VERIFICATION PLAN

Office of Microbiology

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

This verification plan describes how the laboratory units in the Office of Microbiology at the Washington State Public Health Laboratories intend to verify the manufacturer's performance specifications provided in the package insert or info sheet--for accuracy, precision, sensitivity, specificity, reportable range, and reference ranges/Intervals (Normal Values) analytical measurement range (AMR) if applicable--for each FDA approved unmodified, moderate or high complexity test. **This plan must be approved before performing the actual verification.**

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PURPOSE: Please describe **below** the reason for implementing this test and its intended use. Include all acceptable specimen types. **Note:** Each acceptable specimen type to be tested at the WA PHL must be evaluated.

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

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

Reagent	Lot Number	Expiration Date

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Instrument	Serial Number	Manufacturer

SAMPLES: At the WA PHL a minimum of 30 samples/isolates per target and/or sample type is required during the verification process. This must include samples representing a combination of (negative and positive samples at varying levels). **Note:** Less than 30 samples require approval **before** submitting the verification plan. Please list your samples below including data in appropriate fields. Add rows below as needed.

Sample #	Source	Specimen #	Target	Expected Result	Other

ACCURACY: Are your test results correct? This can be determined by testing commercially available calibrators/calibration and quality control materials with known values, proficiency testing materials that have established values, and previously tested patient specimens with established values. Please describe your plan to determine accuracy **below** this will additionally satisfy calculations for PPV & NPV, clinical sensitivity & clinical specificity as well. **Please include the manufacturer's specifications.**

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

PREDICTIVE VALUE PPV& NPV: The predictive value of a test is the probability that a positive result (PPV) accurately indicates the presence of an analyte or a specific disease or that a negative result (NPV) accurately indicates the absence of an analyte or a specific disease. Calculations for these should come from your accuracy sample pool numbers (TP, FP, TN, FN). **Please include the manufacturer's specifications.**

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

SENSITVITY & SPECIFICITY: Clinical sensitivity refers to the ability of a test to detect a disease or clinical condition, while clinical specificity refers to the degree to which a test is negative when disease is absent. Determinations of sensitivity and specificity should be done in a **"blinded"** fashion (i.e. without prior knowledge of the patient's disease status). Calculations for these should come from your accuracy sample pool numbers (TP, FP, TN, FN). **Please include the manufacturer's specifications**

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

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PRECISION/REPRODUCIBILITY: Can you obtain the same test result time after time? The can be done by verifying that the lab can repeatedly test the same samples on the same day, and on different days and get the same or comparable results (reproducible),regardless of which member of the laboratory's testing personnel performs the test (operator variance). Precision/reproducibility should be **at least 95%** compared to the reference method. **Exception:** Fully automated test systems that are not operator dependent, operator variance should not affect the test's precision and may not need to be evaluated by more than one person. Please describe **below** how you plan to verify precision/reproducibility. **Please include the manufacturer's specifications**

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**

REPORTABLE RANGE: How high and how low can test result values be and still be accurate? If applicable this can be done by choosing samples with known values at the highest and lowest levels the manufacturer claims accurate results can be produced by the test system. Please describe **below** how you plan to verify the reportable range if applicable. **Note:** At the WA PHL we list positive, negative, and inconclusive other similar results for not applicable qualitative tests that do not have a reportable range. **Please include the manufacturer's specifications**

REFERENCE RANGE/NORMAL VALUES: Do the reference ranges provided by the test system's manufacturer fit your patient population? You may begin patient testing using the manufacturer's suggested reference range(s) or you may use other published reference ranges from a textbook or a journal publication. When you test known normal patients, the results should be within your reference range and with abnormal patients, you should expect results outside the reference range. Note: At the WA PHL we list negative or not detected for many of the infectious disease conditions we use qualitative tests for. Please describe **below** what and how you plan to verify regarding the reference range.

ANALYTICAL MEASUREMENT RANGE/ AMR: NOTE: QUANTITATIVE ONLY. AMR is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process. AMR verfication is the process of confirming that the assay system will correctly recover the concentration or activity of the analyte over the AMR. Materials used for verification must be known to have matrix characteristics appropriate for the method. The test specimens must have analyte values that, at a minimum, are near the low, midpoint, and high values of the AMR. For quantitative tests please describe below how you plan to establish the AMR.

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

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

Washington State Department of Health

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APPROVAL:

Statement	This verification plan has been reviewed and has been considered acceptable for initiation of verifying performance of the proposed test.
Lead Signature & Date	
Supervisor Signature & Date	
Office Director Signature & Date	
QA Officer Signature & Date	
CLIA Director Signature & Date	