TRICYCLIC ANTIDEPRESSANTS
008A100

One step test device for the qualitative detection of Tricyclic Antidepressants in human urine
For professional in vitro diagnostic use only.

INTENDED USE

The ***Drug*Control TRICYCLIC ANTIDEPRESSANTS** is a lateral flow chromatographic immunoassay for the detection of Nortriptyline and related compounds in human urine at the cut-off concentrations shown below:

TEST DEVICE	SUBSTANCE	CAS - No	Cut Off Limit Value [ng / mL]
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

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.

REAGENTS

The ***Drug*Control TRICYCLIC ANTIDEPRESSANTS** contains anti-TCA antibody-coupled particles and TCA-protein conjugate. A goat antibody is employed in the control line system.

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.
- Use proper sample volume (min 240 µl per assay).
- 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 ***Drug*Control TRICYCLIC ANTIDEPRESSANTS** 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. For long-term storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

MATERIALS PROVIDED

- Test device
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer