CEDIA® AB-PINACA Assay

Thermo SCIENTIFIC

For Criminal Justice and Forensic Use Only

REF 10022971 (3 x 17 mL Kit)
10022977 (65 mL Kit)

Intended Use

The CEDIA® AB-PINACA assay is intended for the qualitative and semi-quantitative detection and estimation of the parent compound and metabolites of AB-PINACA, AB-CHMINACA, and AB-FUBINACA in human urine at a cutoff of 20 ng/mL. The assay is intended to be used in laboratories and provides a simple and rapid analytical screen to detect AB-PINACA-related synthetic cannabinoids compounds and metabolites in human urine.

The assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to confirm an analytical result. Gas chromatography/mass spectrometry (GC/MS) and Liquid Chromatography/tandem mass spectrometry (LC-MS/MS) are the preferred confirmatory method. [1]

The semi-quantitative mode is for detection and for the purpose of enabling laboratories to determine an appropriate dilution of the specimen for confirmation by a confirmatory method such as Liquid chromatography/tandem mass spectrometry (LC-MS/MS) or permitting laboratories to establish quality control procedures.

Clinical and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used. For Criminal Justice and Forensic Use Only.

Summary and Explanation of the Test

Synthetic cannabinoids is a mixture of herbs, spices or shredded plant material that is typically sprayed with a synthetic compound chemically similar to THC, the psychoactive ingredient in marijuana. It is sold in small, silvery plastic bags of dried leaves and marketed as incense that can be smoked. It is said to resemble potpourri. It is also sold as Bliss, Black Mamba, Bombay Blue, Blaze, Genie, Spice, Zohai, JWH -018, JWH-073, JWH-250, Yucatan Fire, Skunk and Moon Rocks. K2 products are usually smoked in joints or pipes, but some users make it into a tea. Short term effects include loss of control, lack of pain response, increased agitation, pale skin, seizures, vomiting, profuse sweating, uncontrolled / spastic body movements, elevated blood pressure, heart rate and palpitations.[2] The onset of this drug is 3-5 minutes, and the duration of the high is 1-8 hours. In addition to physical signs of use, users may experience: dysphoria, severe paranoia, delusions, hallucinations and increased agitation. On March 1, 2011, DEA published a final order in the Federal Register temporarily placing five synthetic cannabinoids into Schedule I of the Controlled Substance Act CSA. Thus, there is an urgent need to develop an immunoassay for detection of synthetic cannabinoids using automated clinical analyzers.[2]

The CEDIA AB-PINACA Assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system.[3] The assay is based on bacterial (*Escherichia coli*) enzyme β-galactosidase, which has been genetically engineered into two inactive fragments (enzyme donor and enzyme acceptor). These fragments spontaneously re-associate to form fully active enzyme that, in assay format, cleave a substrate, generating a color change that can be measured spectro-photometrically.

In the assay, drug in the specimen competes with the drug conjugated to enzyme donor (ED) for antibody binding sites. If the analyte is present in the sample, it binds to the antibody, leaving the ED conjugate free to form active enzyme with the enzyme acceptor (EA). If drug is not present in the sample, the antibody binds to drug conjugated to ED, inhibiting the re-association of ED to EA, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of drug present in the sample.

Reagents

1 EA Reconstitution Buffer
Contains buffer salts, mouse monoclonal anti-AB-PINACA antibody, stabilizer, and preservative.

1a EA Reagent
Contains 0.171 g/L enzyme acceptor, buffer salts, and preservative.

2 ED Reconstitution Buffer
Contains buffer salts, stabilizer, and preservative.

2a ED Reagent
Contains 0.215 mg/L enzyme donor conjugated with the AB-PINACA derivative, 1.67 g/L chlorophenol red-β-D-galactopyranoside, stabilizers, detergent and preservative.

Additional Materials (sold separately):

REF	Kit Description
10022930	CEDIA Negative Calibrator III (1 x 10 mL)
10022931	CEDIA AB-PINACA 5 ng/mL Calibrator (1 x 5 mL)
10022932	CEDIA AB-PINACA 20 ng/mL Calibrator (1 x 5 mL)
10022933	CEDIA AB-PINACA 50 ng/mL Calibrator (1 x 5 mL)
10022934	CEDIA AB-PINACA 100 ng/mL Calibrator (1 x 5 mL)
10022935	CEDIA AB-PINACA Control set (10 ng/mL and 30 ng/mL, 2 x 5 mL each)

⚠ Warnings and Precautions

The reagents are harmful if swallowed.

DANGER: The powder reagents contain ≤ 55% w/w bovine serum albumin (BSA) fragments and ≤ 1% w/w sodium azide.
The liquid reagents contain ≤ 0.5% bovine serum, ≤ 0.2% sodium azide and < 0.1% drug-specific antibody (Mouse).
H317 - May cause allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
EUH032 - Contact with acids liberates very toxic gas.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. Wear protective gloves/eye protection/face protection. In case of inadequate ventilation wear respiratory protection. IF ON SKIN: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Wash contaminated clothing before reuse. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

In a case of accidental spill, clean and dispose of material according to your laboratory's SOP, local and state regulations.

In a case of damaged packaging on arrival, contact your technical support representative (refer to back page of this package Insert).

Reagent Preparation and Storage

For preparation of the solutions, refer to the section below. Remove the kit from refrigerated storage (2-8°C) immediately prior to preparation of the solutions. Do not use the reagents beyond the expiration dates.

Prepare the solutions in the following order to minimize possible contamination.

R2 Enzyme Donor Solution
Connect Bottle 2a (ED reagent) to Bottle 2 (ED Reconstitution Buffer) using one of the enclosed adapters. Mix by gentle inversion, ensuring that all the lyophilized material from Bottle 2a is transferred into Bottle 2. Avoid the formation of foam. Detach Bottle 2a and adapter from Bottle 2 and discard. Cap Bottle 2 and let stand approximately 5 minutes at room temperature (21-25°C). Mix again. Record the reconstitution date on the bottle label. Place the bottle directly into the reagent compartment of the analyzer or into refrigerated storage (2-8°C) and let stand 30 minutes before use.

R1 Enzyme Acceptor Solution
Connect Bottle 1a (EA reagent) to Bottle 1 (EA Reconstitution Buffer) using one of the enclosed adapters. Mix by gentle inversion, ensuring that all the lyophilized material from Bottle 1a is transferred into Bottle 1. Avoid the formation of foam. Detach Bottle 1a and adapter from Bottle 1 and discard. Cap Bottle 1 and let stand approximately 5 minutes at room temperature (21-25°C). Mix again. Record the reconstitution date on the bottle label. Place the bottle directly into the reagent compartment of the analyzer or into refrigerated storage (2-8°C) and let stand 30 minutes before use.

⚠ **NOTE 1:** The components supplied in this kit are intended for use as an integral unit. Do not mix components from different lots.

⚠ **NOTE 1:** Avoid cross-contamination of reagents by matching reagent caps to the proper reagent bottle. The R2 solution (Enzyme Donor) should be yellow-orange in color. A red or red-purple color indicates that the reagent has been contaminated and must be discarded. Discard reagent 1 and/or 2 if turbidity or precipitates are observed.

⚠ **NOTE 1:** The R1 and R2 solutions must be at the reagent compartment storage temperature of the analyzer before performing the assay. Refer to the analyzer specific application sheet for additional information.

Store reagents at 2-8°C. **DO NOT FREEZE.**

For shelf life of the unopened components, refer to the box or bottle labels for the expiration date.

R1 Solution: 60 days refrigerated or at 2-8°C.
R2 Solution: 60 days refrigerated or at 2-8°C.

Specimen Collection and Handling

Collect urine specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed.

Specimens kept at room temperature that do not receive initial test within 7 days of arrival at the laboratory should be placed into a secure refrigeration unit at 2 to 8°C for up to 12 weeks.[4, 5] For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20°C.[5]

Laboratories following the SAMHSA mandatory guidelines should refer to SAMHSA "Short-Term Refrigerated Storage" and "Long-Term Storage" requirements.[4]

To protect the integrity of the sample, do not induce foaming and avoid repeated freezing and thawing. An effort should be made to keep pipetted samples free of gross debris. It is recommended that grossly turbid specimens be centrifuged before analysis. Frozen samples should be thawed and mixed prior to analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

Handle all urine specimens as if they were potentially infectious.

Assay Procedure

The CEDIA AB-PINACA assay is intended for use on automated clinical analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 570 nm and timing the reaction accurately can be used to perform this immunoassay.

Refer to specific application instructions for each analyzer for chemistry parameters before performing the assay.

Qualitative Analysis

For qualitative analysis, use the CEDIA AB-PINACA 20 ng/mL Calibrator as the cutoff level.

Semi-quantitative Analysis

For semi-quantitative analysis, use all five calibrators.

Quality Control and Calibration

Good laboratory practice requires the use of control specimens to ensure proper assay performance. Ensure that control results are within the established ranges, as determined by laboratory procedures and guidelines. If results fall outside of the established ranges, assay results are invalid. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements. Each laboratory should establish its own quality control testing frequency.

Results and Expected Values

Qualitative

The 20 ng/mL calibrator is used as a cutoff reference for distinguishing the 'positive' from the 'negative' samples. A sample that exhibits a change in absorbance values (ΔA) equal to or greater than that obtained from the cutoff calibrator is considered as positive. A sample that exhibits a change in absorbance value (ΔA) lower than that obtained from the cutoff calibrator is considered as negative.

Semi-quantitative

An estimate of drug concentrations in the samples can be obtained by running a standard curve with all calibrators and estimating sample concentrations off the standard curve. Sample results above the high calibrator should be diluted with the negative urine calibrator and be retested.

Limitations

1. A positive result from this assay indicates the presence of AB-PINACA, AB-CHMINACA, AB-FUBINACA and/or other structurally related compounds, and does not necessarily correlate with the extent of physiological and psychological effects. This is a test for primary screening. All positive results must be confirmed via GC/MS or LC-MS/MS.
2. It is possible that substances other than those investigated in the specificity study may interfere with the test and cause false results.
3. Care should be taken when reporting concentration results since there are many factors e.g. fluid intake and other biologic factors that may influence a urine test result.
4. Performance characteristics for the CEDIA AB-PINACA assay performance have not been established with body fluids other than human urine.

Specific Performance Characteristics

Typical performance results obtained on Beckman Coulter AU680 analyzer are shown below. The results obtained in your laboratory may differ from these data.

Precision

The analyte of the assay calibrators and controls was spiked into pooled negative human urine to the levels of 10 ng/mL (50%, Low-control level), 15 ng/mL (75% level), 20 ng/mL (100%, cutoff level), 25 ng/mL (125% level), and 30 ng/mL (150%, High-control level). The spiked urine samples were tested using a modified Clinical Laboratory and Standards Institute (CLSI) protocol to obtain both qualitative and semi-quantitative data. Results presented below were generated by testing the samples in replicates of 6, twice per day for 5 days, total n=60.

Qualitative

Conc. (ng/mL)	% of Cutoff (20 ng/mL)	Total Precision (n=60)	
		Number of Determinations	Immunoassay Results (Negative/Positive)
10	-50%	60	60/0
15	-25%	60	60/0
25	+25%	60	0/60
30	+50%	60	0/60

Semi-quantitative (ng/mL)

Conc. (ng/mL)	Mean (n=60)	% Recovery	Within Run Precision		Total Precision	
			SD	% CV	SD	% CV
10 ng/mL (-50%)	10.1	101%	0.68	6.74%	0.95	9.35%
15 ng/mL (-25%)	51.3	102%	0.53	3.50%	0.62	4.08%
20 ng/mL (100%)	20.0	100%	0.69	3.46%	0.81	2.01%
25 ng/mL (+25%)	25.2	101%	0.93	3.68%	1.06	4.21%
30 ng/mL (+50%)	30.6	102%	0.95	3.10%	1.22	3.98%

Accuracy

A total of 90 urine specimens were tested. Out of the 34 samples positive by immunoassay, 4 samples were confirmed as negative by LC-MS/MS.

		LC-MS/MS +	LC-MS/MS -
CEDIA AB-PINACA Assay (cutoff 20 ng/mL)	+	30	4**
	-	6*	50

* Semi-quantitative results were between 10 and 20 ng/mL.
** Samples were detected as greater than 20 ng/mL, but were not confirmed by LC-MS/MS for all the metabolites.

Specificity

The cross-reactivity of the AB-PINACA assay to synthetic cannabinoids compounds was determined by adding known amounts of each analyte into drug-free human urine.

The following table lists cross-reactivity of compounds structurally related to AB-PINACA (including AB-PINACA metabolites, derivatives, additional synthetic cannabinoids compounds, and natural cannabinoids) using the cutoff at 20 ng/mL.

Synthetic Cannabinoids Compounds	Tested Concentration (ng/mL)	Observed Concentration (SQ Conc) (ng/mL)	% Cross-reactivity
AB CHMINACA M1A	14	25	179%
5F-AB-PINACA	14	20.8	149%
AB-CHMINACA M1B	18	22.2	123%
AB-PINACA 5OH pentyl	20	23.7	119%
AB-PINACA 4OH	20	23.7	119%
AB-PINACA N-(4-fluoropentyl) isomer	20	21.6	108%
AB-PINACA pentanoic acid	20	20	100%
AB-FUBINACA	25	23.4	94%
5F-AB-PINACA N-(4-hydroxypentyl) metabolite	28	24.2	86%
AB-PINACA	25	20.1	80%
AB-PINACA N-(3-fluoropentyl) isomer	32	22.7	71%
AB-FUBINACA 3-fluorobenzyl isomer	40	21.5	54%
AB-CHMINACA	66	25.5	39%
AB-CHMICA	120	35	29%
AB-PINACA N-(2-fluoropentyl) isomer	85	23	27%
AB-FUBINACA isomer 1	150	23.1	15%
5-chloro AB-PINACA	140	21.4	15%
5F-ABICA	200	24.8	12%
ADB-FUBINACA	310	21.2	6.8%

Table continued

Synthetic Cannabinoids Compounds	Tested Concentration (ng/mL)	Observed Concentration (SQ Conc) (ng/mL)	% Cross-reactivity
ADB-PINACA pentanoic acid	450	21	4.7%
APP-CHMINACA	475	21	4.4%
5F-AMB	510	21	4.1%
AMB	730	21.4	2.9%
AB-FUBINACA 2-fluorobenzyl isomer	800	20.4	2.6%
ADB-PINACA RM	2,500	32.1	1.3%
ADBICA	2,500	24.8	1%
APP-FUBINACA	2,500	22.2	0.9%
EMB-FUBINACA	2,500	20.0	0.8%
AB-FUBINACA 2-fluorobenzyl isomer	5,000	31.9	0.6%
MAB-CHMINACA RM (ADB-CHMINACA)	5,000	33.7	0.7%
JWH-250 N-(5-carboxypentyl) metabolite	5,000	26.5	0.5%
ADBICA pentanoic acid	10,000	35.0	0.4%
JWH-250 N-(4-hydroxypentyl) metabolite	10,000	34.1	0.3%
MDMB-CHMINACA	10,000	26.3	0.3%
MA-CHMINACA	10,000	19.5	0.2%
AB CHMINACA M2	10,000	15.9	0.16%
AB-FUBINACA isomer 5	10,000	17.7	0.18%
AB-CHMINACA M3A	10,000	16.5	0.17%
AB-PINACA cabonyl metabolite	10,000	15.1	0.15%
STS-135	10,000	10.3	0.1%
JWH-018 adamantyl carboxyamide	10,000	9.6	0.1%
AB-FUBINACA 2A metabolite	10,000	9.3	0.09%
AB-CHMINACA M6	10,000	8.8	0.09%
JWH-073 N-(4-hydroxybutyl) metabolite	10,000	8.7	0.09%
JWH-250 N-(5-hydroxypentyl) metabolite	10,000	6.7	0.07%
AB-FUBINACA isomer 2	10,000	4.9	0.05%
MDMB-FUBINACA	10,000	4.7	0.05%
AB-FUBINACA 2B metabolite	10,000	4.6	0.05%
5F-AKB-48 4OH pentyl	10,000	0.1	0.001%
5F-JWH-018 adamantyl analog	10,000	1.1	0.01%
A-796260	10,000	1.6	0.02%
A-836339	10,000	0.1	0.001%
AB-CHMINACA 2'-indazole isomer RM	10,000	1.1	0.001%
AB-CHMINACA M4	10,000	0.7	0.011%
AB-CHMINACA M5A	10,000	1.2	0.007%
AB-CHMINACA M7	10,000	0.5	0.012%
AKB-48 N-(4-hydroxypentyl) metabolite	10,000	0.7	0.005%
AKB-48 4OH pentyl	10,000	0.7	0.007%
AKB-48 pentanoic acid	10,000	0.2	0.002%
AM1220	10,000	0.8	0.008%
AM2201 6-hydroxyindole metabolite	10,000	1.3	0.013%
AM2201 N-(4-fluoroentyl) isomer	10,000	1.1	0.011%
AM2201 N-(4-hydroxypentyl) metabolite	10,000	0.7	0.007%
AM2233	10,000	1.1	0.011%
AM694	10,000	0.8	0.008%

Table continued

Synthetic Cannabinoids Compounds	Tested Concentration (ng/mL)	Observed Concentration (SQ Conc) (ng/mL)	% Cross-reactivity
FUB-AMB	10,000	0.5	0.005%
JWH-018 5-hydroxyindole metabolite	10,000	0.6	0.006%
JWH-018 7-hydroxyindole metabolite	10,000	0.8	0.008%
JWH-018 adamantyl analog	10,000	0.9	0.009%
JWH-018 N-(3-methylbutyl) isomer	10,000	0.3	0.003%
JWH-018 N-(4-hydroxypentyl) metabolite	10,000	1.1	0.011%
JWH-018 N-(5-hydroxypentyl) metabolite	10,000	1.2	0.012%
JWH-018 N-(5-hydroxypentyl) beta-D-glucuronide	10,000	1.3	0.013%
JWH-018 N-pentanoic acid	10,000	0.9	0.009%
JWH-019 (exempt group)	10,000	0.8	0.008%
JWH-020	10,000	0.8	0.008%
JWH-073 5-hydroxyindole metabolite	10,000	0.6	0.006%
JWH-073 N-(2-methyl propyl) isomer	10,000	1.9	0.019%
JWH-073 N-(3-hydroxybutyl) metabolite	10,000	1.4	0.014%
JWH-200 (exempt prep)	10,000	0.7	0.007%
JWH-200 5-hydroxyindole metabolite	10,000	1.1	0.011%
JWH-200 6-hydroxyindole metabolite	10,000	0.7	0.007%
JWH-398 (exempt prep)	10,000	1.2	0.012%
JWH-398 N-(5-hydroxypentyl) metabolite	10,000	0.3	0.003%
MDMB-CHMICA	10,000	0.8	0.008%
MDMB-FUBINACA	10,000	4.7	0.047%
PB-22 3 carboxyindole metabolite	10,000	2.1	0.021%
PB-22 N-(4-hydroxypentyl)-3-carboxyindole metabolite	10,000	1.4	0.014%
PB-22 N-(5-hydroxypentyl)-3-carboxyindole metabolite	10,000	1.3	0.013%
PB-22 N-pentanoic acid-3-carboxyindole	10,000	0.5	0.005%
UR-144 N-pentanoic acid	10,000	1.4	0.014%
UR-144 N-(5-bromopentyl) analog	10,000	0.7	0.007%
UR-144 N-(5-hydroxypentyl) beta-D-glucuronide	10,000	1.8	0.018%
UR144 N-(5-hydroxypentyl) metabolite	10,000	1.5	0.015%
UR-144 N-5-chloropentyl analog	10,000	1.1	0.011%
UR-144 N-heptyl analog	10,000	1.4	0.014%
XLR11-N(4-hydroxypentyl)	10,000	0.5	0.005%

The following table lists cross-reactivity of Synthetic Cannabinoids compounds produced **negative** results at the concentrations tested using the cutoff at 20 ng/mL.

Synthetic Cannabinoids Compounds	Tested Concentration (ng/mL)
A-796269	10,000
A-834735	10,000
AB-005	10,000
AB-005	10,000
AKB-48 5OH pentyl	10,000
FUB-144	10,000
JWH-019 N-(6-hydroxyhexyl)	10,000
JWH-022	10,000
JWH-073 6-hydroxyindole metabolite	10,000

Table continued

Synthetic Cannabinoids Compounds	Tested Concentration (ng/mL)
JWH-073 N-(2-hydroxybutyl)	10,000
JWH-122-N-(4-hydroxylpentyl)	10,000
MO-CHMINACA	10,000
UR-144 degradant	10,000
UR-144 N-(2-hydroxylpentyl) metabolite	10,000
UR144-N-(4-hydroxylpentyl)	10,000
UR144-N-(4-hydroxylpentyl)	10,000
UR-144 N-5-chloropentyl analog	10,000
XLR11 N-(2-fluoropentyl) isomer	10,000
XLR11 N-(4-pentanyl) analog	10,000

The potential cross-reactivity posed by drugs commonly co-administered was evaluated by adding each substance to drug free urine at the concentration indicated. A drug was considered to cross-react if the observed AB-PINACA concentrations result exceeded 20 ng/mL. As shown in the tables below, all the pharmacologic compounds evaluated, including a number of opiate compounds, exhibited no cross reactivity at the concentrations tested.

Opiates compounds produced a negative result at the concentration listed below

Opiate Compounds	Tested Concentration (ng/mL)
6-Acetylmorphine	100,000
Buprenorphine	100,000
Codeine	100,000
Codeine glucuronide	100,000
Dextromethorphan	100,000
Dihydrocodeine	100,000
Heroin	100,000
Hydrocodone	100,000
Hydromorphone	100,000
Levorphanol	100,000
Morphine	100,000
Morphine-3-β-D-glucuronide	100,000
Morphine-6-β-D-glucuronide	100,000
Nalbuphine	100,000
Nalorphine	100,000
Naloxone	100,000
Naltrexone	100,000
Norbuprenorphine	100,000
Norcodeine	100,000
Normorphine	100,000
Noroxycodone	100,000
Noroxymorphone	100,000
Oxycodone	100,000
Oxymorphone	100,000
Oxymorphone-β-D-glucuronide	100,000
Thebaine	100,000

Structurally unrelated compounds and other concomitantly used drugs produced a negative result at the concentrations listed below.

Compounds	Tested Concentration (ng/mL)
1,3-dimethyluric acid	100,000
2-Hydroxyethylflurazepam	100,000
3'-methyl-alpha-Pyrrolidinopropiophenone	100,000
3-methyl Xanthine	100,000
4-methoxy PV8	100,000

Table continued

Compounds	Tested Concentration (ng/mL)
4-methyl-alpha-Pyrrolidinobutiophenone	100,000
4'-methyl-alpha-Pyrrolidinohexanophenone	100,000
4'-methyl-alpha-Pyrrolidinopropiophenone	100,000
7-Aminoclonazepam	100,000
7-Aminoflunitrazepam	100,000
7-Aminonitrazepam	100,000
11-hydroxytetrahydrocannabinol	100,000
11-nor-9-Carboxy-tetrahydrocannabinol	10,000
Acetoaminophen	100,000
alpha-Hydroxyalprazolam	100,000
alpha-Hydroxytriazolam	100,000
alpha-PVP	100,000
Amitryptyline	100,000
Amoxicillin	100,000
(+/-)Amphetamine	100,000
S-(+)Amphetamine	100,000
Ampicillin	100,000
Aripiprazole	100,000
Benzoylecgonine	100,000
Bromazepam	100,000
Cannabidiol	100,000
Carbamazepine	100,000
Carbamazepine epoxide	100,000
Ceftriaxone	100,000
Cephalexin	100,000
Chlordiazepoxide	100,000
Chlorpromazine	50,000
Cimetidine	100,000
Clobazam	100,000
Clomipramine	100,000
Clorazepate	100,000
Cocaine	100,000
Delorazepam	100,000
delta-9-Tetrahydrocannabinol	10,000
Desalkylflurazepam	100,000
Desipramine	100,000
Digoxin	100,000
Dihydrocodeine	100,000
DL-Kavain	100,000
EDDP (2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine)	100,000
EMDP (2-Ethyl-5-methyl-3,3-diphenylpyrroline)	100,000
Ephedrine	100,000
Estazolam	100,000
Ethacrynic acid	100,000
Ethylone	100,000
Fentanyl	100,000
Flunitrazepam	100,000
Fluoxetine	100,000
Fluphenazine	9,000
Flurazepam	100,000
Furosemide	100,000
Gabapentin	100,000

Table continued

Compounds	Tested Concentration (ng/mL)
Hydrochlorothiazide	100,000
Hydroxychloroquine	100,000
Imipramine	100,000
Lamotrigine	100,000
Lorazepam	100,000
Lormetazepam	100,000
m-CPP (meta-Chlorophenylpiperazine)	100,000
MDA (3,4-Methylenedioxyamphetamine)	100,000
(+/-)MDEA-D6 (3,4-Methylenedioxy-N-ethylamphetamine)	100,000
MDMA (3,4-methylenedioxy-methamphetamine)	100,000
MDPV	100,000
Medazepam	100,000
Meoproolol Tartrate	100,000
Meperidine	100,000
Mephedrone	100,000
S-(+)Methamphetamine	100,000
Methiopropamine	100,000
Methadone	100,000
Methylone	100,000
Metolazone	100,000
Metoprolol Tartrate	100,000
Midazolam	100,000
Mitragynine (Kratom)	40,000
Nitrazepam	100,000
N,N-Dimethylcathinone	100,000
N,N-DMA	100,000
Norchlordiazepoxide	100,000
(+/-)Norketamine HCl	100,000
Normeperidine	100,000
Norproxyphene	100,000
Norproxyphene (Maleate)	100,000
Nortryptiline	100,000
Oxaprozin	100,000
Oxazepam	100,000
Pentobarbital	100,000
phencyclidine	100,000
Phenobarbital	100,000
Prazepam	100,000
Promazine	100,000
Promethazine	100,000
Propranolol	100,000
Protriptyline	100,000
Ranitidine	100,000
(R,R)Pseudo-ephidrine	100,000
(S,S)Pseudo-ephidrine	100,000
Quetiapine	100,000
Ranitidine	100,000
Reperidone	100,000
Secobarbital	100,000
Sertraline HCl	100,000
Temazepam	100,000
Tetracycline	100,000

Table continued

Compounds	Tested Concentration (ng/mL)
Theophylline	100,000
Thioridazine	100,000
Topiramate	100,000
Thrombin	100,000
Trazadone	60,000
Triazolam	100,000
Trimipramine	100,000
u47700 (trans-3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methyl-benzamide)	100,000
Venlafaxine	100,000
W-15 (4-chloro-N-[1-(2-phenylethyl)-2-piperidinylidene]-benzenesulfonamide)	100,000

Interference

The potential interference of pH and endogenous physiologic substances on recovery of the AB-PINACA immunoassay Controls using the assay was assessed by spiking the known compounds of potentially interfering substances into the Low (10 ng/mL) and the High (30 ng/mL) Controls for testing against 20 ng/mL cutoff. No interference was observed for compounds listed below at the tested concentrations.

Compounds	Tested Concentration (mg/dL)	Spiked calibrator analyte level	
		Low Control	High Control
Acetaminophen	10	NEG	POS
Acetone	500	NEG	POS
Acetyl Salycylic Acid	10	NEG	POS
Ascorbic Acid	150	NEG	POS
Caffeine	10	NEG	POS
Creatinine	400	NEG	POS
Ethanol	10	NEG	POS
Galactose	5	NEG	POS
Glucose	1000	NEG	POS
Hemoglobin	150	NEG	POS
Human Serum Albumin	200	NEG	POS
Ibuprophen	10	NEG	POS
Oxalic acid	50	NEG	POS
Riboflavin	3	NEG	POS
Sodium Chloride	1000	NEG	POS
Urea	1000	NEG	POS
pH 5 to 9	N/A	NEG	POS

References

1. *Mandatory Guideline for Federal Workplace Drug Testing Programs*. National Institute on Drug Abuse. Federal Register Vol. 73, No. 228, 2008:71893.
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3. Henderson D, et al., CEDIA, A new homogenous immunoassay system. Clin. Chem. 1986; 32(9): 1637 – 1641.
4. *Notice of Mandatory Guidelines for Federal Workplace Drug Testing Program: Final Guidelines*; Federal Register, Substance Abuse and Mental Health Administration (SAMHSA), (1994) 110 (June 9):11983.
5. "Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline", Second Edition, C52-A2, Clinical and Laboratory Standards Institute, April 2007.

Key to Symbols Used

 Manufacturer

 Caution

 Lot Number/Batch Code

 Use-by Date

 Consult Instructions for Use

 Catalog Number

 Temperature Limit

 Health Hazard

 Reagents

 Contents

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