DRG® Opiates (serum/blood) (EIA-4927 and EIA-4928)

USA: RUO

As of 29 Dec. 2008 (Vers. 1.0)

INTENDED USE

The Opiates ELISA for serum and whole blood is intended for use in clinical and forensic laboratories. It provides qualitative screening results for Opiates in human serum and whole blood at a cut-off concentration of 100 ng/mL.

This assay provides only a preliminary analytical test result. Clinical consideration and professional judgement must be applied to any substance abuse test result, particularly in evaluating a preliminary positive result. In order to obtain a more confirmed analytical result a more specific alternative chemical method is needed. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method.

For routine analysis of forensic whole blood samples we recommend dilution of the sample in distilled water by a factor of 1 in 5.
For example, 50 µL blood added to 200 µL of water. Please contact technical support for further details.

PRINCIPLE OF THE TEST

The Opiates ELISA Kit is a competitive enzyme immunoassay for the detection of Opiates in human serum and whole blood. The wells of the microtitre strips are coated with anti-Opiates antibody. During the first incubation, the horseradish peroxidase (HRP) labelled Opiates competes with the free Opiates in the patient sample for the anti-Opiates antibody binding sites on the microtitre strips.

The wells are washed to remove any excess enzyme material prior to addition of the TMB substrate solution. Addition of the stop solution terminates the reaction and absorbances are read spectrophotometrically at 450 nm.

REAGENTS

EIA-4927 – 1 plate kit, (EIA-4928 – 5 plate kit)

Anti-Opiates Coated Plate – 1 plate (5 plates) [a]
12 x 8 well strips in break-apart format. Anti-Opiates polyclonal antibody immobilised on a polystyrene plate supplied in dry form. Contains BSA 0.001%

Enzyme Conjugate – 15 mL (55 mL) [b]
Opiate derivative labelled with horseradish peroxidase <0.1% (v/v) and diluted in a protein matrix with stabilisers. Contains preservatives

Wash Buffer – 50 mL (50 mL) [c]
30 x concentrate, 0.1% (v/v) surfactant.
Dilute each vial to 1500 mL with distilled water before use.

Substrate Solution – 20 mL (55 mL) [d]
One bottle containing < 0.05% 3,3',5,5'-tetramethylbenzidine.

Stop Solution – 20 mL (55 mL) [e]
One bottle containing 1 mol/L sulphuric acid. Treat this solution as corrosive.

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Negative Calibrator – 1 mL (4 mL) [f]
Protein matrix negative for Opiates

Positive Calibrators – 1 mL each level (4 mL each level)
Protein matrix containing 5 ng/mL Morphine [g]
Protein matrix containing 10 ng/mL Morphine [h]
Protein matrix containing 100 ng/mL Morphine [i]
Protein matrix containing 500 ng/mL Morphine [j]
Contains preservatives

WARNING AND PRECAUTIONS

1. The handling of food or drink near the kit reagents is not recommended.
2. Any skin complaints, cuts or abrasions should be suitably protected.
3. Proper handling of all reagents is strongly advised. It is suggested that disposable materials are used to avoid contamination of Substrate Solution. Discard Substrate Solution if obvious blue colour develops.
4. Some of the assay reagents contain sodium azide which may react with copper or lead plumbing to form potentially explosive metal azides. When disposing of these reagents, always flush with a large volume of water to prevent azide build up.
5. Do NOT mouth pipette reagents.
6. Do NOT add sodium azide to samples as a preservative!
7. Keep all containers closed when not in use to avoid microbial contamination.
8. Do NOT use reagents after the expiration date.
9. Do NOT mix reagents from different kits or manufacturers.
10. Do NOT freeze reagents.
11. It is suggested that all reagents be kept out of direct sunlight whenever possible
12. Stop Solution is corrosive; handle with care.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Positive and negative controls.
2. Automated microtitre plate reader with a 450 nm filter, no temperature regulation required for the reader.
3. Precision pipettes with disposable tips. Use clean tips for each reagent to avoid contamination.
4. Automated microtitre plate washing machine, manual microtitre plate washer or 350 µL eight-channel pipette for dispensing diluted wash buffer.
5. A timer for timing 30 minute intervals.
6. A clean measuring cylinder for dilution of wash buffer concentrate.

7. Distilled or deionised water.

SPECIMEN COLLECTION AND STORAGE

If the sample cannot be analysed immediately, store at 2-8°C for up to 28 days or at -20°C for longer storage.

Handle all specimens as if they were potentially infectious.

STORAGE AND STABILITY OF REAGENTS

Store all opened/unopened reagents at 2-8°C. The reagents are stable until the expiration date indicated on the reagent labels.

Surplus microtitre strips must be repackaged immediately in the resealable foil pouch with desiccant. Failure to follow the storage instructions may result in deterioration in the performance of the assay.

Crystals may form in the wash buffer on storage. Ensure these are all transferred when diluting the wash buffer.

The substrate should be clear in colour. Any blue colouring indicates that the reagent has been contaminated and must be discarded. Do not expose the substrate to light.

Turbidity or precipitation in any kit component is an indication of deterioration and the component should be discarded.

PROCEDURE

1.1 Assay Procedure

Prepare Wash Buffer by diluting 1:30 in distilled water.

Note: Allow all reagents to come to room temperature (20-27°C) before use. At the discretion of the operator, all samples, calibrators, and controls should be tested in duplicate.

1. Add 25 µL of sample, calibrator, or control to each well within 25 minutes.
2. Add 100 µL of Enzyme Conjugate to each test well.
3. Incubate for 30 minutes.
4. Wash the plate four times with 350 µL Wash Buffer using a plate washer.
5. Add 100 µL of Substrate Solution to each well and incubate for 30 minutes.
6. Add 100 µL of Stop Solution to each well.
7. Measure the absorbance at 450 nm within 15 minutes.

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QUALITY CONTROL

Calibrators should be included each time an assay is performed.

Read the stopped assay within 15 minutes.

Controls are not supplied with the kit but users should follow the appropriate federal, state, and local guidelines concerning the running of external quality controls.

The negative control must have an absorbance greater than the 100 ng/mL calibrator.

The positive control must have an absorbance less than the 100 ng/mL calibrator.

If the positive or negative controls do not have an absorbance less than or greater than the 100 ng/mL calibrator respectively, then the assay results are invalid. The assay should be repeated, if the control results are still out with the limits mentioned above contact Technical Services at DRG.

INTERPRETATION OF THE RESULT

Positive Result

any sample with an absorbance less than or equal to the 100 ng/mL cut off calibrator is considered a positive.

A positive result does not provide any information on the level of intoxication or concentration of the drug, it only indicates that the sample may contain drug above the cut-off level in qualitative terms.

Negative Result

any sample with an absorbance greater than the 100 ng/mL cut-off calibrator is considered a negative.

A negative result does not necessarily indicate the absence of drug in the sample, it only indicates that the sample does not contain drug above the cut-off level in qualitative terms.

Note: Adulteration of reagents, use of instruments without appropriate capabilities, or other failure to follow instructions as set forth in the labelling can affect performance characteristics and stated or implied label claims.

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LIMITATIONS

A positive result from this assay should be confirmed by another generally accepted non-immunological method such as GC/MS. The test is designed for use with human serum and whole blood only.

There is a possibility that other substances and/or factors not listed may interfere in the test and cause false results, eg technical or procedural errors.

In the event of deterioration in the analytical performance of the device or damage to the kit during transport please contact Technical Services at DRG.

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SPECIFICITY

Non Cross Reactants at 100,000 ng/mL, relative to the cut-off concentration

7-Aminoflunitrazepam	EDDP	Nitrazepam
Alprazolam	EMDP	Norbuprenorphine
Amitriptyline	(-) Ephedrine	Nordiazepam
Amobarbital	(+) Ephedrine	Norfluoxetine
Amphetamine	Fenfluramine	Nor-LSD
Anhydroecgonine	Fentanyl	Oxazepam
Anhydroecgonine methyl ester	Flunitrazepam	Paracetamol
Ascorbic Acid	Fluoxetine	Pentobarbital
Aspirin	Hexobarbital	Phencyclidine
Benzoylecgonine	3-Hydroxyflunitrazepam	Pheniramine
Buprenorphine	11-Hydroxy Δ 9-THC	Phenobarbital
Butalbarbital	Ibuprofen	β Phenylethylamine
Caffeine	Ketamine	Phentermine
Cannabidiol	LAAM	Phenylpropanolamine
Chlordiazepoxide	Lidocaine	Prazepam
Chloroquine	Lorazepam	Propoxyphene
Chlorpheniramine	LSD	Propranolol
Clonazepam	MBDB	(-) Pseudoephedrine
Cocaethylene	MDA	(+) Pseudoephedrine
Cocaine	MDEA	Ranitidine
Cotinine	MDMA	Salicylate
Δ 9-THC	Methadone	Secobarbital
Desalkylflurazepam	Methamphetamine	Temazepam
Desmethylflunitrazepam	Midazolam	Triazolam
Diazepam	Naloxone	Tyramine
Dothiepin	Nicotine	Warfarin
Ecgonine methyl ester	11-nor-9-Carboxy- Δ 9-THC	

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Cross Reactants

Compounds Cross Reactants	ng/mL	Apparent morphine ng/mL	% Reactivity
6-Acetyl Morphine	100,000	> 500	--
	1,000	290.0	29.0%
	500	116.3	23.3%
	100	22.8	22.8%
	10	< 5	--
Codeine	100	> 500	--
	10	104.4	1044%
	5	45.1	903%
Dextromethorphan	100,000	115.0	0.12%
	10,000	6.1	0.06%
Dihydrocodeine	500	> 500	--
	100	419.2	419%
	10	45.2	452%
	5	20.0	400%
Heroin	500	> 500	--
	100	170.2	170%
	10	17.8	178%
	5	8.2	164%
Hydrocodone	500	> 500	--
	100	313.4	313%
	10	38.9	389%
	5	20.4	408%
Hydromorphone	100,000	> 500	--
	1,000	452.5	45.3%
	500	291.5	58.3%
	100	50.4	50.4%
	10	7.1	71.0%
	5	< 5	--
Meperidine	100,000	291.0	0.29%
	10,000	27.5	0.27%
	1,000	5.3	0.53%
	500	< 5	--
Morphine-3-Glucuronide	100,000	> 500	--
	1,000	86.3	8.6%

	500 100 10	47.7 12.3 < 5	9.5% 12.3% --
Nalorphine	100,000 10,000 10	283.0 28.9 < 5	0.29% 0.29% --
Norcodeine	100,000 1,000 500 100 10	> 500 31.6 20.7 6.7 < 5	-- 3.2% 4.1% 6.7% --
Normorphine	100,000 10,000 1,000	> 500 55.1 < 5	-- 0.55% --
Oxycodone	100,000 1,000 500 100 10	> 500 40.3 24.8 6.9 < 5	-- 4.0% 5.0% 6.9% --
Oxymorphone	100,000 1,000 100	> 500 8.2 < 5	-- 0.82% --

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SYMBOLS USED WITH DRG ASSAYS

Symbol	English	Deutsch	Français	Español	Italiano
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
CE	European Conformity	CE-Konfirmitäts-kennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
IVD	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
RUO	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
REF	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
LOT	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungstemperatur	Température de conservation	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeits-datum	Date limite d'utilisation	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distribuidor	Distributore
Content	Content	Inhalt	Conditionnement	Contenido	Contenuto
Volume/No.	Volume / No.	Volumen/Anzahl	Volume/Quantité	Volumen/Número	Volume/Quantità

Symbol	Portugues	Dansk	Svenska	Ελληνικά
	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisningen	Εγχειρίδιο χρήστη
CE	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
IVD	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
RUO				
REF	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
LOT	No do lote	Lot nummer	Batch-nummer	Αριθμός Παρτίδος
		Indeholder tilsttrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura de conservação	Opbevarings-temperatur	Förvaringstempratur	Θερμοκρασία αποθήκευσης
	Prazo de validade	Udløbsdato	Bäst före datum	Ημερομηνία λήξης
	Fabricante	Producent	Tillverkare	Κατασκευαστής
Content	Conteúdo	Indhold	Innehåll	Περιεχόμενο
Volume/No.	Volume/Número	Volumen/antal	Volym/antal	Όγκος/αριθ..

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