DrugControl®

URINE CUP INTEGRA
008A510

ultimed™

One step test devicefor the simultaneous,qualitative detection of Amphetamine, Barbiturates, Benzodiazepines, Cocaine metabolites, Ecstasy, Methadone, Methamphetamine, Morphine, Tricyclic Antidepressants, and THC metabolites in human urine
For professional in vitro diagnostic use only.

INTENDED USE

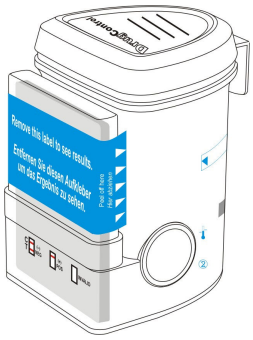
The ***Urine Cup Integra*** 008A510 is a specific arrangement of different lateral flow chromatographic immunoassays for the detection of Amphetamine, Cocaine metabolites, Methamphetamine, Morphines, and THC metabolites in human urine at the following cut-off concentrations:

TEST DEVICE	SUBSTANCE	CAS-No	Cut Off Limit Value [ng / mL]
Amphetamine	D-Amphetamine	[51-64-9]	1,000
	3,4-Methylenedioxy-amphetamine	[4764-17-4]	2,000
	D,L-Amphetamine	[300-62-9]	3,000
	Phentermine	[122-09-8]	3,000
	L-Amphetamine	[156-34-3]	50,000
Barbiturates	Butabarbital	[125-40-6]	75
	Butethal	[77-28-1]	100
	Phenobarbital	[50-06-6]	100
	Alphenal	[115-43-5]	150
	Aprobarbital	[77-02-1]	200
	Amobarbital	[57-43-2]	300
	Secobarbital	[76-73-3]	300
	Pentobarbital	[76-74-4]	300
	Cyclopentobarbital	[76-68-6]	600
	Butalbital	[77-26-9]	2,500
Benzodiazepines	Nitrazepam	[146-22-5]	100
	Clobazam	[22316-47-8]	100
	Temazepam	[846-50-4]	100
	Lorazepam glucuronide	[-]	150
	Alprazolam	[28981-97-7	200
	Diazepam	[439-14-5]	200
	Clorazepate dipotassium	[57109-90-7]	200
	Norchlordiazepoxide	[-]	200
	Oxazepam	[604-75-1]	300
	Desalkylflurazepam	[2886-65-9]	300
	Flunitrazepam	[1622-62-4]	400
	Nordiazepam	[-]	400
	Chlordiazepoxide HCl	[438-41-5]	750
	Clonazepam	[1622-61-3]	800
	α-Hydroxy-alprazolam	[-]	1,200
	Bromazepam	[1812-30-2]	1,500
	Chlordiazepoxide	[58-25-3]	1,500
	Delorazepam	[2894-67-9]	1,500
	Lorazepam	[864-49-1]	1,500
	Estazolam	[29975-16-4]	2,500
	Triazolam [	28911-01-5]	2,500
	Midazolam	[59467-70-8]	12,500
Cocaine	Benzoylecgonine	[-]	300
	Cocaine	[53-21-4]	700
	Cocaethylene	[-]	12,500
	Ecgonine	[-]	32,000
Ecstasy	3,4-Methylenedioxy-ethylamphetamine	[457-87-4]	300
	3,4-Methylenedioxy-methamphetamine	[-]	500
	3,4-Methylenedioxy amphetamine	[4764-17-4]	3,000

TEST DEVICE	SUBSTANCE	CAS-No	Cut Off Limit Value [ng / mL]
Methamphetamine	D-Methamphetamine	[-]	1,000
	3,4-Methylenedioxy-methamphetamine	[-]	2,000
	L-Methamphetamine	[537-46-2]	8,000
	p-Hydroxy-methamphetamine	[-]	30,000
	Mephentermine	[100-92-5]	50,000
Methadone	Methadone	[76-99-3]	300
	Doxylamine	[469-21-6]	50,000
Morphine	Morphine	[57-27-2]	300
	Codeine	[76-57-3]	300
	6-Monoacetyl morphine	[-]	400
	Morphine 3-β-D-glucuronide	[20290-09-9]	1,000
	Levorphanol	[77-07-6]	1,500
	Hydromorphone	[466-99-9]	3,000
	Ethylmorphine	[-]	6,000
	Norcodeine	[467-15-2]	6,000
	Thebaine	[115-37-7]	6,000
	Oxycodone	[76-42-6]	30,000
	Hydrocodone	[125-29-1]	50,000
Tricyclic Antidepressants	Desipramine	[50-47-5]	200
	Imipramine	[50-49-7]	400
	Nordoxepine	[-]	1,000
	Nortriptyline	[894-71-3]	1,000
	Amitriptyline	[50-48-6]	1,500
	Promazine	[58-40-2]	1,500
	Doxepine	[1668-19-5]	2,000
	Maprotiline	[10262-69-8]	2,000
	Trimipramine	[739-71-9]	3,000
	Clomipramine	[303-49-1]	12,500
	Promethazine	[60-87-7]	25,000
Marijuana	11-nor-Δ^9-THC-9 COOH	[-]	30
	11-nor-Δ^9-THC-9 COOH	[-]	50
	Δ^8-THC	[5957-75-5]	15,000
	Δ^9-THC	[1972-08-3]	15,000
	Cannabinol	[521-35-7]	20,000

These assays provide only preliminary analytical test results. 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 ***Urine Cup Integra*** 008A510 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

REAGENTS

The test panel contains mouse monoclonal antibody-coupled particles and drug-protein conjugates. A gold antibody is employed in the control line system.

DrugControl®

URINE CUP INTEGRA
008A510

ultimed TM

PRECAUTIONS
- For in vitro diagnostic use only.
- The test panel should remain in the sealed pouch until use.
- The used test panel should be discarded according to federal, state and local regulations
- Do not use after the expiration date.
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent.

STORAGE AND STABILITY
The ***Urine Cup Integra*** 008A510 can be stored at room temperature or refrigerated (2 – 30 °C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use.
- 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.

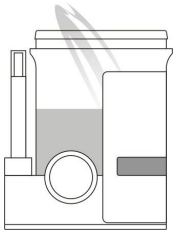
MATERIALS PROVIDED
- Cups with multi-drug panels
- Keys
- Security Seal Labels
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED
- Timer

DIRECTIONS FOR USE

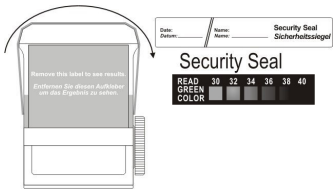
TEST PREPARATION

Allow the test panel, 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.



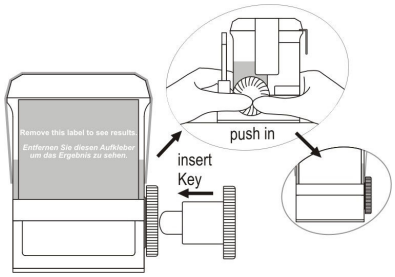
SAMPLING PROCEDURE

Pull tab to remove cap, collect specimen in the cup and secure cap by pressing down on all three corners.



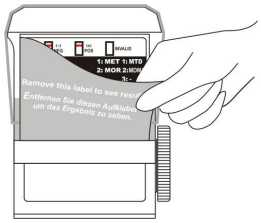
SECURITY SEAL & TEMPERATURE CONTROL

Check the cap for a tight seal, date and initial the security seal label, then place it over the cap.
Check the temperature label (Temperature 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 (32° - 38° C).



TESTING

Remove one key from the kit, place the cup on a flat surface, and push the key into the socket of the cup to begin the test. Start timer.



TEST EVALUATION

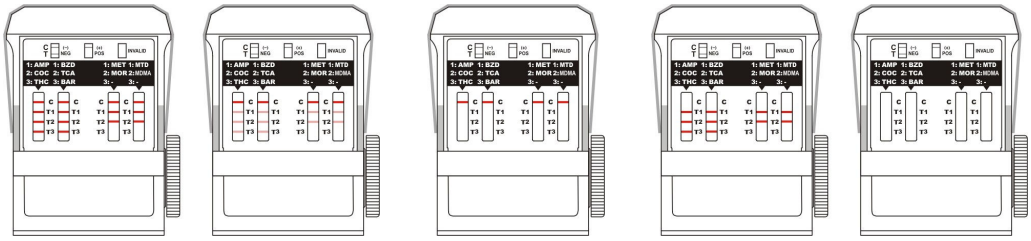
Remove the peel off label covering the test results and wait for the colored line(s) to appear.
The results should be read at 5 minutes.
Do not interpret results after 10 minutes.

DrugControl®

ulti med TM

URINE CUP INTEGRA
008A510

INTERPRETATION OF RESULTS



Negative **Negative** **Positive** **Invalid** **Invalid**

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

Positive: A colored line in the control region (C) but no line in the test 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. 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.

QUALITY CONTROL

A procedural control is included in the test. A red 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 the ***Urine Cup Integra*** 008A510 Test; however, it is recommended that positive and negative controls be tested as good laboratory testing practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The ***Urine Cup Integra*** 008A510 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 urine specimen may cause erroneous results.
3. 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.
4. A positive result indicates presence of the drug or its metabolites but does not indicate level of intoxication, administration route or concentration in urine.
5. 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.
6. Test does not distinguish between drugs of abuse and certain medications.

ulti med Products (Deutschland) GmbH
Reeshoop 1 • 22926 Ahrensburg
Telefon: 04102 - 80090
Fax: 04102 - 50082
e-mail: info@ultimed.de

ulti med Products (Belgium) BVBA
Honzebroekstraat 137 • 8800 Roeselare
Phone: +32 +51 200 425
Fax: +32 +51 200 449
e-mail: belgium@ultimed.org

CE

August 2005 / C
TL