

Chuangxingwell



Alcohol Rapid Test Kit (Saliva & Urine) Package Insert

A rapid test for the semi-quantitative detection of Alcohol/Urine for the determination of relative blood alcohol concentration.

For in vitro diagnostic use only.



INTENDED USE

Alcohol Rapid Test Kit (Saliva & Urine) is a rapid, highly sensitive method to detect the presence of alcohol in Saliva/Urine and provide an approximation of relative blood alcohol concentration (BAC) at 0.02% or greater.

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.

INTRODUCTION

Excessive or inappropriate consumption of alcohol is one of the most common and pervasive social problems in our society.¹ Inappropriate consumption of alcohol can be a contributing factor to many accidents, injuries, and medical conditions.

Screening of individuals for alcohol consumption is an important method for the identification of individuals who might be at risk due to alcohol intoxication, use or abuse. Screening also provides additional benefit as a deterrent against inappropriate alcohol consumption.

It has been well established that the concentration of alcohol in Saliva/Urine is comparable to that in blood.^{2,3} The United States Department of Transportation (DOT) has established a BAC of 0.02% as the level at which an individual is considered positive for the presence of alcohol.

Alcohol Rapid Test Kit (Saliva & Urine) is a rapid Saliva/Urine test that can be performed without the use of an instrument. It determine the presence of 0.02% BAC or more in accordance with the DOT regulations.

PRINCIPLE

Alcohol Rapid Test Kit (Saliva & Urine) is a chemical assay based on an alcohol-sensitive enzymatic reaction. Alcohol, if present in the Saliva/Urine specimen, reacts with chemicals on the reaction pad and causes a color change.

Alcohol Rapid Test Kit (Saliva & Urine) 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 solutions 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 Saliva/Urine specimen. By comparing with the color blocks on the

color chart printed on the pouch, an approximate Blood Alcohol Concentration (BAC) (from 0.02% to 0.30%) can be determined.

MATERIALS

MATERIALS PROVIDED

- Test Strips (contains Tetramethylbenzidine, Alcohol Oxidase, Peroxidase and other additives).
- Package Insert.

MATERIALS NEEDED BUT NOT PROVIDED

- Timer.
- Collection cups.

PRECAUTIONS

1. For medical or other professional in vitro diagnostic use only.
2. Do not use the product beyond expiration date.
3. Discard after first use. The test strip cannot be used more than once.
4. The product is sensitive to the presence of alcohol and moisture. After open the package, the test device should be used immediately.
5. Do not use the kit if the pouch is punctured or not well sealed.
6. All specimens and test materials that have been exposed to Saliva/Urine should be treated as potentially infectious.
7. The used test strip and test materials should be discarded according to local regulations.

STORAGE AND STABILITY

- Store as packaged in the sealed pouch either at room temperature or refrigerated (2-27°C) for 24 months.
- If storage temperatures exceed 27°C, the test performance may degrade. If the product is refrigerated, the Urine Alcohol Rapid Cassette must be brought to room temperature prior to opening the pouch.
- 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.

SPECIMEN COLLECTION AND PREPARATION

1. For Saliva:

- a). Do not place anything in the mouth for 15 minutes before beginning the test. This includes non-alcoholic drinks, tobacco products, coffee, breath mints, food, etc.
- b). Spit the saliva into a sputum cup or a clean container, or directly applied to the reaction pad of the test strip.

Note: For hygienic and sanitary reasons, placing the test strip in the mouth is not recommended.

2. For Urine:

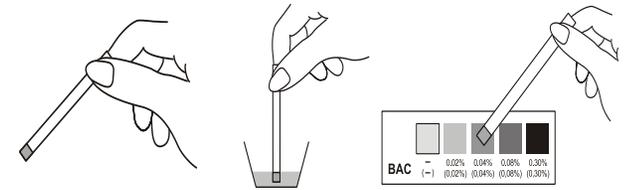
Urine specimen can be collected with a sputum cup or a clean container, or directly applied to the reaction pad of the test strip.

3. Saliva/Urine specimens may be stored in a sealed container at 2-27°C for up to 4 hours prior to testing. Specimens may be refrigerated and stored at 2-8°C. Do not freeze Saliva/Urine specimens. Refrigerated specimens should be brought to room temperature before testing.

PROCEDURE

Allow the test strip, specimens and/or controls to equilibrate to room temperature (15-30 °C) prior to testing.

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. Do not use the test strip if the reaction pad has a blue color before the Saliva/Urine specimen is applied or is otherwise discolored.
2. Saturate the reaction pad with Saliva/Urine: by dipping it into the specimen collection cup or by applying Saliva/Urine directly to the reaction pad. Saturating the reaction pad usually takes 6-8 seconds. Then shake off the excess Saliva/Urine.
3. Start the timer immediately and read results at 2 minutes. Compare the color of the reaction pad to the corresponding color blocks printed on the pouch to determine the relative blood 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 BAC will range from 0.02% to 0.30%, with 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.

NOTE: The test strip is very sensitive to the presence of alcohol. A blue color lighter than the 0.02% color pad should be interpreted as alcohol positive in Saliva/Urine but less than 0.02% concentration of alcohol in blood.

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 Saliva/Urine. If the problem persists, discontinue using the lot immediately and contact your local distributor.

QUALITY CONTROL

Alcohol Rapid Test Kit (Saliva & Urine) may be qualitatively verified by using a test solution prepared by adding 5 drops of 80 proof distilled spirits to 30mL of water. This solution should produce

a color change on the reaction pad corresponding to a 0.02% or greater BAC. The color reaction with alcohol in saliva 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. Alcohol Rapid Test Kit (Saliva &Urine) provides only a preliminary result for the relative BAC. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography (GC) is the preferred confirmatory method.
2. Failure to wait 15 minutes after smoking or placing food, drink, or other non-alcoholic materials in the mouth before performing the test can produce erroneous results due to possible contamination of the saliva by interfering substances.
3. 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.
4. Test Kit should not be used to determine the presence of alcohol in beverages, in undiluted alcohol, or in other liquid solutions.
5. Test Kit 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.
7. Waiting longer than two minutes to interpret the test can result in erroneous or false positive results.

PERFORMANCE CHARACTERISTICS

The detection range of Alcohol Rapid Test Kit (Saliva &Urine) is from 0.02% to 0.30% for the approximate relative blood alcohol concentration. The appropriate limit for determining sobriety varies depending on local regulations.

A. Precision and accuracy

Perform 60 trials under normal laboratory conditions in internal laboratory including 20 trials at 0.000 BAC, 20 trials at 0.008 BAC and 20 trials at 0.032BAC. Results were as below:

n	BAC	Results
20	0.000	0 false positive
20	0.008	0 false positive
20	0.032	0 false negative

B. Specificity

Alcohol Rapid Test Kit (Saliva &Urine) will react with methyl,ethyl, and allyl alcohols. It will not react with alcohols having 5 or more carbons, nor with glycine, glycerol, or serine. This property is a result of the specificity of the alcohol oxidase.

C. Interfering Substances

The following substances may interfere with the Alcohol Rapid Test Kit (Saliva &Urine) when using samples other than Saliva/Urine. The substances do not normally appear in sufficient quantity in saliva 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

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. Jones, A.W.: Inter-and intra individual variations in the saliva/blood alcohol ratio during ethanol metabolism in man, Clin. Chem. 25,1394-1398, 1979.
3. McColl K.E., Whiting, B., Moore, M.R. and Goldberg, A.: Correlation of ethanol concentrations in blood and saliva, Clin.Sci., 56, 283-286, 1979.

SYMBOLS

	Caution		In Vitro Diagnostic Medical Device
	Manufacturer		Date of Manufacture
	CE Marking		Do Not Re-use
	Keep Dry		Keep Away From Sunlight
	Batch Code		Do Not Use if Package is Damaged
	Catalogue Number		Contains Sufficient for <n> Tests
	Use-By Date		Temperature Limit
	Authorized representative in the European Community		



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