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

must be available to laboratory personnel when the electronic versions are inaccessible (e.g. during laboratory information system or network downtime); thus, the laboratory must maintain either paper copies or electronic copies on CD or other media that can be accessed via designated computers.

LB.16 The Laboratory develops a process for the control of deviations and exceptions.

LB.16.1 There is a written policy, process, and forms for the control and documentation of deviations and exceptions to policies and procedures.

LB.16.2 Deviations and exceptions warranted by clinical situations or special circumstances are justified, pre-approved, and documented on a case-by-case basis.

LB.16.3 Deviations and exceptions must be approved for only one implementation event by the authorized person who signs the policy or procedure for implementation.

Standard Intent:

Exceptions to policies, processes, and procedures warranted by clinical situations are justified and pre-approved on a case-by-case basis and for one implementation event. A wide variety of routine procedures may, from time to time, require the medical director or designee to authorize an alternative approach because of specific clinical situations.

LB.17 The laboratory has a comprehensive safety and infection control programs.

LB.17.1 The laboratory implements safety and infection control policies and procedures that are in compliance with the national and international laboratory safety standards as well as the hospital safety and infection control plan. Policies define the following:

LB.17.1.1 Chemical hygiene plan.

LB.17.1.2 Mercury reduction/elimination plan.

LB.17.1.3 Mechanism of fumes and vapors monitoring.

LB.17.1.4 Mechanism of compressed and flammable gases control.

LB.17.1.5 Radiation safety plan.

LB.17.1.6 Biological safety procedures and use of standard precautions.

LB.17.1.7 Tuberculosis and other biological hazards exposure plan.

LB.17.1.8 Electrical safety plan.

LB.17.1.9 Fire prevention and control plan.

LB.17.1.10 Provision and use of Personal Protective Equipment (PPE).

LB.17.1.11 Provision and control of negative pressure in sections dealing with highly infectious materials.

LB.17.1.12 Provision, use, and control of fume hoods.

LB.17.1.13 Provision, use, and control of biological safety cabinets.

LB.17.1.14 Provision of safety equipment (eye wash, emergency shower, fire extinguisher, fire blanket, biological and chemical spill kits).