Part C. BIT Summary Template

☐ **Verification of** ☐ **Validation of** _____ **Breakpoints for (organism/organism group)** _____

tested by (AST Method) _____

Studies performed (dates): _____

I. Purpose

☐ Verify or ☐ Validate performance of (Name of Method or Commercial AST Device) _____

For ☐ organism or ☐ organism group _____

Reference/Comparator results from (see NOTE below, II.B.) _____

For Antimicrobial(s) and Breakpoint Values

Antimicrobial(s)	Old Breakpoints (MIC µg/ml)				New Breakpoints (MIC µg/ml)				Breakpoint Source (FDA/CLSI)
	S	SDD	I	R	S	SDD	I	R	

Abbreviations: I, intermediate; MIC, minimal inhibitory concentration; R, resistant; S, susceptible; SDD, susceptible dose dependent.

II. Verification/Validation Study

A. AST System

Panel/Card _____ Software version _____

B. Accuracy

Number of isolates _____

Isolate source(s) _____
(eg, CDC & FDA Antibiotic Resistance (AR) Isolate Bank, clinical isolates)

Reference result source(s) _____
(eg, CDC & FDA AR Isolate Bank MICs, in-house reference broth microdilution, reference laboratory)

NOTE: Reference result may be obtained from parallel testing using a reference AST method or comparator AST method that is verified/validated for the new breakpoints or preestablished using a reference (eg, CDC & FDA AR Isolate Bank) or verified/validated comparator method.

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C. Reproducibility (precision)

Number of isolates _____

Isolate source(s) _____
(eg, CDC & FDA AR Isolate Bank, clinical isolates quality control strains)

Number of replicates _____

D. Quality Control

Isolate(s) _____ Testing frequency _____
(ie, name/strain number) (eg, per run)

E. Analysis

1. Interpret MIC results manually utilizing new breakpoints as listed above (see I. Purpose).

2. Compare interpretive category results (eg, S, SDD, I, R) obtained from test system to the interpretive category obtained from the reference/comparator results.

3. General guidance for acceptable **accuracy**

Categoric Agreement (CA)	≥90%
Very Major Errors (VME)	<3%
Major Errors (ME)	<3%
Minor Errors (MiE)	Determined by the laboratory director.

4. Note: A category agreement of <90% may be acceptable if the majority of errors are minor and the minor errors have essential agreement (ie, within ±1 two-fold dilution).

5. Acceptable **reproducibility**
95% of replicate results for a single antimicrobial agent/organism fall into either an S, I, SDD, or R category.

III. Procedure

A. Materials and testing procedure for system to be verified/validated

Described in SOP _____ (this Laboratory's SOP #)

B. Record results on **Appendix E2**

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C. Options for discrepancy resolution (following a check for transcription error or other possible human error that could lead to resolution without retesting)

1. Repeat in triplicate.

2. Test using another method that has been verified/validated for new breakpoints (eg, disk diffusion)

3. Send isolate to a reference laboratory.

D. Update data table (Part F or Part G) and perform analyses with resolved results.

IV. Calculation of Accuracy, Reproducibility, and Error Rates

A. Accuracy: Calculate each agent separately.

1. CA (%) = Number of isolates with same category results/total isolates x 100

2. VMEs (%) = Number of "S" isolates (test system results)/number of "R" isolates (reference results) x 100

3. MEs (%) = Number of "R" isolates (test system results)/number of "S" isolates tested (reference results) x 100

4. MiEs (%) = Number of isolates where one result (either test or reference) is "I or SDD" and the other is "S" or "R"/total isolates x 100

B. Reproducibility

Number of results that are reproducible for each organism/drug combination/total number of isolates

V. Summary of Results Obtained

A. Accuracy

Agent(s)	# of Isolates*					CA	VME	ME	MiE
	Total	S	SDD	I	R	# (%)	# (%)	# (%)	# (%)

*Numbers represent a summary of the reference results.

Abbreviations: CA, categorical agreement; I, intermediate; ME, major errors; MiE, minor errors; S, susceptible; SDD, susceptible dose dependent; R, resistant; VME, very major errors.

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B. Reproducibility

_____% of _____ (agent/organism) results were reproducible.

I have reviewed the _____ (verification/validation) data for accuracy and precision, for the (AST test method) _____, and the performance of the method is considered acceptable for patient testing.

Reviewed by: _____ Date:_____

Signature: _____

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