Verification/Validation Summary: Name of Test System

Summary Prepared by: Click or tap here to enter text.

Date Prepared: Click or tap here to enter text.

Planned "Go-Live" Date: Click or tap here to enter text.

Actual "Go-Live" Date: Click or tap here to enter text.

Associated SOP: Click or tap here to enter text.

New test/methodology/instrument: Click or tap here to enter text.

Old test/methodology/instrument: Click or tap here to enter text.

Summary:

Summarize the reasons for modifying or adding the testing. Describe what was tested and any additional relevant information. If the validation is due to a change in method, outline briefly the changes that were made to the current process. The summary should state the purpose of the study and include the method/platform and the number of samples tested for each experiment. The summary should provide a brief summary of all experiments run to verify/validate the method/platform being tested.

Performance Data:

Describe the experiments performed and summarize the results of each experiment including acceptance criteria. Make note of any deviations from the validation plan and explain the reason for the deviation. Include graphs, tables, or charts from FCHDL's 'Method Validation Verification' policy, as appropriate. Provide data for each instrument to be used for routine testing and/or as a back-up instrument. Add or remove performance characteristic as applicable.

		REFERENCE/ CURRENT METHOD	
		Positive	Negative
NEW METHOD	Positive	TP	FP
	Negative	FN	TN

Diagnostic Sensitivity = TP / (TP+FN) X100
TP = True Positives

Diagnostic Specificity = TN / (TN+FP) X 100
TN = True Negatives

FN = False Negatives FP = False Positives

		REFERENCE/ CURRENT METHOD		
		Positive	**Negative**	
NEW METHOD	**Positive**	a	b	**Positive Predictive Value** a/(a+b) x 100
	Negative	c	d	**Negative Predictive Value** d/(d+c) x 100
		Diagnostic Sensitivity a/(a+c) x 100	**Diagnostic Specificity** d/(b+d) x 100	

Total Accuracy % = [(a+d)/ (a+b+c+d)]*100

Example:

ID	DAY 1			DAY 2			DAY 3			DAY 4			DAY 5			BETWEEN RUN %
#1 POS	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	15/15 X 100 = 100%
#2 POS	Pos	Pos	Neg	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	Pos	14/15 X 100 = 93%
#1 NEG	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	14/15 X 100 = 93%
#2 NEG	Neg	Neg	Neg	Neg	Pos	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	Neg	15/15 X 100 = 100%
Within Run %	11/12 X 100=92%			11/12 X 100=92%			12/12 X 100=100%			12/12 X 100=100%			12/12 X 100=100%			

Total Precision = 58/60X100=96.7%

Performance Characteristic	FCHDL Stated	Manufacturer Stated	Observed	All Acceptability Criteria Met? (Y/N)
Accuracy				
Precision				
Reportable Range/AMR				
Reference Range				

Conclusion:

The summary should state whether the Verification/Validation study met the stated acceptance criteria or not and its suitability for use in the laboratory. It should also include an investigation and explanation of any discrepant results

Method Approval:

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

Example:

Verification/Validation Summary: Hemoglobin / UniCel® DxH™ 800 Coulter® Cellular Analysis System

Summary Prepared by: Jane Smith

Date Prepared: 1/20/1900

Planned "Go-Live" Date: 2/1/1900

Actual "Go-Live" Date: 4/1/1900

Associated SOP: UniCel® DxH™ 800 Coulter® Cellular Analysis System Procedure

New test/methodology/instrument: Hemoglobin / UniCel® DxH™ 800 Coulter® Cellular Analysis System

Old test/methodology/instrument: Hemoglobin / COULTER® LH 750 Hematology Analyzer

Summary:

Patients ran on the UniCel® DxH™ 800 Coulter® Cellular Analysis System yielded more accurate hemoglobin results compared to the previous COULTER® LH 750 Hematology Analyzer. 40 samples spanning AMR were used to establish accuracy as well as the reportable range. 10 samples were used to establish acceptable precision. See below chart for the observed parameters.

Performance Data:

Specification	Stated	Observed	Acceptable (Y/N)
Accuracy	Slope (m) = 1.0 ± 0.05 Correlation of Coefficient (r) between -1 and +1 EP evaluator="pass"	m=1.12 r=1.23 EP evaluator="pass"	Y
Precision	Inter-run CV≤ 8.4 Intra-run CV≤ 8.4	Inter-run CV≤ 3.4 Intra-run CV≤ 4.1	Y

AMR	Linear Relationship within CLIA criteria	Linear Relationship with CLIA criteria	Y
Reference Range	20 Female & 20 Male <= 2 of each fall outside the proposed limits	20 Female & 20 Male <= 2 of each fall outside the proposed limits	Y

Conclusion:

All performance specifications met stated acceptability criteria and are considered acceptable for patient testing. The analytical sensitivity and interfering substances as published by the manufacturer for this assay also have been reviewed and are considered acceptable for patient testing.

Method Approval:

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