

DRG[®] Morphine (urine) (EIA-4925 and EIA-4926)

USA: 

Revised 10 Mar. 2010 rm (Vers. 2.0)

Please use only the valid version of the package insert provided with the kit.

INTENDED USE

The Morphine (Urine) ELISA is intended for use in the qualitative and quantitative determination of morphine in urine. Other versions of this kit are available in blood, serum, saliva and hair matrices.

The Morphine (Urine) ELISA provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC-MS) is the preferred confirmatory method. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

For routine analysis of urine samples we recommend dilution of the calibrators, controls and samples in distilled water by a factor of 1 in 10.

For example, 50 µL urine added to 450 µL of water.

REAGENTS

EIA-4925 - 1 plate kit (EIA-4926 - 5 plate kit)

Anti-Morphine coated plate - 1 plate (1 plate) (a)

12 x 8 well strips. Antibody immobilised on a polystyrene plate.

Contains BSA <0.001%

Enzyme conjugate -- 1 vial (1 vial) (b)

Morphine derivative labelled with horseradish peroxidase. Presented as a lyophilised powder.

Reconstitute with 1 mL of reconstitution buffer.

See attached data sheet for working dilution.

Enzyme should be aliquoted and frozen on the day of reconstitution.

Enzyme aliquot vials (empty) 5 vials (5 vials) (b)

Vials for enzyme storage.

Aliquot enzyme conjugate and store at -20°C.

Enzyme diluent -- 20 mL (2 x 30 mL) (bi)

Buffer containing a protein matrix with stabilisers. Ready to use.

Store at 2-8°C.

Enzyme reconstitution buffer -- 3 mL (3 mL) (bii)

Wash buffer -- 50 mL (50 mL) (c)

30 x concentrate, 0.1% (v/v) surfactant. Crystals may form on storage.

Dilute each vial to 1500 mL with distilled water before use.

DRG[®] Morphine (urine) (EIA-4925 and EIA-4926)

USA: 

Revised 10 Mar. 2010 rm (Vers. 2.0)

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 M sulphuric acid. Treat this solution as corrosive.

Negative calibrator -- 1 mL (4 mL) (f)

Urine matrix negative for morphine.

Positive calibrators -- 1 mL (4 mL) each level

Urine matrix containing 5 ng/mL morphine (g)

Urine matrix containing 25 ng/mL morphine (h)

Urine matrix containing 100 ng/mL morphine (i)

Contains preservatives.

WARNINGS 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. Do NOT mouth pipette reagents. Handle all specimens and reagents as if potentially infectious.
5. Do NOT add sodium azide to samples as a preservative!
6. Keep all containers closed when not in use to avoid microbial contamination.
7. Do NOT use reagents after the expiration date.
8. Do NOT mix reagents from different kits or manufacturers.
9. Do NOT freeze reagents.
10. It is suggested that all reagents be kept out of direct sunlight whenever possible.
11. Stop solution is corrosive; handle with care.
12. Sample addition should take no longer than 30 minutes.

REAGENT PREPARATION

Enzyme Conjugate

Using a calibrated pipette, add 1 mL of reconstitution buffer (bii) to the enzyme conjugate (b). Gently mix the vial for 10 minutes.

Prepare working enzyme conjugate in enzyme diluent (bi) as specified in the attached instructions.

Aliquot any reconstituted enzyme conjugate in the vials provided. Store at -20°C.

Discard unused working enzyme conjugate.



DRG[®] Morphine (urine) (EIA-4925 and EIA-4926)

USA: **RUO**

Revised 10 Mar. 2010 rm (Vers. 2.0)

Wash Buffer

Prepare wash buffer (c) by diluting 1:30 in distilled water.

ASSAY PROCEDURE

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.

We recommend diluting calibrators, controls and urine samples by 1 in 10 dilution with distilled water before assay

1. Add 10 µL of sample, calibrator (f, g, h, i), or control to each well. (See note 12 above)
2. Add 100 µL of working 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 (d) to each well and incubate for 30 minutes.
6. Add 100 µL of stop solution (e) to each well.
7. Measure the absorbance at 450 nm within 30 minutes.

STORAGE/STABILITY

Store all reagents at 2-8°C. The stability of this kit is a minimum of 6 months from the date of manufacture when stored at 2-8°C. The expiration date appears on all components.

DRG[®] Morphine (urine) (EIA-4925 and EIA-4926)

USA: 

Revised 10 Mar. 2010 rm (Vers. 2.0)

SPECIFICITY

A large range of non-related drugs were tested at 10,000 ng/mL in urine. No cross-reactivity was found. Please contact technical support for a full listing of these compounds.

The following compounds were tested using the qualitative procedure and compared to morphine.

Compound	ng/mL tested	Apparent morphine ng/mL	% cross-reactivity
Codeine	1000	<10	<1
	10,000	<10	<0.1
Morphine-3-glucuronide	1000	<10	<1
	10,000	62	0.62
Diacetylmorphine	1000	<10	<1
	10,000	21	0.2
Normorphine	10	4	40
	100	30	30
	1000	>200	---
Nalorphine	10	49	490
	100	>200	---
	1000	>200	---
6-Monoacetylmorphine	100	<10	<10
	1000	<10	<1
	10,000	<10	<0.1
Hydromorphone	100	<10	<10
	1000	<10	<1
	10,000	25	0.25
Hydrocodone	100	<10	<10
	1000	<10	<1
	10,000	<10	<0.1

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.

DRG® Morphine (urine) (EIA-4925 and EIA-4926)

USA: **RUO**

Revised 10 Mar. 2010 rm (Vers. 2.0)

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
	European Conformity	CE-Konformitätskennzeichnung	Conformité aux normes européennes	Conformidad europea	Conformità europea
	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
	For research use only	Nur für Forschungszwecke	Seulement dans le cadre de recherches	Sólo para uso en investigación	Solo a scopo di ricerca
	Catalogue number	Katalog-Nr.	Numéro de catalogue	Número de catálogo	Numero di Catalogo
	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
	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
	Diagnóstico in vitro	In vitro diagnostik	Diagnostik in vitro	in vitro διαγνωστικό
	Catálogo n.º	Katalognummer	Katalog nummer	Αριθμός καταλόγου
	No do lote	Lot nummer	Batch-nummer	Αριθμός Παρτίδος
		Indeholder tilstrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura de conservação	Opbevarings-temperatur	Förvaringstemperatur	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.