REGULATORY REQUIREMENT AND SPECIMEN LABELING

REGULATORY REQUIREMENTS

- Blood collections must be supported by a test order from the physician responsible for the patient. CMS Regulations require that ICD-9 diagnosis code for each patient visit justifies the medical necessity of the tests ordered. Therefore, screening panels are not available and tests should be ordered according to patient needs.

Only the following approved disease organ specific panels are available:

- Electrolytes: carbon dioxide, chloride, potassium, and sodium.
- Hepatic Function: albumin, alkaline phosphatase, ALT, AST, protein and bilirubin (total and direct).
- Basic Metabolic: calcium, carbon dioxide, chloride, creatinine, glucose, potassium, sodium, and urea nitrogen.
- Lipid: cholesterol, HDL cholesterol, LDL cholesterol, triglycerides.
- Comprehensive Metabolic: albumin, alkaline phosphatase, AST, ALT, bilirubin (total), calcium, chloride, creatinine, glucose, potassium, protein, sodium, carbon dioxide and urea nitrogen.

SPECIMEN LABELING

1. Assure correct identification of the patient by checking the patient's wristband for name and patient identification number prior to collection and labeling. For patient without armbands, ask the patient to state his/her name and date of birth.
2. The sample container (not the transport bag) must be labeled at the time of collection by the person obtaining the specimen.
3. For proper identification **two positive patient identifiers** must be on the label as mandated by Federal Patient Safety Guidelines and JCAHO.

   Labels must include the

   - patient's full legal name,
   - patient's date of birth or identification number,
   - date and time of collection.
4. Additionally, **Blood Bank** specimen labels also require the initials of the person collecting the specimen.
5. Cytology, Histology and Surgical Pathology samples, as mandated by patient safety guidelines, must be labeled on the specimen container not on the cover to the container.
6. Provide the following information on the request form: name of the patient, physician full name, Date of birth, medical record number, clinical history, diagnosis and any other pertinent information need to interpret the result.
7. If requesting insurance billing by Fairview Diagnostic Laboratories complete information must be provided at time of sample receipt.

COMPLETION OF REQUEST FORMS

1. Laboratory testing requires a completed request form.
2. The request form must include:
   - the patient's legal name,
   - identification number or SSN or date of birth,
   - collection date and time,
   - specimen type, body site (when applicable),
   - ICD-9 code or diagnostic narrative and
   - ordering physician's name and UPIN / NPI number.
3. Include information as requested on specific request forms, e.g. height/weight, time of last dose for drugs, clinical history/diagnosis, race, age/sex as applicable.
4. Additionally **Blood Bank Samples** require:
   - The signature of the person collecting the specimen on the Blood Bank Request form
   - Crossmatched Blood Products form if blood products or blood type is requested. Whether irradiated components or CMV antibody negative products are requested.
   - An indication for transfusion, product, number of units, and date and time the product is needed.
   - An indication of the procedure with crossmatch ordered for surgery.

UNLABELED/MISLABELED SPECIMEN DEFINITION

The labeling information on the specimen container and the request form must be identical.

Unlabeled Specimen: Patient identification is not present on the tube or container holding the specimen. It is not adequate to place the label on the bag, the container cover or on the box used to transport the specimen.

Mislabeled Specimen: A specimen is considered improperly labeled when:

- The name and/or identification number on the specimen label do not agree with the name and/or identification number on the request form.
- When the sample has only one positive patient identifier on the sample label.
- The specimen and request form identification agree but the laboratory or patient care personnel detect an error in test results.

UNLABELED/MISLABELED SPECIMEN POLICY

If a specimen arrives unlabeled or mislabeled, the referring facility will be contacted to resolve the discrepancy. If the submitting facility requests that the specimen be returned to them, we will honor this request.

Recollection of the specimen is recommended.

If the specimen cannot be recollected and/or the customer insists on the analysis, a comment will be added to the final report to alert the physician of the labeling problem.

The referring facility manager or their designee will be asked in writing via return fax to confirm the directives conveyed to our laboratories concerning specimen identity and testing on mislabeled / unlabeled samples.

Fairview Diagnostic Laboratories assumes no responsibility or liability for any problems or misdiagnoses that may result due to the analysis of an unlabeled or mislabeled specimen.