

One Step Drug Screen Test Device (Urine) Package Insert

English

Package insert for testing of the following drugs:

Amphetamine 300, Amphetamine 500, Amphetamine, Barbiturates, Benzodiazepines 200, Benzodiazepines, Buprenorphine, Cocaine 150, Cocaine, Cotinine, Fentanyl, Ketamine, Marijuana 20, Marijuana, Marijuana 150, Methadone, EDDP 100 (Methadone metabolite), EDDP 300 (Methadone metabolite), Methamphetamine 300, Methamphetamine 500, Methamphetamine, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene, Tramadol and Tricyclic Antidepressants.

A rapid, one step screening test for the simultaneous, qualitative detection of drugs and drug 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 SPINREACT One Step Drug Screen Test Device (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 300)	d-Amphetamine	300
Amphetamine (AMP 500)	d-Amphetamine	500
Amphetamine (AMP)	d-Amphetamine	1,000
Barbiturates (BAR)	Secobarbital	300
Benzodiazepines (BZO 200)	Oxazepam	200
Benzodiazepines (BZO)	Oxazepam	300
Buprenorphine (BUP)	Buprenorphine	10
Cocaine (COC 150)	Benzoyllecgonine	150
Cocaine (COC)	Benzoyllecgonine	300
Cotinine (COT)	Cotinine	100
Fentanyl (FTY)	Norfentanyl	20
Ketamine (KET)	Ketamine	1,000
Marijuana (THC 20)	11-nor-Δ ⁹ -THC-9 COOH	20
Marijuana (THC)	11-nor-Δ ⁹ -THC-9 COOH	50
Marijuana (THC 150)	11-nor-Δ ⁹ -THC-9 COOH	150
Methadone (MTD)	Methadone	300
Methadone metabolite (EDDP 100)	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	100
Methadone metabolite (EDDP 300)	2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300
Methamphetamine (MET 300)	d-Methamphetamine	300
Methamphetamine (MET 500)	d-Methamphetamine	500
Methamphetamine (MET)	d-Methamphetamine	1,000
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
Tramadol (TRA)	Tramadol	100
Tricyclic Antidepressants (TCA)	Nortriptyline	1,000

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 SPINREACT One Step Drug Screen Test Device (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

Each test contains specific drug 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 device should remain in the sealed pouch until use.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.
- The used test device should be discarded according to local regulations.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device 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 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 devices
- Droppers
- Package insert

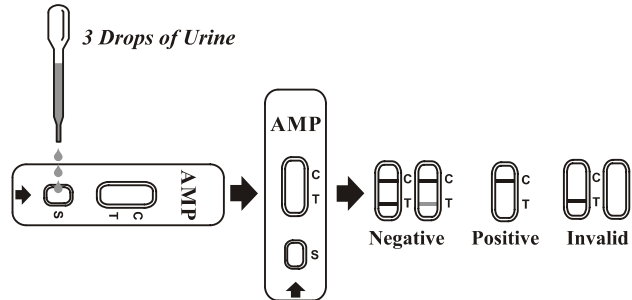
Materials Required But Not Provided

- 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 device from the sealed pouch and use it as soon as possible.
2. Place the test device on a clean and level surface. Hold the dropper vertically and **transfer 3 full drops of urine** (approx. 100 µL) to the specimen well (S) of the test device, and then start the timer. Avoid trapping air bubbles in the specimen well (S). See the illustration below.
3. 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) will vary, but it should always be considered as 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 SPINREACT One Step Drug Screen Test Device (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 SPINREACT One Step Drug Screen Test Device (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:

Specimen	% Agreement with Commercial Kit															
	AMP 300	AMP 500	AMP	BAR	BZO 200	BZO	BUP**	COC 150	COC	COT	FTY	KET	THC 20	THC	THC 150	
Positive	>99%	*	96%	>99%	*	90%	88%	>99%	95%	>99%	*	*	*	>99%	*	
Negative	>99%	*	>99%	99%	*	97%	>99%	>99%	>99%	>99%	*	*	*	>99%	*	
Total	>99%	*	98%	99%	*	94%	97%	>99%	98%	>99%	*	*	*	>99%	*	

Specimen	% Agreement with GC/MS													
	MTD	EDDP 100	EDDP 300	MET 300	MET 500	MET	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TRA	TCA
Positive	>99%	*	*	*	>99%	99%	>99%	>99%	99%	96%	97%	>99%	*	95%
Negative	>99%	*	*	*	82%	>99%	99%	>99%	>99%	99%	>99%	>99%	*	>99%
Total	>99%	*	*	*	89%	>99%	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

Specimen	% Agreement with GC/MS															
	AMP 300	AMP 500	AMP	BAR	BZO 200	BZO	BUP*	COC 150	COC	COT*	FTY*	KET	THC 20	THC	THC 150	
Positive	>99%	97%	96%	92%	98%	96%	98%	99%	96%	>99%	99%	>99%	91%	97%	91%	
Negative	99%	99%	95%	98%	99%	96%	>99%	99%	90%	>99%	89%	97%	99%	96%	96%	
Total	99%	98%	95%	95%	99%	96%	>99%	99%	93%	>99%	93%	97%	96%	97%	95%	

Specimen	% Agreement with GC/MS													
	MTD	EDDP 100	EDDP 300	MET 300	MET 500	MET	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TRA*	TCA**
Positive	99%	>99%	>99%	98%	99%	99%	>99%	>99%	98%	99%	>99%	94%	96%	>99%
Negative	94%	>99%	95%	>99%	98%	93%	98%	94%	97%	98%	97%	99%	97%	89%
Total	96%	>99%	99%	98%	98%	96%	99%	97%	98%	99%	98%	96%	97%	91%

* NOTE: BUP, COT, FTY and TRA 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 300		AMP 500		AMP		BAR		BZO 200		BZO		BUP		COC 150		COC		COT	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	90	0	30	0	30	0	60	0	30	0	90	0	30	0	30	0	90	0
-50% Cut-off	30	0	90	0	30	0	30	0	60	0	30	0	90	0	30	0	30	0	90	0
-25% Cut-off	25	5	88	2	23	7	20	10	60	0	26	4	78	12	27	3	30	0	90	0
Cut-off	16	14	45	45	9	21	13	17	22	38	12	18	48	42	13	17	9	21	49	41
+25% Cut-off	4	26	1	89	1	29	8	22	2	58	3	27	24	66	7	23	7	23	4	86
+50% Cut-off	0	30	0	90	0	30	0	30	0	60	0	30	0	90	0	30	0	30	0	90

Drug Conc. (Cut-off range)	FTY		KET		THC 20		THC		THC 150		MTD		EDDP 100		EDDP 300		MET 300		MET 500			
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	90	0	90	0	30	0	30	0	90	0	30	0	90	0	90	0	30	0	30	0	30	0
-50% Cut-off	90	0	90	0	30	0	30	0	90	0	30	0	90	0	90	0	30	0	30	0	30	0
-25% Cut-off	79	11	48	42	29	1	30	0	90	0	26	4	80	10	79	11	27	3	27	3	27	3
Cut-off	36	54	6	84	19	11	21	9	45	45	16	14	51	39	51	39	15	15	13	17	17	17
+25% Cut-off	7	83	0	90	6	24	17	13	10	80	4	26	3	87	13	77	5	25	7	23	23	23
+50% Cut-off	0	90	0	90	0	30	0	30	0	90	0	30	0	90	0	90	0	30	0	30	0	30

Drug Conc. (Cut-off range)	MET		MDMA		MOP 300		OPI 2000		OXY		PCP		PPX		TRA		TCA	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	90	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30	0	90	0	30	0
-25% Cut-off	24	6	23	7	28	2	24	6	30	0	26	4	26	4	90	0	26	4
Cut-off	18	12	15	15	20	10	10	20	21	9	11	19	19	11	58	32	14	16
+25% Cut-off	1	29	6	24	3	27	4	26	6	24	8	22	8	22	22	68	4	26
+50% Cut-off	0	30	0	30	0	30	0	30	0	30	0	30	0	30	2	88	0	30

Analytical Specificity

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

AMPHETAMINE 300	
d-Amphetamine	300
d,l-Amphetamine	390
l-Amphetamine	50,000
p-Hydroxyamphetamine	1,560
p-Hydroxymorephedrine	100,000
3,4-Methylenedioxyamphetamine (MDA)	1,560
β-Phenylethylamine	100,000
Phenylpropanolamine (d,l-Norephedrine)	100,000
Tyramine	100,000

AMPHETAMINE 500	
d-Amphetamine	500
d,l-Amphetamine	1,500
Methamphetamine	780
p-Hydroxybuprenorphine	1,562
l-Amphetamine	25,000

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

BARBITURATES	
Secobarbital	300
Alphenal	150
Amobarbital	300
Aprobarbital	200
Butobarbital	75
Butalbital	2,500
Butethal	100
Cyclopentobarbital	600
Pentobarbital	300
Phenobarbital	100

BENZODIAZEPINES 200	
Oxazepam	200
Alprazolam	30
7-Aminoclonazepam	4,000
7-Aminoflunitrazepam	390
7-Aminonitrazepam	625
Bromazepam	390
Chlordiazepoxide	300
Clobazam	48
Clorazepate	97

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 150	
11-nor-Δ ⁹ -THC-9 COOH	150
Cannabinol	25,000
11-nor-Δ ⁸ -THC-9 COOH	500
Δ ⁸ -THC	25,000
Δ ⁹ -THC	25,000

EDDP 100	
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	100

EDDP 300	
2-Ethylidene-1,5-dimethyl-3,3-diphenylpyrrolidine (EDDP)	300

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-Methylenedioxyamphetamine (MDMA)	780
Trimethobenzamide	25,000

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-Methylenedioxyamphetamine (MDMA)	1,000
l-Phenylephrine	100,000
β-Phenylethylamine	75,000

METHAMPHETAMINE	
d-Methamphetamine	1,000

Desalkylflurazepam	1,560
Diazepam	97
Estazolam	125
Flunitrazepam	25,000
α-Hydroxyalprazolam	30
d-Lorazepam	3,125
Midazolam	195
Nitrazepam	780
Norchlordiazepoxide	780
Nordiazepam	780
Temazepam	33
Triazolam	150

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	156
Midazolam	12,500
Nitrazepam	98
Norchlordiazepoxide	195
Nordiazepam	390
Temazepam	98
Triazolam	2,500

BUPRENORPHINE	
Buprenorphine	10
Buprenorphine 3-D-glucuronide	15
Norbuprenorphine	20
Norbuprenorphine 3-D-glucuronide	200

COCAINE 150	
Benzoyllecgonine	150
Cocaine	400
Cocaethylene	6,250
Ecgonine	12,500
Ecgonine methylester	50,000

COCAINE	
Benzoyllecgonine	300
Cocaine	780
Cocaethylene	12,500
Ecgonine	32,000

COTININE	
l-Cotinine	100
S-1-Nicotine	12,500

FENTANYL	
Norfentanyl	20
Alfentanyl	562,500
Buspirone	12,500
Fenfluramine	37,500
Fentanyl	100
Sufentanyl	57,500

KETAMINE	
Ketamine	1,000
Pentobarbital	50,000
Secobarbital	100,000
Norketamine	50,000

METHADONE	
p-Hydroxymethamphetamine	30,000
Mephentermine	50,000
Triazolam	150

p-Hydroxymethamphetamine	30,000
Mephentermine	50,000
Triazolam	150

p-Hydroxymethamphetamine	30,000
Mephentermine	50,000
Triazolam	150

p-Hydroxymethamphetamine	30,000
Mephentermine	50,000
Triazolam	150

p-Hydroxymethamphetamine	30,000
Mephentermine	50,000
Triazolam	150

p-Hydroxymethamphetamine	30,000
Mephentermine	50,000
Triazolam	150

p-Hydroxymethamphetamine	30,000
Mephentermine	50,000
l-Methamphetamine	8,000
d,l-3,4-Methylenedioxyamphetamine (MDMA)	2,000

METHYLENEDIOXYMETHAMPHETAMINE (MDMA)	
d,l-3,4-Methylenedioxyamphetamine (MDMA)	500
d,l-3,4-Methylenedioxyamphetamine (MDA)	3,000
3,4-Methylenedioxyethylamphetamine (MDEA)	300

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

OXYCODONE	
Oxycodone	100
Hydrocodone	6,250
Hydromorphone	50,000
Levorphanol	50,000
Naloxone	37,500
Naltrexone	37,500
Oxymorphone	200

PHENCYCLIDINE	
Phencyclidine	25
4-Hydroxyphencyclidine	12,500

PROPOXYPHENE	
d-Propoxyphene	300
d-Norpropoxyphene	300

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

TRICYCLIC ANTIDEPRESSANTS	
Nortriptyline	1,000
Amitriptyline	1,500
Clomipramine	12,500
Desipramine	200
Doxepin	2,000
Imipramine	400

Methadone	300
Doxylamine	50,000
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

Maprotiline	2,000
Nordoxepin	1,000
Promazine	1,500
Promethazine	25,000
Trimipramine	3,000

Cross-Reactivity

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

Non Cross-Reacting Compounds

4-Acetamidophenol	Diclofenac	Labeltalol	Prednisolone
Acetone	Dicyclomine	Lidocaine	Prednisone
Acetophenetidin	Diffunisal	Lindane	d,l-Propranolol
Acetylsalicylic acid	Digoxin	Lithium	Quinacrine
Albumin	4-Dimethylaminoantipyrine	Loperamide	Quinidine
alpha-Naphthaleneacetic Acid	Diphenhydramine	l-Thyroxine	Quinine
Aminopyrine	5,5-Diphenylhydantoin	Meperidine	R(-) Deprenyl
Amoxapine	EMDP	Meprobamate	Riboflavin
Amoxicillin	Erythromycin	Methaqualone	Salicylic acid
Ampicillin	β-Estradiol	Methoxyphenamine	Ser