

Package insert for testing of any combination of the following drugs:
 Amphetamine 300, Amphetamine 500, Amphetamine, Barbiturates, Benzodiazepines 200, Benzodiazepines, Buprenorphine 5, Buprenorphine, Clonazepam, 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, Methaqualone, Methylenedioxymethamphetamine, Morphine 300, Opiate 2000, Oxycodone, Phencyclidine, Propoxyphene, Tramadol and Tricyclic Antidepressants.

Including Specimen Validity Tests (S.V.T.) for Oxidants/ Pyridinium Chlorochromate (OX/PCC), Specific Gravity (S.G.), pH, Nitrite (NIT), Glutaraldehyde (GLUT) and Creatinine (CRE).

A rapid, one step screen test for the simultaneous, qualitative detection of multiple drugs and metabolites in human urine. For medical and other professional *in vitro* diagnostic use only.

INTENDED USE & SUMMARY

Urine based screen tests for multiple 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 multiple drugs of abuse.

The SPINREACT Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key® Cup II (Urine) is a lateral flow chromatographic immunoassay for the qualitative detection of following drugs without the need of instruments.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 5)	Buprenorphine	5
Buprenorphine (BUP)	Buprenorphine	10
Clonazepam (ACL)	7-Aminoclonazepam	100
Cocaine (COC 150)	Benzoylcegonine	150
Cocaine (COC)	Benzoylcegonine	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-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
Methaqualone (MQL)	Methaqualone	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
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.

S.V.T. SUMMARY

Each S.V.T. strip contains chemically treated reagent pads. Three to five minutes following the activation of the reagent pads by the urine sample, the colors that appear on the pads can be compared with the printed color chart card. The color comparison provides a semi-quantitative screen for any combination of oxidants/pyridinium chlorochromate (PCC), specific gravity, pH, nitrite, glutaraldehyde and creatinine in human urine which can help assess the integrity of the urine sample.

PRINCIPLE

The SPINREACT Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key® Cup II (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 coated on the particles. The antibody coated particles will then be captured by the immobilized drug conjugate and a visible colored line will show up in the test line region of the specific drug strip. The colored line will not form in the test line region if the drug level is above its cut-off concentration because it will saturate all the binding sites of the antibody coated on the particles.

A drug-positive urine specimen will not generate a colored line in the specific test line region of the strip because of drug competition, while a drug-negative urine specimen or a specimen containing a drug concentration less than the cut-off will generate a line in the test line region. 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.

S.V.T. PRINCIPLE

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.

One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as pH and specific gravity and to detect the presence of oxidants/PCC, specific gravity, pH, nitrite, glutaraldehyde and creatinine in urine.

- Oxidants/PCC** (Pyridinium chlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is a commonly used adulterant.² Normal human urine should not contain oxidants or PCC.
- Specific gravity** tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.
- pH** tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.
- Nitrite** tests for commonly used commercial adulterants such as Klear or Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH.³ Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.
- Glutaraldehyde** tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative screening results by disrupting the enzyme used in some immunoassay tests.² Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.
- Creatinine** is a waste product of creatine, an amino acid contained in muscle tissue and found in urine.¹ A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to “flush” the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine and specific gravity levels may indicate dilute urine. The absence of creatinine (< 5 mg/dL) is indicative of a specimen not consistent with human urine.

REAGENTS

Each test contains specific drug antibody-coupled particles and corresponding drug-protein conjugates. A goat antibody is employed in each control line.

S.V.T. REAGENTS

Adulteration Pad	Reactive indicator	Buffers and non-reactive ingredients
Oxidants/PCC	0.36%	99.64%
Specific Gravity	0.25%	99.75%
pH	0.06%	99.94%
Nitrite	0.07%	99.93%
Glutaraldehyde	0.02%	99.98%
Creatinine	0.04%	99.96%

PRECAUTIONS

- For medical and other professional *in vitro* diagnostic use only. Do not use after the expiration date.
- The test cup 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 cup 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 cup is stable through the expiration date printed on the sealed pouch. The test cup 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. When tests include S.V.T., storage of urine specimens should not exceed 2 hours at room temperature or 4 hours refrigerated prior to testing. For best results, test specimens immediately following collection.

MATERIALS

Materials Provided

- Cups with multi-drug panels
- Security seal labels
- Keys
- SVT/Adulterant color chart (if applicable)
- Package insert

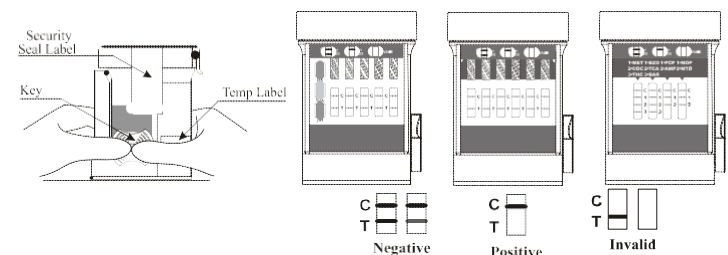
Materials Required But Not Provided

- Timer

DIRECTIONS FOR USE

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

- Bring the pouch to room temperature before opening it. Remove the cup from the sealed pouch and use it as soon as possible.
- Remove the key** by twisting it from the center of the cup cap.
- Collect specimen in the cup** and secure the cap tightly by pressing down on the pull tab until an audible click is heard.
- Check the temperature label** (Temp Label) up to 4 minutes after specimen collection. A green color will appear to indicate the temperature of the urine specimen. The proper range for an unadulterated specimen is 33-38°C (91-100°F).
- Date and initial the security seal label then place it over the cap.
- Place the cup on a flat surface and **push the key into the socket** of the cup to initiate the test. **Start the timer.**
- Remove the peel off label covering the test results. **Read the adulteration strip between 3 and 5 minutes.**
- Compare the colors on the adulteration strip to the enclosed color chart. If the result indicates adulteration, do not interpret the drug test results. Either retest the urine or collect another specimen.
- Read the drug strip results at 5 minutes.** The drug strip results remain stable for up to sixty minutes.



INTERPRETATION OF RESULTS

(Please refer to the illustration above)

NEGATIVE:* A colored line in the control line region (C) and a colored line in the test line region (T) for a specific drug indicate a negative result. This indicates that the drug concentration in the urine specimen is below the designated cut-off level for that specific drug.

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

POSITIVE: A colored line in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This indicates that the drug concentration in the urine specimen exceeds the designated cut-off for that specific drug.

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 cup. If the problem persists, discontinue using the lot immediately and contact your local distributor.

SVT/ADULTERANT INTERPRETATION

(Please refer to the color chart)

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strip to the printed color blocks on the color chart. No instrumentation is required.

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 Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key Cup II (Urine) provides only a preliminary analytical result. A more specific chemical method must be used to obtain a confirmed result. Gas chromatography/mass

- spectrometry (GC/MS) is the preferred confirmatory method.^{4,5}
- It is possible 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 indicates presence of the drug or its metabolites but does not indicate level of 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 might be obtained from certain foods or food supplements.

S.V.T. ADULTERATION LIMITATIONS

- The adulteration tests included with this product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an “all-inclusive” representation of possible adulterants.
- Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
- Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
- Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
- Glutaraldehyde: Is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
- Creatinine: Normal creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

PERFORMANCE CHARACTERISTICS

Accuracy

A side-by-side comparison was conducted using the SPINREACT Multi-Drug One Step Multi-Line Screen Test Panel with Integrated E-Z Split Key® Cup II (Urine) and commercially available drug rapid tests. Testing was performed on approximately 300 specimens previously collected from subjects presenting for Drug Screen Testing. Presumptive positive results were confirmed by GC/MS. The following results were tabulated:

% Agreement with Commercial Kit

Specimen	AMP 300	AMP 500	AMP	BAR	BZO 200	BZO	BUP 5	BUP**	ACL	COC 150	COC
Positive	>99%	*	>99%	>99%	*	>99%	*	88%	*	>99%	>99%
Negative	>99%	*	>99%	>99%	*	>99%	*	>99%	*	>99%	99%
Total	>99%	*	>99%	>99%	*	>99%	*	97%	*	>99%	99%

Specimen	COT	FTY	KET	THC 20	THC	THC 150	MTD	EDDP 100	EDDP 300	MET 300	MET 500
Positive	>99%	*	*	*	>99%	*	89%	*	*	*	>99%
Negative	>99%	*	*	*	99%	*	>99%	*	*	*	80%
Total	>99%	*	*	*	99%	*	94%	*	*	*	87%

Specimen	MET	MQL	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TRA	TCA
Positive	>99%	*	96%	95%	98%	96%	99%	>99%	*	92%
Negative	>99%	*	>99%	>99%	>99%	99%	>99%	>99%	*	>99%
Total	>99%	*	98%	97%	99%	98%	99%	>99%	*	98%

* NOTE: Commercial kit unavailable for comparison testing.

** NOTE: BUP was compared to the self-reported use of Buprenorphine.

% Agreement with GC/MS

Specimen	AMP 300	AMP 500	AMP	BAR	BZO 200	BZO	BUP 5	BUP*	ACL	COC 150	COC
Positive	99%	95%	95%	92%	98%	98%	>99%	98%	>99%	97%	95%
Negative	99%	>99%	99%	98%	99%	98%	>99%	99%	>99%	>99%	>99%
Total	99%	98%	97%	95%	99%	98%	>99%	99%	>99%	99%	98%

Specimen	COT*	FTY*	KET	THC 20	THC	THC 150	MTD	EDDP 100	EDDP 300	MET 300	MET 500
Positive	>99%	99%	>99%	87%	95%	91%	93%	98%	>99%	97%	99%
Negative	>99%	90%	95%	99%	95%	96%	>99%	>99%	94%	>99%	>99%
Total	>99%	93%	95%	95%	95%	96%	97%	99%	96%	98%	99%

Specimen	MET	MQL	MDMA	MOP 300	OPI 2000	OXY	PCP	PPX	TRA*	TCA**
Positive	90%	>99%	99%	98%	99%	98%	90%	>99%	99%	>99%
Negative	>99%	>99%	99%	97%	99%	99%	99%	>99%	96%	94%
Total	96%	>99%	99%	97%	99%	99%	96%	>99%	97%	95%

* 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.

