

# Ecotest®

D-ALC-U11

Urine Alcohol Test Strip

## INTENDED USE

The Urine Alcohol Test Strip is a rapid, highly sensitive method to detect the presence of alcohol in human urine.

This test provides a preliminary result only. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography (GC) is the preferred confirmatory method. Clinical consideration and professional judgment should be applied to any result, particularly when preliminary positive results are indicated.

## PRINCIPLE

The Urine Alcohol Test Strip is a chemical assay based on an alcohol-sensitive enzymatic reaction. Alcohol, if present in the specimen, reacts with chemicals on the reaction pad and causes a color change.

The Urine Alcohol Test Strip consists of a plastic strip with a reaction pad attached at the tip. The reaction pad employs a solid-phase chemistry system which uses a highly specific enzyme reaction. On contact with specimens of alcohol, the reaction pad will rapidly change colors depending on the concentration of alcohol present. This color change is proportional to the concentration of alcohol in the specimen. By comparing with the color blocks on the color chart printed on the pouch, an approximate alcohol concentration can be determined.

## REAGENTS

The test strip contains 1.3%(w/w) 3,3',5,5'-Tetramethylbenzidine, 0.3%(w/w) Alcohol Oxidase, 0.1%(w/w) Peroxidase, 12.6%(w/w) buffer and 85.8% non-reaction additives.

## PRECAUTIONS

- For medical or other professional *in vitro* diagnostic use only.
- Do not use after the expiration date.
- All specimens and test materials that have been exposed to the specimen should be treated as potentially infectious.
- Follow proper precautions and local regulations when disposing of the test.
- The appropriate limit for determining sobriety varies depending on local regulations.

## STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-27°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

## SPECIMEN COLLECTION AND PREPARATION

The alcohol contained specimens may be stored in a sealed container at 15-27°C for up to 4 hours prior to testing. Specimens may be refrigerated and stored at 2-8°C. Do not freeze the specimens. Refrigerated specimens should be brought to room temperature before testing.

## MATERIALS PROVIDED

- Test strips
- Package insert

## MATERIALS REQUIRED BUT NOT PROVIDED

- Timer

## DIRECTIONS FOR USE

1. Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible after observing the reaction pad on the end of the test strip. The reaction pad should have a light cream color. Do not use the test strip if the reaction pad has a blue color before the specimen is applied or is otherwise discolored.
2. Saturate the reaction pad with specimen from the specimen collection container or by applying the specimen directly to the reaction pad. Start the timer immediately after saturating the reaction pad with the specimen.

3. Read results at 2 minutes by visually comparing the color of the reaction pad to the corresponding color blocks printed on the pouch to determine the alcohol concentration. Do not interpret the result after 3 minutes.

## INTERPRETATION OF RESULTS

**NEGATIVE:** No color change appears on the reaction pad. The color should match the color block on the pouch corresponding to a negative (-) result. This indicates that alcohol has not been detected.

**POSITIVE:** A color change appears on the reaction pad. The color on the reaction pad varying from a light blue to a dark blue, falling on or between the corresponding color blocks on the pouch.

**INVALID:** The outer edges of the reaction pad produce a slight color but the majority of the reaction pad remains colorless. Repeat the test with a new test strip, ensuring complete saturation of the reaction pad with the specimen. If the problem persists, do not continue the test and contact your local distributor.

## Q QUALITY CONTROL

The Urine Alcohol Test Strip may be qualitatively verified by using a test solution prepared by adding 5 drops of 80 proof distilled spirits to 30 mL of water. This solution should produce a color change on the reaction pad corresponding to 0.02% or greater. The color reaction with alcohol in the human urine is somewhat slower and less intense than with alcohol in an aqueous solution.

Do not perform the control test with undiluted alcohol, as pure alcohol solutions will not produce a positive result.

## LIMITATIONS

1. The Urine Alcohol Test Strip provides only a preliminary result for detection alcohol concentration in human urine. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography (GC) is the preferred confirmatory method.
2. Interpretation of visual results is dependent on several factors: the variability of color perception, the presence or absence of inhibitory factors, and the lighting conditions when the strip is read. Caution should be taken when interpreting test results due to the subjective nature of the test.
3. The Urine Alcohol Test Strip should not be used to determine the presence of alcohol in beverages, in undiluted alcohol, or in other liquid solutions.
4. Alcohol concentration in human body slowly increases after the alcohol ingestion. Generally, the maximum of alcohol concentration in human urine, appears in the range from 30 minutes to 60 minutes after the last alcohol ingestion. After the maximum appearance, the alcohol concentration in human body reduces. How long the alcohol concentration reduces to zero depends on how much alcohol ingested.
5. The Urine Alcohol Test Strip is highly sensitive to the presence of alcohol. Alcohol vapors in the air are sometimes detected by the test strip. 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.
6. Ingestion or general use of over-the-counter medications and products containing alcohol such as cold medicines, breath sprays and mouthwashes can produce positive results. Wait at least 20 minutes after ingesting any such products before using the test strip.

## Assay Specificity

The Urine Alcohol Test Strip will react with methyl, ethyl and allyl alcohols. The following substances may interfere with the Alcohol Test Strip. These substances do not normally appear in sufficient quantity in human urine to interfere with the test.

Peroxidases	Mercaptans	Bilirubin
Strong oxidizers	Tosylates	L-dopa
Ascorbic acid	Oxalic acid	L-methyldopa
Tannic acid	Uric acid	Methamphetamine
Pyrogallol		

## BIBLIOGRAPHY

Volpicelli, Joseph R., M.D., Ph.D. *Alcohol Dependence: Diagnosis, Clinical Aspects and Biopsychosocial Causes*, Substance Abuse Library, University of Pennsylvania, 1997.

## GLOSSARY OF SYMBOLS

REF	Catalog number	1	Temperature limitation
1	Consult instructions for use	LOT	Batch code
IVD	In vitro diagnostic medical device	2	Use by
2	Manufacturer	2	Do not reuse

Ecotest®

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