Introduction:

A clinical laboratory often requires the assistance of an outside facility or facilities to perform unique or unusual services, as a backup service, or for routine services that the referring (primary) laboratory does not perform. Choosing a referral laboratory requires thorough research.

Deciding which laboratory to use can be based on several factors (eg. References, cost, turnaround time, salesperson claims, proficiency, proximity, or “gut feelings”). Frequently it is only one of these criteria that is the deciding factor. While the cost of referral laboratory services may be an important consideration, the selection of a referral laboratory should be based primarily on the quality of services provided.

The director of the referring laboratory is responsible for selecting a referral laboratory and for its ongoing evaluation based on objective evidence of acceptable quality and responsiveness in consultation with the institutional medical staff or physician clients where appropriate.

Quality of Referral Laboratory Service:

Although the assessment of quality is difficult, an objective evaluation can be made using a systematic approach. The referral laboratory should expect, permit, and encourage an onsite evaluation of its facility. Onsite laboratory evaluation during peak operating hours is recommended and appropriate. Consider the following criteria in evaluating quality.

Facilities and Equipment:

1) Determine whether the equipment, supplies, and instrumentation are consistent with the scope and volume of testing being conducted.

2) During an onsite visit, examine the physical facility, general level of housekeeping, adherence to sound laboratory safety principles, and appearance, attitude, and general demeanor of the laboratory staff. Although the latter is a subjective determination, the decorum of the laboratory may significantly influence the quality of laboratory work.

Availability of Documents:

The referral laboratory should willingly demonstrate the quality of its service by supplying information in several categories of laboratory operation. If the referring laboratory desires to review any documents or manuals, this may be accomplished during the onsite visit of the referral laboratory.
Documents include:

- **Personnel:**
  
  Inspect the qualifications of the referral laboratory’s director, professional staff, and consultants. Information should include but not be limited to:
  
  1) Educational experience
  2) Licensure, when appropriate
  3) Certification
  4) Participating in continuing educational activities
  5) Significant areas of special expertise

- **Internal Quality Control:**
  
  Review records of internal quality control programs, including:
  
  1) Appropriateness and quality of test materials
  2) Frequency of insertion of appropriate quality control materials into test runs
  3) Tolerance limits
  4) Appropriate statistical records
  5) Procedure manuals and the related section of the Evaluation Checklist to determine whether the procedure manuals meet the guidelines of NCCLS document GP2 *Clinical Laboratory Procedure Manuals*.

  Also review test procedures in use.

- **External Quality Assessment Activities (EQAS):**
  
  1) The referral laboratory should provide the records of its participation in pertinent inter-laboratory proficiency testing programs.
  2) A documented program for review of proficiency test results and a record of any corrective action taken should be available.
  3) If requested, the laboratory should agree to split testing of specimens by the prospective referring laboratory.
  4) Information on participation in voluntary accreditation programs and certification of licensure, where appropriate, by various governmental/regulatory agencies should also be made available.
5) The referring laboratory must ascertain that the referral laboratory is certified / accredited / licensed where required and appropriate.

- **Instrument Maintenance:**
  1) Examine documents on routine instrument maintenance and repair records.
  2) Determine whether the instrumentation in use is appropriate for the scope and volume of testing being referred.

- **Client Satisfaction:**
  Although reputation may be a very subjective indicator of quality, valuable information may be gained from current clients. The referral laboratory should provide the names of clients as references. The referral laboratory should also be willing to describe its internal program to assess and assure client satisfaction.

- **Other Quality Assurance/Improvement Issues:**
  All laboratories should have a program to assess quality, identify opportunities for improvement, and implement improvements. The best laboratories actively involve all employees in quality planning and assurance activities. A review of quality assurance / improvement meetings may demonstrate the types of issues discussed and how resolution was achieved by the laboratory.

**Efficiency of Referral Laboratory Services:**

When evaluating acceptable efficiency of a referral laboratory, the scope of available testing, specimen collection procedures, test ordering, transportation, turnaround time, and reporting of results, including critical (imminently life threatening) values, should be considered. The acceptability of each of these elements will vary depending on the individual needs of the referring laboratory.

**Scope of Available Testing:**

The importance of the variety of tests offered by a referral laboratory will be greatly influenced by individual requirements. Some referring laboratories may need a specialty laboratory offering very limited procedures, while others will seek a facility with a full range of services. Before selecting a referral laboratory, clearly define specific needs. An acceptable referral laboratory may have to refer to another laboratory in order to provide complete referral needs. If the referral laboratory refers specimens to another laboratory, the laboratory(ies) should be identified, their qualifications should be made available, and their name should appear on the report form.
Specimen Collection and Test Ordering:

The referral laboratory should provide comprehensive instructions for properly preparing patients and collecting specimens, including:

1) Quantity of specimen required;

2) Special handling needs, including separate pediatric requirements if indicated;

3) Labeling;

4) Use of anticoagulants or preservatives;

5) Desired clinical information.

The actual procedure for test ordering should be clearly defined. The referral laboratory should have clearly defined criteria for unacceptable specimens and should document its adherence to its policy for rejecting specimens. Changes in specimen requirements should be communicated to referring laboratories in advance. In addition, the referral laboratory should define the mechanism whereby the client is notified of changes in normal reference ranges and must include these changes in current reports.

Transportation:

The method of transporting specimens from the referring to the referral laboratory should be clearly defined. If a courier service is used, establish satisfactory pick-up schedules. The mechanism of specimen transport must satisfy the requirements of the referring laboratory and ensure the integrity of patient specimens. Special requirements, such as for transportation of frozen specimens, should be addressed and clearly defined.

Turnaround Time:

Although the needs of an individual referring laboratory may vary, the expected interval from receipt of specimen to reporting of results should be published. Unanticipated delays in reporting results should be communicated to the referring laboratory. Current or former clients should be consulted to document the referral laboratory’s compliance with its stated policy. If limiting specific testing to certain days of the week will impact turnaround time, this information should be available to the referring laboratory.

Communications Systems:

Referral laboratories should use a standardized order entry or results reporting communication protocols / systems. Communication capabilities should be acceptable to meet the needs of the referring laboratory (eg. bi-directional interfaces, result printer, and referral laboratory computer connection).
Reporting of Results and Interpretations:

The importance of the method of reporting test results will depend on the needs of the prospective client laboratory.

**Note:** *Timely communication* is a significant issue in all relationships between the referring and the referral laboratories.

1) Automated data communication systems may be required by some clients while others may need less sophisticated reporting methods. Referral laboratory reports should indicate the name of the referring laboratory and the name and address of the laboratory where the tests were actually carried out, whether the reports are charted directly or recopied.

2) Reports, whether written, printed, electronic, or verbal, should include age and sex adjusted reference ranges and/or other therapeutic or diagnostic reference ranges, where possible.

3) Critically (imminently life threatening) values should be immediately communicated to the referring laboratory. Other unexpected or unusual results should be communicated in a timely fashion in the context of the clinical findings.

4) The referral laboratory should respond promptly to inquiries concerning test results.

5) The referral laboratory should also provide the client with expert consulting service if necessary.

6) The referral laboratory should also provide the client with its written policies for dealing with inappropriate / compromised specimens.

7) The referral laboratory must have a policy concerning corrected and amended reports.

8) The referral laboratory should have a written policy concerning direct reporting of results to patients which cites as appropriate, any local, state, or federal regulations which may be applicable. This policy should be provided to the referring laboratory.

**Summary:**

The needs of the laboratory seeking the services of a referral laboratory may vary widely. The primary referring laboratory should therefore clearly understand its own requirements before initiating the selection process. The referring laboratory should evaluate all areas where referral testing may be required. It may be necessary to select more than one referral laboratory to ensure acceptable testing in all required areas.
The referring laboratory must select a referral laboratory that meets the current standards of clinical laboratory practices. Useful selection criteria permit a systematic evaluation and are sufficiently flexible to satisfy the divergent needs of individual laboratories.

It should be noted that evaluation of a referral laboratory must be an ongoing process, and it is therefore suggested that the referring laboratory set up meetings at regular intervals with the referral laboratory to review all of the above.