VALIDATION REPORT

Office of Microbiology

Validation Title	
Qualitative or Quantitative Assay	
Date	
Lab Unit	
Written by	
Proposed Test Implementation Date	

This validation report describes how the laboratory units in the Office of Microbiology at the Washington State Public Health Laboratories have established the performance characteristics of lab developed tests (LDTs) or modified FDA cleared tests. Performance characteristics established for each test included: accuracy, precision, sensitivity, specificity, analytical sensitivity (limit of detection), and analytical specificity (cross reactivity/interfering substances), reportable range, and reference ranges/Intervals (Normal Values), analytical measurement range (AMR) as applicable **before performing patient testing**.

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Please **summarize** final results below in table and final outcomes for each component if applicable. Calculations and explanations should be shown under the appropriate header in the report.

Validation Study Component	Expected	Observed	Outcome
Accuracy	≥ 90%		PASS/FAIL
PPV	≥ 95%		
NPV	≥ 95%		
Precision/Reproducibility	≥ 95%		
Sensitivity	≥ 95%		
Specificity	≥ 95%		
Analytical Sensitivity/LOD			
Analytical Specificity/ Cross Reactivity	None		
Interfering Substances	None or Known		
Reportable Range			
Reference Interval			
Analytical Measurement Range/AMR	If applicable		

PURPOSE: Please describe **below** the reason for implementing this test and its intended use.

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TEST PRINCIPLE: Please describe **below** the scientific basis of how this tests works.

INSTRUMENTATION & REAGENTS: Please describe **below** the reagents/ kit and instrumentation that was used in the validation. Add rows below as needed.

Reagent	Lot Number	Expiration Date

Instrument	Serial Number	Manufacturer

SAMPLES: Please list your final samples **below** including data in appropriate fields. Add rows below as needed. *** Samples that were excluded. ** Samples that were added as a replacement.**

Sample #	Source	Specimen #	Target	Expected Result	Other

ACCURACY: Please show how you determined accuracy **below** along with calculations for PPV & NPV, clinical sensitivity & clinical specificity as well.

$$\textbf{Accuracy (Agreement)} = \frac{\textbf{No. of correct results}}{\textbf{Total no. of results}} \times 100$$

PREDICTIVE VALUE PPV& NPV: Calculations for these should come from your accuracy sample pool numbers (TP, FP, TN, FN). Please show your calculations below.

Accuracy PPV= [TP/(TP+FP)] X 100 **Accuracy NPV = [TN/(TN+FN)] X 100**

SENSITVITY & SPECIFICITY: Calculations for these should come from your accuracy sample pool numbers (TP, FP, TN, FN). Please show your calculations for diagnostic sensitivity and diagnostic specificity **below**.

Sensitivity = [TP/(TP+FN)] X 100 **Specificity= [TN/(TN+FP)] X 100.**

PRECISION/REPRODUCIBILITY: Please show your calculations **below** how you established the intra-run and inter-run precision/reproducibility.

Qualitative Test **Reproducibility = [No. of repeated results in agreement/Total no. results] x 100**

Quantitative Test **Precision= (Coefficient of Variation (CV)) = [Standard Deviation/Average] x 100**

ANALYTICAL SENSITIVITY/LIMIT OF DETECTION: LOD is expressed as a concentration (usually copies/ml; copies/µgDNA for molecular assays) such that the lower the detectable concentration of analyte, the greater the analytical sensitivity of the assay. Please describe **below** your calculations for determining the analytical sensitivity of the assay.

ANALYTICAL SPECIFICITY/CROSS REACTIVITY/INTERFERING SUBSTANCES: For molecular assays please **list** cross reactivity tested and result (e.g No cross reactivity), also include primers/probe sequences and whether known cross reactivity was identified during blast searches. Also list interfering substances tested for. Add or remove rows as needed.

Target	Cross Reactivity Result
Primer Sequences	**Cross Reactivity Result**
Probe Sequences	**Cross Reactivity Result**
Interfering Substances	**Interference Result**

REPORTABLE RANGE: Please describe and show calculations **below** how the reportable range was established.

REFERENCE RANGE/NORMAL VALUES: Please describe and show calculations **below** how the reference range was established.

ANALYTICAL MEASUREMENT RANGE/ AMR: For quantitative tests please describe and show calculations below for how the AMR was established.

LITERATURE REFERENCES/PACKAGE INSERTS: List **below** any technical and/or literature used in the validation process.

OTHER PERFORMANCE CHARACTERISITCS: List **below** any known limitations or unusual characteristics of the test that people performing the test should be aware of.

NEED FOR CLIENT EDUCATION: Please describe **below** how this will be provided **if needed**.

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APPROVAL:

Statement	This validation report has been reviewed and has been considered acceptable for patient testing.
Lead Signature & Date	
Supervisor Signature & Date	
Office Director Signature & Date	
QA Officer Signature & Date	
CLIA Director Signature & Date	
Validation Data Retention	Records should be maintained for the life of the test.
Date Discontinued	
Archived Record Retention	Records should be maintained for a minimum of 2 years after discontinuing test.