Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

Multi Panel Drugs of Abuse
RapiCard™ (Cassette)
For Any drug Combination

IVD see external label 2-30ºC Σ = 1

INTENDED USE
Cortez RapiCard™ InstaTest all DOA Panel is based on immunochromatography one step in vitro test. It is designed for qualitative determination of drug substances in human urine specimens. This assay may be used in the point of care setting. Below is a list of cut-off concentrations for each drug using our test.

Amphetamine	1000 ng/ml of d-amphetamine
Barbiturate	300 ng/ml of secobarbital
Benzodiazepine	300 ng/ml of oxazepam
Buprenorphine	10 ng/ml of Buprenorphine-3-β-d-glucoronide
Cocaine	300 ng/ml of benzoylecgonine
EDDP	100 ng/ml of EDDP
Ketamine	1000 ng/ml of Ketamine
Methadone	300 ng/ml of methadone
Methamphetamine (Ecstasy)	1000 ng/ml of (+)methamphetamine
MDMA	500 ng/ml of MDMA
Opiate*	300 ng/ml of morphine
Opiate II*	2000 ng/ml of morphine
Oxycodone	100 ng/ml of oxycodone
Phencyclidine	25 ng/ml of phencyclidine
Propoxyphene	300 ng/ml of Norpropoxyphene
Cannabinoid (THC)	50 ng/ml of 11-nor-Δ^9-THC-9-COOH
Tramadol	200 ng/ml of Tramadol
Tricyclic antidepressant (TCA)	1000 ng/ml of Nortriptyline
Methylphenidate	300 ng/ml Methylphenidate
Fentanyl	200ng/ml Fentanyl
K2 (synthetic cannabinoid)	50 ng/ K2 synthetic cannabinoid

TEST PRINCIPLE
Each component strip of Cortez DOA Panel RapiCard ™ InstaTest is based on the principle of specific immunochemical reaction between antibodies and antigen to analyze particular compound in human urine specimen. The assay relies on the competition for binding antibody. When drug is present in the urine specimen, it competes with drug conjugate for the limited amount of antibody-dye conjugate. When the amount of drug is equal or more than the cut-off, it will prevent the binding of drug conjugate to the antibody. Therefore, a positive urine specimen will not show a colored band on the test line zone, indicating a positive result, while the presence of a colored band indicates a negative result. A control line is present in the test window to work as procedural control. This colored band should always appear on the control line zone if the test device is stored in good condition and the test is performed appropriately.

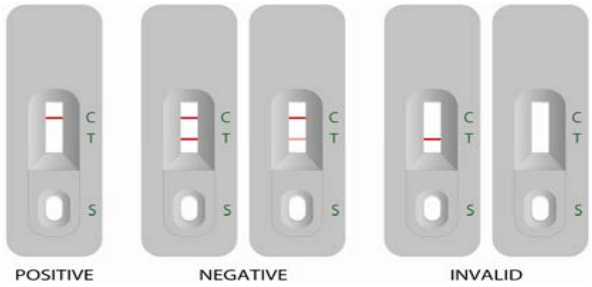
This assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/ mass spectrometry (GC/MS) has been established as the preferred confirmatory method by the Substance Abuse Mental Health Services Administration (SAMHSA). Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are indicated.

SPECIMEN COLLECTION AND PREPARATION
Fresh urine does not require any special handling or pretreatment. Specimen should be collected in a clean, dry, plastic or glass container. If the assay is not performed immediately, urine specimen may be refrigerated at 2-8 °C or frozen up to 7 days. Specimens should be brought to room temperature before testing. Urine specimens exhibiting a large amount of precipitate or turbidity should be centrifuged or allowed to settle before testing. Avoid contact with skin by wearing gloves and proper laboratory attire.

Materials provided with the test kits
1. DOA Panel RapiCard ™
2. Instruction for use.

Materials required but not provided
1. Urine collection container.
2. Timer or clock

ASSAY PROCEDURE
1. Bring all materials and specimens to room temperature.
2. Remove the test card from the sealed foil pouch.
3. Place the transfer pipette in the specimen and depress the bulb to withdraw a sample.
4. Hold the pipette in a vertical position over the sample well of the test card add deliver 3 drops.
5. (120-150 µl) of sample in to the sample well.
6. Read the results at 5 minutes after adding the sample.

RESULTS


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Negative
Two colored bands form on any strip of the card. The appearance of two colored bands, one in test line zone and the other in control line zone, indicates negative result for that particular test(s). The negative result does not indicate the absence of drug in the specimen; it only indicates the level of tested drug in the specimen is less than cut-off level.

Positive
One colored band form on any strip of the card. One colored band appears in control line zone. No colored band is found in test line zone. This is an indication the level of tested drug(s) in the specimen is above the cut-off level.

Invalid
If there is no colored band in control line zone of any strip, the test result is invalid. Retest the sample with a new device.

LIMITATIONS OF PROCEDURE

The assay is designed for use with human urine only. A positive result with any of the tests indicates only the presence of a drug/metabolite and does not indicate or measure intoxication. There is a possibility that technical or procedural error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer "SPECIFICITY" for lists of substances that will produce either positive results, or that do not interfere with test performance. If a drug/metabolite is found present in the urine specimen, the assay does not indicate frequency of drug use or distinguish between drug of abuse and certain foods and medicines.

PRECAUTIONS

Good Laboratory practice recommends the daily use of control materials to validate the reliability of device. Control materials should be assayed as clinical specimen and challenging to the assay cutoff concentration, e.g., 25% above and below cutoff concentration. If control values do not fall within establish range, assay results are invalid. Control materials which are not provided with this test kit are commercially available.

The Rapid Drugs of Abuse Test provides a built-in process control with a different antigen/antibody reaction at the control region (C). This control line should always appear regardless the presence of drug or metabolite. If the control line does not appear, the test device should be discarded and the obtained result is invalid. The presence of this control band in the control region serve as 1) verification that sufficient volume is added, 2) that proper flow is obtained.

PERFORMANCE CHARACTERISTICS

Please contact the technical support department email: tech@rapidtest.com or call (818) – 591-3030.

Cat #	Drug Test Name
121020-1	Amphetamine RapiCard
121060-1	Barbiturate RapiCard
121061-1	Benzodiazepine RapiCard
121003-1	Buprenorphine RapiCard
121040-1	Cocaine RapiCard
121005-1	EDDP RapiCard * **
120302-1	Ketamine RapiCard * **
121030-1	MDMA RapiCard *
121070-1	Methadone RapiCard
121035-1	Methamphetamine RapiCard
121058-1	Opiate 300 RapiCard
120304-1	Opiate 2000 RapiCard
121002-1	Oxycodone RapiCard
121065-1	PCP RapiCard * **
120312-1	Propoxyphene RapiCard
121027-1	THC RapiCard
121007-1	Tramodol Rapid * **
121025-1	TCA RapiCard *
121149-1	Methylphenidate RapiCard New! * **
121151-1	Fentanyl RapiCard New! * **
121153-1	K2 Rapicard New! * **

* The Product is not FDA approved to be sold in USA for investigation; it can be used for research purpose only.

** The product is not CE marked. CE mark pending approval.

ISO 13485
ISO 9001

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Date Adopted	Reference No.
2005-07-03	CORTEZ-DOA- RapiCard-2012
EC REP	CEpartner4U , Esdoornlaan 13, 3951DB Maarn. The Netherlands.
Revision Date: 02-14-2012	