LB.15 The laboratory has comprehensive work instructions and procedures manuals.

LB.15.1 The laboratory develops work instructions and procedures manuals that fulfill the following:

LB.15.1.1 Conform to the hospital document control/management system.

LB.15.1.2 Readily available at the work areas.

LB.15.1.3 Prepared in accordance with the instrument operating manual, reagent inserts and/or manufacturer's instructions.

Standard Intent:

Procedures have specified ways to carry out an activity (also referred to by ISO as "work instructions"). The procedure manual should be used by personnel at the workbench and must include the following elements, when applicable to the test procedure:

1. Principle of the test and clinical significance.
2. Requirements for specimen collection, labeling, storage, preservation, transportation, processing, and criteria for specimen acceptability and rejection.
3. Step-by-step performance of the procedure, including test calculations and interpretation of results.
4. Preparation of solutions, calibrators, controls, reagents, and other materials used in testing.
5. Calibration and calibration verification procedures.
6. Quality Control procedures.
7. Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability.
8. Limitations in the test methodology, including interfering substances.
9. Reference intervals (normal values).
10. Entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life-threatening (critical) results.

The specific style and format of procedure manuals are at the discretion of the laboratory director.

Reagent inserts or instrument operating manuals provided by the manufacturer are not acceptable in place of a procedure manual. However, such documents may be used as part of a procedure description, if they accurately and precisely describe the procedure as it was performed in the laboratory.

Electronic (computerized) manuals are fully acceptable. There is no requirement for paper copies to be available for the routine operation of the laboratory, so long as the electronic versions are readily available to all personnel. However, procedures