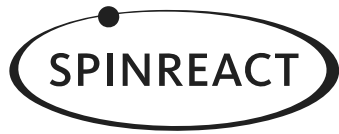


Effective date: 2014-07-10

Number: 1156100501



One Step Drug Screen Test Strip (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, Fentanyl, Ketamine, Marijuana 20, Marijuana, Marijuana 150, Methadone, EDDP 100 (Methadone metabolite), EDDP 300 (Methadone metabolite), Methamphetamine 300, Methamphetamine 500, Methamphetamine, Methylendioxyamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene, Tramadol and Tricyclic Antidepressants.

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 SPINREACT 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 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)	Benzoylcegonine	150
Cocaine (COC)	Benzoylcegonine	300
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-dipheylpyrrolidine (EDDP)	100
Methadone metabolite (EDDP 300)	2-Ethylidene-1,5-dimethyl-3,3-dipheylpyrrolidine (EDDP)	300
Methamphetamine (MET 300)	d-Methamphetamine	300
Methamphetamine (MET 500)	d-Methamphetamine	500
Methamphetamine (MET)	d-Methamphetamine	1,000
Methylendioxyamphetamine (MDMA)	d,l-Methylendioxyamphetamine	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 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

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 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

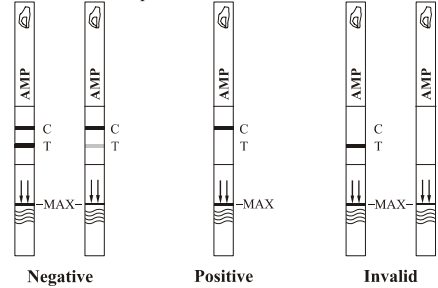
Allow the test, urine specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

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

- The SPINREACT 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}
- There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
- 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.
- A positive result does not indicate level or intoxication, administration route or concentration in urine.
- 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.
- The test does not distinguish between drugs of abuse and certain medications.
- 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 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:

Specimen	% Agreement with Commercial Kit													
	AMP 300	AMP 500	AMP	BAR	BZO 200	BZO	BUP**	COC 150	COC	FTY	KET	THC 20	THC	THC 150
Positive	>99%	*	97%	>99%	*	90%	88%	>99%	95%	*	*	*	98%	*
Negative	>99%	*	>99%	99%	*	97%	>99%	>99%	>99%	*	*	*	>99%	*
Total	>99%	*	98%	99%	*	94%	97%	>99%	98%	*	*	*	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%	98%	>99%	>99%	99%	96%	98%	>99%	*	95%
Negative	>99%	*	*	*	80%	>99%	99%	>99%	>99%	99%	>99%	>99%	*	>99%
Total	>99%	*	*	*	87%	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	FTY*	KET	THC 20	THC	THC 150
Positive	>99%	95%	97%	92%	98%	97%	98%	99%	96%	99%	>99%	87%	96%	91%
Negative	99%	>99%	95%	98%	99%	95%	>99%	99%	90%	90%	95%	99%	97%	96%
Total	99%	98%	96%	95%	99%	96%	>99%	99%	93%	93%	95%	95%	96%	96%

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%	98%	>99%	97%	>99%	99%	>99%	>99%	98%	99%	>99%	94%	99%	>99%
Negative	94%	>99%	94%	>99%	97%	94%	98%	94%	97%	98%	96%	99%	96%	89%
Total	96%	99%	96%	98%	98%	96%	99%	97%	98%	99%	97%	96%	97%	91%

* NOTE: BUP, 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 \pm 50% cut-off and \pm 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	
	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	60	0	30	0	90	0	30	0	30	0
-50% Cut-off	30	0	30	0	30	0	30	0	60	0	30	0	90	0	30	0	30	0
-25% Cut-off	27	3	25	5	22	8	27	3	60	0	27	3	75	15	24	6	30	0
Cut-off	13	17	11	19	12	18	22	8	22	38	11	19	60	30	14	16	4	26
+25% Cut-off	4	26	5	25	2	28	8	22	2	58	5	25	31	59	7	23	0	30
+50% Cut-off	0	30	0	30	0	30	2	28	0	60	0	30	0	90	0	30	0	30

