# SUNY DOWNSTATE MEDICAL CENTER
## DEPARTMENT OF PATHOLOGY
### POLICY AND PROCEDURE

☒ CLINICAL LABORATORIES ☒ BAY RIDGE

Subject: INTRODUCTION OF NEW INSTRUMENTATION AND TESTING METHODOLOGIES FOR LABORATORY ANALYSIS

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Discontinuation Date: _____

**POLICY:** The clinical laboratories are required to verify the manufacturer's claim regarding precision, linearity, accuracy, reference range and reportable range prior to introduction of new testing methodologies and instrumentation. The protocol for this is listed below.

**Verification of Precision**:

Analyte levels to measure the reproducibility of the test/procedure. Low, intermediate and high level analyte precision will be determined by performing 10 replicate measurements. These results will verify the within-run precision. These studies will be repeated on no less than five separate days to permit validation of the day-to-day (run-to-run) precision. Collected data will be evaluated to determine mean values, SD and coefficient-of-variation. Three levels of quality control materials and/or retained patient samples will be used to quantify precision at low, intermediate and high levels.

**Verification of Accuracy**:

Left-over patient samples, proficiency testing samples, and assayed QC material will be used to verify accuracy of analyte measurement. No less than 20 patient samples will be used in these studies. Selection of lipemic, hemolized, and icteric specimens will be included in the evaluation. Measured values will be obtained from both old and new methodologies. Should the test methodology under study represent a new procedure not currently performed by the laboratory, cross-correlation studies will be conducted by comparing results obtained from analysis by a reference laboratory on split samples. All efforts should be made to use patient samples having values that span a normal and pathological (high and low) clinical range. In addition to these studies, measurements will be performed using proficiency testing materials currently employed by the laboratory. Old and new test methodology results will be compared by computing the best fit line using

linear regression. The intercept, slope and correlation value will be determined and compared to equivalent results reported by the manufacturer. Significant discrepancies will be reported to the laboratory director.

Results of all studies will be summarized and a final report issued to the laboratory director prior to implementing new methodology. This report will include units, reference range, panic values, description of QC material, frequency of testing and response time. Written approval by the laboratory director is required prior to routine analysis of patient results.