

	ORA LABORATORY PROCEDURE Food and Drug Administration	Document No.:	Version No.: 1.4
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Title: ATTACHMENT B – EXAMPLE VALIDATION FORM		Effective Date: 10-01-03 Revised: 02-24-09	

REPORT FOR: _____

REQUEST #: _____

ANALYST(S) NAME AND DATE: _____

METHOD NAME: _____

RESULTS:

ACCURACY: ___PASS ___FAIL ___N/A (Criteria – Define)

PRECISION: ___PASS ___FAIL ___N/A (Criteria – Define)

DETECTION LEVEL: ___PASS ___FAIL ___N/A (Criteria-Define)

INTERFERENCE(S): ___PASS ___FAIL ___N/A (Criteria – Pass=interferences resolved; Fail=interferences not resolved)

t TEST: ___PASS ___FAIL ___N/A F TEST: ___PASS ___FAIL ___N/A
 (Criteria = < t Critical; < F Critical)

ADDITIONAL PERFORMANCE MEASUREMENTS (i.e. linearity, corr.coef..)

____PASS ____FAIL ____N/A

COMMENTS: _____

ANALYST(S) SIGNATURE AND DATE: _____

FIT FOR INTENDED USE: ___YES ___NO

CONCURRENCES:

SUPERVISOR: ___YES ___NO

SIGNATURE AND DATE: _____

QMS MANAGER: ___YES ___NO

SIGNATURE AND DATE: _____

LABORATORY DIRECTOR: ___YES ___NO

SIGNATURE AND DATE: _____