



Gebrauchsanweisung
Instructions for use
Instructions d'utilisation
Instrucciones de uso
Istruzioni per l'uso
Sposób użycia

nal von minden

Drug-Screen[®] Diptest

CE

IVD

Version 1.0

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1. Anwendungsbereich

Einstufige Sandwich-Immunoassays zur qualitativen Bestimmung verschiedener Drogen und Drogenmetaboliten im humanen Urin. Der Test ist nur für den professionellen Gebrauch vorgesehen (medizinische Fachkreise).

2. Testdurchführung

- Entnehmen Sie den Test der Umverpackung. Bei Multitests Schutzkappe abziehen. Kühl gelagerte Tests bzw. Urinproben vorher auf Raumtemperatur bringen.
- Tauchen Sie die Streifen ca. 10 - 15 Sekunden in den Urin; der Plastikrand darf den Urin nicht berühren.
- Lesen Sie das Ergebnis nach ca. 5 Minuten ab.



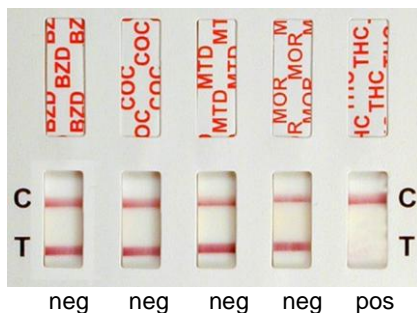
3. Testauswertung

Im Reaktionsfeld befinden sich die Testzonen (T) der nachzuweisenden Substanzen sowie eine Kontrollzone (C).

> Bei einem **negativen Ergebnis**, also einer drogen-freien Urinprobe, erscheint ein pinkfarbener Streifen in der Testzone (T) und ein Streifen in der Kontrollzone (C).

> Bei einem **positiven Ergebnis** ist nur noch ein Streifen in der Kontrollzone (C) erkennbar.

Ist in der Kontrollregion (C) kein Streifen erkennbar, so ist z.B. nicht genügend Urin aufgetragen worden und der Test ist ungültig!



4. Hinweis

Die Farbintensität der Streifen auf der Testmembran kann bei den einzelnen Parametern unterschiedlich sein. Nur wenn kein Streifen erscheint, ist der Test positiv. Positive und unklare Resultate sollten mit einer zweiten analytischen Methode bestätigt werden (z.B. GC/MS).

Buprenorphin wird ab einer Tagesdosis von 2 mg zuverlässig erfasst.

5. Warnungen und Vorsichtsmaßnahmen

- Nur für die *in vitro* Diagnose vorgesehen.
- Gebrauch nur für den Fachkreis bestimmt.
- Nach Ablauf des Verfalldatums den Test nicht mehr verwenden.
- Urinproben können infektiös sein. Deshalb werden saubere Handhabung und sichere Aufbewahrung von verwendeten Teststreifen in geeigneten Laborabfallbehältern empfohlen.
- Die Tests bei 2-30°C lagern und nicht einfrieren.
- Test bei beschädigter Schutzverpackung nicht mehr verwenden.
- Nach der Entnahme aus der Schutzverpackung Test sofort verwenden und nicht auf die Saugfläche greifen.
- Nur zum Einmalgebrauch.

6. Cut-offs (Abkürzung auf den Teststreifen in Klammern)

Parameter	Droge/Metabolit**	Cut-off (ng/ml)
AMP (Amphetamin)*	Amphetamin	1000
AMP (Amphetamin)*	Amphetamin	500
AMP (Amphetamin)*	Amphetamin	300
BAR (Barbiturate)	Secobarbital	300
BZD (Benzodiazepine)*	Oxazepam	300
BZD (Benzodiazepine)*	Oxazepam	200
BZD (Benzodiazepine)*	Oxazepam	100
BUP (Buprenorphin)	Buprenorphin-β3-D-Glucuronid	10
COC (Kokain)*	Benzoyllecgonin	300
COC (Kokain)*	Benzoyllecgonin	100
COT (Cotinin)	Cotinin	200
EDDP (Methadon Metabolit)	2-Ethylidin-1,5-Dimethyl-3,3-Diphenylpyrrolidin	100
FYL (Fentanyl)	Fentanyl	10
KET (Ketamin)	Ketamin	1000
MDA (Amphetamin)	Methylenedioxyamphetamin	500
MDMA/ XTC (Ecstasy)*	3,4-Methylenedioxy-	1000
MDMA/ XTC (Ecstasy)*	3,4-Methylenedioxy-	500
MET (Methamphetamin)*	Methamphetamin	1000
MET (Methamphetamin)*	Methamphetamin	500
MET (Methamphetamin)*	Methamphetamin	300
MOR 2000 (Morphin/Heroin)*	Morphin	2000
MOR 300 (Morphin/Heroin)*	Morphin	300
MOR 100 (Morphin/Heroin)*	Morphin	100
MQL (Methaqualon)	Methaqualon	300
MTD (Methadon)	Methadon	300
OXY (Oxycodon)	Oxycodon	100
PCP (Phencyclidin)	Phencyclidin	25
PCM (Paracetamol)	Paracetamol/Acetaminophen	5000
PPX (Propoxyphen)	Norpropoxyphen	300
TCA (Trizyk. Antidepressiva)	Nortriptylin	1000
THC (Marihuana)*	11-nor-Δ9-THC-9-COOH	150
THC (Marihuana)*	11-nor-Δ9-THC-9-COOH	50
THC (Marihuana)*	11-nor-Δ9-THC-9-COOH	25
TML (Tramadol)	Tramadol	100

* Es werden Teststreifen für die entsprechende Droge geliefert, bei denen der „Cut-off“ unterschiedlich hoch ist.

** Verbindung, die als Kalibrator zur Einstellung des jeweiligen Cut-Offs benutzt wurde.

7. Literatur

- Aniline O., Pittes, F. N., Phencyclidine (PCP): A review and perspectives. CRC Crit. Rev. Toxicol, 1982, 10, 145-177.
- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.
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- Urine Testing for Drugs of Abuse, National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.
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- Harvey, R.A., Champe, P.C. Lippincotts Illustrated Reviews. Pharmacology. 91-95, 1992.
- Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
- McBay, A. J., Clin. Chem. 33, 33B-40B, 1987.

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1. Intended Use

Single-sandwich immunoassays for qualitative determination of various drugs and drug metabolites in human urine. The test should only be used by medical professionals.

2. Procedure of the Test

- 1) Remove the test from the packaging. Bring urine samples to room temperature before performing the test.
- 2) Immerse the strip for approximately 10 to 15 seconds in the urine; be sure that the edge of the plastic does not touch the urine.
- 3) Wait approximately 5 minutes before reading the results.



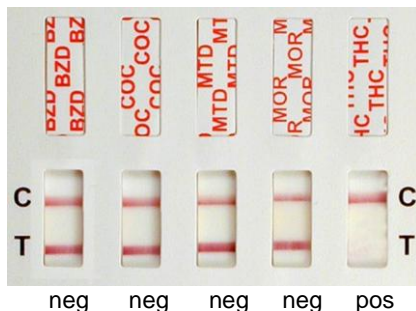
3. Interpretation of the Results

The test zone (T) detects drug substances found in the urine sample, the remaining zone (C) is the control zone.

> With a **negative result**, and therefore a drug-free urine sample, a pink stripe will appear in both the test zone (T) and in the control zone (C).

> With a **positive result** a pink stripe will only appear in the control zone (C).

If the control region (C) has no distinguishable line, not enough urine has been applied and the test is invalid!



4. Note

The intensity of the color stripe on the test field can vary depending on the parameters that are being tested. It is only when no stripe appears that the test is positive. Positive results should be confirmed by an additional testing method (GC / MS).

Buprenorphine will start being detected at a daily dose of 2 mg.

5. Warnings and Precautions

- For *in vitro* diagnostic use only.
- To be used by medical professionals only.
- After the expiry date, the test is no longer valid.
- Urine samples can be infectious. Therefore, clean handling and secure storage of test strips is recommended.
- Store the tests between 2-30°C and be sure to not freeze the tests.
- Tests with damaged packaging should not be used.
- After removing the test from the protective packaging, the test should be used immediately.
- For one time use only.

6. Cut-offs

Parameter	Drug / Metabolite**	Cut-off (ng/ml)
AMP (Amphetamine)*	Amphetamine	1000
AMP (Amphetamine)*	Amphetamine	500
AMP (Amphetamine)*	Amphetamine	300
BAR (Barbiturate)	Secobarbital	300
BZD (Benzodiazepine)*	Oxazepam	300
BZD (Benzodiazepine)*	Oxazepam	200
BZD (Benzodiazepine)*	Oxazepam	100
BUP (Buprenorphine)	Buprenorphine-β3-D-	10
COC (Cocain)*	Benzoylcegonine	300
COC (Cocain)*	Benzoylcegonine	100
COT (Cotinine)	Cotinine	200
EDDP (Methadone Metabolite)	2-Ethylidene-1,5-Dimethyl-3,3-Diphenylpyrrolidine	100
FYL (Fentanyl)	Fentanyl	10
KET (Ketamine)	Ketamine	1000
MDA (Amphetamine)	Methylenedioxyamphetamine	500
MDMA/ XTC (Ecstasy)*	3,4-Methylenedioxy-	1000
MDMA/ XTC (Ecstasy)*	3,4-Methylenedioxy-	500
MET (Methamphetamine)*	Methamphetamine	1000
MET (Methamphetamine)*	Methamphetamine	500
MET (Methamphetamine)*	Methamphetamine	300
MOR 2000	Morphine	2000
MOR 300 (Morphine/Heroin)*	Morphine	300
MOR 100 (Morphine/Heroin)*	Morphine	100
MQL (Methaqualone)	Methaqualone	300
MTD (Methadone)	Methadone	300
OXY (Oxycodone)	Oxycodone	100
PCP (Phencyclidine)	Phencyclidine	25
PCM (Paracetamol)	Paracetamol/Acetaminophen	5000
PPX (Propoxyphene)	Norpropoxyphene	300
TCA (Tricyclic Antidepress.)	Nortriptyline	1000
THC (Marihuana)*	11-nor-Δ9-THC-9-COOH	150
THC (Marihuana)*	11-nor-Δ9-THC-9-COOH	50
THC (Marihuana)*	11-nor-Δ9-THC-9-COOH	25
TML (Tramadol)	Tramadol	100

* The cut-off level can vary

7. Literature

- Aniline O., Pittes, F. N., Phencyclidine (PCP): A review and perspectives. CRC Crit. Rev. Toxicol, 1982, 10, 145-177.
- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.
- Thomas L. eds., Labor und Diagnose, 6. ed., TH-Books Verlagsgesellschaft, Frankfurt, 2005
- Urine Testing for Drugs of Abuse, National Institute on Drug Abuse (NIDA), Research Monograph 73, 1986.
- Ellenhorn, M.J. and Barceloux, D.G. Medical Toxicology. Elsevier Science Publishing Company, Inc., New York, 1988.
- Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69,11970-11979, 1988.
- Gilman, A. G., and Goodman, L. S. The Pharmacological Basis of Therapeutics, eds. MacMillan Publishing, New York NY, 1980.
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- Greenblatt, D.J., Shader, R.I. Benzodiazepines in Clinical Practice. New York: Raven Press, 1974.
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- Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
- McBay, A. J., Clin. Chem. 33, 33B-40B, 1987.

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1. Domaine d'application

Ce test utilise la méthode de Sandwich-Immunoassays pour la détection qualitative de drogues et de leurs métabolites dans les urines humaines. Le test est uniquement prévu à un usage professionnel (milieux spécialisés).

2. Exécution du test

- Retirer le test de son emballage. Les tests ainsi que les urines conservés au frais doivent être amenés à température ambiante.
- Tremper la bandelette dans l'urine pendant 15-30 secondes; la partie en plastique ne doit pas entrer en contact avec l'urine
- Lire les résultats après 5 minutes.



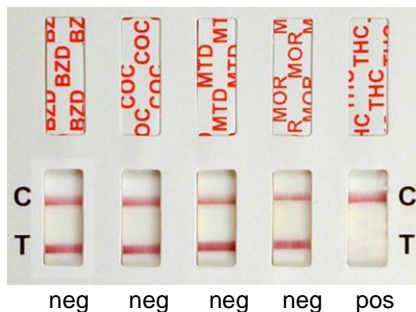
3. Interprétation des résultats

Au niveau de la zone de réaction, se trouvent les zones de test (T) et les zones de contrôle. (C).

> Pour un **résultat négatif**, donc réalisé sur un échantillon d'urine ne contenant pas de drogue, une ligne de couleur rose apparaît dans la zone de test (T) ainsi que dans la zone de contrôle (C).

> Pour un **résultat positif**, une seule ligne apparaît dans la zone de contrôle (C).

Si aucune ligne n'apparaît dans la zone de contrôle (C), cela peut provenir du fait qu'il n'y a pas assez d'urine. Le test est considéré comme non valide.



4. Indication

L'intensité de la couleur de la bandelette sur la membrane du test peut être différente selon les paramètres unitaires. Le test est positif seulement quand aucune ligne n'apparaît. Les résultats positifs et douteux devront être confirmés par une deuxième méthode d'analyse (par exemple GC/MS). La buprénorphine sera détectée à partir d'une dose journalière de 2 mg.

5. Précautions et mesures de sécurité

- Réservé uniquement à une utilisation In-vitro
- Réservé à un usage professionnel.
- Ne pas utiliser au-delà de la date de péremption.
- Les échantillons d'urines doivent être considérés comme potentiellement infectieux. Les manipuler et procéder à l'élimination selon les règles en vigueur.
- Conserver les tests à une température de 2-30°C et ne pas congeler.
- Ne pas utiliser le test si son emballage est endommagé.
- Utiliser immédiatement le test après ouverture de son emballage.
- Réservé à une utilisation unique.

6. Cut-offs (Abréviation des paramètres entre parenthèses)

Paramètres	Drogue/Métabolite**	Cut-off (ng/ml)
AMP (Amphétamine)*	Amphétamine	1000
AMP (Amphétamine)*	Amphétamine	500
AMP (Amphétamine)*	Amphétamine	300
BAR (Barbiturique)	Secobarbital	300
BZD (Benzodiazépine)*	Oxazepam	300
BZD (Benzodiazépine)*	Oxazepam	200
BZD (Benzodiazépine)*	Oxazepam	100
BUP (Buprenorphine)	Buprénorphine-β3-D-	10
COC (Cocaïne)*	Benzoylcgonine	300
COC (Cocaïne)*	Benzoylcgonine	100
COT (Cotinine)	Cotinin	200
EDDP (métabolite de la Méthadone)	2-Ethylidin-1,5-Dimethyl-3,3-Diphenylpyrrolidin	100
FYL (Fentanyl)	Fentanyl	10
KET (Kétamine)	Kétamine	1000
MDA (Amphétamine)	Méthylendioxyamphétamine	500
MDMA (Ecstasy)*	3,4-Méthylendioxy-	1000
MDMA (Ecstasy)*	3,4-Méthylendioxy-	500
MET (Méthamphétamine)*	Méthamphétamine	1000
MET (Méthamphétamine)*	Méthamphétamine	500
MET (Méthamphétamine)*	Méthamphétamine	300
MOR 2000	Morphine	2000
MOR 300 (Morphine/Héroïne)*	Morphine	300
MOR 100 (Morphine/Héroïne)*	Morphine	100
MQL (Métaqualone)	Métaqualone	300
MTD (Méthadone)	Méthadone	300
OXY (Oxycodon)	Oxycodon	100
PCP (Phencyclidine)	Phencyclidine	25
PCM (Paracétamol)	Paracétamol/Acétaminophène	5000
PPX (Propoxyphène)	Norpropoxyphène	300
TCA (antidépresseur tricyclique)	Nortriptyline	1000
THC (Marijuana)*	11-nor-Δ9-THC-9-COOH	150
THC (Marijuana)*	11-nor-Δ9-THC-9-COOH	50
THC (Marijuana)*	11-nor-Δ9-THC-9-COOH	25
TML (Tramadol)	Tramadol	100

Les tests peuvent être fournis individuellement pour chaque drogue. *Pour certaines drogues, différents cut-off sont disponibles.

7. Bibliographie

- Aniline O., Pittes, F. N., Phencyclidine (PCP): A review and perspectives. CRC Crit. Rev. Toxicol, 1982, 10, 145-177.
- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.
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- Fed. Register, Department of Health and Human Services, Mandatory Guidelines for Federal Workplace Drug Testing Programs, 53, 69, 11970-11979, 1988.
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- McBay, A. J., Clin. Chem. 33, 33B-40B, 1987.

1. Previsto

Immunoensayos "Single-sandwich" para la detección cualitativa de diversas drogas y sus metabolitos en orina humana. Test diseñado únicamente para uso profesional.

2. Procedimiento del Test

- 1) Extraer el test del envoltorio. Dejar que las muestras alcancen la temperatura ambiente antes de ser testadas.
- 2) Sumergir la tira en la orina durante aproximadamente 10-15 segundos. La zona de plástico no debe entrar en contacto con la orina.
- 3) Esperar aproximadamente 5 minutos antes de leer los resultados.



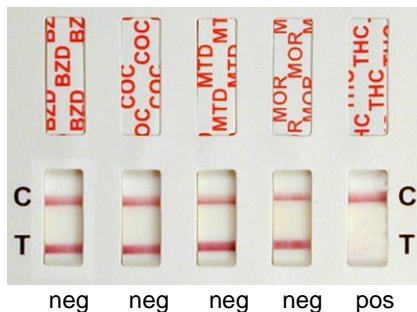
3. Interpretación de resultados

La zona de test (T) detecta las drogas que puedan encontrarse en la muestra de orina. La otra es la zona de control (C).

> Cuando el **resultado es negativo** (muestra libre de drogas), una línea rosa aparecerá tanto en la zona de test (T) como en la zona de control (C).

> Cuando el **resultado es positivo** solo aparecerá una línea rosa en la zona de control (C).

Si en la zona de control no puede distinguirse claramente la línea rosa, esto significa que no se ha aplicado suficiente orina a la tira, por lo que el test es inválido.



4. Nota

La intensidad del color de la línea en la zona de test puede variar dependiendo de los parámetros que están siendo testados. El test solamente es positivo cuando no aparece ninguna línea en la zona de test (T). Los resultados positivos deberían ser contrastados mediante un método adicional (GC/MS).

El umbral de detección de la Buprenorfina comienza a una dosis diaria de 2 mg.

5. Advertencias y precauciones

- Sólo para diagnóstico In-vitro.
- Sólo para uso por profesionales de la salud.
- No utilizar después de la fecha de caducidad
- Las muestras de orina pueden ser infecciosas. Manipular todas las muestras como si se tratara de agentes infecciosos.
- Almacenar los test a una temperatura de entre 2-30°. No congelar los test.
- Desechar el test si el envoltorio se encuentra dañado.
- Utilizar el test inmediatamente tras sacarlo del envoltorio protector.
- Único uso.

6. Umbrales de detección

Droga (Abreviatura)	Droga de abuso/ droga psicotrópica	Umbral
AMP*	Anfetamina	300 ng/ml
AMP*	Anfetamina	500 ng/ml
AMP*	Anfetamina	1.000 ng/ml
BAR	Barbitúricos	300 ng/ml
BUP	Buprenorfina	10 ng/ml
BZD	Benzodiazepina	100 ng/ml
BZD	Benzodiazepina	200 ng/ml
BZD	Benzodiazepina	300 ng/ml
COC*	Cocaína/ Benzoyllecgonina	100 ng/ml
COC*	Cocaína/ Benzoyllecgonina	300 ng/ml
COT	Cotinina	200 ng/ml
EDDP	2- Etilidina -1,5-DiMetyl -3,3-Difenilpyrrolidina	100 ng/ml
FYL	Fentanilo	10 ng/ml
KET	Ketamina	1.000 ng/ml
MDA	Metilenedioxianfetamina	500 ng/ml
MDMA/XTC*	Éxtasis	500 ng/ml
MET*	Metanfetamina	300 ng/ml
MET*	Metanfetamina	500 ng/ml
MET*	Metanfetamina	1.000 ng/ml
MQL	Metacualona	300 ng/ml
MTD	Metadona	300 ng/ml
OPI / MOR*	Opiáceos/Morfina	100 ng/ml
OPI / MOR*	Opiáceos/Morfina	300 ng/ml
OPI / MOR*	Opiáceos/Morfina	2.000 ng/ml
OXY	Oxicodona	100 ng/ml
PCP	Fenciclidina	25 ng/ml
PCM	Paracetamol/Acetaminofeno	5000 ng/ml
PPX	Propoxifeno	300 ng/ml
TCA	Antidepresivos tricíclicos	1.000 ng/ml
THC*	Marihuana, Hachis	25 ng/ml
THC*	Marihuana, Hachis	50 ng/ml
THC*	Marihuana, Hachis	150 ng/ml
TML	Tramadol	100 ng/ml

* El Umbral („Cut-off“) puede variar.

7. Bibliografía

- Aniline O., Pittes, F. N., Phencyclidine (PCP): A review and perspectives. CRC Crit. Rev. Toxicol, 1982, 10, 145-177.
- Baselt, R.C. Disposition of Toxic Drugs and Chemicals in Man. Biomedical Publications, Davis, CA, 1982.
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- Hofmann F.E., A Handbook on Drug and Alcohol Abuse: The Biomedical Aspects, New York, Oxford University Press, 1983.
- McBay, A. J., Clin. Chem. 33, 33B-40B, 1987.

1. Uso Previsto

Il single-sandwich immunoassays è un test qualitativo immunocromatografico per rilevare rapidamente la presenza di diversi tipi di droghe d'abuso e dei loro metaboliti nell'urina umana. Il test è destinato unicamente ad uso professionale.

2. Procedura del Test

- 1) Rimuovere il test dall'involucro. Portare i campioni a temperatura ambiente prima di effettuare il test.
- 2) Immergere la striscia nel campione di urina per 10-15 secondi. Fare in modo che l'urina non venga a contatto con la finestra di controllo in plastica.
- 3) Leggere I risultati dopo 5-10 minuti.



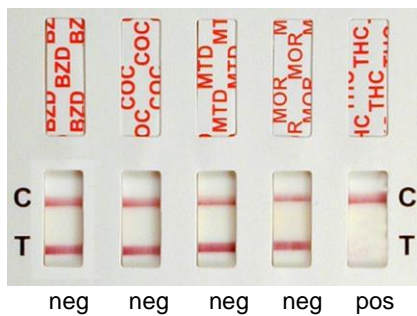
3. Interpretazione dei Risultati

La zona del test (T) rileva sostanze trovate nel campione d'urina e l'altra è la zona di controllo.

> Con **risultato negativo**, appariranno una linea colorata (rosa) nella banda di rilevazione del test (T) e una linea colorata nell'area di controllo (C).

> Con un **risultato positivo** è visibile una linea colorata solo nell'area di controllo (C).

Se non appare nessuna banda nella zona di controllo, il test non è valido, forse per un volume di urina insufficiente.



4. Note

L'intensità del colore delle linee di test può variare per i diversi parametri. Il test è considerato positivo solo se non compare la linea del test.

I risultati positivi e quelli non chiari devono essere ripetuti con un metodo analitico alternativo (GC/MS).

La buprenorfina è rilevabile in modo attendibile con un dosaggio giornaliero di 2 mg o superiore.

5. Avvertenze e precauzioni

- Solo per uso in vitro.
- Solo per uso professionale.
- Non utilizzare dopo la data di scadenza.
- I campioni possono essere potenzialmente infetti. Manipolarli con le dovute precauzioni e smaltirli in modo adeguato.
- Conservare e trasportare sempre a temperature comprese tra 2-30°C e assicurarsi di non congelare i test.
- Non utilizzare il test se l'involucro è danneggiato.
- Utilizzare il test subito dopo aver aperto l'involucro.
- Monouso.

6. Cut-off

Droga (Abbreviazione)	Droga/ psicotropo	Cut-off
AMP*	Amfetamina	300 ng/ml
AMP*	Amfetamina	500 ng/ml
AMP*	Amfetamina	1.000 ng/ml
BAR	Barbiturici	300 ng/ml
BUP	Buprenorfina	10 ng/ml
BZD	Benzodiazepina	100 ng/ml
BZD	Benzodiazepina	200 ng/ml
BZD	Benzodiazepina	300 ng/ml
COC*	Cocaina/ Benzoilecgonina	100 ng/ml
COC*	Cocaina/ Benzoilecgonina	300 ng/ml
COT	Cotina	200 ng/ml
EDDP	2- Etilidene -1,5-Dimetil - 3,3-Difenilpirrolidina	100 ng/ml
FYL	Fentanile	10 ng/ml
KET	Chetamina	1.000 ng/ml
MDA	Metilenediossiamfetamina	500 ng/ml
MDMA/XTC*	Ecstasy	500 ng/ml
MDMA/XTC*	Ecstasy	1.000 ng/ml
MET*	Metamfetamina	300 ng/ml
MET*	Metamfetamina	500 ng/ml
MET*	Metamfetamina	1.000 ng/ml
MQL	Metaqualone	300 ng/ml
MTD	Metadone	300 ng/ml
OPI / MOR*	Oppiacei/Morfina	100 ng/ml
OPI / MOR*	Oppiacei/Morfina	300 ng/ml
OPI / MOR*	Oppiacei/Morfina	2.000 ng/ml
OXY	Ossicodone	100 ng/ml
PCP	Feniclidina	25 ng/ml
PPX	Propoxifene	300 ng/ml
TCA	Antidepressivi triciclici	1.000 ng/ml
THC*	Marijuana, Hashish	25 ng/ml
THC*	Marijuana, Hashish	50 ng/ml
THC*	Marijuana, Hashish	150 ng/ml
TML	Tramadolo	100 ng/ml

* Il Cut-off può variare.

7. Riferimenti Bibliografici

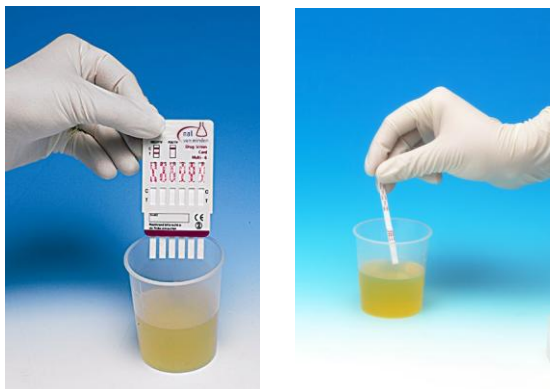
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1. Zastosowanie

Testy zanurzeniowe nal von minden są immunologicznymi badaniami chromatograficznymi do szybkiego wykrywania różnych narkotyków lub leków psychotropowych i ich metabolitów w ludzkim moczu. Testy są przeznaczone tylko do profesjonalnego użytku.

2. Przeprowadzenie testu

- Wyjąć test zanurzeniowy z foliowego opakowania. Przy testach multi zdjąć nasadkę. Przed wykonaniem testu, próbka moczu powinna osiągnąć temperaturę pokojową (15-30°C).
- Pasek testowy zanurzyć przez 10 – 15 sekund w moczu. Proszę zwrócić uwagę, żeby mocz nie stykał się z plastikową obudową.
- Odczytać wyniki po upływie 5 – 10 minut.



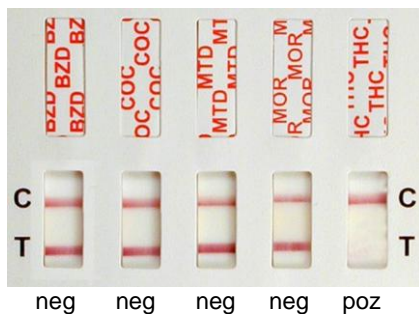
3. Interpretacja wyników

W polu reakcji znajduje się obszar testowy (T) do wykrycia narkotyku i obszar kontrolny (C).

> Przy **negatywnym wyniku**, tzn. brak obecności narkotyków w moczu, pojawią się różowe prążki, jeden w obszarze testowym (T) i jeden w obszarze kontrolnym (C).

> Przy **pozytywnym wyniku** pojawia się tylko jeden prążek w obszarze kontrolnym (C).

Nie pojawia się prążek kontrolny (C), to np. użyto za mało moczu i test jest nieważny!



4. Uwaga

Odcień różowych prążków może różnić się na polu reakcji. Tylko jak nie pojawia się prążek testowy, to wynik jest pozytywny. Pozytywne albo niejasne wyniki trzeba sprawdzić inną metodą (np. GC/MS). Buprenorfinę można wykryć przy dawce dziennej od 2mg.

5. Uwagi i środki ostrożności

- Tylko do użytku diagnostycznego in vitro.
- Tylko do profesjonalnego użytku.
- Nie używać po upływie daty ważności.
- Wszystkie próbki należy traktować jako potencjalnie biologicznie niebezpieczne i traktować w taki sam sposób, co czynnik zakaźny.
- Testy przechowywać i transportować w temperaturze 2-30°C i nie zamrażać.
- Nie używać testu w przypadku, gdy torebka, w której się znajduje, jest uszkodzona.
- Test musi pozostać w zamkniętej torebce aż do użycia.
- Trzymać test za uchwyt albo za plastikową obudowę.
- Używać tylko jednokrotnie.

6. Cut-off's (wartości progowe)

Parametr	Narkotyk/metabolit**	Cut-off
AMP (Amfetamina)*	Amfetamina	1000
AMP (Amfetamina)*	Amfetamina	500
AMP (Amfetamina)*	Amfetamina	300
BAR (Barbituraty)	Sekobarbital	300
BZO (Benzodiazepiny)*	Oksazepam	300
BZO (Benzodiazepiny)*	Oksazepam	200
BZO (Benzodiazepiny)*	Oksazepam	100
BUP (Buprenorfina)	Buprenorfina-β3-D-glucuronid	10
COC (Kokaina)*	Benzoilekgonina	300
COC (Kokaina)*	Benzoilekgonina	100
COT (Kotynina)*	Kotynina	200
EDDP (Metabolit metadonu)	2-Etylidin-1,5-Dimetyl-3,3-Difenylpyrrolidin	100
FYL (Fentanyl)	Fentanyl	10
KET (Ketamina)	Ketamina	1000
MDA (Amfetamina)	Metylendioksyamfetamina	500
MDMA (Ekstaza)*	3,4-metylendioksymetamfetamina	1000
MDMA (Ekstaza)*	3,4-metylendioksymetamfetamina	500
MTD (Metadon)	Metadon	300
MET (Metamfetamina)*	Metamfetamina	1000
MET (Metamfetamina)*	Metamfetamina	500
MET (Metamfetamina)*	Metamfetamina	300
MOR2000 (Morfina/Heroina)*	Morfina	2000
MOR300 (Morfina/Heroina)*	Morfina	300
MOR100 (Morfina/Heroina)*	Morfina	100
MQL (Metakwalon)	Metakwalon	300
OXY (Oksykodon)	Oksykodon	100
PCP (Fencyklidyna)	Fencyklidyna	25
PCM (Paracetamol)	Paracetamol/Acetaminofen	5000
PPX (Propoksyfen)	Norpropoksyfen	300
TCA (Trójkl. Antydepresanty)	Nortryptyliina	1000
THC (Marihuana) *	11-nor-Δ9-THC-9-COOH	150
THC (Marihuana) *	11-nor-Δ9-THC-9-COOH	50
THC (Marihuana) *	11-nor-Δ9-THC-9-COOH	25
TML (Tramadol)	Tramadol	100

* Paski testowe wykrywające dany narkotyk o różnych wartościach cut-off

**Substancje, które miały funkcje kalibratora dla ustalenia wartości cut-off.

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1. Detailed list of cut-offs

The following structurally related substances resulting from the concentration following a positive result.

Amphetamine

Amphetamine -Test with Cut-off 300 ng/ml (AMP300).

Drug	Concentration (ng/ml)
D-Amphetamine	300
3,4-Methylendioxy-amphetamine (MDA)	500
3,4-Methylendioxy-methamphetamine (MDMA)	>20.000
L-Amphetamine	>50.000

Amphetamine -Test with Cut-off 500 ng/ml (AMP500).

Drug	Concentration (ng/ml)
D-Amphetamine	500
L-Amphetamine	15.000
(+/-)3,4-methylenedioxyamine (MDA)	700
MDMA	12.000

Amphetamine-Test with Cut-off 1000 ng/ml (AMP1000)

Drug	Concentration (ng/ml)
D-Amphetamine	1.000
L-Amphetamine	>50.000
D-Methamphetamine	>20.000
L-Methamphetamine	>20.000
3,4-Methylendioxyamphetamine (MDA)	2.400
3,4-Methylendioxy-methamphetamine (MDMA)	>20.000
3,4-Methylendioxyethylamphetamine (MDEA)	>100.000
Paramethoxyamphetamine (PMA)	1.000

Barbiturate

Barbiturat-Test with Cut-off 300 ng/ml (BAR)

Drug	Concentration (ng/ml)
Secobarbital	300
Phenobarbital	300
Butalbital	3.000
Allobarbital	5.000
Alphenal	625
Amobarbital	600
Aprobarbital	600
Hexobarbital	>100.000
Butobarbital	75
Pentobarbital	300

Buprenorphine

Buprenorphine -Test with Cut-off 10 ng/ml (BUP).

Drug	Concentration (ng/ml)
Buprenorphine	10
Buprenorphine-3- β -d-glucuronide	10
Nor-Buprenorphine	>1.000
Nor-Buprenorphine-3- β -d-glucuronide	>1.000

Benzodiazepine

Benzodiazepin-Test with Cut-off 100 ng/ml (BZD100)

Drug	Concentration (ng/ml)
Oxazepam	100
a-Hydroxyalprazolam	625
Alprazolam	63
Bromazepam	250
Chlordiazepoxid	1.250
Clobazam	31
Clonazepam	625
Clorazepat	1.670
Delorazepam	625
Desalkflurazepam	125
Diazepam	125
Estazolam	1.250
Flunitrazepam	125
Lorazepam	313
Lormetazepam	750
Midazolam	2.500
Nitrazepam	12.500
Norchlordiazepoxid	63
Nordiazepam	250
Temazepam	63
Triazolam	750

Benzodiazepine-Test with Cut-off 200 ng/ml (BZD200)

Drug	Concentration (ng/ml)
Oxazepam	200
a-Hydroxyalprazolam	1.250
Alprazolam	188

Bromazepam	500
Chlordiazepoxid	2.500
Clobazam	63
Clonazepam	1.250
Clorazepat	3.330
Delorazepam	1.250
Desalkflurazepam	400
Diazepam	250
Estazolam	2.500
Flunitrazepam	250
Lorazepam	1.250
Lormetazepam	1.250
Midazolam	7.500
Nitrazepam	25.000
Norchlordiazepoxid	125
Nordiazepam	500
Temazepam	125
Triazolam	1.250

Benzodiazepine-Test with Cut-off 300 ng/ml (BZD)

Drug	Concentration (ng/ml)
Oxazepam	300
a-Hydroxyalprazolam	2.500
Alprazolam	250
Bromazepam	625
Chlordiazepoxid	3.750
Clobazam	100
Clonazepam	2.500
Clorazepat	5.000
Delorazepam	2.500
Desalkflurazepam	500
Diazepam	300
Estazolam	5.000
Flunitrazepam	375
Lorazepam	1.500
Lormetazepam	2.000
Midazolam	10.000
Nitrazepam	37.500
Norchlordiazepoxid	250
Nordiazepam	750
Temazepam	150
Triazolam	1.875

Cocaine

Cocaine-Test with Cut-off 100 ng/ml (COC100)

Drug	Concentration (ng/ml)
Cocaine	3.000
Benzoyllecgonine	100
Ecgonine-Methylester	>100.000
Ecgonine	>40.000

Cocaine-Test mit Cut-off 300 ng/ml (COC300)

Drug	Concentration (ng/ml)
Cocaine	1.000
Benzoyllecgonine	300
Ecgonine-Methylester	>100.000
Ecgonine	>40.000

Cotinine-Test

Cotinine-Test mit Cut-off 200 ng/ml (COT)

Drug	Concentration (ng/ml)
Cotinine	200
(-)-Nicotine	>50.000

EDDP/Methadone-Metabolites

EDDP-Test with Cut-off 100 ng/ml (EDDP)

Drug	Concentration (ng/ml)
2-ethyliden-1,5-dimethyl-3,3-diphenylpyrolidine (EDDP)	100
Doxylamine	>1.000.000
Methadone	>10.000
Methadol	>10.000

Fentanyl-Metabolites

Fentanyl-Test with Cut-off 10 ng/ml (Fentanyl)

Drug	Concentration (ng/ml)
Fentanyl-Metabolite	10

Ketamine

Ketamine-Test with Cut-off 1000 ng/ml (Ketamine)

Drug	Concentration (ng/ml)
Ketamine	1.000
Norketamine	2.000
Phencyclidine	>10.000
Dextromethorphan	1.000
Lidocaine	>100.000
Promethazine	20.000

d-Amphetamine	>100.000
Methadone	25.000
Methadol	50.000
Pethidine	12.500
Methamphetamine	12.500
MDMA	>100.000
MDA	
MDA-Test with Cut-off 500 ng/ml (MDA)	
Drug	Concentration (ng/ml)
(+/-)3,4-Methylenedioxyamphetamine (MDA)	500
3,4-Methylenedioxyethylamphetamine	300
MDMA/XTC	
MDMA-Test with Cut-off 500ng/ml (MDMA/XTC500)	
Drug	Concentration(ng/ml)
3,4-Methylenedioxy-methamphetamine (MDMA)	500
3,4-Methylenedioxyamphetamine (MDA)	1.000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
D-Amphetamine	>100.000
D-Methamphetamine	>100.000
Paramethoxyamphetamine (PMA)	5.000
MDMA/XTC-Test with Cut-off 1000 ng/ml (MDMA/XTC1000)	
Drug	Concentration(ng/ml)
3,4-Methylenedioxy-methamphetamine (MDMA)	1.000
3,4-Methylenedioxyamphetamine (MDA)	2.000
3,4-Methylenedioxyethylamphetamine (MDEA)	600
D-Amphetamine	>100.000
D-Methamphetamine	100.000
L-Methamphetamine	>100.000
Methamphetamine	
Methamphetamine-Test with Cut-off 300 ng/ml (MET300).	
Drug	Concentration (ng/ml)
(+)-Methamphetamine	300
D-Amphetamine	>40.000
Chloroquine	5.000
(+/-)-Ephedrine	>100.000
L(-)-Methamphetamine	10.000
Mephentermine	50.000
(+/-)3,4-Methylenedioxy-methamphetamine (MDMA)	1.000
(+/-)3,4-Methylenedioxy-ethylamphetamine e(MDEA)	10.000
Procaine	35.000
β-Phenylethylamine	35.000
Ranitidine	35.000
Methamphetamine-Test with Cut-off 500 ng/ml (MET500).	
Drug	Concentration (ng/ml)
(+)-Methamphetamine	500
D-Amphetamine	>50.000
Chloroquine	>50.000
(+/-)-Ephedrine	>50.000
L(-)-Methamphetamine	>50.000
Mephentermin	>50.000
(+/-)3,4-Methylenedioxy-methamphetamine (MDMA)	700
Procaine	20.000
□-Phenylethylamine	30.000
Ranitidin	>50.000
Methamphetamine-Test with Cut-off 1000 ng/ml (MET1000)	
Drug	Concentration (ng/ml)
D-Methamphetamine	1.000
D-Amphetamine	>40.000
Chloroquine	10.000
(+/-)-Ephedrine	>100.000
L-Methamphetamine	15.000
3,4-Methylenedioxy-amphetamine (MDA)	>10.000
3,4-Methylenedioxy-methamphetamine (MDMA)	2.000
3,4-Methylenedioxy-ethylamphetamine (MDEA)	20.000
Procaine	100.000
Methaqualone	
Methaqualone-Test with Cut-off 300 ng/ml (MQL)	
Drug	Concentration (ng/ml)
Methaqualone	300

Mecloqualone	500
3'-Hydroxy methaqualone	500
4'-Hydroxy methaqualone	500
2'-Hydroxy methaqualone	3.000
Amitriptyline	50.000
Carbamazepine	20.000
Nortriptyline	50.000
Phenytoine	40.000
Primidone	24.000
Theophylline	40.000
Methadone & Derivats	
Methadone-Test with Cut-off 300 ng/ml (MTD)	
Drug	Concentration (ng/ml)
Methadone	300
Methadole	1.000
2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine (EDDP)	>40.000
Doxylamine	>40.000
Opiate/Morphine	
Morphine-Test with Cut-off 100 ng/ml (MOR100).	
Drug	Concentration (ng/ml)
Morphine	100
Codeine	100
Diacetylmorphine	100
Ethylmorphine	100
Hydromorphone	500
Hydrocodone	500
Meperidine	>100.000
6-Monoacetylmorphine	100
Morphin-3-β-d-glucuronide	2.000
Oxycodone	>20.000
Oxymorphone	>20.000
Promethazine	>250.000
Rifampicin	8.400
Thebain	8.400
Trimipramine	>20.000
Morphine-Test with Cut-off 300 ng/ml (MOR300)	
Drug	Concentration (ng/ml)
Morphine	300
Codeine	300
Diacetylmorphine (Heroine)	300
Ethylmorphine	300
Hydromorphone	1.500
Hydrocodone	1.500
Merperidine	>100.000
6-Monoacetylmorphine	300
Morphin-3-β-d-glucuronide	6.000
Oxycodon	>20.000
Oxymorphon	>20.000
Promethazin	>250.000
Rifampicin	25.000
Thebain	2.50
Trimipramine	>20.000
Morphine-Test with Cut-off 2000 ng/ml (MOR2000).	
Drug	Concentration (ng/ml)
Morphine	2.000
Codeine	2.000
Diacetylmorphine (Heroine)	2.000
Ethylmorphine	600
Hydromorphone	15.000
Hydrocodone	15.000
Merperidine	>100.000
6-Monoacetylmorphine	5.000
Morphin-3-β-d-glucuronide	10.000
Oxycodon	>20.000
Oxymorphone	>20.000
Rifampicin	>50.000
Thebain	20.000
Morphine	2.000
Oxycodone	
Oxycodone-Test with Cut-off 100 ng/ml (OXY).	
Drug	Concentration (ng/ml)
Oxycodone	100
Oxymorphone	500
Codeine	>100.000
Diacetylmorphine (Heroine)	>100.000
Ethylmorphine	10.000
Hydrocodone	10.000
Hydromorphone	10.000
Merperidine	>100.000
6-Monoacetylmorphine	>100.000
Morphin-3-beta-D-glucuronide	>250.000
Thebain	>100.000

Phencyclidine	
PCP-Test with Cut-off 25 ng/ml (PCP)	
Drug	Concentration(ng/ml)
Phencyclidine	25
Tenocyclidine	2.000

Paracetamol	
PCM-Test with Cut-off 5000 ng/ml (PCM)	
Drug	Concentration (ng/ml)
Paracetamol	5.000

Propoxyphene	
PPX-Test with Cut-off 300 ng/ml (PPX)	
Drug	Concentration (ng/ml)
D-Propoxyphene	300
D-Norpropoxyphene	300

TCA	
TCA-Test with Cut-off 1000 ng/ml (TCA)	
Drug	Concentration(ng/ml)
Nortriptyline	1.000
Amitriptyline	1.000
Chlorpromazine	3.500
Clomipramine	10.000
Cyclobenzaprine	1.500
Desipramine	500
Diphenhydramine	20.000
Doxepine	1.000
Imipramine	800
Nordoxepine	1.000
Opi Pramol	4.000
Protriptylin	3.000
Doxepin	1.000
Perphenazine	25.000
Promazin	200
Promethazin	40.000
Protriptylin	3.000
Trimipramine	2.500

THC & Derivats	
THC-Test with Cut-off 25 ng/ml (THC25).	
Drug	Concentration (ng/ml)
11-nor- Δ^9 -THC-9-COOH	25
11-nor- Δ^8 -THC-9-COOH	25
11-hydroxy- Δ^9 -Tetrahydrocannabinol	>100.000
Δ^8 -Tetrahydrocannabinol	10.000
Δ^9 -Tetrahydrocannabinol	10.000
Cannabinol	15.000
Cannabidiol	>100.000










THC-Test with Cut-off 50 ng/ml (THC50)	
Drug	Concentration(ng/ml)
11-nor Δ^8 -THC-9-COOH	50
11-nor- Δ^9 -THC-9-COOH	50
11-hydroxy- Δ^9 -Tetrahydrocannabinol	>100.000
Δ^8 - Tetrahydrocannabinol	15.000
Δ^9 - Tetrahydrocannabinol	15.000
Cannabinol	20.000
Cannabidiol	>100.000


THC-Test with Cut-off 150 ng/ml (THC150)	
Drug	Concentration (ng/ml)
11-nor- Δ^8 -THC-9-COOH	150
11-nor- Δ^9 -THC-9-COOH	150
11-hydroxy- Δ^9 -Tetrahydrocannabinol	>100.000
Δ^8 -Tetrahydrocannabinol	80.000
Δ^9 -Tetrahydrocannabinol	80.000
Cannabinol	>20.000
Cannabidiol	>100.000

Tramadol	
Tramadol-Test with Cut-off 100 ng/ml (Tramadol)	
Drug	Concentration (ng/ml)
Tramadol	100
N-desmethyl-tramadol	250
O-desmethyl-tramadol	10.000

With exception of the respective parameters positive reacting drugs and drug metabolites, which are listed above, all below listed compounds react negatively up to a concentration of 100 μ g/ml.

Acetaminophene	Guaiacol Glyceryl Ether
Acetone	Hämoglobin
Albumin	Ibuprofen
Ampicillin	(+/-)-Isoproterenol
Aspartam	Koffein
Aspirin	Kreatin
Atropin	Lidocain
Benzocaine	L-Phenylephrin
Beta-Phenylethylamine	N-Methyl-Ephedrin
Chinidine	(+)-Naproxen ([S]-6-Methoxy--Methyl-2-Naphthalenessigsäure)
Chloroquine	Oxalsäure
Chlorpheniramine	Penicillin-G (Benzylpenicillin)
4-Dimethylaminoantipyrine	Pheniramin
Dopamin (3-Hydroxytyramin)	Phenothiazin
(-)-Ephedrine	Procain
(+/-)-Ephedrine	Ranitidin
Ethanol	Sulindac
Furosemid	Tyramin
	Vitamin C (Ascorbinsäure)

Symbol	English	Deutsch	Français	Nederlands	Español	Italiano
	Consult instructions for use	Gebrauchsanweisung beachten	Consulter les instructions d'utilisation	Gebruiksaanwijzing	Consulte las instrucciones de uso	Consultare le istruzioni per l'uso
	European Conformity	CE-Konformitätskennzeichnung	Conformité aux normes européennes	Conform Europese richtlijnen	Conformidad europea	Conformità europea
	In vitro diagnostic device	In-vitro-Diagnostikum	Usage Diagnostic in vitro	In vitro diagnostisch gebruik	Para uso Diagnóstico in vitro	Per uso Diagnostica in vitro
	Catalogue number	Katalog-Nr.	Numéro de catalogue	Catalogus nummer	Número de catálogo	Numero di Catalogo
	Lot. No. / Batch code	Chargen-Nr.	Numéro de lot	Lot nummer	Número de lote	Numero di lotto
	Contains sufficient for <n> tests/	Ausreichend für "n" Ansätze	Contenu suffisant pour "n" tests	Geschikt voor <n> tests	Contenido suficiente para <n> ensayos	Contenuto sufficiente per "n" saggi
	Storage Temperature	Lagerungs-temperatur	Température de conservation	Opslag temperatuur	Temperatura de conservación	Temperatura di conservazione
	Expiration Date	Mindesthaltbarkeitsdatum	Date limite d'utilisation	Houdbaarheids datum	Fecha de caducidad	Data di scadenza
	Legal Manufacturer	Hersteller	Fabricant	Fabrikant	Fabricante	Fabbricante
Distributed by	Distributor	Vertreiber	Distributeur	Distributeur	Distribuidor	Distributore
	Content	Inhalt	Conditionnement	Inhoud	Contenido	Contenuto

Symbol	Polski	Suomi	Portugues	Dansk	Svenska	Ελληνικά
	Patrz: ulotka informacyjna	Katso käyttöohjeet	Consulte as instruções de utilização	Se brugsanvisning	Se bruksanvisningen	Εγχειρίδιο χρήστη
	Znak zgodności CE	CE-merkitty	Conformidade com as normas europeias	Europaeisk overensstemmelse	Europeisk överensstämmelse	Ευρωπαϊκή Συμμόρφωση
	Tylko do użytku in-vitro	In vitro-diagnostiikka	Diagnóstico in vitro	In vitro diagnostik	In vitro diagnostik	in vitro διαγνωστικό
	Numer katalogowy	Luettelo-numero	Catálogo n.º	Katalognummer	Katalognummer	Αριθμός καταλόγου
	Numer serii	Eränumero	No do lote	Lot nummer	Batchnummer	Αριθμός Παρτίδος
	Wystarszajonce na "n" powtórzeń	Sisältää tarvikkeet "n" testiin		Indeholder tilstrækkeligt til "n" test	Innehåller tillräckligt till "n" tester	Περιεχόμενο επαρκές για «n» εξετάσεις
	Temperatura przechowywania	Säilytys-lämpötila	Temperatura de conservação	Opbevarings-temperatur	Förvaringstemperatur	Θερμοκρασία αποθήκευσης
	Data ważności	Viimeinen käyttöpäivä	Prazo de validade	Udløbsdato	Utgångsdatum	Ημερομηνία λήξης
	Producent	Valmistaja	Fabricante	Producent	Tillverkare	Κατασκευαστής
Distributed by	Dystrybutor	Tukkumyyjä			Distributör	
	Zawartość	Sisältö	Conteúdo	Indhold	Innehåll	Περιεχόμενο



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