National Laboratory Certification Program
DRUG TESTING MATTERS

2023

Validating Immunoassays for Urine and Oral Fluid Drug Testing

*This is the updated first part of a five-part **Drug Testing Matters** series on urine and oral fluid drug testing method validation, originally published in 2014. This part covers validating immunoassay methods. The second part will cover validating specimen validity tests (SVTs); the third and fourth parts will cover validating mass spectrometry methods; and the fifth part will cover validation of oral fluid collection devices.*

Immunoassay Overview

Immunoassays used for laboratory testing date back to the 1950s with Berson and Yalow's Nobel Prize–winning development of the first radio-immunoassay (RIA) (1). All immunoassays are based on an antigen and antibody reaction being coupled to an analytical chemistry application that measures the antigen–antibody binding. Depending on the application, the antibody or the antigen may be the measurand of interest.

For drug testing, drugs or drug metabolites in the sample are both the antigens and the measurands targeted by the assay antibody (2). Immunoassay design can take many forms, including competitive/homogeneous and competitive/heterogeneous assays. The competitive assay format is a common drug testing immunoassay. For example, with the competitive/homogeneous immunoassay, the native measurand in the sample and labeled measurand in the assay compete for binding with the antibody. The residual concentration of the unbound labeled measurand is directly proportional to concentration of the measurand in the sample.

Depending on the use of the drug test, immunoassay antibodies may be designed to exhibit varying degrees of antigen cross-reactivity. Antibody binding affinity to the measurand can range from a broad spectrum to a very limited span of drugs/drug metabolites within a drug class.

Drug testing immunoassays are typically calibrated for qualitative analysis using a single standard measurand and at a calibrated cutoff concentration. Some immunoassays support the use of multiple calibration points for semi-quantitative application and reporting of results. Regardless of qualitative or semi-quantitative assay configuration, the combination of antibody cross-reactivity (binding affinity), reagent formulation, and limits of the analytical instrumentation measurement range define the immunoassay's relative sensitivity, linearity, and cutoff precision. By measuring whether the cumulative antigen–antibody response of a donor's specimen is equal to or greater than the calibrated cutoff, the immunoassay test provides results that are used to differentiate "negative" from "presumptive positive" specimens. Immunoassay test results that are equal to or greater than the cutoff are always considered "presumptive" positive for the following reasons:

- Immunoassays do not provide a definitive identification of the measurand.
- False positive, non-drug class cross-reactivity, or interference cannot be distinguished from true positive results.

Over the years, immunoassays have evolved beyond the original RIA. There are now many variations of immunoassay methods, including these common applications (3):

Exhibit 1. Immunoassay Methods

Method	Abbreviation	Description
Cloned Enzyme Donor Immunoassay	CEDIA	An immunoassay using enzyme fragments engineered by recombinant DNA techniques. Two fragments, the enzyme donor (ED) and enzyme acceptor (EA), are inactive when separated. CEDIA is based on competition for antibody binding sites between drug molecules conjugated with ED and drug molecules in the specimen. Enzyme activity decreases when the ED-drug fragment is bound, so the drug concentration in the specimen can be measured in terms of enzyme activity (i.e., drug concentration and enzyme activity are directly related).
Enzyme Immunoassay	EIA	An immunoassay based on competition for antibody binding sites between drug in the specimen and drug labeled with an enzyme. Enzyme activity decreases upon binding to the antibody, so the drug concentration in the specimen can be measured in terms of enzyme activity.
Microplate Enzyme-Linked Immunosorbent Assay	ELISA	A competitive binding enzyme immunoassay using drug-specific antibodies immobilized on the sides of a microplate well.

Exhibit 1. Immunoassay Methods (continued)

Method	Abbreviation	Description
Fluorescence Polarization Immunoassay	FPIA	An immunoassay based on competition between drug in the specimen and drug labeled with a fluorophore. Light emitted by the fluorescently labeled drug/antibody complex will be more polarized. The specimen's fluorescence polarization value is inversely related to the drug concentration.
Fluorescence Resonance Energy Transfer	FRET	A fluorescent donor molecule (dye or chromophore) conjugated to an antigen will transfer fluorescent energy to an acceptor molecule conjugated to an antibody. Drug in the specimen competes with the antibody binding sites, causing the donor fluorescence to increase and acceptor fluorescence to decrease.
Kinetic Interaction of Microparticles in Solution	KIMS	An immunoassay based on the principle of the kinetic interaction of microparticles in a solution where the drug content of the sample is directly proportional to the inhibition of the microparticle aggregation.

Immunoassay Validation[a]

The remainder of this publication focuses on validating immunoassay methods for initial tests.

Industry Standards

The method validation requirements described in this article are defined by the Department of Health and Human Services (HHS) and the National Laboratory Certification Program (NLCP) (4-7) for HHS-certified laboratories that test donor specimens in compliance with the *Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine* (UrMG) and the *Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid* (OFMG). HHS-certified laboratories conduct forensic drug testing for federal agencies under Executive Order 12564 and Public Law 100-71 and for specific federally regulated industries. The HHS *Mandatory Guidelines for Federal Workplace Drug Testing Programs* affect all federal employees in a testing designated position, which is defined by each agency's Drug-Free Workplace Program.

The American National Standards Institute and the American Academy of Forensic Sciences Standards Board (ANSI/ASB) publishes additional standards and guidance for forensic drug testing applications (8). The ANSI/ASB Standard 036 "Standard Practices for Method Validation in Forensic Toxicology" publication defines forensic toxicology validation practices, such as consensus standards, practice, and protocols, including quality assurance and quality control.

[a] *For clarity, this series of articles will use "validation" to cover all aspects of laboratory methods performance assessments, including verification of unmodified Food and Drug Administration (FDA)-cleared and FDA-approved assays and the validation of laboratory-developed assays.*

For Clinical Laboratory Improvement Amendments (CLIA) certification of clinical laboratories, the Centers for Medicare & Medicaid Services (CMS) requires laboratories to verify or establish performance specifications for any test system used by the laboratory on or after April 24, 2003 (9).

The goal of validating immunoassay methods is to provide objective data that (1) demonstrate that the method performs according to its intended use and (2) establish the method limitations under normal operating conditions.

Before implementing for use with donor specimen testing, all laboratories are required to validate the performance specifications of new methods, new instrumentation, and modifications to existing methods or instrumentation. Some laboratories perform supplemental immunoassays (e.g., to eliminate cross-reacting compounds, when the desired specificity cannot be obtained using the primary method). These supplemental immunoassays are subject to the same method validation requirements as the primary immunoassays.

Performance characteristic measurements include the following:

- the ability to differentiate negative specimens from those requiring further testing,
- the precision and accuracy of the test around the cutoff,
- the effective linearity of the test,
- the potential for carryover,
- the specificity and potential for interfering substances, and
- the comparison of results using existing and new/revised procedures (i.e., parallel study).

Documentation

Immunoassay validation studies must be organized in a format that facilitates record review. Study records must include sufficient information to allow for a comprehensive review of the studies that were performed. Laboratories must have criteria for accepting the validation study data, agreeing on replicate study samples, and defining or excluding true outlier values.

At a minimum, the study records must include the following components:

- A stated purpose for the validation,
- Description of test methods,
- Identity of the instrument(s) used for the study,
- A list of the instrument parameters used for the study,
- A description of the study samples,
- A summary of the statistical data collected to characterize the assay,
- A discussion,
- A summary with conclusions, and
- All raw analytical data from the samples analyzed in the study.

The laboratory must maintain the immunoassay validation study records for an indefinite period. Records for validation studies performed within the last 12 months must be available for review during NLCP inspections.

Each "end-user laboratory" must perform the validation. Off-site validations performed by other entities (e.g., manufacturer, other laboratory) may be used only to provide additional documentation.

Types of Validations

The types of validation studies to be used depend on whether the laboratory is implementing a new test, a new instrument model, or an additional instrument of the same model. Examples of validations include Assay, Full Instrument, and Abbreviated Instrument.

Notes:

Where multiple instrument models are used for an immunoassay, using the most conservative performance limits that can be determined for all of the models is acceptable, provided that this approach is described in the standard operating procedures (SOPs) and validation study summaries.

Periodic re-verification studies are not required for immunoassays.

Assay

Assay validation studies must be performed before use with regulated specimens for the following:

- a new primary or alternate method,
- a revised method,* or
- method calibration scheme changes.

**Note: It is usually necessary to perform complete validation studies for revised assays. However, if the modification is relatively minor, the validation studies may focus on those parameters that may have been affected.*

The following studies are required:

- linearity,
- precision and accuracy around the cutoff,
- carryover,
- specificity/interference,
- positive/negative sample differentiation studies, and
- parallel study using new versus existing procedures.

Full Instrument

Full Instrument validation must be performed before implementing a new instrument model or a new instrument component that may affect analysis (i.e., implementing a new manufacturer's immunoassay reagent, modifying an existing method, or changing the calibration scheme).

The following studies are required:

- linearity,
- precision and accuracy around the cutoff,
- carryover,
- positive/negative sample differentiation, and
- parallel study using the existing and new instrument models.

Abbreviated Instrument

Abbreviated Instrument validation must be performed before implementing an additional immunoassay instrument (a model that has been previously validated by the laboratory), with the following studies:

- precision and accuracy around the cutoff,
- carryover, and
- positive/negative sample differentiation studies.

Note: Abbreviated Instrument validation is required when new ring positions are used in a previously validated instrument model.

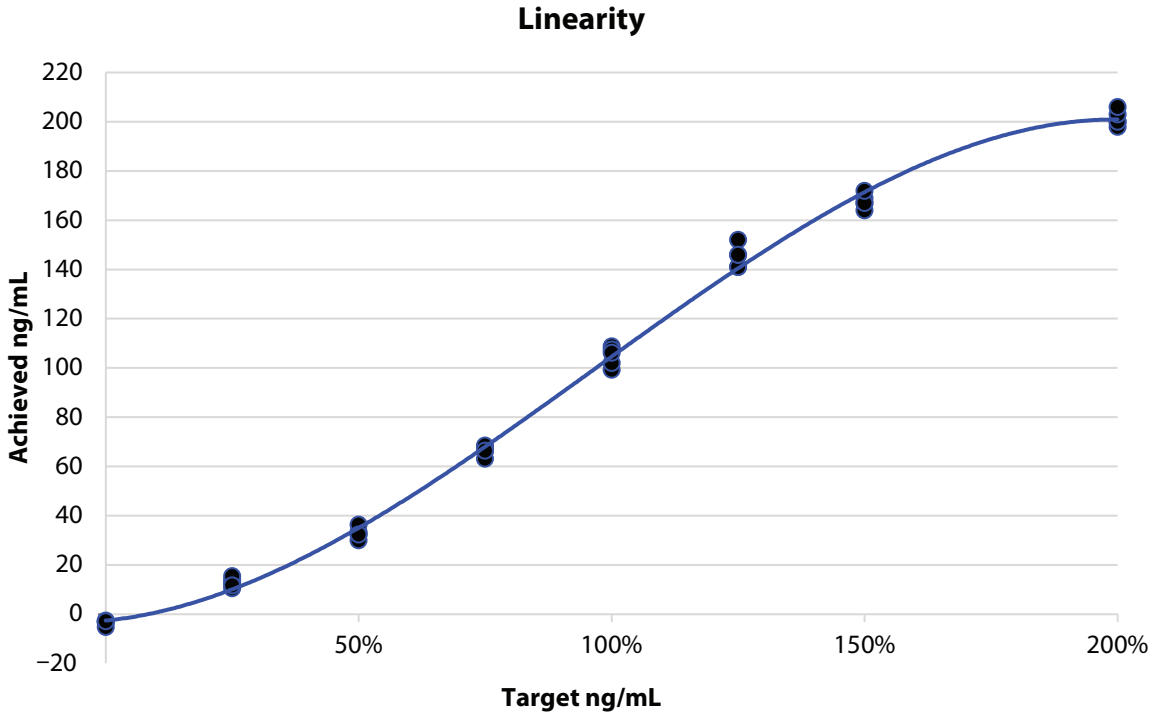
Minimum General Study Requirements for Assay Validation, Full Instrument Validation, and Abbreviated Instrument Validation

Linearity Studies

Immunoassay linearity study plots typically exhibit a sigmoidal or "S-curve," as shown in Exhibit 2. The low end of the S-curve represents insufficient measurand concentration for a competitive binding to the antibody. The upper end of the S-curve represents saturation of the competitive binding process by the measurand. The laboratory must determine the linear portion of the S-curve using at least five replicates for each of at least seven concentrations of the calibrator measurand. The concentrations should be distributed as follows:

- a minimum of three levels below the cutoff,
- one level at the cutoff, and
- a minimum of three levels above the cutoff.

Exhibit 2. Example of Immunoassay Linearity Study



Percentage of Cutoff	Linearity Results							
	1	2	3	4	5	Mean	−2SD	+2SD
0%	−3.0	−3.4	−2.7	−5.2	−2.9	−3.4	−5.5	−1.4
25%	13.9	12.8	15.4	10.5	11.6	12.8	9.0	16.7
50%	32.5	33.3	30.0	36.3	32.3	32.9	28.3	37.4
75%	67.9	66.1	63.1	68.5	66.4	66.4	62.2	70.6
100%	109	99	107	102	106	105	97	113
125%	141	152	141	146	146	145	136	155
150%	167	164	169	167	172	168	162	174
200%	200	198	200	203	206	202	195	208

The validation of a new immunoassay should also include very high concentrations of the measurand (20 to 200 times the cutoff) to demonstrate that very high concentrations will not produce "negative" readings that are below the initial test cutoff. "Negative" readings with very high concentrations of measurand are caused by depletion of the antibody or substrate ("hook effect").

The linearity results must be plotted for review. For example, for an enzyme immunoassay validation, delta absorbance units (Y axis) are plotted against concentration (X axis).

Note: Determining the limit of detection (LOD) and the limit of quantification (LOQ) is not required for immunoassays.

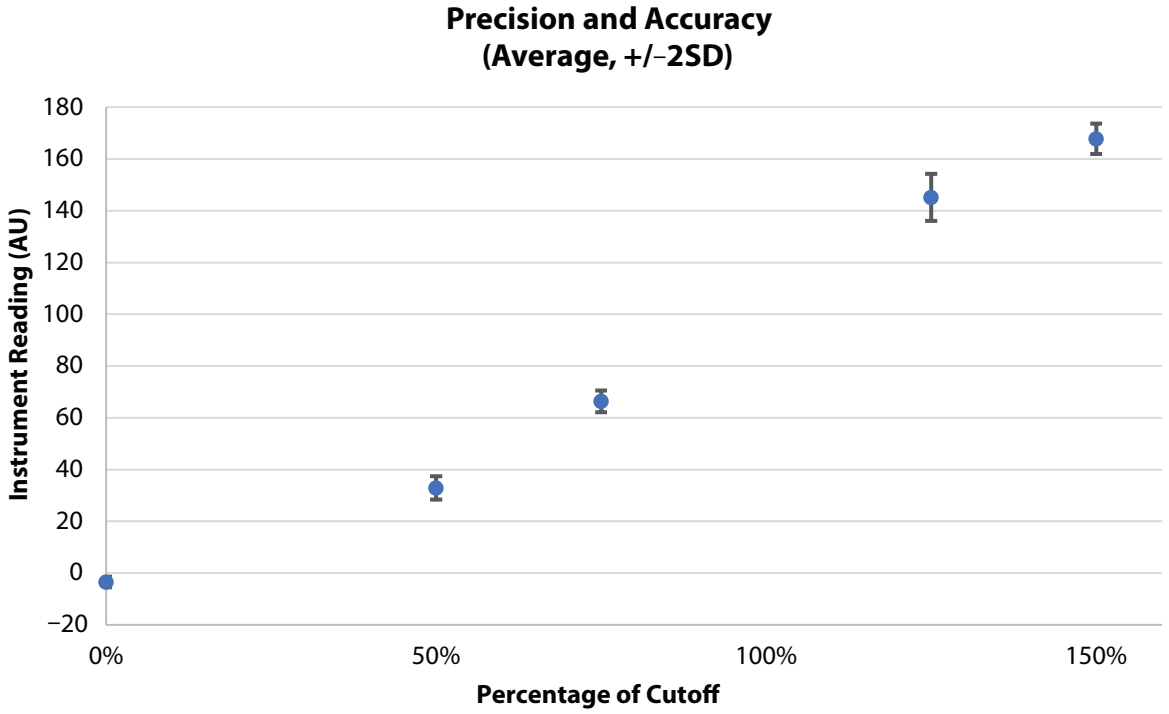
Precision and Accuracy

The laboratory must characterize the precision of the immunoassay using at least five replicates of calibrator measurand at critical concentrations relative to the cutoff. The concentrations relative to the cutoff should be distributed as follows:

- 0% of cutoff,
- 50% of cutoff,
- 75% of cutoff,
- 125% of cutoff, and
- 150% of cutoff.

The precision data are evaluated by calculating the mean, standard deviation (SD), and the coefficient of variation (CV). There should be no overlap of the 2SD ranges of the absorbance readings for the 0%, 75%, and 125% cutoff study samples. The study samples must exhibit the appropriate response relative to one another (i.e., study samples should yield appropriate responses versus the cutoff and the other study samples).

Exhibit 3. Example of Immunoassay Precision and Accuracy Study



Precision and Accuracy 50 ng/mL Cutoff			
Target	**Reps**	**Result AU**	**Precision**
0% of cutoff	1 2 3 4 5	–3.0 –3.4 –2.7 –5.2 –2.9	Mean: –3.4 SD: 1.0 CV: N/A 2SD range: –5.5 to –1.4
50% of cutoff	1 2 3 4 5	32.5 33.3 30.0 36.3 32.3	Mean: 32.9 SD: 2.3 CV: 6.9% 2SD range: 28.3 to 37.4
75% of cutoff	1 2 3 4 5	67.9 66.1 63.1 68.5 66.4	Mean: 66.4 SD: 2.1 CV: 3.2% 2SD range: 62.2 to 70.6

Precision and Accuracy 50 ng/mL Cutoff			
Target	**Reps**	**Result AU**	**Precision**
125% of cutoff	1 2 3 4 5	141 152 141 146 146	Mean: 145 SD: 4.5 CV: 3.1% 2SD range: 136 to 154
150% of cutoff	1 2 3 4 5	167 164 169 167 172	Mean: 168 SD: 2.9 CV: 1.8% 2SD range: 162 to 174

The precision and accuracy studies may be performed using separate batches on multiple days to characterize the intra-batch and inter-batch variability.

The laboratory must establish criteria for evaluating the statistical analysis. These must be described in the SOPs and the validation study summary.

Specificity and Interference

The laboratory is required to characterize and document immunoassay cross-reactivity for single and grouped analytes. For a single immunoassay for grouped analytes:

- The cross-reactivity to each "non-target" analyte in the group must be 80% or greater;
- The laboratory must maintain documentation of acceptable cross-reactivity from the kit manufacturer (e.g., package insert) and demonstrate that cross-reactivity of each non-target analyte is consistent with the manufacturer information;
- For the target analyte, the laboratory must analyze samples above and below the cutoff (at least 5 replicates at each concentration); and
- For each non-target analyte, the laboratory must analyze samples at the cutoff AND samples targeted to be 125% to 150% of the cutoff (at least 5 replicates at each concentration).

The laboratory is required to characterize the immunoassay performance when challenged with compounds that are commonly encountered in the testing population. Whether the presence of a compound would reduce or increase the immunoassay response of the target analyte is of concern. Compounds to be evaluated include illicit drugs, over-the-counter and prescription drugs at concentrations exceeding those encountered with therapeutic doses, and known adulterants (e.g., glutaraldehyde, iodate).

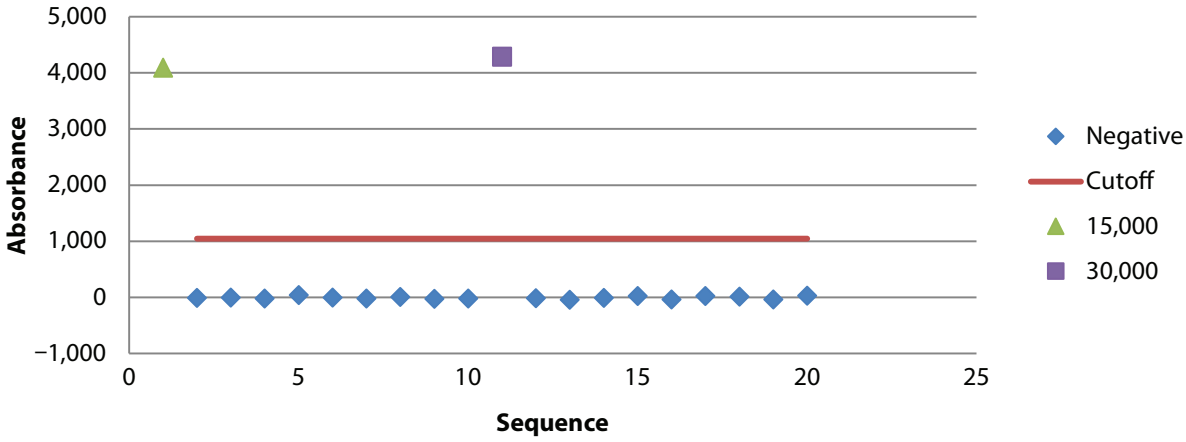
Some adulterants yield characteristic abnormal immunoassay responses. The laboratory should configure the analyzer to allow detection of immunoassay depression (e.g., "super-negative") and should establish criteria for identifying invalid or adulterated specimens based on the study results. Laboratories should follow requirements to identify immunoassay interference correctly:

- Correctly configure analyzers to allow detection of immunoassay depression,
- Evaluate the effect of varying concentrations of known adulterants (i.e., glutaraldehyde, iodate),
- Set criteria for identifying invalid specimens, and
- Correctly report performance testing samples containing compounds with known immunoassay interference.

Carryover

The laboratory is required to characterize the potential for carryover from one sample to another during testing. The laboratory should perform the carryover studies by analyzing highly concentrated samples followed by negative samples (i.e., without the analyte of interest) and evaluate the negative samples for carryover. The measurand concentrations in the highly concentrated samples should be realistic (i.e., high concentrations that may be found in the testing population) and at least as high as the established upper limit of linearity.

Exhibit 4. Example of Immunoassay Carryover Study



Immunoassay Carryover Check Samples		Absorbance Values (AU)	
		Sample Result	Cutoff Calibrator
1	15,000 ng/mL Spike	4,088	1,044
2	Certified Negative	−10	1,044
3	Certified Negative	−5	1,044
4	Certified Negative	−22	1,044
5	Certified Negative	37	1,044
6	Certified Negative	−4	1,044
7	Certified Negative	−23	1,044
8	Certified Negative	3	1,044
9	Certified Negative	−26	1,044
10	Certified Negative	−25	1,044
11	30,000 ng/mL Spike	4,285	1,044
12	Certified Negative	−18	1,044
13	Certified Negative	−44	1,044
14	Certified Negative	−13	1,044
15	Certified Negative	21	1,044
16	Certified Negative	−39	1,044
17	Certified Negative	24	1,044
18	Certified Negative	10	1,044
19	Certified Negative	−38	1,044
20	Certified Negative	26	1,044

The laboratory must establish criteria (i.e., allowable response or concentration) for evaluating the negative sample tested after a highly concentrated sample in carryover studies. These must be described in the validation study summary.

Positive/Negative Sample Differentiation

The laboratory is required to assess the ability of the assay to differentiate positive and negative samples. A mix of positive and negative samples that have been verified by a reference or confirmatory drug test method (i.e., a chromatographic method coupled with a mass spectrometric method, such as GC-MS or LC-MS/MS) are analyzed by the immunoassay method.

The samples used for testing may be a combination of negative donor specimens, controls, negative samples fortified with known amounts of the assayed drugs, non-NLCP performance test samples, or discarded positive donor specimens. The tested samples should be distributed at a minimum of 10 positive samples and 10 negative samples at differing concentrations.

All samples (positive and negative) should be tested in duplicate by immunoassay for a minimum of 40 results.

Exhibit 5. Example of Immunoassay Negative/Positive Differentiation Study

Immunoassay Negative/Positive Differentiation					
Sample	Absorbance Values (AU)			Result	GC-MS Reference
	Replicate #1	Replicate #2	Cutoff Calibrator		Morphine = m Codeine = c
654321	1635	1676	1029.5	POS	m-5481
654322	1340	1405	1029.5	POS	c-3093
654323	2656	2727	1029.5	POS	m-14602
654324	2506	2498	1029.5	POS	c2645, m4258
654325	3283	3229	1029.5	POS	c2332,m7791
654326	2745	2870	1029.5	POS	c6619, m3023
654327	2308	2349	1029.5	POS	c12977
654328	2614	2638	1029.5	POS	m7779
654329	2228	2204	1029.5	POS	c9182
654330	2978	2974	1029.5	POS	c3871
123456	−32	4	1029.5	NEG	CONFIRMED NEG
123457	−29	−30	1029.5	NEG	CONFIRMED NEG
123458	−26	9	1029.5	NEG	CONFIRMED NEG
123459	−27	−35	1029.5	NEG	CONFIRMED NEG
123460	−54	−48	1029.5	NEG	CONFIRMED NEG
123461	10	29	1029.5	NEG	CONFIRMED NEG
123462	−39	−2	1029.5	NEG	CONFIRMED NEG
123463	−60	1	1029.5	NEG	CONFIRMED NEG
123464	−17	−44	1029.5	NEG	CONFIRMED NEG
123465	−20	−18	1029.5	NEG	CONFIRMED NEG

Exhibit 5. Example of Immunoassay Negative/Positive Differentiation Study (continued)

Positive/Negative Concordance	Reference Negative	Reference Positive
Outcome Negative	20	0
Outcome Positive	0	20
Sensitivity	$= \frac{\text{true positives}}{\text{true positives} + \text{false negatives}}$	100%
Specificity	$= \frac{\text{true negatives}}{\text{true negatives} + \text{false positives}}$	100%
Overall	$= \frac{\text{true negatives} + \text{true positives}}{(\text{true} + \text{false negatives}) + (\text{true} + \text{false positives})}$	100%

The laboratory must establish criteria (allowable response or concordance) for evaluating the differentiation studies. These must be described in the validation study summary.

Parallel Studies

The laboratory must perform a parallel study using the existing and new/revised procedures or new instrument. The laboratory must analyze at least 100 specimen aliquots that were tested in the past 24 hours and are scheduled to be discarded. Results from the revised/new method or new instrument are compared with results from the existing method/instrument. Any discrepancies should be investigated and explained. Parallel studies may not be necessary if the validation is for an original assay (i.e., the laboratory has no existing assay for that measurand).

Exhibit 6. Example of Immunoassay Parallel Study

Immunoassay Comparison						
Sample	Absorbance Values (AU)			Reference Result	Test Result	Comparison
	Replicate #1	Replicate #2	Cutoff Calibrator			
654321	1635	1676	1029.5	POS	POS	TRUE
654322	1340	1405	1029.5	POS	POS	TRUE
654323	2656	2727	1029.5	POS	POS	TRUE
654324	2506	2498	1029.5	POS	POS	TRUE
654325	3283	3229	1029.5	POS	POS	TRUE
654326	2745	2870	1029.5	POS	POS	TRUE
654327	2308	2349	1029.5	POS	POS	TRUE
654328	2614	2638	1029.5	POS	POS	TRUE
654329	2228	2204	1029.5	POS	POS	TRUE
654330	2978	2974	1029.5	POS	POS	TRUE
654331	3564	2015	1029.5	POS	POS	TRUE
654332	3309	2079	1029.5	POS	POS	TRUE
654333	2646	2668	1029.5	POS	POS	TRUE
654334	1878	1441	1029.5	POS	POS	TRUE
654335	399	232	1029.5	NEG	NEG	TRUE
654336	2079	2645	1029.5	POS	POS	TRUE
654337	1141	1028	1029.5	POS	NEG	FALSE
654338	1445	2080	1029.5	POS	POS	TRUE
654339	3699	1315	1029.5	POS	POS	TRUE
654340	2942	1336	1029.5	POS	POS	TRUE
654341	3492	3216	1029.5	POS	POS	TRUE
654342	1038	2957	1029.5	POS	POS	TRUE
654343	2769	2051	1029.5	POS	POS	TRUE
654344	2489	2701	1029.5	POS	POS	TRUE
654345	2583	1418	1029.5	POS	POS	TRUE
654346	800	986	1029.5	NEG	NEG	TRUE
654347	3264	3810	1029.5	POS	POS	TRUE

Exhibit 6. Example of Immunoassay Parallel Study (continued)

Positive/Negative Concordance	Reference Negative	Reference Positive
Outcome Negative	18	2
Outcome Positive	0	80
Sensitivity	$= \frac{\text{true positives}}{\text{true positives} + \text{false negatives}}$	98%
Specificity	$= \frac{\text{true negatives}}{\text{true negatives} + \text{false positives}}$	100%
Overall	$= \frac{\text{true negatives} + \text{true positives}}{(\text{true} + \text{false negatives}) + (\text{true} + \text{false positives})}$	98%

The laboratory must establish criteria (allowable response or concordance) for evaluating the parallel studies. These must be described in the validation study summary.

References

1. Guillemin R, Schally AV, Yalow R. The Nobel Prize in Physiology or Medicine. 1977. Available from: http://neurosci.info/courses/systems/Nobels/1977%20Guillemin%20&%20Schally/Press%20Release.pdf
2. RTI International. Analytical methods in workplace drug testing immunoassay, National Laboratory Certification Program Training Courses. RTI International; n.d. Contract No.: available to NLCP inspectors and staff of HHS-certified laboratories.
3. U.S. Department of Health and Human Services, Substance Abuse and Mental Health Services Administration, Center for Substance Abuse Prevention. Medical review officer guidance manual for federal agency workplace drug testing programs. 2020. Contract No.: Rev 0722. Available from: https://www.samhsa.gov/sites/default/files/2020-mro-manual.pdf
4. Mandatory Guidelines for Federal Workplace Drug Testing Programs using Oral Fluid (effective January 1, 2020), 84 FR. Sect. 57554-57600 (2019).
5. Mandatory Guidelines for Federal Workplace Drug Testing Programs using Urine (effective October 1, 2017), 82 FR. Sect. 7920-7970 (2017).
6. RTI International, Center for Forensic Sciences Manual for Oral Fluid Laboratories, National Laboratory Certification Program (NLCP). Research Triangle Park, NC: RTI International, Center for Forensic Sciences; 2020. Contract No.: Rev. 0222.

7. RTI International, Center for Forensic Sciences. Manual for Urine Laboratories, National Laboratory Certification Program (NLCP). Research Triangle Park, NC: RTI International, Center for Forensic Sciences; 2017. Contract No.: Rev. 0222.
8. ANSI/ASB Standard 036. Standard Practices for Method Validation in Forensic Toxicology. 2019. Available from: https://www.aafs.org/sites/default/files/media/documents/036_Std_e1.pdf
9. Clinical Laboratory Improvement Amendments (CLIA), Standards and Certification, Laboratory Requirements, Subpart K, Standard: Establishment and verification of performance specifications, 42 CFR. Sect. Part 493.1253.

F. Leland McClure, MSc, PhD, F-ABFT, is a recognized expert in the fields of pharmacology and toxicology, with over 30 years of toxicology experience, including testing for drugs of abuse. He is an inspector for the National Laboratory Certification Program and previously served as the Responsible Person for an HHS-certified laboratory. Dr. McClure is a Fellow of the American Board of Forensic Toxicology (ABFT). From 1989 to 2019, he was employed by Quest Diagnostics, most recently as the Corporate Medical Affairs Director for Prescription Drug Monitoring and Toxicology. He currently works as a drug testing, toxicology, and pharmacology subject matter consultant.