

PRINCIPLE:

The Johns Hopkins Pathology Department utilizes the services of reference laboratories for laboratory testing that is not normally performed at a Johns Hopkins Medical Laboratory or for cases when back up services are needed during unusual situations. More than one reference laboratory may be utilized to ensure acceptable testing in all required areas. Laboratory accreditation standards require an effective mechanism for evaluating and selecting reference laboratories. A list of reference laboratories recommended by the laboratory director and approved by the Laboratory Advisory Committee is maintained in the Pathology Data System-Online Handbook and is accessible to all JHMI providers. Testing may not be referred to non-approved laboratories.

Selection and Ongoing Evaluation

A. Criteria For Selection

An approved reference laboratory meets the quality standards and the needs of the laboratory as well as clinical services.

1. Quality of Service

- a. For ALL referred testing, the Johns Hopkins Pathology Department must verify that the reference laboratory is CLIA-88 certified for high complexity testing in the applicable specialty/subspecialty. A copy of the current CLIA certificate is kept on file for each approved reference laboratory.
- b. ALL approved reference laboratories must have a current registration permit with the State of Maryland, including all laboratories from out of state.
- c. Other documents that may be requested to demonstrate quality of services include a copy of the current laboratory accreditation, personnel qualification records (i.e.; Laboratory Director CV), the reference laboratory's QA Plan and client references.
- d. The Johns Hopkins Pathology Department assesses the ongoing quality of approved reference laboratories by monitoring service concerns and documenting resolution of problems in performance improvement activities. An on site meeting with a reference laboratory representative may be scheduled to address and resolve issues.

2. Efficiency of Reference Laboratory Services

- a. Scope of testing - A reference laboratory is usually selected with a test menu that meets the needs of the referring laboratory. The primary reference laboratory used by Johns Hopkins Pathology is Quest Diagnostics, a laboratory with a full range of services. Occasionally, Quest Diagnostics may have to refer to another laboratory in order to complete referral needs when a unique or unusual test is requested. Quest is required to obtain quality documentation for those laboratories

to whom they may refer laboratory specimens. Quest documents the appropriate testing laboratory on their report form.

Johns Hopkins Pathology refers laboratory specimens to a few other approved reference laboratories, other than the primary reference laboratory (Quest Diagnostics), for special testing requirements not available through Quest. See Appendix A for a list of approved laboratories for referral of laboratory specimens.

- b. Specimen Collection/Transportation – An approved reference laboratory provides comprehensive instructions for properly preparing patients and collecting specimens. The method for transporting specimens is clearly defined and ensures the integrity of the laboratory specimens.
- c. Turnaround Time – An approved reference laboratory publishes their expected turnaround times from receipt of specimen to reporting of results. Turnaround times are evaluated when a reference laboratory is selected to ensure they meet clinical needs. Selected tests may be monitored periodically for turnaround time performance.
- d. Reports and Interpretations – Timely communication of results from the primary reference laboratory (Quest Diagnostics) is accomplished through a data interface between PDS and the reference lab's data system. The laboratory report includes the name and address of the laboratory where testing was performed, as well as age and sex adjusted reference ranges. Critical values are immediately communicated by the reference laboratory to Pathology.

3. Cost Effectiveness

Although selection of a reference laboratory is based primarily on the quality of services provided, the cost of services is considered during the evaluation and selection.

B. List of Approved Reference Laboratories

1. The Johns Hopkins Pathology Department maintains a list of all laboratories approved for specimen referral by the laboratory director. (See Appendix A). The approved list can also be found on the JHH Pathology website at: <http://pathology2.jhu.edu/department/index.cfm>

The approved list will be updated annually.

A copy of a current and valid CLIA certification for each approved reference laboratory is kept on file in the Customer Services Department.

2. Medical records from a non-approved reference laboratory - Patients admitted to Johns Hopkins Hospital may have had preadmission or presurgical laboratory testing performed by an outside laboratory. Outside laboratory data used for clinical decision making obtained from a laboratory not found on the List of Approved Reference Laboratories (Appendix A) cannot be used to treat patients at JHH unless the laboratory holds a valid CLIA license. If licensure is unknown, lab testing must be repeated by an approved laboratory before medical decisions

are made. Contact the Pathology CQI Office (ext 5-2658) if more information is needed.

C. Medical Staff Approval

1. Reference laboratory selection and ongoing assessment is discussed and documented at the Hospital's Laboratory Advisory Committee. The medical staff is involved in the selection and approval process.
2. Arrangements with referral laboratories will be reviewed annually at the Hospital's Laboratory Advisory Committee and whenever specific issues need to be addressed.

D. Performance Improvement

1. Johns Hopkins Pathology has a performance improvement program to assess quality, identify opportunities for improvement and implement improvements. The program includes ongoing monitoring of reference laboratory performance. Quality and service issues are documented and addressed with the reference laboratory representatives.
2. Selected reference laboratory tests may be reviewed periodically for turnaround times to ensure clinical needs are met.

E. Direct Marketing to Clinicians

1. Reference laboratory representatives from laboratories not on the approved list may try to directly market their laboratory services to clinicians. It is the policy of Johns Hopkins Medical Institutions that reference laboratory representatives register in Pathology with the Administrator for Clinical Affairs, or his designee, prior to contacting any staff within JHMI. See *Policy For Sales Representatives of In Vitro Diagnostic Tests and Devices* on the JHH Intranet site <http://www.insidehopkinsmedicine.org/icpm>.
2. All requests to add a new reference laboratory to the approved list must proceed through the same criteria for selection and approval process as cited in this policy.

F. Reference Laboratory Reports

1. The referring laboratory must retain the original or an exact copy of the reference laboratory's results for all samples referred. If referral results are not interfaced to the laboratory's information system, then a paper copy of reference lab results must be retained for 2 years.
2. The referring laboratory must report essential and required elements of test results as received by the reference laboratory. Exact wording of interpretive remarks or format of the reference laboratory report is not required, however any alterations that could affect clinical interpretation should not be used.

Laboratory Accreditation Review:

During the Laboratory Survey accreditation review, the surveyor will review the laboratory's processes for reference laboratory selection.

The survey will include the following review:

- The laboratory director recommends in writing reference laboratory services, including outside services that provide blood and blood products, to the clinical staff.
- The clinical staff is involved in selecting reference laboratory services, and the clinical staff's approval of those used by the laboratory is documented.
- The retention of the following documents for at least **two** years: CLIA certificates and accreditation documents for each approved reference laboratory
- Evidence that the laboratory has documented problems or potential problems with reference laboratory services and remedial action when indicated.

To facilitate this review, each laboratory should have its records organized and ready at the time of the survey.

References

CLIA Regulations: Department of Health and Human Services for Medicare and Medicaid Services. Clinical laboratory improvement amendments of 1988; final rule. *Fed Register*, 2003 (Jan 24):7163 (42CFR493.1242)

JCAHO. Comprehensive Accreditation Manual for Laboratory and Point of Care Testing 2004, LD.2.130

NCCLS, Selecting and evaluating a referral laboratory; approved guideline GP9-A, NCCLS, 940 West Valley Road, Suite, 1400, Wayne PA 19078, 2002

College of American Pathologists, Laboratory General Checklist March 31, 2004; GEN.41350.

Follas, D. The Do's and Don't's of Selecting a Reference Laboratory. *Advance for Laboratory Administrators* March 1999: 43-46.

Reviewd by Lab Director:

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