Laboratory: **REPLACE WITH NAME OF LABORATORY**

Reset Form

Method Validation Approval Checklist

For unmodified, FDA-approved tests, you must verify accuracy, precision, reportable range, and reference ranges for quantitative tests (tests that give a numerical result). If the test is qualitative (a test that gives a negative or positive result), only verification of accuracy is applicable.

Assay:	
Instrument:	
Live Date:	

	The following parameters to be completed before the go-live date for this assay:
Accuracy	**Accuracy** is how close a test result is to the true value. You must verify that the test gives correct results in your Laboratory. Accuracy can be verified by testing samples with known values and comparing the results you obtain. Acceptable limits must be established to define how close the results need to be. It is recommended to evaluate accuracy and precision using samples with values in the normal patient range and at one other level, depending on where you expect clinically significant patient results to fall.
Precision	**Precision** is the degree to which repeated test results (day-to-day, run-to-run, and within run) on the same sample agree. You must verify that results are reproducible in your lab, even when different testing personnel perform the test.
Reportable Range	**Reportable range** is the lowest and highest result the test can accurately measure and all the values in between. The manufacturer has established a reportable range for the test, which you must verify by testing known samples with values at the low and high end of that stated range. Your laboratory may only report results that fall within your verified range. You must establish a policy for how the lab will report results that are higher or lower than the verified levels at each end of the range.
Linearity	**T**he approximate **Linear Range** of each analyte is generally specified by the manufacturer or in the literature, but should be confirmed by each laboratory. If a linear relationship between analyte concentration and method response is not obtained, it will be impossible to report quantitative patient results by that method. If the linear range does not span the range of analyte concentrations generally expected in patient samples, the need for frequent dilutions may make the method too expensive and inconvenient.
Reference Range	**Reference range** is the span of values for a particular test that represents the results you would expect to see in a healthy (normal) patient population. Reference ranges establish the normal values for the test and should reflect the medical decision limits for clinicians. You may use the manufacturer's suggested reference range initially. The laboratory is required to monitor the applicability of this range and make adjustments as necessary. you may need to adjust your reference range to more closely match your patient population.
Method Comparison	**Method comparison** is encouraged to determine the relationship between the normal ranges and medical decision limits of the previous method, and the normal ranges and medical decision limits of the new method. Method comparison could involve performing a linear regression and analyzing the results.

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Method Validation Approval Checklist

Assay: _____

The following parameters have been completed before the go-live date for this assay:

- ☐ Clinical application
- ☐ Accuracy
- ☐ Precision – within run
- ☐ Precision – between run
- ☐ Linearity
- ☐ Method comparison
- ☐ Quality control
- ☐ Reference range / unit of measure
- ☐ Reportable range
    - Analytical Measurement Range
    - Clinical Reference Range
    - Repeat Values
    - Critical Values (when applicable)
- ☐ LIS report format
- ☐ Interface
- ☐ Cost accounting-direct/indirect cost
- ☐ COLA notification – add assay/analyte to activity menu
- ☐ Proficiency survey ordered or Alternate Proficiency organized
- ☐ CPT coding
- ☐ Written procedure/s; approved by Laboratory Director
- ☐ Staff training/competency; paperwork placed in personnel files

Complexity: ☐ Non-Waived or ☐ Waived

FDA status: ☐ Approved or ☐ Non-approved

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

TC/TS
Signature: _____ Date:_____

Laboratory Director/Clinical Consultant
Signature: _____ Date:_____

Intermittent Testing:.

PT or alternative assessment performed within 30 days prior to restarting patient testing.
Method performance specifications verified, as applicable, within 30 days prior to restarting patient testing.
Competency assessed for analysts within 12 months prior to restarting patient testing.*References: COLA LabGuide 13 VerPerfSpecs.pdf , clinlabnavigator.com*