephone numbers where they can be contacted. These individuals must serve in full time capacity and be available for consultation.

5. Contractor must supply an interface with current CERNER LIS System used by the State University of New York-Downstate Medical Center.

6. Contractor must supply an emergency service, providing pick-up within three (3) hours of request and results within accepted state-of-the-art time frame.

7. Subcontract, when necessary and appropriate, to other reference laboratories for tests included in the reference lab test list. Contractor shall be responsible for delivering specimens to subcontracted laboratory testing facility and incorporating charges in regular billing process, i.e., the contractor shall bill SUNY-Downstate for the subcontracted costs. The laboratory must submit with its proposal copies of any subcontracts that are proposed to be used to carry out the performance of the required tests. Include with the proposal documentation required pursuant to paragraphs A (2 and 3) above for the subcontracted laboratory facility.

8. In order to ensure specimen quality tests must be performed at a reference laboratory facility with four hours travel time from SUNY-Downstate, for labile analytes.

9. Provide with the proposal documentation of training for drivers in the handling of biohazard materials.

10. Provide with the proposal copies of all applicable permits, certificates and licenses for transportation.

C. Specifications for Written Standard Operating Procedures:

The Laboratory shall include with its proposal written standard operating procedures (SOPs) for receipt of samples, maintenance of custody, sample identification, sample storage, sample tracking. Assembly of completed data and turn-around-time. An SOP is defined as a written narrative stepwise description of laboratory operating procedures including examples of laboratory documents. The SOPs shall accurately describe the actual procedures used in the Laboratory, and copies of the written SOPs shall be available to the appropriate laboratory personnel. These procedures are necessary to ensure that analytical data produced under the contract resulting from the RFP are acceptable for use in UHB medical treatment and potential litigation. The Laboratory's

SOPs shall provide mechanisms and documentation to meet each of the following specifications and shall be used by UHB as the basis for laboratory evidence audits.

1. The laboratory shall have written SOPs describing the sample custodian's duties and responsibilities.

2. To ensure that the laboratory samples are properly controlled and maintained, the contractor must submit, as part of its proposal, its SOPs for transportation of samples from the point of receipt at the specific SUNY Downstate office to the arrival of the sample at the vendor's testing site.

3. The Laboratory shall have written SOPs for receiving and logging in of the samples.

4. The Laboratory shall have written SOPs for maintaining identification of SUNY Downstate samples throughout the Laboratory.

   The Laboratory assigns unique laboratory identifiers, written SOPs shall include a description of the method used to assign the unique laboratory identifier and shall include a description of the document used to cross-reference the unique laboratory identifier to the SUNY Downstate sample number.

5. The Laboratory shall have written SOPs describing all storage areas for samples in the laboratory. The SOPs shall include a list of authorized personnel who have access or keys to secure storage areas.

6. The Laboratory shall have written SOPs describing the method by which the Laboratory maintains samples under custody.

7. The Laboratory shall have written SOPs describing the method by which the Laboratory maintains the security of any areas identified as secure.

8. The Laboratory shall have written SOPs for tracking the work performed on any particular samples. The tracking SOP shall include:

   - A description of the documents used to record sample receipt, sample storage, sample transfers, sample preparations, and sample analyses.
   - A description of the documents used to record calibration and AQ/QC laboratory work.
   - Example of document formats and laboratory documents used in the sample receipt, sample storage, sample transfer, and sample analyses.
   - A narrative step-wise description of how documents are used to track samples.

9. The Laboratory shall have written SOPs for organization and assembly of all documents relating to each sample. Documents shall be filed on a sample delivery group-specific basis. The procedures shall ensure that all documents including logbook pages, sample tracking records, chromatographic charts, computer printouts, raw data summaries, correspondence, and any other written documents having reference to the sample are compiled on one location for submission to SUNY Downstate. The written SOPs shall include:

   - A description of the numbering and inventory method.

- A description of the method used by the Laboratory, to verify the consistency and completeness of the sample analytical report.

D. Educational Programs:

Contractor must make available continuing education programs to personnel of SUNE Downstate. Contractor will be expected to supply, at the beginning of each calendar year, an annual curriculum of such programs or courses including the topics covered, the method of instruction, the instructors or lecturers addressing the topics covered and the length of the programs. As part of its proposal, Contractor must include a sample annual curriculum which it is prepared to offer.

E. Handling of Confidential Information:

A Laboratory conducting work under the contract resulting from an RFP will receive protected health information from UHB. Confidential information must be handled separately from other documentation developed under this contract. To accomplish this, the contractor must include with its proposal procedures it has adopted and implemented, including the following:

1. All confidential documents shall be under the supervision of a designated document control officer.