Veti-Screen™ 6
VETERINARY DRUG SCREEN

INSERT

Instruction Sheet for testing of any combination of the follow drugs:
OPI / METH / COC / AMP / THC Delta 9 & Delta 8
A rapid test for the simultaneous, qualitative detection of multiple drugs and drug metabolites in urine.

INTENDED USE
The Veti-Screen 6 DOA test is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in urine at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/mL)
Amphetamine (AMP)	d-Amphetamine	250
Cocaine (COC)	Benzoylecgonine	100
Marijuana (THC) Delta 9	11-nor-Δ^9-THC-9 COOH	18
Marijuana (THC) Delta 8	8-OHΔ^9-THC Alpha & Beta	500
Methamphetamine (METH)	d-Methamphetamine	250
Opiate/Morphine (OPI)	Morphine	100

This assay provides only a preliminary 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 indicated.

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 region of the specific drug dipstick. 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 region.

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

REAGENTS FOR DOA TESTS Each test line contains anti-drug mouse monoclonal antibody and corresponding drug-protein conjugates. The control line contains goat anti -rabbit IgG polyclonal antibodies and rabbit IgG

PRECAUTIONS:

- Immunoassay for *in vitro* diagnostic use only. The Test 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 should be discarded according to local regulations.

CASSETTE STORAGE STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date on the sealed pouch. The test must remain in the sealed pouch until use. **DO NOT REFRIDGERATE OR FREEZE**. Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

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

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 froze, and stored below –20°C. Frozen specimens should be thawed and mixed well before testing.

MATERIALS

Materials Provided: Test Cassettes, Dropper, Package Insert

Material Required But Not Provided: Timer, Specimen collection container

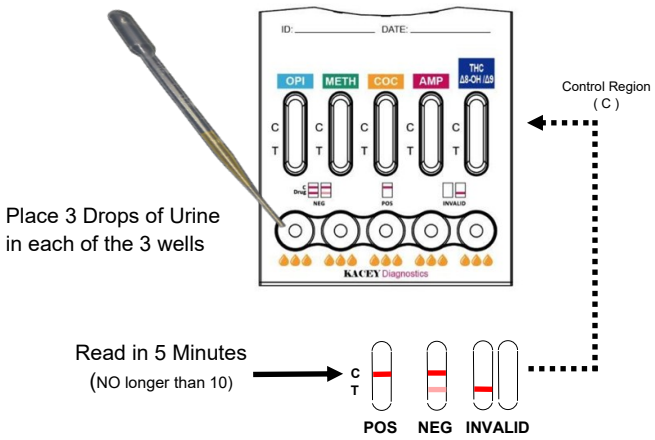
DIRECTIONS FOR USE

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

1) Bring the pouch to room temperature before opening. Remove the test cassette from the seated pouch, and use it within one hour.

2) Place the test cassette on a clean and level surface. Hold the dropper vertically and transfer 3 full drops of urine to the specimen to each well marked with three black drop icons. **3 drops in each of the wells**, and then start timer. Avoid trapping air bubbles in the specimen wells. See illustration in next column.

3) The cassette results should be read at **5 minutes**.
Do not interpret results after 10 minutes.



INTERPRETATION OF RESULTS

POSTIVE: A colored line appears next to the "C" (control) and NO line appears next to the "T" assigned to each drug tested. The positive result means that the drug concentration in the urine sample is greater than the designated cut-off for the specific drug.

NEGATIVE: A colored line appears next to the "C" (control) and colored lines appears next to the "T" assigned to each drug tested. This negative result means that the concentrations in the urine samples are below the designated cut-off levels for a particular drug tested. NOTE: The shade of the colored line(s) next to the "T" for the drug tested may vary.
The result should be considered negative whenever there is even a faint line.

INVALID: No line appears next to the "C" (control). Without the a line next to the "C" a line present or missing next to the "T" is considered Invalid. Insufficient specimen volume or incorrect procedural technique are the most likely reason for control line failure. Read the instructions again and repeat the test with a new cassette. If the result is still invalid, contact Kacey.

QUALITY CONTROL

A procedural control is included in the test. A line appearing next to the "C" (control) is considered an internal procedural control. It contains sufficient volume, adequate membrane wicking, and correct procedural technique has been employed.

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 teh test procedure, and to verify proper test performance.

LIMITATIONS

1) The Veti-Screen 6 DOA Test Cassette provides only a qualitative, preliminary result. A secondary analytical method must be used to obtain a confirmed result. Gas Chromatography/Mass Spectrometry (GC/MS) is the preferred confirmatory method. [4,5]

2) There is a possibility that technical or procedural errors, as wel as interfering substances in the urine specimen may cause erroneous results.

3) A positive result does not indicate level or intoxication, administration route or concentration in urine.

4) 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.

5) This test does not distinguish between drugs of abuse and certain medications.

PERFORMANCE CHARACTERISTICS
Accuracy % Agreement with GC/MS

% Agreement with Commercial Kit

*** Commercial kits for % agreement could not be determined due to the 40-60% higher threshold values than the Kacey Veti-Screen 6**

Precision

A study was conducted using three different lots of this cassette test to determine "within run, between run, and between operator" precision. An identical card of coded specimens containing drugs at concentrations of negative, 50%, and 25% cut-off level were labeled and blind tested at each site. The results gained = or ≥ 75% cut-off level specimen and 100% accuraacy in negative and +/-50% cut-off level specimen.

	AMP 250	OPI 100	COC 100	THC 18 (500/2000)	METH 250
Positive Agreement	*	>99.9%	>99.9%	*	*
Negative Agreement	*	>99.9%	>99.9%	*	*
Total Results	*	>99.9%	>99.9%	*	*

Analytical Sensitivity

A drug-free urine pool was spiked with drugs at listed concentrations. The results are summarized below:

Drug Concentration Cut-off Range	AMP 250		OPI 100		COC 100		THC 18 (500/2000)		METH 250	
	-	+	-	+	-	+	-	+	-	+
0% Cut-off	30	0	30	0	30	0	30	0	30	0
50% Cut-off	30	0	30	0	30	0	30	0	30	0
75% Cut-off	26	4	26	4	27	3	25	5	27	3
Cut-off	15	15	15	15	16	14	15	15	14	16
125% Cut-off	4	26	3	27	4	26	4	26	4	26
150% Cut-off	0	30	0	30	0	30	0	30	0	30
300% Cut-off	0	30	0	30	0	30	0	30	0	30

Analytical Specificity

The following table lists the concentrations of components (ng/ml) that are detected as positive in urine by the Veti-Screen 6 DOA Test cassette at 5 minutes:

Analytes	conc. (ng/mL)	Analytes	conc. (ng/mL)
METHAMPHETAMINE (METH 250)			
p-Hydroxymethamphetamine	6,250	(±)-3,4-Methylenedioxy - methamphetamine	3,125
D-Methamphetamine	250		
L-Methamphetamine	5,000	Mephentermine	12,500
MORPHINE (OPI 100)			
Codeine	80	Norcodeine	2,000
Levorphanol	500	Normorphone	20,000
Morphine-3-β-D-Glucuronide	300	Oxycodone	10,000
Ethylmorphine	2,000	Oxymorphone	20,000
Hydrocodone	20,000	Procaine	5,000
Hydromorphone	1,000	Thebaine	2,000
6-Monoacethylmorphine	200	Morphine	100
COCAINE (COC 100)			
Benzoylecgonine	100	Cocaethylene	7,000
Cocaine HCl	80	Ecgonine	10,000
MARIJUANA (THC 18)			
Cannabinol	12,600	THC	6,120
11-nor-Δ^9-THC-9 COOH	18 (500/2000)	Δ^9-THC	6,120
8-OHΔ^8-THC	500	Δ^8-THC Alpha & Beta	2000
AMPHETAMINE (AMP 250)			
D,L-Amphetamine sulfate	75	Phentermine	250
L-Amphetamine	6,250	Maprotiline	12,500
(±) 3,4-Methylenedioxy amphetamine	125	Methoxyphenamine	1,500
		D-Amphetamine	250

Effects of Urinary Specific Gravity

Fifteen (15) urine samples of normal, high, and low specific gravity ranges (1.005 - 1.045) were spiked with drugs at 50% below and 50% above cut-off levels respectively. The Veti-Screen 6 DOA Test Cassette was tested in duplicate using fifteen drug-free and spiked urine samples. 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 drugs at 50% below and 50% above cut-off levels. The spiked, pH adjusted urine was tested with the Veti-Screen 6 DOA Test cassette. 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 drug positive urine containing above related caliber substances. The following compounds show no cross reactivity when tested with the Veti-Screen 6 DOA Test cassette at concentrations of 100 µg/mL

Non Cross Reacting Compounds

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

BIBLIOGRAPHY

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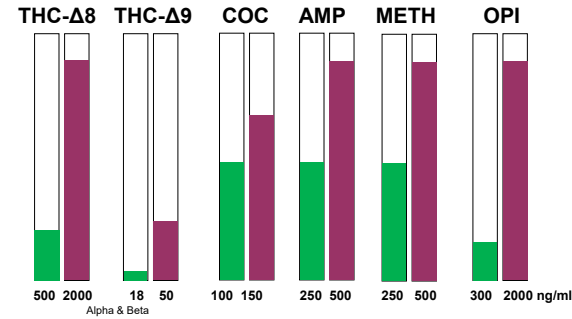
2. B. Cody. J.T. "Specimen Adulteration in drug urinalysis. Forensic Sci Rev, 1990, 2:63.
3. C. Tsai, S.C, et.al,, J. Anal. Toxicol. 1998; 22 (6): 474
4. Hawks RL, CN Chiang. Urine Testing for Drugs of Abuse. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986

Veti-Screen 6 DOA Level of Detection as compared to human diagnostics.

There is a tremendous difference between the Kacey Veti-Screen 6 DOA (Drug of Abuse) tests and common office human DOA test. Standard office DOA Humane tests are required to have LOD (level of detection) as mandated by Federal Law under **SAMHSA and DOT** using their guidelines. The Kacey Veti-Screen 5 DOA test is for animals and not humans, therefore the Federally mandated lowest level of detection does not apply. However, the Kacey DOA tests have a lower LOD which can detect clinical levels which would otherwise appear as a "False Negative" on human tests.

The difference is shown here in the level of detection chart:



In all cases the Veti-Screen 6 detection level is 68%- 85% lower which in the human DOA tests would indicate a false NEGATIVE, while the Kacey DOA would indicate a POSITIVE as part of Veterinary diagnostic drug screen.

NOTE: Veti-Screen 6 DOA test are means tested using certified protocols and only on Verified Animal Urine for QC (Quality Control) and QA (Quality Assurance) testing; All controls used to test for performance characteristics, precision reproducibility, and accuracy are performed on Certified Animal Urine Specimens.

Available in:

Part # 30444
Veti-Screen 6 5 pack

Part # 30445
Veti-Screen 6 10 pack

Order through your distributor or go to the Kacey website www.kaceydiagnostics.com On the main webpage **"click"** on the upper right hand corner "Order Form". An a order form will appear. Fill out the order form and press submit.

It is that Simple !

KACEY® DIAGNOSTICS

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