SureScreen Diagnostics

Ethyl Glucuronide Rapid Test Panel (Urine)

【INTENDED USE】
The Ethyl Glucuronide (ETG) Rapid Test Panel (Urine) is a rapid chromatographic immunoassay for the detection of Ethyl Glucuronide in urine at a cut-off concentration of 1,000 ng/mL. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

【SUMMARY】
Ethyl glucuronide (ETG) is a metabolite of ethyl alcohol which is formed in the body by glucuronidation following exposure to ethanol, usually from drinking alcoholic beverages. After Alcohol is absorbed by the body, 90-95% Alcohol is oxidized with the help of emzymes. Only 0.5%-1.5% Alcohol integrates with glucose into Ethyl Glucuronide, ETG remains in urine longer period than Alcohol. When low Alcohol volume is drunk (such as 0.1g/kg), ETG detection window varies from 13 - 20hours after drinking. However, maximum ETG detection window can be 80 hours for high Alcohol volume drinking.[1,2,3,4,5]

【REAGENTS】
Test line contains anti-Ethyl Glucuronide(anti-ETG) monoclonal antibody and corresponding ETG-BSA conjugate. A goat antibody is employed in the control line system.

【PRECAUTIONS】
- For healthcare professionals including professionals at point of care sites.Immunoassay for in vitro diagnostic use only.
- The test panels should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner by an infectious agent.
- The used test panel should be discarded according to federal, state and local regulations.

【STORAGE AND STABILITY】
Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test panels must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay
The urine specimen should be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing.

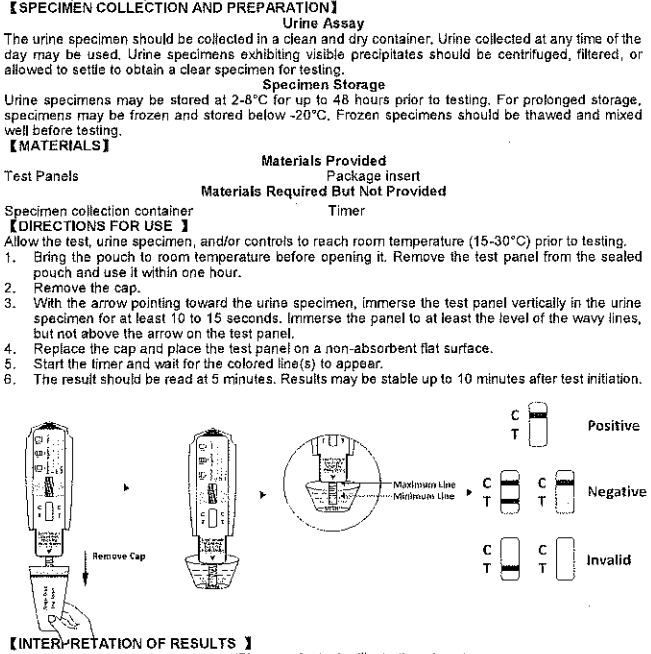
Specimen Storage
Urine specimens may be stored at 2-8°C for up to 48 hours prior to testing. For prolonged storage, specimens may be frozen and stored below -20°C. Frozen specimens should be thawed and mixed well before testing.

【MATERIALS】

Materials Provided
Test Panels — Package insert

Materials Required But Not Provided
Specimen collection container — Timer

【DIRECTIONS FOR USE 】
Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.
1. Bring the pouch to room temperature before opening it. Remove the test panel from the sealed pouch and use it within one hour.
2. Remove the cap.
3. With the arrow pointing toward the urine specimen, immerse the test panel vertically in the urine specimen for at least 10 to 15 seconds. Immerse the panel to at least the level of the wavy lines, but not above the arrow on the test panel.
4. Replace the cap and place the test panel on a non-absorbent flat surface.
5. Start the timer and wait for the colored line(s) to appear.
6. The result should be read at 5 minutes. Results may be stable up to 10 minutes after test initiation.



【INTERPRETATION OF RESULTS 】
(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Ethyl Glucuronide concentration is below the detectable level (1,000 ng/mL).
***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.
POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Ethyl Glucuronide concentration exceeds the detectable level (1,000ng/mL).
INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL 】
A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking.
Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】
1. The Ethyl Glucuronide Rapid Test Panel (Urine) provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/ mass spectrometry (GC/MS) is the preferred confirmatory method.
2. It is possible that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen.
4. A positive result indicates presence of Ethyl Glucuronide but does not indicate level of intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate Ethyl Glucuronide -free urine. Negative results can be obtained when Ethyl Glucuronide is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】
This negative result indicates that the Ethyl Glucuronide concentration is below the detectable level of 1,000ng/ml. Positive result means the concentration of Ethyl Glucuronide is above the level of 1,000ng/ml.

【PERFORMANCE CHARACTERISTICS】

Accuracy
The Ethyl Glucuronide Rapid Test Panel (Urine) has been tested with GC/MS Test using clinical samples. The following results were tabulated:

Method		GC/MS		Total Result
	Results	Positive	Negative	
Ethyl Glucuronide Rapid Test Panel	Positive	179	2	181
	Negative	4	223	227
Total Result		183	225	408

Analytical Sensitivity
A drug-free urine pool was spiked with Ethyl Glucuronide at the following concentrations: 0ng/mL, 500ng/mL, 750ng/mL, 1,000ng/mL, 1,250ng/mL,1,500ng/mL and 3,000ng/mL. The result demonstrates 97% accuracy at 50% above and 50% below the cut-off concentration. The data are summarized below:

Ethyl Glucuronide Concentration	Percent of Cut-off	n	Visual Result	
			Positive	Negative
0ng/mL	0	20	0	20
500ng/mL	-50%	20	0	20
750ng/mL	-25%	20	1	19
1,000ng/mL	Cut-off	20	9	11
1,250ng/mL	+25%	20	18	2
1,500ng/mL	+50%	20	20	0
3,000ng/mL	3X	20	20	0

Analytical Specificity
The following table lists compounds that are positively detected in urine by the Ethyl Glucuronide Rapid Test Panel (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
Ethyl Glucuronide	1,000

Precision
A study was conducted at three hospitals by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing no Ethyl Glucuronide, 25% Ethyl Glucuronide above and below the cut-off, and 50% Ethyl Glucuronide above and below the 1,000 ng/mL cut-off was provided to each site. The following results were tabulated:

Ethyl Glucuronide Concentration	N Per site	Site A		Site B		Site C	
		+	-	+	-	+	-
0ng/mL	10	0	10	0	10	0	10
500ng/mL	10	0	10	0	10	0	10
750ng/mL	10	4	6	3	7	4	6
1,250ng/mL	10	8	2	9	1	9	1
1,500ng/mL	10	10	0	10	0	10	0

Effect of Urinary Specific Gravity
Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 500 ng/mL and 1,500 ng/mL of Ethyl Glucuronide respectively. The Ethyl Glucuronide Rapid Test Panel (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

Effect of Urinary pH
The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Ethyl Glucuronide to 500 ng/mL and 1,500 ng/mL. The spiked, pH-adjusted urine was tested with The Ethyl Glucuronide Rapid Test Panel (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity
A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Ethyl Glucuronide positive urine. The following compounds show no cross-reactivity when tested with The Ethyl Glucuronide Rapid Test Panel (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

4-Acetamidophenol	4-Dimethylaminoantipyrine	Lithium carbonate	Phentermine
Acetone	Diphenhydramine	Loperamide	trans-2-Phenyl
Acetophenetidin	5,5-Diphenylhydantoin	Maprotiline	cyclopropylamine
Acetylsalicylic acid	Disopyramide	Meperidine	l-Phenylephrine
N-Acetylprocainamide	Doxylamine	Mephentermine	β-Phenylethylamine
Albumin	Ecgonine	Meprobamate	Phenylpropanolamine
Aminopyrine	Ecgoninemethylester	Methadone	(d,l-norephedrine)
Amitriptyline	EDDP	d-Methamphetamine	(±) Phenyl- propanolamine
Amobarbital	Efavirenz (Sustiva)	l-Methamphetamine	Prednisolone
Amoxapine	EMDP	Methaqualone	Prednisone
Amoxicillin	Ephedrine	Methoxyphenamine	5β-Pregnane-3α, 17α, 21-triol
l-Amphetamine	l-Ephedrine	(-) 3,4-Methylenedioxy-methamphetamine	Procaine
l-Ascorbic acid	Erythromycin	MDMA	d,l-Propanolol
Aspartame	β-Estradiol	Methylphenidate	d-Propoxyphene
Atropine	Estrone-3-sulfate	Methyprylon	d-Pseudoephedrine
Benzilic acid	Ethanol (Ethyl alcohol)	Methaqualone	Quinacrine
Benzoic acid	Ethyl-p-aminobenzoate	Metoprolol	Quinidine
Benzoylecgonine	Etodolac	Morphine sulfate	Quinine
Benzphetamine	Famprofazone	Morphine-3-β-D-Glucuronide	Ranitidine
Bilirubin	Fenfluramine	Nalidixic acid	Riboflavin
(±)-Brompheniramine	Fenoprofen	Nalorphine	Salicylic acid
Buspirone	Fentanyl	Naloxone	Secobarbital
Caffeine	Fluoxetine	Naltrexone	Serotonin
Cannabidiol	Furosemide	Methyprylon	(5-hydroxytryptamine)
Cannabinol	Gentisic acid	Metoprolol	Sodium chloride
Chloral hydrate	d (+) Glucose	Morphine sulfate	Sulfamethazine
Chloramphenicol	Guaiacol glyceryl ether	α-Naphthaleneacetic acid	Sulindac
Chlordiazepoxide	Guaiacol glyceryl ether	Norethindrone	Temazepam
Chloroquine	carbamate	Normorphine	Tetracycline
Chlorothiazide	Hemoglobin	d,l-Octopamine	Tetrahydrocortisone. 3-acetate
(+)-Chlorpheniramine	Hydralazine	Orphenadrine	Tetrahydrozoline
(±)-Chlorpheniramine	Hydrochlorothiazide	Oxalic acid	Thebaine
Chlorpromazine	Hydrocodone	Oxazepam	Theophylline
Chlorprothixene	Hydrocortisone	Oxolinic acid	Thiamine
Cholesterol	Hydromorphone	Oxycodone	Thioridazine (chlorpromazine)
Cimetidine	p-Hydroxyamphetamine	Oxymetazoline	l-Thyroxine
Clomipramine	o-Hydroxyhippuric acid	Oxymorphone	Tolbutamide
Clonidine	p-Hydroxymethamphetamine	Papaverine	cis-Tramadol
Cocaine	p-Hydroxynorephedrine	Pemoline	Trazodone
Codeine	Hydroxyzine	Penicillin-G	Triamterene
Cortisone	3-Hydroxytyramine	Pentazocine	Trifluoperazine
Creatinine	Ibuprofen	Pentobarbital	Trimethobenzamide
Cyclobarbital	Imipramine	Perphenazine	Trimethoprim
Cyclobenzaprine	Iproniazid	Phencyclidine	Trimipramine
Deoxycorticosterone	(-)-Isoproterenol	Phenelzine	Tryptamine
(-) Deoxyephedrine	Isoxsuprine	Pheniramine	d,l-Tryptophan
R (-) Deprenyl	Kanamycin	Phenobarbital	Tyramine
Dextromethorphan	Ketamine	Phenothiazine	d,l-Tyrosine
Diazepam	Ketoprofen		Uric acid
Diclofenac	Labetalol		Verapamil
Dicyclomine	Levorphanol		Zomepirac
Diflunisal	Lidocaine		
Digoxin	Lindane		
hexachlorocyclohexane			

【BIBLIOGRAPHY】

1. Droenner P, Schmitt G, Aderjan R, et al. A kinetic model describing the pharmacokinetics of ethyl Glucuronide in humans[J]. Forensic Sci Int,2002,126 (1): 24-29.
2. Bergström J, Helander A,Jones AW. Ethyl Glucuronide concentrations in two successive urinary voids from drinking drivers:relationship to creatinine content and blood and urine ethanol concentrations[J]. Forensic Sci Int,2003,33(1-2):86-94.
3. Wurst FM, Kempter C, Metzger J, et al. Ethyl Glucuronide: a marker of recent alcohol consumption with clinical and forensic implications[J]. Alcohol,2000,20(2):111-116.
4. Wurst FM,Vogel R, Jachau K, et al. Ethyl Glucuronide discloses recent covert alcohol use not detected by standard testing in forensic psychiatric inpatients[J]. Alcohol Clin Exp Res,2003,27(3): 471-476.
5. HøHseth G, Bernard JP, Karinen R, et al. A pharmacokinetic study of ethyl Glucuronide in blood and urine: applications to forensic toxicology[J]. Forensic Sci Int, 2007, 172(2-3): 119-124.

Index of Symbols

	Consult Instruction for use	Σ	Tests per kit
IVD	For *in vitro* diagnostic use only		Use by
2°C 30°C	Store between 2-30°C	LOT	Lot Number
	Do not use if package is damaged	EC REP	Authorized Representative
			Do not reuse
		REF	Catalog #

SureScreen Diagnostics Ltd
1 Prime Parkway, Derby, DE1 3QB, UK
T: +44 (0)1332 365318
www.surescreen.com

EC REP SureScreen Ireland Ltd.
9 Exchange Place I.F.S.C
Dublin 1
Ireland

Number: RP5251801
Effective date: 2021-02-22

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Ethyl Glucuronide Rapid Test Panel

(Urine)

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【SPECIMEN COLLECTION AND PREPARATION】

Urine Assay

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【MATERIALS】

Materials Provided

Test Panels　　Package insert

Materials Required But Not Provided

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【DIRECTIONS FOR USE 】

Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

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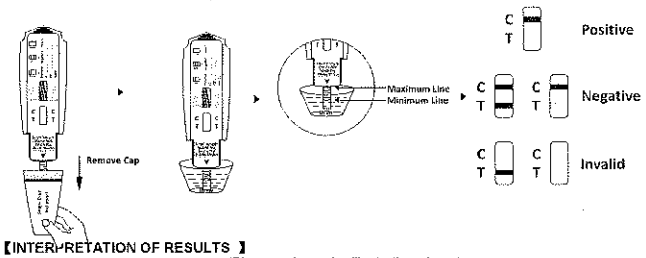

【INTERPRETATION OF RESULTS 】

(Please refer to the illustration above)

NEGATIVE:* Two lines appear. One colored line should be in the control line region (C), and another apparent colored line should be in the test line region (T). This negative result indicates that the Ethyl Glucuronide concentration is below the detectable level (1,000 ng/mL).

***NOTE:** The shade of color in the test line region (T) may vary, but it should be considered negative whenever there is even a faint colored line.

POSITIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). This positive result indicates that the Ethyl Glucuronide concentration exceeds the detectable level (1,000ng/mL).

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【QUALITY CONTROL 】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

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5. A negative result may not necessarily indicate Ethyl Glucuronide -free urine. Negative results can be obtained when Ethyl Glucuronide is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.

【EXPECTED VALUES】

This negative result indicates that the Ethyl Glucuronide concentration is below the detectable level of 1,000ng/ml. Positive result means the concentration of Ethyl Glucuronide is above the level of 1,000ng/ml.

【PERFORMANCE CHARACTERISTICS】

Accuracy

The Ethyl Glucuronide Rapid Test Panel (Urine) has been tested with GC/MS Test using clinical samples. The following results were tabulated:

Method		GC/MS		Total Result
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Analytical Sensitivity

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1,000ng/mL	Cut-off	20	9	11
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3,000ng/mL	3X	20	20	0

Analytical Specificity

The following table lists compounds that are positively detected in urine by the Ethyl Glucuronide Rapid Test Panel (Urine) at 5 minutes.

Compound	Concentration (ng/mL)
Ethyl Glucuronide	1,000

Precision

A study was conducted at three hospitals by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision. An identical panel of coded specimens, containing no Ethyl Glucuronide, 25% Ethyl Glucuronide above and below the cut-off, and 50% Ethyl Glucuronide above and below the 1,000 ng/mL cut-off was provided to each site. The following results were tabulated:

Ethyl Glucuronide Concentration	N Per site	Site A		Site B		Site C	
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Fifteen urine specimens of normal, high, and low specific gravity ranges were spiked with 500 ng/mL and 1,500 ng/mL of Ethyl Glucuronide respectively. The Ethyl Glucuronide Rapid Test Panel (Urine) was tested in duplicate using the fifteen neat and spiked urine specimens. The results demonstrate that varying ranges of urinary specific gravity do not affect the test results.

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The pH of an aliquoted negative urine pool was adjusted to a pH range of 5 to 9 in 1 pH unit increments and spiked with Ethyl Glucuronide to 500 ng/mL and 1,500 ng/mL. The spiked, pH-adjusted urine was tested with The Ethyl Glucuronide Rapid Test Panel (Urine) in duplicate. The results demonstrate that varying ranges of pH do not interfere with the performance of the test.

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Ethyl Glucuronide positive urine. The following compounds show no cross-reactivity when tested with The Ethyl Glucuronide Rapid Test Panel (Urine) at a concentration of 100 µg/mL.

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Acetophenetidin	5,5-Diphenylhydantoin	Maprotiline	cyclopropylamine
Acetylsalicylic acid	Disopyramide	Meperidine	l-Phenylephrine
N-Acetylprocainamide	Doxylamine	Mephentermine	β-Phenylethylamine
Albumin	Ecgonine	Meprobamate	Phenylpropanolamine
Aminopyrine	Ecgoninemethylester	Methadone	(d,l-norephedrine)
Amitriptyline	EDDP	d-Methamphetamine	(±) Phenyl- propanolamine
Amobarbital	Efavirenz (Sustiva)	l-Methamphetamine	Prednisolone
Amoxapine	EMDP	Methaqualone	Prednisone
Amoxicillin	Ephedrine	Methoxyphenamine	5β-Pregnane-3α, 17α, 21-triol
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l-Ascorbic acid	Erythromycin	MDMA	d,l-Propanolol
Aspartame	β-Estradiol	Methylphenidate	d-Propoxyphene
Atropine	Estrone-3-sulfate	Methyprylon	d-Pseudoephedrine
Benzilic acid	Ethanol (Ethyl alcohol)	Methaqualone	Quinacrine
Benzoic acid	Ethyl-p-aminobenzoate	Metoprolol	Quinidine
Benzoylecgonine	Etodolac	Morphine sulfate	Quinine
Benzphetamine	Famprofazone	Morphine-3-β-D-Glucuronide	Ranitidine
Bilirubin	Fenfluramine	Nalidixic acid	Riboflavin
(±)-Brompheniramine	Fenoprofen	Nalorphine	Salicylic acid
Buspirone	Fentanyl	Naloxone	Secobarbital
Caffeine	Fluoxetine	Naltrexone	Serotonin
Cannabidiol	Furosemide	Methyprylon	(5-hydroxytryptamine)
Cannabinol	Gentisic acid	Metoprolol	Sodium chloride
Chloral hydrate	d (+) Glucose	Nimesulide	Sulfamethazine
Chloramphenicol	Guaiacol glyceryl ether	Norcodein	Sulindac
Chlordiazepoxide	Guaiacol glyceryl ether carbamate	Morphine sulfate	Temazepam
Chloroquine	Hemoglobin	α-Naphthaleneacetic acid	Tetracycline
Chlorothiazide	Hydralazine	Norethindrone	Tetrahydrocortisone, 3-acetate
(+)-Chlorpheniramine	Hydrochlorothiazide	Normorphine	Tetrahydrozoline
(±)-Chlorpheniramine	Hydrocodone	d-Norpropoxyphene	Thebaine
Chlorpromazine	Hydrocortisone	Noscapine	Theophylline
Chlorprothixene	Hydromorphone	d,l-Octopamine	Thiamine
Cholesterol	p-Hydroxyamphetamine	Orphenadrine	Thioridazine (chlorpromazine)
Cimetidine	o-Hydroxyhippuric acid	Oxalic acid	l-Thyroxine
Clomipramine	p-Hydroxymethamphetamine	Oxazepam	Tolbutamide
Clonidine	p-Hydroxynorephedrine	Oxolinic acid	cis-Tramadol
Cocaine	Hydroxyzine	Oxycodone	Trazodone
Codeine	3-Hydroxytyramine	Oxymetazoline	Triamterene
Cortisone	Ibuprofen	Oxymorphone	Trifluoperazine
Creatinine	Imipramine	Papaverine	Trimethobenzamide
Cyclobarbital	Iproniazid	Pemoline	Trimethoprim
Cyclobenzaprine	Isoxsuprine	Penicillin-G	Trimipramine
Deoxycorticosterone	(-)-Isoproterenol	Pentazocine	Tryptamine
(-) Deoxyephedrine	Kanamycin	Pentobarbital	d,l-Tryptophan
R (-) Deprenyl	Ketamine	Perphenazine	Tyramine
Dextromethorphan	Ketoprofen	Phencyclidine	d,l-Tyrosine
Diazepam	Labetalol	Phenelzine	Uric acid
Diclofenac	Levorphanol	Pheniramine	Verapamil
Dicyclomine	Lidocaine	Phenobarbital	Zomepirac
Diflunisal	Lindane		
Digoxin	Phenothiazine		
hexachlorocyclohexane			

【BIBLIOGRAPHY】

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Index of Symbols

	Consult Instruction for use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
	Store between 2-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged				

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