SUNY Downstate Medical Center -University Hospital of Brooklyn Network
Department of Pathology Policy and Procedure

Subject: GENERAL QUALITY CONTROL

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SUNY DOWNSTATE MEDICAL CENTER
DEPARTMENT OF PATHOLOGY
POLICY AND PROCEDURE

☒ CLINICAL LABORATORIES ☒ BAY RIDGE

Subject: GENERAL QUALITY CONTROL

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PURPOSE: Provide a quality control program to comply with regulatory agency standards and to assure the highest quality of service.

POLICY: Each laboratory section maintains a quality control program to monitor and evaluate the quality of its laboratory service, and for identifying and resolving problems. The Quality control records will be reviewed regularly by the appropriate supervisory personnel.

REFER TO LABORATORY SECTION MANUALS FOR SPECIFIC PROGRAMS.

The laboratory's quality control program includes but is not limited to the following general policies:

(a) Quality control samples and standards are assayed as required to validate the results obtained on patient samples, and to monitor the reagents, operating characteristics of the instruments and accuracy of volumetric equipment.

(b) Quality control samples are tested in the same manner as patient samples.

(c) Acceptable limits for control material is established over time by the laboratory, through concurrent testing with a control material having previously determined ranges.

(d) Statistical quality control limits, such as mean and standard deviation, for each lot number of material is determined through repetitive testing.

(e) Assayed control limits established by the manufacturer are verified by the laboratory, and correspond to the methodology and instrumentation employed by the laboratory.

(f) Records are kept of the actual results for each determination of all control samples, including quality control charts and/or records which identify by date and lot number the controls and/or standards used by the laboratory. Records are maintained for a minimum of 2 years.

(g) The laboratory establishes clinically reportable ranges for each method before reporting patient results.

(h) Patient values are reported only if controls and standards meet limits and criteria for acceptance established by the laboratory section. Whenever controls or standards do not meet such established limits and criteria for acceptance, remedial action is taken and documented.

(i) For patient results above or below the analytical measurement range, or below the minimum calibration point, results are reported as greater then the upper limit or less than the lower limit.

(j) If diluted samples are used, the laboratory provides evidence that the dilution process yields accurate, reliable and valid test results.

(k) Each reagent, solution, stain and antiserum is labeled to indicate its identity and, as appropriate, titer, strength or concentration; its storage conditions, if other than environmental; its preparation date; expiration date if pertinent to the performance of the reagent; and other pertinent information.

(l) Each batch or shipment of materials is to be checked for reactivity and/or sterility as appropriate and removed from use on the expiration date.

(m) Materials of substandard reactivity and/or deteriorated materials are also discarded, regardless of their expiration date.

(n) Whenever kits are used, components of each kit or reagents are not interchanged unless otherwise specified by the manufacturer, or verified by the laboratory.

(o) Validation is performed prior to the introduction of new test procedures and/or equipment. Validation criteria includes: precision, linearity, within run and run to run C.V., and cross-correlation study.

(p) Test methodologies and equipment are selected and testing performed in a manner that provides test results within a laboratory's stated performance specifications for each test method.

(q) A laboratory that performs the same test using different methodologies or instruments, or performs the same test at multiple test sites, will have a system in place that evaluates and defines the relationship between test results at least two (2) times a year.

(r) Current laboratory manuals or other procedural guides are available at all times in the immediate bench area of the personnel engaged in collecting or examining specimens and performing related work.

1. These manuals include complete descriptions and instructions for collecting, accepting, processing, storing and testing samples; preparation of the appropriate reagents; validation; quality assurance; quality control; calibration; limitations of the procedure; preventive maintenance; criteria for the referral of specimens; and test reporting procedures, including the reporting of life-threatening or critical values.

2. These manuals contain references to pertinent literature.

3. Textbooks are used as supplements, but are not used in lieu of the procedure manual.

4. All procedures are signed and dated by the current laboratory director and assistant director(s).

5. Revisions of laboratory policies or procedures are approved, signed and dated by the laboratory director and assistant director(s).

6. Each page of the procedure manual contains the date the procedure was implemented.

7. Copies of all earlier versions of the procedure manual are kept on file for a minimum of two (2) years; and

8. All policies and procedures are followed by the laboratory staff.

(s) The laboratory has a mechanism in place to assure that corrective action is taken and documented whenever unacceptable or unsatisfactory proficiency test results are obtained;

(t) No specimen is examined unless the laboratory premises and equipment used meet the requirements specified.

(u) Space and facilities are adequate to perform properly the services performed or offered by the laboratory; workbench space is adequate and well lighted;

1. The equipment and instruments are periodically inspected and tested for all operating characteristics of critical importance, as recommended by the manufacturer;

2. All equipment is kept in proper operating condition by preventive maintenance;

3. Environmentally controlled spaces and equipment is monitored and such monitoring recorded when of critical importance; continuous monitoring is assured and documented.