Method Validation Plan

Test Name:
Method:
Department:
Prepared by:
Date:

Instructions:
Summarize the method performance characteristics in the table below. Attach all supporting documentation to this plan. The number of samples and sample type is determined by the clinical laboratory and approved by the medical director prior to initiation of the validation.

Method Performance Characteristic	Summary
Accuracy/Method Comparison	
Verify or establish the accuracy of the method. Number of samples:_____ Reference method:_____ Sample type:_____ Other information:_____ Include a copy of regression statistics from a statistical evaluation program.	Achieved performance - include summarized data for reference and comparison methods. Brief description of number of samples, sample type, how samples were chosen, brief description of comparative method/name of comparative method. This should include regression statistics. Use of reference materials with known concentrations is suggested in establishing or verifying accuracy.
Analytical Precision	
Verify or establish the precison of the method Number of samples:_____ Concentrations tested:_____ Sample type:_____ Include a copy of statistics including mean, SD, and CV from a statistical evaluation program.	Achieved performance - include summarized pertinent data for all levels. Analytic precision can be established by making measurements on a series of aliquots of the same test sample within a specified period of time. There should be a minimum of 10 data points for each precision check. Precision should be checked at 2 or 3 concentrations whenever possible. Use concentrations as close as possible to the medical decision level for the analyte.
Analytic Sensitivity	
Verify or establish the analytic sensitivity of the method. Include a copy of the calculated mean and SD statistics.	Include a brief description of how the data was obtained. The method should be sensitive enough to detect differences in the level of the analyte, especially at the decision point level. Run material of known lowest concentration such as linearity material to determine analytic sensitivity at that range.

Interferences	
Verify or establish interferences for the method. Include brief description of the manufacturer information reviewed and substances tested. Include data results for interferences if tested.	Brief description of how data was obtained. May include manufacturer information. Analytical system should be evaluated for cross reactivity or interferences by compounds known to be similar in chemical structure, or known to be interfering substances. This investigation should also focus on substances that are unique to the population being served.
Reportable Range/AMR	
Determine the analytical measurement range for the method. Verify or establish AMR for the method. Include copy of statistical evaluation from a statistical evalaution program.	Achieved performance - include summarized results for samples tested. Materials of appropriate matrix with known target values must be used. In order for a test of linearity, five analyte concentrations must be utilized. Replicate samples must be run. (Minimum duplicate analysis.)
Reference Intervals	
Reporting of results with reference intervals.	Achieved performance - summary of data obtained. Include a brief description of how data was obtained. This may include the number of subjects, criteria for inclusion, composition of patient pool, number of assays, etc. The minimum number of values is 20; 100 values are recommended.
Other Method Performance Characteristics	
Describe: (Specimen stability studies) (Specimen type comparisons) (Carryover studies) Include documentation of evaluation or manufacturers literature summary review.	Summary of assessment: (description here)

This validation study has been reviewed and the performance of the method is considered acceptable for patient testing.

Laboratory Medical Director Approval:_____

Date:_____