

One step test device for the simultaneous, qualitative detection of Amphetamines, Barbiturates, Benzodiazepines, Cocaine metabolites, Methamphetamines Morphine, Methadone, Ecstasy (MDMA), Tricyclic Antidepressants, and THC metabolites in human urine

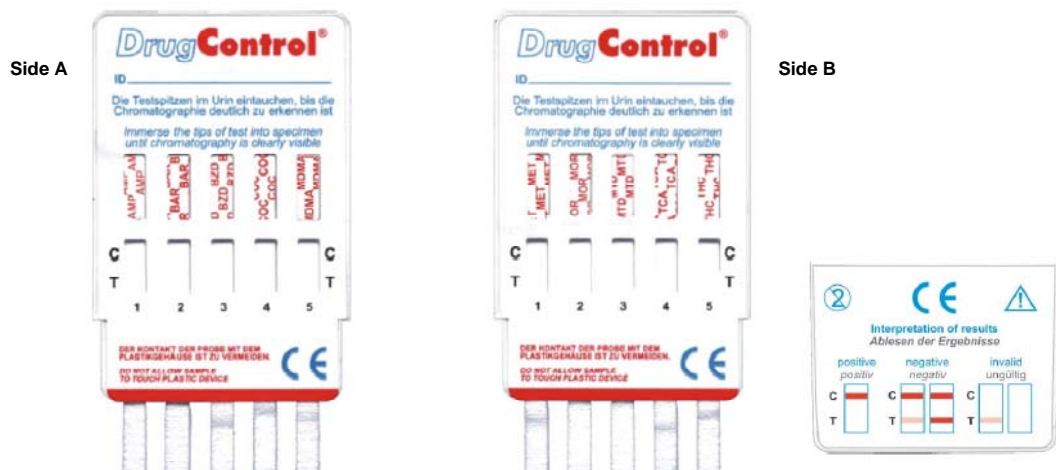
For professional in vitro diagnostic use only.

INTENDED USE

The **Multi DrugControl 008A410** is a specific arrangement of different lateral flow chromatographic immunoassays for the detection of Amphetamines, Barbiturates, Benzodiazepines, Cocaine metabolites, Methamphetamines Morphine, Methadone, Ecstasy (MDMA), Tricyclic Antidepressants, and THC metabolites in human urine at the following cut-off concentrations:

TEST DEVICE Side A	SUBSTANCE	CAS-No	Cut-off Limit Value [ng / mL]	TEST DEVICE Side B	SUBSTANCE	CAS-No	Cut-off Limit Value [ng / mL]	
Amphetamines (AMP)	D-Amphetamine	[51-64-9]	1000	Methamphetamines (MET)	D-Methamphetamine [-]	[-]	1000	
	3,4-Methylenedioxy-amphetamine	[4764-17-4]	2000		3,4-Methylenedioxy-methamphetamine	[-]	2000	
	D,L-Amphetamine	[300-62-9]	3000		L-Methamphetamine	[537-46-2]	8000	
	Phentermine	[122-09-8]	3000		p-Hydroxy-methamphetamine	[-]	30000	
	L-Amphetamine	[156-34-3]	50000		Mephentermine	[100-92-5]	50000	
Barbiturates (BAR)	Butobarbital	[125-40-6]	75	Morphine (MOR)	Morphine	[57-27-2]	300	
	Butethal	[77-28-1]	100		Codeine	[76-57-3]	300	
	Phenobarbital	[50-06-6]	100		6-Monoacetylmorphine	[-]	400	
	Alphenal	[115-43-5]	150		Morphine 3-β-D-glucuronide	[20290-09-9]	1000	
	Aprobarbital	[77-02-1]	200		Levorphanol	[77-07-6]	1500	
	Amobarbital	[57-43-2]	300		Hydromorphone	[466-99-9]	3000	
	Secobarbital	[76-73-3]	300		Ethylmorphine	[-]	6000	
	Pentobarbital	[76-74-4]	300		Norcodeine	[467-15-2]	6000	
	Cyclopentobarbital	[76-68-6]	600		Thebaine	[115-37-7]	6000	
	Butalbital	[77-26-9]	200		Oxycodone	[76-42-6]	30000	
Benzodiazepines (BZD)	Nitrazepam	[146-22-5]	100	Methadone (MTD)	Methadone	[76-99-3]	300	
	Clobazam	[22316-47-8]	100		Doxylamine	[469-21-6]	50000	
	Temazepam	[846-50-4]	100	Tricyclic Antidepressants (TCA)	Desipramine	[50-47-5]	200	
	Lorazepam glucuronide	[-]	150		Imipramine	[50-49-7]	400	
	Alprazolam	[28981-97-7]	200		Nordoxepine	[-]	1000	
	Diazepam	[439-14-5]	200		Nortriptyline	[894-71-3]	1000	
	Clorazepate dipotassium	57109-90-7]	200		Amitriptyline	[50-48-6]	1500	
	Norchlordiazepoxide	[-]	200		Promazine	[58-40-2]	1500	
	Oxazepam	[604-75-1]	300		Doxepine	[1668-19-5]	2000	
	Desalkylflurazepam	[2886-65-9]	300		Maprotiline	[10262-69-8]	2000	
	Flunitrazepam	[1622-62-4]	400		Trimipramine	[739-71-9]	3000	
	Nordiazepam	[-]	400		Clomipramine	[303-49-1]	12500	
	Chlordiazepoxide HCl	[438-41-5]	750		Promethazine	[60-87-7]	25000	
	Clonazepam	[1622-61-3]	800		Marijuana (THC)	11-nor-Δ ⁹ -THC-9 COOH	[-]	30
	α-Hydroxy-alprazolam	[-]	1200			11-nor-Δ ⁹ -THC-9 COOH	[-]	50
	Bromazepam	[1812-30-2]	1500			Δ ⁸ -THC	[5957-75-5]	15000
	Chlordiazepoxide	[58-25-3]	1500	Δ ⁹ -THC		[1972-08-3]	15000	
	Delorazepam	[2894-67-9]	1500	Cannabinol		[521-35-7]	20000	
	Lorazepam	[864-49-1]	1500					
	Estazolam	[29975-16-4]	2500					
Triazolam	[28911-01-5]	2500						
Midazolam	[59467-70-8]	12500						
Cocaine (COC)	Benzoylcegonine	[-]	300					
	Cocaine	[53-21-4]	700					
	Cocaehtylene [-]	[-]	12500					
	Ecgonine [-]	[-]	32000					
Ecstasy (MDMA)	3,4-Methylenedioxy-ethylamphetamine	[457-87-4]	300					
	3,4-Methylenedioxy-methamphetamine	[-]	500					
	3,4-Methylenedioxyamphetamine	[4764-17-4]	3000					

These assays provide only preliminary analytical test results. An alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.



REAGENTS

The **MultiDrugControl** contains mouse monoclonal antibody-coupled particles and drug-protein conjugates. The control line system contains a goat anti-mouse antibody.

PRECAUTIONS

- For in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- Do not moisten nitrocellulose membrane with urine samples.
- Immerse tips of test strips for at least 10-15 seconds in the urine specimen.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample
- 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 federal state and local regulations.

STORAGE AND STABILITY

The **MultiDrugControl** can be stored at room temperature or refrigerated (2 – 30 °C). The test is stable through the expiration date printed on the sealed pouch.

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

SPECIMEN COLLECTION AND PREPARATION

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 specimen for testing. Urine specimens may be stored at 2 - 8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

MATERIALS PROVIDED

- Multi test device
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

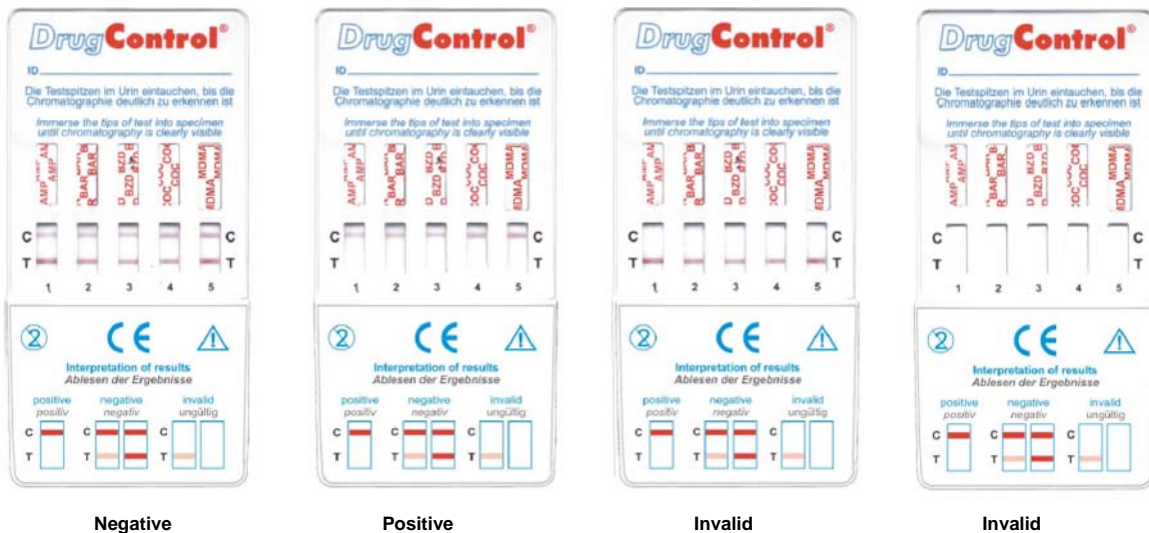


Dip **MultiDrugControl**
into urine specimen

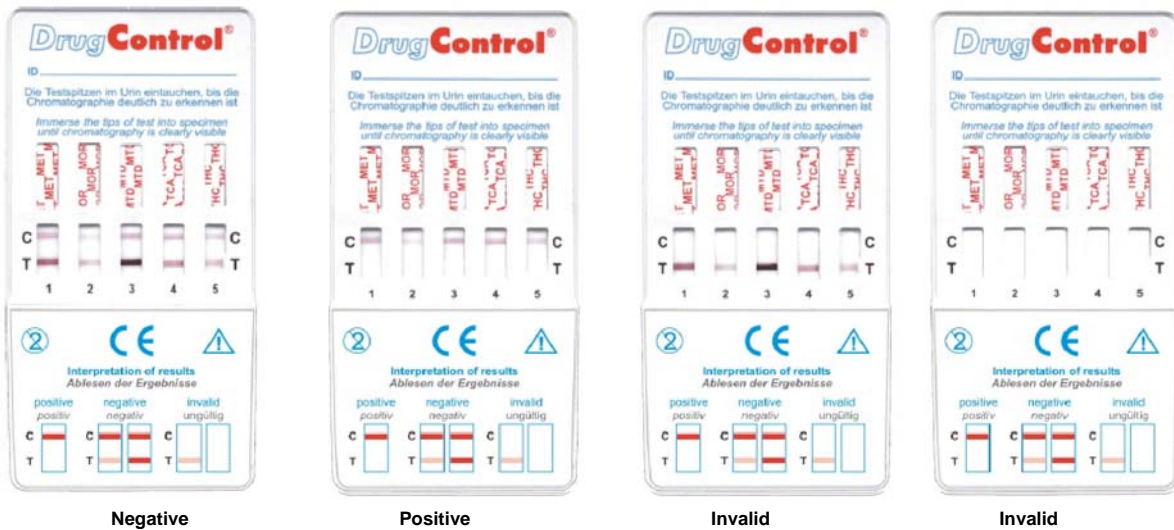
DIRECTIONS FOR USE

- 1 Allow the urine specimen, test device, and / or controls to reach room temperature (15 – 30 °C) prior to testing.
- 2 Bring pouch to room temperature before opening it.
- 3 Remove the Multi test from the sealed pouch and use it as soon as possible.
- 4 Immerse the tips of the Multi test vertically in the urine specimen for at least 10-15 seconds.
- 5 Do not pass the maximum line (dipping line) on the test when immersing the tips of the Multi test.
- 6 Place the test on a non-absorbent flat and clean surface. Start the timer and wait for the red lines to appear.
- 7 The result should be read at 5-8 minutes. Do not interpret after more than 10 minutes.

INTERPRETATION OF RESULTS



SIDE B



- Negative:*** Two lines appear in each window. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the concentrations of the substances detectable with the corresponding test are below the cut-off concentration (substances & cut-off concentrations see table on page 1) or that they are not present.
- Positive:** One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the concentration of at least one of the substances detectable with the corresponding test exceeds the cut-off concentration (substances & cut-off concentrations see table on page 1).
- 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 distributor / manufacturer.

* **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.

The Multi DrugControl tests are available in the following combinations of parameters:

Product no.	Product	Parameters
008A300	Multi-DrugControl-Card (3)	BUP, MTD, MOR
008A400	Multi-DrugControl-Card (5)	BZD, THC, MET, MOR, MDMA
008A403	Multi-DrugControl-Card (3)	COC, MOR, THC
008A405	Multi-DrugControl-Card (5)	AMP, BZD, COC, MOR, MTD
008A406	Multi-DrugControl-Card (6)	AMP, COC, MDAMA, MOR, THC
008A406DN	Multi-DrugControl-Card (6)	BZD, COC, MET, MOR, MTD, THC
008A424	Multi-DrugControl-Card (5)	AMP, COC, MDMA, MOR, THC
008A434	Multi-DrugControl-Card (5)	AMP, COC, MET, MOR, THC
008A437	Multi-DrugControl-Card (5)	AMP, BZD, COC, MOR, THC
008A441	Multi-DrugControl-Card (5)	AMP, BAR, BZD, MOR, MET
008A442	Multi-DrugControl-Card (5)	BZD, COC, MOR, MET, THC
008A444	Multi-DrugControl-Card (10)	AMP, BAR, BZD, COC, MET, MOR, MTD, PCP, TCA, THC
008A445	Multi-DrugControl-Card (10)	AMP, BAR, BZD, COC, MET, MOR, MTD, MDMA, MDA, THC
008A639	Multi-DrugControl-Card (6)	AMP, BUP, BZD, COC, MTD, MOR



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October 2007/G