

	ORA LABORATORY PROCEDURE Food and Drug Administration	Document No.: ORA- LAB.5.4.5	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: _____