Method Verification Summary Template

Laboratory name: _____

CLIA #: _____

Location / department: _____

Month / Year: _____

Test / analyte: _____

Test system / manufacturer / model: _____

FDA status: [ ] Unmodified FDA-cleared/approved [ ] Modified or LDT (establishment, more characteristics apply)

Verification start / end dates: _____

Performed by: _____

Characteristic	**Study design (samples, # runs, comparison method)**	**Acceptance criteria**	**Result**	**Meets? Y/N**
Accuracy				
Precision (within-run / day-to-day)				
Reportable range				
Reference intervals (verify applicability to patient population)				
Analytical sensitivity (if applicable)				
Analytical specificity / interferences (if applicable)				
Other characteristic required by the test				

Calibration and control procedures determined from these results: _____

Conclusion: [ ] Approved for patient testing [ ] Not approved

Laboratory director signature / date: _____

Regulatory reference (verify against current eCFR): 42 CFR 493.1253(b) – before reporting patient results, verify (for unmodified FDA-cleared/approved tests) or establish performance specifications such as accuracy, precision, reportable range, and reference intervals.

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