TESTING SENT TO REFERENCE LABORATORIES

It is the policy of Fairview Diagnostic Laboratories to refer specimens only to CLIA 88 licensed and accredited laboratories. Decisions concerning the selection of these reference laboratories are at the discretion of Fairview Diagnostic Laboratories. Decisions on outsourcing testing are at the discretion of Fairview laboratory managers and supervisors.

ANALYTE-SPECIFIC REAGENTS (ASR)

In accordance with the HHS policy, the following comment will print on the report for tests utilizing ASR's. "This test was developed and its performance characteristics determined by Fairview Diagnostic Laboratories. It has not been cleared by the U.S. Food and Drug Administration."

RESULT REPORTING:

Individual patient results include the patient's name, identification number, collection date and time. Final results are mailed to the referring institution. Reports are available by FAX; please contact the Customer Service to make arrangements 612-273-7838.

Critical Values: Patient results are generally reported with a reference range (normal or therapeutic value). Patient results that require immediate intervention are identified as critical and telephoned immediately to the referring institution. Refer to the table of critical values in the Appendix.

BILLING:

Fairview Diagnostic Laboratories will issue a monthly itemized invoice. Payment is due within 45 days of receipt of the invoice.

- **Billing Policy**: Fairview Diagnostic Laboratories will bill the referring institution, e.g. hospital, clinic or physician. Third party billing is generally not available without prior arrangement. All Third party billing is contingent on the provision of the necessary billing information at sample receipt. If a sample arrives without the necessary billing information the sender will be billed for the services.

- **Medicare/Medicaid**: Provide all necessary information to facilitate billing. Note: If the patient is covered by a HMO or PPO that is primary to Medicare/Medicaid, the referring institution must bill the carrier directly.

  As required by federal and state regulation, we will bill Medicare and Medicaid (if a provider for your state). All necessary billing information must be provided upon specimen receipt to include:

  1. Full legal name of the patient
  2. Primary payor information
  3. Secondary payer information if applicable
  4. Responsible party if different than patient
  5. Physician full name
  6. Physician UPIN number or NPI
  7. ICD-9 code or diagnostic narrative for each test
  8. Signed advanced beneficiary notice (ABN) if required (see Medical Necessity page 10)

  If the information provided is incomplete, the customer will be billed and held responsible for the charges.

- **Direct Patient**: Direct patient billing is generally not available.

- **Third Party Billing**: Third party billing is generally not available without prior arrangement.

Contact the Sales and Marketing at 612-273-7838 to discuss additional billing services needed.

CLINICAL RESEARCH STUDIES

Fairview Diagnostic Laboratories provide laboratory services to investigators involved in research. It is the responsibility of the principal investigator to obtain prior approval of specimen collection and testing and to obtain informed consent for the tests from the subject. Requests for laboratory processing or testing on research samples must be approved and a special research account number must be assigned before research specimens can be accepted by the clinical laboratories for analysis. Allow at least two weeks for the approval process.

The Research Project application form and policy are available from the Research Coordinator at 612-273-1977.