



OneStep Alcohol Urine RapiDip™ InstaTest

REF 121012

PIC DAL121012VV86

IVD See External Label 2°C - 30°C 25 Tests

Alcohol Urine RapiDip™	
Approximate Relative Blood Alcohol Level	0.02% – 0.30%
Detection	Semi-Quantitative

PRODUCT FEATURES

- High Sensitivity and Specificity
- Built in Internal Controls
- Simplified Workflow, Non-invasive, and Safe
- Rapid and Faster Results

INTENDED USE

The Cortez Alcohol Urine RapiDip™ is a rapid, highly sensitive method to detect the presence of alcohol in urine and

provide an approximation of relative blood alcohol concentration.

This test provides a preliminary screen only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Clinical consideration and professional judgment should be applied to any test screen result, particularly when preliminary positive screens are indicated.

SIGNIFICANCE AND SUMMARY

Two-thirds of all adults drink alcohol.¹ The blood alcohol concentration at which a person becomes impaired is variable dependent upon the individual. Each individual has specific parameters that affect the level of impairment such as size, weight, eating habits and alcohol tolerance. Inappropriate consumption of alcohol can be a contributing factor to many accidents, injuries, and medical conditions.

ASSAY PRINCIPLE

It is well established that the concentration of alcohol in urine is comparable to that of blood.^{2,3} The Cortez Alcohol Urine RapiDip™ consists of a plastic dipstick with a reaction pad attached at the middle. On contact with solutions of alcohol, the reaction pad will rapidly turn colors depending on the concentration of alcohol present. The pad employs a solid-phase chemistry which uses a highly specific enzyme reaction.

REAGENTS

Materials provided with the kit

- Test Dipsticks
- Collection Cup
- Package Insert
- Tetramethylbenzidine
- Alcohol Oxidase (EC 1.1.3.13)

- Peroxidase (EC 1.11.1.7)
- Other additives

Materials required but not provided

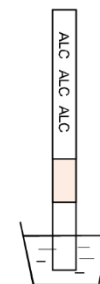
- Timer

ASSAY PROCEDURE

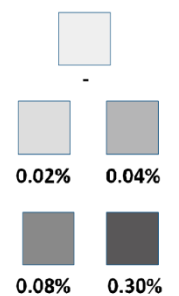
Allow the pouched dipstick to equilibrate to room temperature (15-30°C) prior to testing.

1. Collect the urine in the collection cup provided.
2. Open the foil package and remove the test dipstick. Observe the reactive pad on the middle of the test dipstick. If the reaction pad shows the blue color before applying urine sample, do not use.
3. Immerse the test dipstick vertically in the urine specimen for at least 15 seconds. Start timer immediately after urine application.
4. Read the result in 3-5 minutes. Compare the color of the reaction pad and standard color card to determine the relative blood alcohol concentration.

① Dip in the Urine for 15 seconds



② 3-5 Minutes



RESULTS

Positive: The Cortez Alcohol Urine RapiDip™ will produce a color change in the presence of urine alcohol. The color will



range from light blue color at 0.02% relative blood alcohol concentration to a dark blue color near 0.30% relative blood alcohol concentration. Color pads are provided within this range to allow an approximation of relative blood alcohol concentration. The test may produce colors that appear to be between adjacent color pads.

NOTE: The Cortez Alcohol Urine RapiDip™ is very sensitive to the presence of alcohol. A blue color that is lighter than the 0.02% color pad should be interpreted as being positive to the presence of alcohol in urine but less than 0.02% relative blood alcohol.

Negative: When the Cortez Alcohol Urine RapiDip™ shows no color change this should be interpreted as a negative result indicating that alcohol has not been detected.

Invalid: If the color pad has a blue color before applying urine sample, do not use the test.

NOTE: A result where the outer edges of the color pad produces a slight color but the majority of the pad remains colorless the test should be repeated to ensure complete saturation of the pad with urine. The test is not reusable.

LIMITATIONS OF THE ASSAY

1. The Cortez Alcohol Urine RapiDip™ is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the Urine Alcohol RapiDip™. Alcohol vapors are present in many institutions and homes. Alcohol is a component in many household products such as disinfectant, deodorizers, perfumes, and glass cleaners. If the presence of alcohol vapors is suspected, the test should be performed in an area known to be free of vapors.
2. Ingestion or general use of over-the-counter medications and products containing alcohol can produce positive results.

PERFORMANCE CHARACTERISTICS

The detection limit on the Cortez Alcohol Urine RapiDip™ is from 0.02% to 0.30% for approximate relative blood alcohol level. The cutoff level of the Cortez Alcohol Urine RapiDip™ can vary based on local regulations and laws. Test results can be reference of the color table level standard than color card.

ASSAY SPECIFICITY

The Cortez Alcohol Urine RapiDip™ will react with methyl, ethyl and allyl alcohols.

INTERFERING SUBSTANCES

The following substances may interfere with the Urine Alcohol RapiDip™ when using samples other than urine. The named substances do not normally appear in sufficient quantity in urine to interfere with the test.

- A. Agents which enhance color development
 - Peroxidases
 - Strong oxidizers
- B. Agents which inhibit color development
 - Reducing agents: Ascorbic acid, Tannic acid, Pyrogallol, Mercaptans and Tosylates, Oxalic acid, Uric Acid.
 - Bilirubin
 - L-dopa
 - L-methyl-dopa
 - Methamphetamine

CONTROLS

The Cortez Alcohol Urine RapiDip™ may be qualitatively verified by using a test solution prepared by adding 5 drops

of 80 proof distilled spirits to 8 oz. (1 cup) of water. This solution should produce a color reaction on the pad. The color reaction with alcohol in urine is somewhat slower and less intense than with alcohol in an aqueous solution.

PRECAUTIONS

The Cortez Alcohol Urine RapiDip™ is a visually interpreted test where color matching is used to provide an approximation of relative blood alcohol concentration. Test materials that have been exposed to urine should be treated as potentially infectious. Do not use the Cortez Alcohol Urine RapiDip™ after the expiration date marked on the foil package.

STORAGE CONDITIONS



The Cortez Alcohol Urine RapiDip™ is to be stored at 2-30°C (36-86°F) in its sealed foil package. If storage temperatures exceed 30°C, the test performance may degrade. If the product is refrigerated, the Cortez Alcohol Urine RapiDip™ must be brought to room temperature prior to opening the pouch.

REFERENCES

1. Volpicellim, Joseph R., M.D., Ph.D.: Alcohol Dependence: Diagnosis, Clinical Aspects and Biopsychosocial Causes., Substance Abuse Library, University of Pennsylvania, 1997.
2. Bendtsen p, Hultberg J, Carlsson M, Jones AW.: Monitoring Ethanol Exposure in a Clinical Setting by Analysis of Blood, Breath, Saliva, and Urine. Alcohol Clin Exp Res.1999 Sep;23(9):1446-51.
3. Jones AW, Kugelberg FC. : Relationship between blood and urine alcohol concentrations in apprehended drivers who claimed consumption of alcohol after driving with and without supporting evidence. Forensic Sci Int.2010 Jan 30;194(1-3):97-102.



MANUFACTURER AND BRAND DETAILS

<p>ISO 13485:2016</p>  <p>ISO 13485 Quality Management for Medical Devices CERTIFIED</p>	
<p> Diagnostic Automation/Cortez Diagnostics, Inc. 21250 Califa Street, Suite 102 and 116, Woodland Hills, California 91367 USA</p>	
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