

## MULTI DrugControl MultiLine (Blood Stain) 008BL601

Rapid test for the simultaneous, qualitative detection of any combination of Amphetamine, Cocaine, MDMA, Methamphetamine, Morphine and Marijuana.

A screening test for detection of multiple drugs and drug metabolites in blood stain of human.

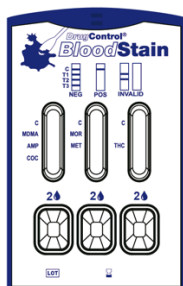
Only for forensic use.

### INTENDED USE

The ulti med DrugControl Test is a rapid chromatographic immunoassay for the qualitative detection of multiple drugs and drug metabolites in blood stain at the following cut-off concentrations:

Test	Calibrator	Cut-off (ng/sample)
Amphetamine	d-Amphetamine	5
Cocaine	Benzoyllecgonine	5
Marijuana	11-nor- $\Delta^9$ -THC-9 COOH	10
Methamphetamine	d-Methamphetamine	8
Methylenedioxymethamphetamine	d,l-Methylenedioxymethamphetamine	5
Morphine	Morphine	2

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 indicated.



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### PRINCIPLE

During testing, a blood specimen migrates upward by capillary action. A drug, if present in the blood 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 strip. 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 blood stain specimen will not generate a colored line in the specific test region of the strip because of drug competition, while a drug-negative blood 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.

### PRECAUTIONS

- Only for forensic use.
- Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens or kits are handled.
- The test cassette should remain in the sealed pouch until use.
- Humidity and temperature can adversely affect results.
- Do not use test if pouch is damaged.
- Do not moisten nitrocellulose membrane.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being tested.
- Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout testing and follow the standard procedures for proper disposal of specimens.
- The used test cassette should be discarded according to federal state and local regulations.

### STORAGE AND STABILITY

Store as packaged in the sealed pouch at 2-30°C. The test is stable through the expiration date printed on the sealed pouch. The test cassettes must remain in the sealed pouch until use. The product is humidity-sensitive and should be used immediately after being opened.

- Do not freeze.
- Do not use beyond the expiration date.

### MATERIALS PROVIDED

- Multi test cassette
- Swab
- Extraction tube with buffer
- Package insert

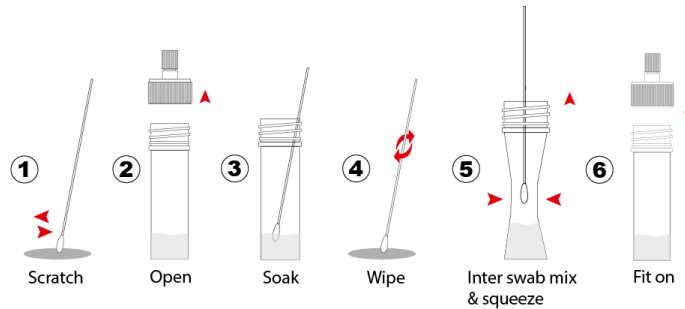
### MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

### SPECIMEN COLLECTION AND PREPARATION

For blood stain on hard surface:

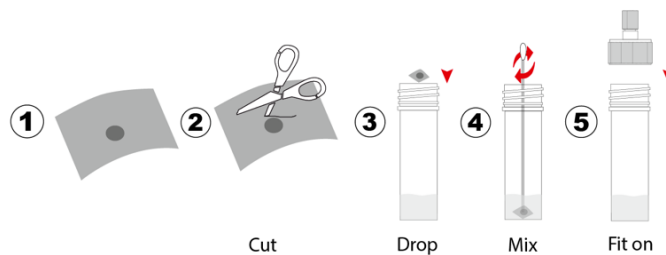
- Scratch the blood stain with the solid end of the swab provided inside the kit.
- Take out the sample extraction tube with buffer inside and open the lid.
- Insert the swab into the buffer for 5-10 seconds to allow swab head to be thoroughly soaked in the buffer.
- Take out the swab and wipe the blood stain gently at least 3 times.
- Reinsert the swab into the tube and agitate the swab vigorously 15 times. Leave the swab in the tube for 1 minute. Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube.
- Discard the swab and then screw the lid tightly. Use the extraction solution as test sample. See the illustration below.



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For blood stain on soft cloth:

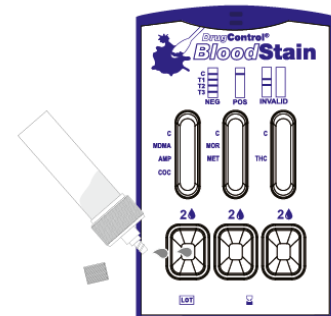
- Cut the blood stain (about 1cm<sup>2</sup>) and drop into the sample extraction tube, agitate the swab vigorously 15 times and leave it for 1 minute.
- Discard the swab and then screw the lid tightly. Use the extraction solution as test sample. See the illustration below.



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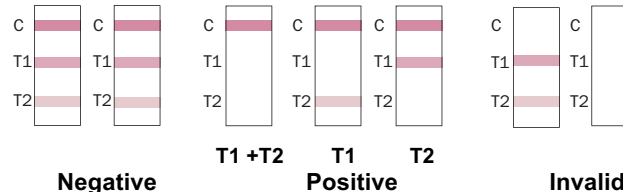
### DIRECTIONS FOR USE

- Allow the extraction solution, test cassette, and / or controls to reach room temperature (15 – 30 °C) prior to testing.
- Bring pouch to room temperature before opening it. **Do not open pouches until ready to perform the assay.**
- Remove the test cassette from the sealed pouch just prior to testing. Place the test on a flat and clean surface.
- Open the tip of the sample extraction tube, invert the tube and add **2 drops** of test sample (approx. 80 µl) into the sample well of the test cassette.
- Wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.



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### INTERPRETATION OF RESULT



**Negative:\*** One red line in the control line region (C) and a red line in the test line region (T) for a specific drug indicate a negative result. This negative result indicates that the concentrations of the substances detectable with the corresponding test are below the cut-off concentration or that they are not present.

**Positive:** One red line appears in the control line region (C) but no line in the test line region (T) for a specific drug indicates a positive result. This positive result indicates that the concentration of at least one of the substances detectable with the corresponding test exceeds the cut-off concentration.

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

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

**MULTI DrugControl MultiLine (Blood Stain)**  
**008BL601****SUMMARY**

The ulti med **DrugControl** Test is a rapid blood stain screening test that can be performed without the use of an instrument. The test utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in blood.

**Amphetamine (AMP):** Amphetamine is a Schedule II controlled substance available by prescription (Dexedrine<sup>®</sup>) and is also available on the illicit market. Amphetamines are a class of potent sympathomimetic agents with therapeutic applications. They are chemically related to the human body's natural catecholamines: epinephrine and norepinephrine. Acute higher doses lead to enhanced stimulation of the central nervous system (CNS) and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to amphetamines include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, and psychotic behavior. The effects of Amphetamines generally last 2-4 hours following use and the drug has a half-life of 4-24 hours in the body. About 30% of amphetamines are excreted in the urine in unchanged form, with the remainder as hydroxylated and deaminated derivatives.

**Cocaine (COC):** Cocaine is a potent central nervous system stimulant and a local anesthetic. Initially, it brings about extreme energy and restlessness while gradually resulting in tremors, over-sensitivity and spasms. In large amounts, cocaine causes fever, unresponsiveness, difficulty in breathing and unconsciousness. Cocaine is often self-administered by nasal inhalation, intravenous injection and free-base smoking. It is excreted in the urine in a short time primarily as benzoylecgonine.<sup>3,4</sup> Benzoylecgonine, a major metabolite of cocaine, has a longer biological half-life (5-8 hours) than cocaine (0.5-1.5 hours), and can generally be detected for 24-48 hours after cocaine exposure.<sup>4</sup>

**Marijuana (THC):** THC ( $\Delta^9$ -tetrahydrocannabinol) is the primary active ingredient in cannabis (marijuana). When smoked or orally administered, THC produces euphoric effects. Users have impaired short-term memory and slowed learning. They may also experience transient episodes of confusion and anxiety. Long-term, relatively heavy use may be associated with behavioral disorders. The peak effect of marijuana administered by smoking occurs in 20-30 minutes and the duration is 90-120 minutes after one cigarette. Elevated levels of urinary metabolites are found within hours of exposure and remain detectable for 3-10 days after smoking. The main metabolite excreted in the urine is 11-nor- $\Delta^9$ -tetrahydrocannabinol-9-carboxylic acid (THC-COOH).

**Methamphetamine (MET)** Methamphetamine is an addictive stimulant drug that strongly activates certain systems in the brain. Methamphetamine is closely related chemically to Amphetamine, but the central nervous system effects of Methamphetamine are greater. Methamphetamine is made in illegal laboratories and has a high potential for abuse and dependence. The drug can be taken orally, injected, or inhaled. Acute higher doses lead to enhanced stimulation of the central nervous system and induce euphoria, alertness, reduced appetite, and a sense of increased energy and power. Cardiovascular responses to Methamphetamine include increased blood pressure and cardiac arrhythmias. More acute responses produce anxiety, paranoia, hallucinations, psychotic behavior, and eventually, depression and exhaustion. The effects of Methamphetamine generally last 2-4 hours and the drug has a half-life of 9-24 hours in the body. Methamphetamine is excreted in the urine primarily as Amphetamine, and oxidized and deaminated derivatives. However, 10-20% of Methamphetamine is excreted unchanged. Thus, the presence of the parent compound in the urine indicates Methamphetamine use. Methamphetamine is generally detectable in the urine for 3-5 days, depending on urine pH level.

**Methylenedioxymethamphetamine (MDMA):** Methylenedioxymethamphetamine (ecstasy) is a designer drug first synthesized in 1914 by a German drug company for the treatment of obesity.<sup>5</sup> Those who take the drug frequently report adverse effects, such as increased muscle tension and sweating. MDMA is not clearly a stimulant, although it has, in common with amphetamine drugs, a capacity to increase blood pressure and heart rate. MDMA does produce some perceptual changes in the form of increased sensitivity to light, difficulty in focusing, and blurred vision in some users. Its mechanism of action is thought to be via release of the neurotransmitter serotonin. MDMA may also release dopamine, although the general opinion is that this is a secondary effect of the drug (Nichols and Oberlander, 1990). The most pervasive effect of MDMA, occurring in virtually all people who took a reasonable dose of the drug, was to produce a clenching of the jaws.

**Morphine (MOR):** Opiate refers to any drug that is derived from the opium poppy, including the natural products, morphine and codeine, and the semi-synthetic drugs such as heroin. Opioid is more general, referring to any drug that acts on the opioid receptor. Opioid analgesics comprise a large group of substances which control pain by depressing the CNS. Large doses of morphine can produce higher tolerance levels, physiological dependency in users, and may lead to substance abuse. Morphine is excreted unmetabolized, and is also the major metabolic product of codeine and heroin. Morphine is detectable in the urine for several days after an opiate dose.<sup>2</sup>

**QUALITY CONTROL**

A procedural control is included in the test. A line appearing in the control 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 ulti med **DrugControl** Test 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. It is possible that technical or procedural errors, as well as other interfering substances in the blood stain specimen may cause erroneous results.
3. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in blood stain
4. A negative result may not necessarily indicate drug-free blood stain. Negative results can be obtained when drug is present but below the cut-off level of the test.
5. Test does not distinguish between drugs of abuse and certain medications.

**EXPECTED VALUES**

A negative result indicates that the drug concentration is below the detectable level. Positive result means the concentration of drug is above the detectable level.

**REAGENTS**

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.

**PERFORMANCE CHARACTERISTICS**

**Specificity**

The following table lists the concentrations of compounds (ng/sample) that are detected as positive in blood by the ulti med DrugControl Test at 5 minutes. The study use 10µl sample to dry then operating method in accordance with the specifications. The results are summarized below.

TEST CASSETTE	Calibrator / related compounds	Cut-off Limit Value [ng / sample]	TEST CASSETTE	Calibrator / related compounds	Cut-off Limit Value [ng / sample]
<b>Amphetamines (AMP)</b>	<b>D-Amphetamine</b>	<b>5</b>	<b>Ecstasy (MDMA)</b>	<b>(±) 3,4-Methylenedioxy-methamphetamine HCl</b>	<b>8</b>
	L-Amphetamine	150		<b>(±) 3,4-Methylenedioxy-amphetamine HCl</b>	50
	D,L-Amphetamine sulfate	2		<b>3,4-Methylenedioxyethyl-amphetamine</b>	5
	Maprotiline	250			
	Methoxyphenamine	30			
<b>Cocaine (COC)</b>	<b>Benzoyllecgonine</b>	<b>5</b>	<b>Morphine (MOR)</b>	<b>Morphine</b>	<b>2</b>
	Cocaine HCl	3		Codeine	2
	Cocaehtylene	300		Levorphanol	100
	Ecgonine	500		Morphine-3-β-D-Glucuronide	7
				Ethylmorphine	40
<b>Marijuana (THC)</b>	<b>11-nor-Δ9-THC-9 COOH</b>	<b>10</b>		Hydrocodone	340
	11-nor-Δ8-THC-9 COOH	8		Hydromorphone	27
	Cannabinol	5000		6-Monoacethylmorphine	3
	Δ8-THC	3500		Norcodeine	40
	Δ9-THC	4000		Normorphine	340
<b>Methamphetamine (MET)</b>	<b>D-Methamphetamine</b>	<b>8</b>		Oxycodone	200
	L-Methamphetamine	160		Oxymorphone	340
	(±)-3,4-Methylenedioxy-methamphetamine	120		Procaine	100
	Mephentermine	400		Thebaine	40
	ρ-Hydroxymethamphetamine	200			

**Precision**

A study was conducted by untrained operators using three different lots of product to demonstrate the within run, between run and between operator precision.

A drug-free blood pool was spiked with drugs at the listed concentrations. 10µl of such blood specimens were allowed to dry to reach specific concentrations after spiking. The results are given below:

Amphetamine (ng/sample)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
2.5	10	9	1	9	1	9	1
7.5	10	2	8	2	8	1	9

Benzoyllecgonine (ng/sample)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
2.5	10	9	1	9	1	9	1
7.5	10	2	8	2	8	1	9

11-nor-Δ9-COOH (ng/sample)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
5	10	9	1	8	2	9	1
15	10	2	8	2	8	2	8

Methamphetamine (ng/sample)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
4	10	9	1	9	1	9	1
12	10	2	8	2	8	1	9

Methylenedioxy-methamphetamine (ng/sample)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
2.5	10	9	1	9	1	9	1
7.5	10	1	9	2	8	2	8

Morphine (ng/sample)	n per site	Site A		Site B		Site C	
		-	+	-	+	-	+
0	10	10	0	10	0	10	0
1	10	9	1	9	1	9	1
3	10	2	8	2	8	1	9

### Analytical Sensitivity

A drug-free blood pool was spiked with drugs at the listed concentrations and use 10µl sample to dry then operating method in accordance with the specifications. The results are summarized below.

Drug concentration Cut-off Range	n	AMP		COC		MDMA		MET		MOR		THC	
		-	+	-	+	-	+	-	+	-	+	-	+
0 % Cut-off	30	30	0	30	0	30	0	30	0	30	0	30	0
-50 % Cut-off	30	28	2	28	2	28	2	27	3	27	3	28	2
Cut-off	30	16	14	15	15	15	15	16	14	15	15	17	3
+50 % Cut-off	30	3	27	2	28	3	27	3	27	3	27	5	25
3X Cut-off	30	0	30	0	30	0	30	0	30	0	30	0	30

### Cross-Reactivity

A study was conducted to determine the cross-reactivity of the test with compounds in either drug-free blood or drug positive blood containing, Amphetamine, Cocaine, Marijuana, Methamphetamine, Morphine and MDMA. The study use 10µl sample to dry then operating method in accordance with the specifications. The following compounds show no cross-reactivity when tested with the ulti med DrugControl Test at a concentration of 100 µg/mL.

### Non Cross-Reacting Compounds

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











### LIMITATIONS

It is impossible to check any and all - other than those drugs mentioned in the product insert - for cross-reactivity or any other influences to the to be detected drug of abuse ( DOA ).

If the blood stain contains a „cocktail“ of several different drugs or medication cannot be excluded that a non-reproducible cross-reaction can falsified the test result.

### BIBLIOGRAPHY

- Hawks RL, CN Chiang. *Urine Testing for Drugs of Abuse*. National Institute for Drug Abuse (NIDA), Research Monograph 73, 1986.
- Tietz NW. *Textbook of Clinical Chemistry*. W.B. Saunders Company. 1986; 1735.
- Stewart DJ, Inaba T, Lucassen M, Kalow W. *Clin. Pharmacol. Ther.* April 1979; 25 ed: 464, 264-8.
- Ambre J. J. *Anal. Toxicol.* 1985; 9:241.
- Winger, Gail. *A Handbook of Drug and Alcohol Abuse*, Third Edition, Oxford Press, 1992, page 146.
- Robert DeCresce. *Drug Testing in the workplace*, 1989 page 114.
- Glass, JB. *The International Handbook of Addiction Behavior*. Routledge Publishing, New York, NY. 1991; 216
- B. Cody, J.T., "Specimen Adulteration in drug urinalysis. *Forensic Sci. Rev.*, 1990, 2:63.
- C. Tsai, S.C. *et al.*, *J. Anal. Toxicol.* 1998; 22 (6): 474
- Baselt RC. *Disposition of Toxic Drugs and Chemicals in Man*. 6th Ed. Biomedical Publ., Foster City, CA 2002.
- Hardman JG, Limbird LE. *Goodman and Gilman's: The Pharmacological Basis for Therapeutics*. 10th Edition. McGraw Hill Medical Publishing, 2001; 208-209.

 Manufacturer	 Contents sufficient for <n> tests
 For single use only	 Lot. no.
 Read instructions for use	 Expiration date
 Keep away from direct sunlight	 Store at
 Keep dry	 Ordering number

This operating manual conforms to the latest technology / revision. Subject to change without prior notice!



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