innovacon™

One Step Drug Screen Test Strip (Urine)
Package Insert

English

Package insert for testing of the following drugs:
Amphetamine, Amphetamine 500, Amphetamine 300, Barbiturates, Benzodiazepines, Benzodiazepines 200, Buprenorphine, Cocaine, Cocaine 150, Marijuana, Marijuana 150, Marijuana 20, Methadone, EDDP 300 (Methadone metabolite), EDDP 100 (Methadone metabolite), Methamphetamine, Methamphetamine 500, Methamphetamine 300, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants, Tramadol, Ketamine and Fentanyl.

A rapid, one step screen test for the qualitative detection of drugs and metabolites in human urine.

For medical and other professional in vitro diagnostic use only.

INTENDED USE & SUMMARY

Urine based tests for drugs of abuse range from simple immunoassay tests to complex analytical procedures. The speed and sensitivity of immunoassays have made them the most widely accepted method to screen urine for drugs of abuse.

The One Step Drug Screen Test Strip (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of drugs and drug metabolites in urine at the following cut-off concentrations in urine:[1]

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	1,000
Amphetamine (AMP 500)	d-Amphetamine	500
Amphetamine (AMP 300)	d-Amphetamine	300
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO)	Oxazepam	300
Benzodiazepines (BZO 200)	Oxazepam	200
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC)	Benzoylecgonine	300
Cocaine (COC 150)	Benzoylecgonine	150
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50
Marijuana (THC 150)	11-nor-Δ^9-THC-9 COOH	150
Marijuana (THC 20)	11-nor-Δ^9-THC-9 COOH	20
Methadone (MTD)	Methadone	300
Methadone metabolite (EDDP 300)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300
Methadone metabolite (EDDP 100)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	100
Methamphetamine (MET)	d-Methamphetamine	1,000
Methamphetamine (MET 500)	d-Methamphetamine	500
Methamphetamine (MET 300)	d-Methamphetamine	300
Methylenedioxymethamphetamine (MDMA)	d,l-Methylenedioxymethamphetamine	500
Morphine (MOP 300)	Morphine	300
Opiate (OPI 2000)	Morphine	2,000
Oxycodone (OXY)	Oxycodone	100
Phencyclidine (PCP)	Phencyclidine	25
Propoxyphene (PPX)	Propoxyphene	300
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000
Tramadol (TRA)	Tramadol	100
Ketamine (KET)	Ketamine	1,000
Fentanyl (FTY)	Norfentanyl	20

This test will detect other related compounds, please refer to the Analytical Specificity table in this package insert.

This assay provides only a preliminary analytical test result. A more specific alternate 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 judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

PRINCIPLE

The One Step Drug Screen Test Strip (Urine) is an immunoassay based on the principle of competitive binding. Drugs which may be present in the urine specimen compete against their respective drug conjugate for binding sites on their specific antibody.

During testing, a urine specimen migrates upward by capillary action. A drug, if present in the urine specimen below its cut-off concentration, will not saturate the binding sites of its specific antibody. The antibody will then react with the drug-protein conjugate and a visible colored line will show up in the test line region. The presence of drug above the cut-off concentration will saturate all the binding sites of the antibody. Therefore, the colored line will not form in the test line region.

A drug-positive urine specimen will not generate a colored line in the test line region because of drug competition, while a drug-negative urine specimen will generate a line in the test line region because of the absence of drug competition. To serve as a procedural control, a colored line will always appear at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test contains mouse monoclonal antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in the control line.

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test strip should remain in the sealed pouch or closed canister until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test strip should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch or label of the closed canister. The test must remain in the sealed pouch or closed canister until use. **DO NOT FREEZE.** Do not use beyond the expiration date. NOTE: Once the canister has been opened, the remaining test(s) are stable for 90 days only.

SPECIMEN COLLECTION AND PREPARATION

Urine Assay

The urine specimen must 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 supernatant 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 strips
- Package insert

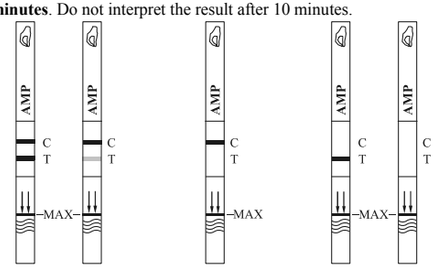
Materials Required But Not Provided

- 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 or canister to room temperature before opening it. Remove the test strip from the sealed pouch or canister and use it as soon as possible.
   NOTE: For canister packaging, immediately close the canister tightly after removing the required number of the test strip(s). Record the initial opening date on the canister. Once the canister has been opened, the remaining test strip(s) are stable for 90 days only.
2. With arrows pointing toward the urine specimen, **immerse the test strip vertically in the urine specimen for at least 10-15 seconds**. Do not pass the maximum line (MAX) on the test strip when immersing the strip. See the illustration below.
3. Place the test strip on a non-absorbent flat surface, start the timer and wait for the colored line(s) to appear. **Read results at 5 minutes**. Do not interpret the result after 10 minutes.



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 drug concentration is below the detectable level.

***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 drug concentration exceeds the detectable level.

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 using a new test. If the problem persists, discontinue using the lot 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 and correct procedural technique.

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

LIMITATIONS

1. The One Step Drug Screen Test Strip (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, 3]
2. There is a possibility 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 does not indicate level or intoxication, administration route or concentration in urine.
5. A negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. The test does not distinguish between drugs of abuse and certain medications.
7. A positive result may be obtained from certain foods or food supplements.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the One Step Drug Screen Test Strip (Urine) and a commercially available drug rapid test. Testing was performed on approximately 300 specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. Negative urine specimens were screened initially by Predicate test, 10% negative specimens were confirmed by GC/MS. The following results were tabulated:

% Agreement with Commercial Kit

Specimen	AMP	AMP 500	AMP 300	BAR	BZO	BZO 200	BUP**	COC	COC 150	THC	THC 150	THC 20	MTD	EDDP 300
Positive	97%	*	>99%	>99%	90%	*	88%	95%	>99%	98%	*	*	>99%	*
Negative	>99%	*	>99%	99%	97%	*	>99%	>99%	>99%	>99%	*	*	>99%	*
Total	98%	*	>99%	99%	94%	*	97%	98%	>99%	99%	*	*	>99%	*

Specimen	EDDP 100	MET	MET 500	MET 300	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TCA	TRA	KET	FTY
Positive	*	98%	>99%	*	>99%	>99%	99%	96%	98%	>99%	95%	*	*	*
Negative	*	>99%	80%	*	99%	>99%	>99%	99%	>99%	>99%	>99%	*	*	*
Total	*	99%	87%	*	99%	>99%	>99%	98%	>99%	>99%	99%	*	*	*

*** NOTE:** Commercial kit unavailable for comparison testing.
**** NOTE:** BUP was compared to the self-reported use of Buprenorphine.

% Agreement with GC/MS

Specimen	AMP	AMP 500	AMP 300	BAR	BZO	BZO 200	BUP*	COC	COC 150	THC	THC 150	THC 20	MTD	EDDP 300
Positive	97%	95%	>99%	92%	97%	99%	98%	96%	99%	96%	91%	87%	99%	>99%
Negative	95%	>99%	99%	98%	95%	99%	>99%	90%	99%	97%	96%	99%	94%	94%
Total	96%	98%	99%	95%	96%	99%	>99%	93%	99%	96%	96%	95%	96%	96%

Specimen	EDDP 100	MET	MET 500	MET 300	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TCA**	TRA*	KET	FTY*
Positive	98%	99%	>99%	97%	97%	>99%	98%	99%	>99%	94%	>99%	99%	>99%	99%
Negative	>99%	94%	97%	>99%	>99%	94%	97%	98%	96%	99%	89%	96%	95%	90%
Total	99%	96%	98%	98%	98%	97%	98%	99%	97%	96%	91%	97%	95%	93%

*** NOTE:** BUP, TRA and FTY were based on LC/MS data instead of GC/MS.
**** NOTE:** TCA was based on HPLC data instead of GC/MS.

Analytical Sensitivity

A drug-free urine pool was spiked with drugs to the concentrations at ± 50% cut-off and ± 25% cut-off. The results are summarized below.

Drug Conc. (Cut-off range)	AMP		AMP 500		AMP 300		BAR		BZO		BZO 200		BUP		COC		COC 150	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	90	0	90	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	90	0	90	0	30	0	30	0
-25% Cut-off	22	8	25	5	27	3	27	3	27	3	81	9	75	15	30	0	24	6
Cut-off	12	18	11	19	13	17	22	8	11	19	55	35	60	30	4	26	14	16
+25% Cut-off	2	28	5	25	4	26	8	22	5	25	27	63	31	59	0	30	7	23
+50% Cut-off	0	30	0	30	0	30	2	28	0	30	0	90	0	90	0	30	0	30

Drug Conc. (Cut-off range)	THC		THC 20		THC 150		MTD		EDDP 300		EDDP 100		MET		MET 500		MET 300	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	90	0	30	0	90	0	90	0	30	0	30	0	30	0
-50% Cut-off	30	0	30	0	90	0	29	1	90	0	90	0	30	0	30	0	30	0
-25% Cut-off	12	18	27	3	90	0	24	6	90	0	90	0	30	0	23	7	27	3
Cut-off	1	29	24	6	46	44	21	9	51	39	37	53	18	12	13	17	15	15
+25% Cut-off	1	29	17	13	5	85	2	28	14	76	8	82	1	29	8	22	4	26
+50% Cut-off	0	30	5	25	0	90	0	30	0	90	0	90	0	30	0	30	0	30

Drug Conc. (Cut-off range)	MDMA		MOP		OPI 2000		OXY		PCP		PPX		TCA		TRA		KET		FTY	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	90	0	90	0	90	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	90	0	90	0	90	0
-25% Cut-off	26	4	25	5	25	5	30	0	19	11	24	6	29	1	90	0	61	29	82	8
Cut-off	17	13	17	13	15	15	18	12	16	14	17	13	18	12	61	29	20	70	48	42
+25% Cut-off	4	26	1	29	6	24	6	24	6	24	7	23	5	25	21	69	2	88	11	79
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	2	88	0	90	0	90

Analytical Specificity

The following table lists the concentration of compounds (ng/mL) that are detected positive in urine by the One Step Drug Screen Test Strip (Urine) at 5 minutes.

AMPHETAMINE	
d-Amphetamine	1,000
d,l-Amphetamine	3,000
l-Amphetamine	50,000
d,l-3,4-Methylenedioxyamphetamine (MDA)	2,000
Phentermine	3,000
AMPHETAMINE 500	
d-Amphetamine	500
d,l-Amphetamine	1,500
3,4-Methylenedioxyamphetamine (MDA)	800
Phentermine	1,500
β-Phenylethylamine	50,000
Tryptamine	50,000
Tyramine	25,000
AMPHETAMINE 300	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
p-Hydroxyamphetamine	1,560
p-Hydroxynorephedrine	100,000
3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine (d,l-Norephedrine)	100,000
Tyramine	100,000
BARBITURATES	
Secobarbital	300
Alphenal	150
Amobarbital	300
Aprobarbital	200
Butabarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100
OXYCODONE	
Oxycodone	100
Hydrocodone	6,250
Hydromorphone	50,000
Levorphanol	50,000
Naloxone	37,500
Naltrexone	37,500

BUPRENORPHINE	
Buprenorphine	10
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine	20
Norbuprenorphine 3-D-glucuronide	200
METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
d,l-3,4-Methylenedioxymethamphetamine (MDMA)	500
d,l-3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300
METHAMPHETAMINE	
d-Methamphetamine	1,000
p-Hydroxymethamphetamine	30,000
Mephentermine	50,000
l-Methamphetamine	8,000
d,l-3,4-Methylenedioxymethamphetamine (MDMA)	2,000
METHAMPHETAMINE 500	
d-Methamphetamine	500
d,l-Amphetamine	75,000
d-Amphetamine	50,000
Chloroquine	12,500
(1R,2S)-l-Ephedrine	50,000
p-Hydroxymethamphetamine	15,000
Mephentermine	25,000
l-Methamphetamine	4,000
3,4-Methylenedioxymethamphetamine (MDMA)	1,000
l-Phenylephrine	100,000
β-Phenylethylamine	75,000
METHAMPHETAMINE 300	
d-Methamphetamine	300
d,l-Amphetamine	100,000
Chloroquine	25,000
Ephedrine	100,000
(1R,2S)-l-Ephedrine	100,000
l-Epinephrine	50,000
Fenfluramine	12,500
p-Hydroxymethamphetamine	25,000
Mephentermine	50,000
l-Methamphetamine	3,125
3,4-Methylenedioxymethamphetamine (MDMA)	780
Trimethobenzamide	25,000
PHENCYCLIDINE	
Phencyclidine	25

Oxymorphone	200
BENZODIAZEPINES	
Oxazepam	300
Alprazolam	196
Bromazepam	1,562
Chlordiazepoxide	1,562
Clobazam	98
Clonazepam	781
Clorazepate	195
Delorazepam	1,562
Desalkylflurazepam	390
Diazepam	195
Estazolam	2,500
Flunitrazepam	390
α-Hydroxyalprazolam	1,262
d,l-Lorazepam	1,562
RS-Lorazepam glucuronide	1,562
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500
BENZODIAZEPINES 200	
Alprazolam	195
7-Aminoclonazepam	>100,000
7-Aminoflunitrazepam	200
7-Aminonitrazepam	5,000
Bromazepam	390
Benzydamine hydrochloride	1,562
Chlordiazepoxide	780
Clobazam	390
Clorazepate	1,562
Desalkylflurazepam	1,000
Diazepam	200
Estazolam	780
Flunitrazepam	12,500
α-Hydroxyalprazolam	1,562
d-Lorazepam	100,000
Midazolam	6,250
Nitrazepam	100
Norchlordiazepoxide	3,125
Nordiazepam	780
Oxazepam	200
Sertraline	12,500
Temazepam	100
Triazolam	50,000
MARIJUANA	
11-nor-Δ^9-THC-9 COOH	50
Cannabinol	20,000
11-nor-Δ^8-THC-9 COOH	30
Δ^8-THC	15,000
Δ^9-THC	15,000
MARIJUANA 20	
11-nor-Δ^9-THC-9 COOH	20
Cannabinol	12,500
11-nor-Δ^8-THC-9 COOH	20
Δ^8-THC	10,000
Δ^9-THC	12,500
MARIJUANA 150	
11-nor-Δ^9-THC-9 COOH	150

4-Hydroxyphencyclidine	12,500
COCAINE	
Benzoylecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000
COCAINE 150	
Benzoylecgonine	150
Cocaine	400
Cocaethylene	6,250
Ecgonine	12,500
Ecgonine methylester	50,000
METHADONE	
Methadone	300
Doxylamine	50,000
EDDP 300	
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300
EDDP 100	
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	100
MORPHINE 300	
Morphine	300
Codeine	300
Ethylmorphine	6,250
Hydrocodone	50,000
Hydromorphone	3,125
Levorphanol	1,500
6-Monoacetylmorphine (6-MAM)	400
Morphine 3-β-D-glucuronide	1,000
Norcodeine	6,250
Normorphine	100,000
Oxycodone	30,000
Oxymorphone	100,000
Procaine	15,000
Thebaine	6,250
OPIATE 2000	
Morphine	2,000
Codeine	2,000
Ethylmorphine	5,000
Hydrocodone	12,500
Hydromorphone	5,000
Levorphanol	75,000
6-Monoacetylmorphine (6-MAM)	5,000
Morphine 3-β-D-glucuronide	2,000
Norcodeine	12,500
Normorphine	50,000
Oxycodone	25,000
Oxymorphone	25,000
Procaine	150,000
Thebaine	100,000
TRICYCLIC ANTIDEPRESSANTS	
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	12,500
Desipramine	200
Doxepin	2,000
Imipramine	400
Maprotiline	2,000
Nordoxepin	1,000
Promazine	1,500
Promethazine	25,000
Trimipramine	3,000

Cannabinol	25,000
11-nor-Δ^8-THC-9 COOH	500
Δ^8-THC	25,000
Δ^9-THC	25,000
PROPOXYPHENE	
d-Propoxyphene	300
d-Norpropoxyphene	300
FENTANYL	
Alfentanyl	562,500
Buspirone	12,500
Fenfluramine	37,500
Fentanyl	100
Norfentanyl	20
Sufentanyl	57,500

TRAMADOL	
n-Desmethyl-cis-tramadol	195
o-Desmethyl-cis-tramadol	6,250
Cis-tramadol	100
Phencyclidine	100,000
Procyclidine	100,000
d,l-O-Desmethyl venlafaxine	25,000
KETAMINE	
Ketamine	1,000
Pentobarbital	50,000
Secobarbital	100,000
Norketamine	50,000

Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free urine or Amphetamine, Amphetamine 500, Amphetamine 300, Barbiturates, Benzodiazepines, Benzodiazepines 200, Buprenorphine, Cocaine, Cocaine 150, Marijuana, Marijuana 150, Marijuana 20, Methadone, EDDP 300, EDDP 100, Methamphetamine, Methamphetamine 500, Methamphetamine 300, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene, Tricyclic Antidepressants, Tramadol, Ketamine and Fentanyl positive urine. The following compounds show no cross-reactivity when tested with the One Step Drug Screen Test Strip (Urine) at a concentration of 100 µg/mL.

Non Cross-Reacting Compounds

Acetophenetidin	Cortisone	Isoxsuprine	d-Pseudoephedrine
N-Acetylprocainamide	l-Cotinine	Ketoprofen	Quinidine
Acetylsalicylic acid	Creatinine	Labetalol	Quinine
Aminopyrine	Deoxycorticosterone	Loperamide	Salicylic acid
Amoxicillin	Dextromethorphan	Meprobamate	Serotonin
Ampicillin	Diclofenac	Methoxyphenamine	Sulfamethazine
l-Ascorbic acid	Diflunisal	Methylphenidate	Sulindac
Apomorphine	Digoxin	Nalidixic acid	Tetracycline
Aspartame	Diphenhydramine	Naproxen	Tetrahydrocortisone,
Atropine	Ethyl-p-aminobenzoate	Niacinamide	3-Acetate
Benzilic acid	β-Estradiol	Nifedipine	Tetrahydrocortisone
Benzoic acid	Estrone-3-sulfate	Norethindrone	Tetrahydrozoline
Bilirubin	Erythromycin	Noscapine	Thiamine
d,l-Brompheniramine	Fenoprofen	d,l-Octopamine	Thioridazine
Caffeine	Furosemide	Oxalic acid	d,l-Tyrosine
Cannabidiol	Gentisic acid	Oxolinic acid	Tolbutamide
Chloral hydrate	Hemoglobin	Oxymetazoline	Triamterene
Chloramphenicol	Hydralazine	Papaverine	Trifluoperazine
Chlorothiazide	Hydrochlorothiazide	Penicillin-G	Trimethoprim
d,l-Chlorpheniramine	Hydrocortisone	Perphenazine	d,l-Tryptophan
Chlorpromazine	o-Hydroxyhippuric acid	Phenelzine	Uric acid
Cholesterol	3-Hydroxytyramine	Prednisone	Verapamil
Clonidine	d,l-Isoproterenol	d,l-Propanolol	Zomepirac

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Index of Symbols

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

Manufacturer

Innovacon, Inc.
9975 Summers Ridge Road
San Diego, CA 92121, USA

CE

EC REP
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