Laboratory: _____ Instrument/Test: _____

Instrumentation acceptable? YES NO Procedure approved? YES NO

Pathologist Review/ Date:_____

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

CLIA required Verification of Performance Specifications for new tests/instrumentation

Every laboratory is required to check (verify) the manufacturer's performance specifications provided in the package insert--for accuracy, precision, reportable range, and reference ranges--for each new unmodified, moderate or high complexity test that the laboratory performs **before** reporting patient test results. The verification process helps to assure that the test, when used in your laboratory by your testing personnel for your patient population, is performing as the manufacturer intended. This requirement applies when the laboratory **REPLACES** a test system or instrument (with the same model or a different model); **ADDS** a new test; or **CHANGES** the manufacturer of a test kit. *(Pathologist/Consultant/Specialist initial each item below when that item is met and acceptable)*

____ **ACCURACY or CORRELATION COEFFICIENT** (are your test results correct?)

Do results fall within the manufacturer's stated acceptability limits and are the correlation coefficients acceptable?

1. Assaying materials with known values
2. Comparing patient specimen results with a method currently in use
3. Verifying results from proficiency survey data
4. Splitting samples with another laboratory

_____ **PRECISION/ REPRODUCIBILITY** (can you obtain the same test result time after time?)

Test the same specimen(s) at least 10 times by different operators on *different days/shifts/within runs & between runs*, calculate to ensure the standard deviation falls within the manufacturer's stated acceptability limits. (Using control material over 20 days can also be used to set QC limits)

_____ **REPORTABLE RANGE** (verification of the range of patient values that can be reported)

(Also called AMR--analytical measurement range--by CAP)

Methods of testing: linearity standards, controls, or calibrators can be used, they must verify the lowest and highest values that can be reported per analyte by your laboratory.

_____ **VERIFICATION OF REFERENCE INTERVALS (NORMAL RANGES)**

Establishment of reference intervals requires >120 samples. *Verification* is more common and performed by using at least 20 samples from normal individuals and comparing the results to the published ranges or another laboratory's ranges to ensure that the reference intervals you report out fit your population

_____ **HAVE PERSONNEL BEEN FULLY EDUCATED ON HOW TO PERFORM TESTING AND QUALITY CONTROL?**

_____ **IQCP REQUIRED? IF YES, IS IT COMPLETED?_____**

_____ **HAVE ALL CALCULATIONS BEEN VERIFIED?**

_____ **VERIFY/PRINT A SAMPLE REPORT AND CHECK REFERENCE INTERVALS, FLAGGING, ETC.**

_____ **PROFICIENCY TESTING OR COMPARISON TESTING SET UP?**

_____ **ADDED TO TEST MENU?**

_____ **NOTIFICATION GIVEN TO APPROPRIATE DEPARTMENTS/PROVIDERS?** (ex. Ref range changes)

_____ **INTERFACE TESTING COMPLETE IF APPLICABLE**

_____ **AUTOVERIFICATION TESTING COMPLETE IF APPLICABLE**

_____ **PROCEDURE/POLICY WRITTEN AND/OR IN POLICY STAT** (Policy approved, acknowledgements assigned)

_____**MANUFACTURER TEMP AND HUMIDITY REQUIREMENTS-** verify instrument/reagent storage with manual check limits or automated monitoring system