CEDIA® Buprenorphine OFT Assay

Thermo SCIENTIFIC

For Criminal Justice and Forensic Use Only
(For Use with Oral-Eze® Oral Fluid Collection System)

REF 10022352 (65 mL Kit)

Intended Use

The Thermo Scientific CEDIA® Buprenorphine OFT Assay is intended for use in the qualitative determination of Buprenorphine in human oral fluid at a cutoff concentration of 3 ng/mL in neat oral fluid. The assay is calibrated against Buprenorphine and is performed on clinical chemistry analyzers. The assay must be used with the CEDIA Buprenorphine OFT Calibrators and Controls. The oral fluid specimen must be collected exclusively with the Oral-Eze® Oral Fluid Collection System. This device is not intended for use for clinical diagnostic applications.

The CEDIA Buprenorphine OFT Assay provides only a preliminary analytical test result. A more specific alternative method must be used to obtain a confirmed analytical result. Gas Chromatography/Mass Spectrometry (GC/MS) and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS/MS) are the preferred confirmatory methods.[1] Clinical consideration and professional judgment should be applied to any drug of abuse test result particularly when preliminary positive results are used.

Summary and Explanation of the Test

Buprenorphine is a semi-synthetic opioid derived from thebaine, and is used clinically as a substitute therapy for opioid dependence.[2] Subutex® and Suboxone® are the commonly prescribed drugs containing buprenorphine.[3-5] Buprenorphine and its metabolite norbuprenorphine are both commonly found in oral fluid specimens.[6]

The CEDIA Buprenorphine OFT Assay uses recombinant DNA technology to produce a unique homogeneous enzyme immunoassay system.[8] The assay is based on the bacterial enzyme β-galactosidase, which has been genetically engineered into two inactive fragments. These fragments spontaneously re-associate to form fully active enzyme that, in the assay format, cleaves a substrate, generating a color change that can be measured spectrophotometrically.

In the assay, analyte in the sample competes with analyte conjugated to one inactive fragment (enzyme donor) of β-galactosidase for antibody binding site. If analyte is present in the sample, it binds to antibody, leaving the inactive enzyme fragment free to form active enzyme. If the analyte is not present in the sample, antibody binds to analyte conjugated on the inactive fragment, inhibiting the re-association of inactive β-galactosidase fragments, and no active enzyme is formed. The amount of active enzyme formed and resultant absorbance change are directly proportional to the amount of analyte present in the sample.

Reagents

1 EA Reconstitution Buffer
Contains buffer salts, mouse monoclonal anti-buprenorphine antibody 0.2 - 0.25 mg/L, stabilizer, and preservative.

1a EA Reagent
Contains 0.171 g/L Enzyme Acceptor *(Escherichia coli)*, buffer salts and preservative.

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

2a ED Reagent
Contains 0.175 mg/L Enzyme Donor *(Escherichia coli)* conjugated to buprenorphine derivative, 1.67 g/L chlorophenol red-β-D-galactopyranoside, stabilizers, detergent and preservative.

Additional Materials Required (sold separately)

REF	Kit Description
10014954	CEDIA Multi-Drug OFT Negative Calibrator
10022376	CEDIA Buprenorphine OFT Cutoff Calibrator
10022377	CEDIA Buprenorphine OFT Control Set
96100-050	Oral-Eze Oral Fluid Collection System (50/Box)
96100-500	Oral-Eze Oral Fluid Collection System (500/Box)
96105-050	Oral-Eze Oral Fluid Sample Extractor (50/Box)
96105-500	Oral-Eze Oral Fluid Sample Extractor (500/Box)

⚠ Precautions and Warning

The test is for Criminal Justice and Forensic use only. The reagents are harmful if swallowed. Do not use the reagents beyond their expiration dates.

DANGER: The powder reagents contain ≤55% w/w Bovine Serum Albumin (BSA.) and ≤1% w/w Sodium Azide. 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 the case of accidental spill, clean and dispose of material according to your laboratory's SOP, local, and state regulations.

In the 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.

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 for 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 for 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 2: 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.

NOTE 3: 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 on analyzer or at 2-8°C.

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

Specimen Collection and Handling

Oral fluid samples are suitable for use in the CEDIA Buprenorphine OFT Assay. Collect oral fluid samples using the Oral-Eze Oral Fluid Collection System. Care should be taken to preserve the chemical integrity of the oral fluid sample from the time it is collected until the time it is assayed by securely capping the samples, storing the samples at 2-8°C or at room temperature (21-25°C), and testing within 21 days after collection.

NOTE: Handle oral fluid samples as if they were potentially infectious.

Samples within a pH range of 5-9 are suitable for testing with this assay.

Oral-Eze Sample Processing Procedure

1. Label the sample collection vial with proper identification.
2. Check the sample collection date on the vial to ensure that the sample is within 21 days from the date of collection.
3. Open the cap and compress the pad to express the sample.
4. Recap the vial and the sample is ready for testing.
5. Ensure that the oral fluid samples are maintained between 4°C and 37°C during shipping.
6. Samples can be stored at room temperature (21-25°C) for 21 days. They should be stored at 2-8°C.

Assay Procedure

The Oral-Eze Oral Fluid Collection System contains a preservative buffer that dilutes the neat oral fluid sample. The calibrator and control levels are set at diluted levels so that sample absorbance values can be compared directly to the absorbance value of the cutoff calibrator. The assay result is reported as a positive or negative result relative to the neat oral fluid cutoff of 3 ng/mL. The concentrations reported in this insert refer to the neat oral fluid concentration, unless otherwise noted.

NOTE: To correlate the Oral-Eze result from the assay or the associated LC-MS/MS confirmation result to a neat oral fluid value, the result from the Oral-Eze sample should be multiplied by a factor of 3.

1. Pipet the processed oral fluid samples, calibrators, and controls into labeled cups and place the cups onto the analyzer.
2. Load reagents (reagent 1 and reagent 2) into the reagent compartment of the analyzer.
3. Program the run setup using 570 nm as a primary wavelength and 660 nm as the secondary wavelength. Refer to the parameter sheet for detailed instructions on how to program the analyzer.
4. Use the cutoff calibrator as a reference for distinguishing negative from positive samples.

Quality Control

The CEDIA Buprenorphine OFT Control Set is designed to be used with the CEDIA Buprenorphine OFT Assay. Good laboratory practice suggests the use of control specimens to ensure proper assay performance. Ensure that control results are within the established ranges determined by laboratory practices and guidelines. If control results fall outside of 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.

Interpretation of Results

A sample that exhibits a change in absorbance (ΔA) value equal to or greater than the value obtained with the cutoff calibrator is considered positive. A sample that exhibits a change in absorbance (ΔA) value lower than the value obtained with the cutoff calibrator is considered negative.

Drug Recovery

Recovery of drugs from the collection pad using the preservative buffer was determined by LC-MS/MS method. Processed oral fluid samples on average recovered within ± 20% of their expected value based on the corresponding neat oral fluid result.

Limitations

A positive result from this assay indicates only the presence of buprenorphine and does not necessarily correlate with the extent of physiological and psychological effects.

It is possible that other substances and/or factors (e.g. technical or procedural), other than those investigated in the specificity study may interfere with the test and cause false results.

Specific Performance Characteristics

Typical performance results obtained on the Beckman Coulter AU680 analyzer are shown below.

Precision and Cutoff Characterization

Negative neat oral fluid samples were collected and prepared by spiking buprenorphine at negative, -75%, -50% and -25% below the cutoff, at the cutoff, and +25%, +50%, +75% and 100% above the cutoff. All spiked neat oral fluid sample concentrations were confirmed by LC-MS/MS. The neat oral fluid samples were processed using the Oral-Eze Oral Fluid Collection System to obtain diluted oral fluid samples. The diluted oral fluid samples were confirmed by LC-MS/MS and tested in the CEDIA Buprenorphine OFT Assay in qualitative mode.

The randomized CLSI (EP5-A2) precision protocol was followed with two replicates of each sample for each run, two runs per day for twenty non-consecutive days, total N= 80/level.

The results are summarized in the table below.

Analyte	Tested Concentration in Neat Oral Fluid (ng/mL)	Neat Oral Fluid LC-MS/MS (ng/mL)	Diluted Oral Fluid LC-MS/MS (ng/mL)	CEDIA Buprenorphine OFT Assay # Neg / # Pos
Buprenorphine	0	0	0	80 Neg / 0 Pos
Buprenorphine	0.75	0.75	0.28	80 Neg / 0 Pos
Buprenorphine	1.50	1.53	0.54	80 Neg / 0 Pos
Buprenorphine	2.25	2.34	0.78	80 Neg / 0 Pos
Buprenorphine	3.00	3.24	0.98	57 Neg / 23 Pos

Table continued

Analyte	Tested Concentration in Neat Oral Fluid (ng/mL)	Neat Oral Fluid LC-MS/MS (ng/mL)	Diluted Oral Fluid LC-MS/MS (ng/mL)	CEDIA Buprenorphine OFT Assay # Neg / # Pos
Buprenorphine	3.75	3.9	1.28	0 Neg / 80 Pos
Buprenorphine	4.50	4.8	1.6	0 Neg / 80 Pos
Buprenorphine	5.25	5.61	1.79	0 Neg / 80 Pos
Buprenorphine	6.00	6.51	2.13	0 Neg / 80 Pos

Specificity and Cross-Reactivity

Buprenorphine, its metabolites, and compounds structurally related to buprenorphine were tested for cross-reactivity in the assay. The cross-reactant solutions were prepared by adding the compounds to neat oral fluid samples at the concentration listed in the table below. The neat oral fluid samples were processed using the Oral-Eze Oral Fluid Collection System to obtain diluted oral fluid samples which were tested in the CEDIA Buprenorphine OFT Assay. The compounds listed below produced a positive result at the lowest concentrations tested.

Compounds	Tested Concentration In Neat Oral Fluid (ng/mL)	CEDIA Buprenorphine OFT Assay Negative/Positive	% Cross-reactivity
Burenorphine	3	Positive	100%
Norbuprenorphine	3	Positive	100%
Buprenorphine glucuronide	7,500	Positive	0.04%
Norbuprenorphine glucuronide	7,500	Positive	0.04%

The compounds listed below produced a negative result at the concentrations tested.

Compounds	Tested Concentration In Neat Oral Fluid (ng/mL)	CEDIA Buprenorphine OFT Assay Negative/Positive	% Cross-reactivity
6-Acetylmorphine	30,000	Negative	0.01
Amisulpride	300,000	Negative	0.001
Chloroquine	100,000	Negative	0.003
Codeine	300,000	Negative	0.001
Dextromethorphan	100,000	Negative	0.003
Dihydrocodeine	100,000	Negative	0.003
EDDP	100,000	Negative	0.003
EMDP	100,000	Negative	0.003
Fentanyl	100,000	Negative	0.003
Heroin	60,000	Negative	0.005
Hydrocodone	100,000	Negative	0.003
Hydromorphone	100,000	Negative	0.003
Hydroxy chloroquine	300,000	Negative	0.001
7-Hydroxymitragynine	20,000	Negative	0.015
LAAM	300,000	Negative	0.001
Levorphanol	100,000	Negative	0.003
Meperidine	100,000	Negative	0.003
Methadone	100,000	Negative	0.003
Mitragynine (Kratom)	20,000	Negative	0.015
Morphine	100,000	Negative	0.003
Morphine-3β-D-glucuronide	100,000	Negative	0.003
Morphine-6β-D-glucuronide	100,000	Negative	0.003
Nalorphine	100,000	Negative	0.003
Naloxone	100,000	Negative	0.003
Naltrexone	100,000	Negative	0.003
Norcodeine	100,000	Negative	0.003
Norpropoxyphene	100,000	Negative	0.003
Noroxycodone	100,000	Negative	0.003

Table continued

Compounds	Tested Concentration In Neat Oral Fluid (ng/mL)	CEDIA Buprenorphine OFT Assay Negative/Positive	% Cross-reactivity
Oxycodone	100,000	Negative	0.003
Oxymorphone	100,000	Negative	0.003
Sulpiride	300,000	Negative	0.001
Tapentadol	100,000	Negative	0.003
Tramadol	100,000	Negative	0.003

Various common over-the-counter medications and structurally unrelated compounds were tested for cross-reactivity in the assay. The cross-reactant solutions were prepared by adding the compounds at the concentrations listed in the table below to neat oral fluid samples containing buprenorphine at ± 50% of the cutoff concentration. The neat oral fluid samples were processed using the Oral-Eze Oral Fluid Collection System to obtain diluted oral fluid samples which were tested in the CEDIA Buprenorphine OFT Assay. The ± 50% cutoff level samples were detected accurately indicating that the added compounds did not exhibit any cross-reactivity in the assay.

Compounds	Tested Concentration In Neat Oral Fluid (ng/mL)	CEDIA Buprenorphine OFT Assay Negative/Positive	
		-50% Buprenorphine	+50% Buprenorphine
Acetaminophen	60,000	Negative	Positive
Acetylsalicylic Acid	60,000	Negative	Positive
Alprazolam	60,000	Negative	Positive
Amobarbital	60,000	Negative	Positive
Amoxicillin	7,500	Negative	Positive
Ampicillin	60,000	Negative	Positive
Atropine	60,000	Negative	Positive
Benzoylecgonine	60,000	Negative	Positive
Buproprion	60,000	Negative	Positive
Butabarbital	60,000	Negative	Positive
Butalbital	60,000	Negative	Positive
Caffeine	60,000	Negative	Positive
Captopril	60,000	Negative	Positive
Chlordiazepoxide	60,000	Negative	Positive
Chlorpromazine	60,000	Negative	Positive
Cimetidine	60,000	Negative	Positive
Clonazepam	60,000	Negative	Positive
Cocaethylene	60,000	Negative	Positive
Cocaine	60,000	Negative	Positive
l-Cotinine	60,000	Negative	Positive
Cyclizine	60,000	Negative	Positive
Diacetylmorphine	60,000	Negative	Positive
Diazepam	60,000	Negative	Positive
Digoxin	60,000	Negative	Positive
Enalapril	60,000	Negative	Positive
Fluoxetine	60,000	Negative	Positive
Gentisic Acid	60,000	Negative	Positive
Ibuprofen	60,000	Negative	Positive
Imipramine	60,000	Negative	Positive
Lidocaine	60,000	Negative	Positive
Loperamide	60,000	Negative	Positive
Metoprolol	60,000	Negative	Positive
Nalbuphine	60,000	Negative	Positive
Naproxen	60,000	Negative	Positive
Niacinamide	60,000	Negative	Positive
Nicotine	60,000	Negative	Positive
Nifedipine	60,000	Negative	Positive

Table continued

Compounds	Tested Concentration In Neat Oral Fluid (ng/mL)	CEDIA Buprenorphine OFT Assay Negative/Positive	
		-50% Buprenorphine	+50% Buprenorphine
Nordiazepam	60,000	Negative	Positive
Penicillin	60,000	Negative	Positive
Pentobarbital	60,000	Negative	Positive
Phencyclidine	60,000	Negative	Positive
β-Phenethylamine	60,000	Negative	Positive
Phenobarbital	60,000	Negative	Positive
Procainamide	60,000	Negative	Positive
Propoxyphene	60,000	Negative	Positive
Quinidine	60,000	Negative	Positive
Salbutamol	60,000	Negative	Positive
Salicylic Acid	60,000	Negative	Positive
Secobarbital	60,000	Negative	Positive
Temazepam	60,000	Negative	Positive
Δ9 -THC	60,000	Negative	Positive
11-nor- Δ9 -THC-COOH	60,000	Negative	Positive
Theophylline	60,000	Negative	Positive
Tolmetin	60,000	Negative	Positive
Verapamil	60,000	Negative	Positive
Zomepirac	60,000	Negative	Positive

Endogenous and Exogenous Substances and pH Interference

The potential interference from several endogenous and exogenous substances, and pH on the detection accuracy of samples containing buprenorphine at ± 50% of the cutoff concentration was tested in the assay. The interfering substances were added to neat oral fluid at the concentrations listed in the table below. The neat oral fluid samples were processed using the Oral-Eze Oral Fluid Collection System to obtain diluted oral fluid samples which were tested in the CEDIA Buprenorphine OFT Assay. The ± 50% cutoff level samples were detected accurately indicating that the added compounds did not show any interference in the assay.

Substances	Tested In Neat Oral Fluid	CEDIA Buprenorphine OFT Assay Negative/Positive	
		-50% Buprenorphine	+50% Buprenorphine
Low Control	1.5 ng/mL	Negative	Positive
High Control	4.5 ng/mL	Negative	Positive
Cotinine	0.03 mg/mL	Negative	Positive
Nicotine	0.03 mg/mL	Negative	Positive
Human Serum Albumin	30 mg/mL	Negative	Positive
Sodium Chloride	18 mg/mL	Negative	Positive
Ascorbic Acid	0.9375 mg/mL	Negative	Positive
Coffee	6% v/v	Negative	Positive
Orange Juice	6% v/v	Negative	Positive
Cranberry Juice	6% v/v	Negative	Positive
Soft Drink	6% v/v	Negative	Positive
Mouthwash	6% v/v	Negative	Positive
Tea	6% v/v	Negative	Positive
Denture Adhesive	6% v/v	Negative	Positive
Alcohol (Ethanol)	6% v/v	Negative	Positive
Baking Soda	6% v/v	Negative	Positive
Cough Syrup	6% v/v	Negative	Positive
Whole Blood	6% v/v	Negative	Positive
Hydrogen Peroxide	1.5% v/v	Negative	Positive
pH	5-9	Negative	Positive

Additional Interference From Other Food and Dental Products

Potential interference from additional compounds was tested by collecting neat oral fluid from volunteers after use of the following substances: hard candy, chewing gum, chewing tobacco, cigarettes, water, milk, toothpaste and tooth whitening strips. The ± 50% cutoff level samples in the presence of above interfering substances were detected accurately in the CEDIA Buprenorphine OFT Assay.

Method Comparison

Eighty six samples were tested in the CEDIA Buprenorphine OFT Assay in qualitative mode and the results were compared to LC-MS/MS. Comparison of the LC-MS/MS to the CEDIA Buprenorphine OFT Assay are shown below.

When run by immunoassay with no programming of extra wash steps to counteract potential sample carryover, the overall concordance between the CEDIA Buprenorphine OFT Assay and LC-MS/MS using a cutoff of 3.0 ng/mL in neat oral fluid is 94.2%. The comparison of sample results by the CEDIA Buprenorphine OFT Assay to LC-MS/MS showed 100% sensitivity and 87.5% specificity.

Candidate Device Results	Negative (Less than half the cutoff concentration by LC-MS/MS analysis)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff by LC-MS/MS analysis)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS analysis)	High Positive (greater than 50% above the cutoff concentration by LC-MS/MS analysis)
Negative	31	4	0	0
Positive	*1	*4	8	38

*Discrepant samples by Immunoassay.

When all the positive samples by immunoassay were rerun in the assay using the recommended wash protocol comprising two detergent washes and one water wash on the AU680, the overall concordance between the CEDIA Buprenorphine OFT Assay and LC-MS/MS using a cutoff of 3.0 ng/mL in neat oral fluid improved to 98.8%. The comparison of sample results by the CEDIA Buprenorphine OFT Assay to LC-MS/MS showed 100% sensitivity and 97.5% specificity.

Candidate Device Results	Negative (Less than half the cutoff concentration by LC-MS/MS analysis)	Near Cutoff Negative (Between 50% below the cutoff and the cutoff by LC-MS/MS analysis)	Near Cutoff Positive (Between the cutoff and 50% above the cutoff concentration by LC-MS analysis)	High Positive (greater than 50% above the cutoff concentration by LC-MS/MS analysis)
Negative	32	7	0	0
Positive	0	**1	8	38

**Discrepant sample is borderline.

References

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4. Fischer G, Gombas W, Eder H, Jagsch R, Peternell A, Stuhlinger G, Pezawas L, Aschauer HN, Kasper S. Buprenorphine versus methadone maintenance for the treatment of opioid dependence. Addiction 1999; 94:1337-47.
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7. Henderson DR, Friedman SB, Harris JD, et al. CEDIA, a new homogeneous immunoassay system. Clin Chem 1986; 32:1637-1641.

Explanation of Symbols

LOT	Lot Number
REF	Catalog Number
	Temperature Limitation
	Consult Instructions for Use
	Use By
	Caution
	Manufacturer
	Health Hazard
REAGENT	Reagent
CONTENTS	Contents
→	Require Reconstitution

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