Urine Alcohol Testing Strip

For Forensic and Research Use Only

INTENDED USE

Urine Alcohol Test is intended for use as a rapid method to detect the presence of alcohol in urine greater than 0.04%.
The test is intended for the detection of ethyl alcohol in human urine. To confirm the concentration of positive specimens, an alternate, non-enzymatic technology such as headspace gas chromatography should be used.

SUMMARY

Excess or inappropriate consumption of alcohol is a common and pervasive social problem. It is a contributory 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 use or intoxication.

Screening is also an important deterrent against inappropriate alcohol consumption. The blood alcohol concentration at which a person becomes impaired is variable dependent on the individual. Parameters specific to the individual such as physical size, weight, activity level, eating habits and alcohol tolerance all affect the level of impairment.

Determination of ethyl alcohol in urine, blood and saliva is commonly used for measuring legal impairment, alcohol poisoning, etc. Gas chromatography techniques and enzymatic methods are commercially available for the determination of ethyl alcohol in human fluids. Alcohol Test is designed to detect ethyl alcohol in urine specimens.

PRINCIPLE

Alcohol Test is based on the high specifity of alcohol oxidase (ALOx) for ethyl alcohol in the presence of peroxidase and enzyme substrate such as tetramethylbenzidine (TMB) as shown in the following:

$$\text{EtOH} + \text{TMB} \xrightarrow{\text{ALOx/Peroxidase}} CH_3CHO + \text{Colored TMB}$$

The distinct color on reactive pad could be observed in less than 60 seconds after the reaction pad was wetted with urine specimens with the ethyl alcohol concentration greater than 0.04%. It should be pointed out that other alcohols such as methyl, propanyl and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in human urine.

MATERIALS PROVIDED

1. Instruction for use
2. Alcohol Test

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or clock

PRECAUTIONS

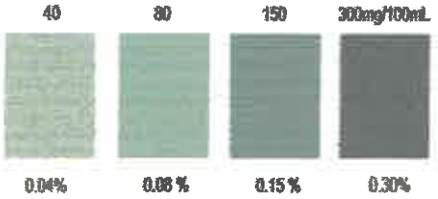
1. For Forensic and Research use only.
2. Do not use the product beyond expiration date.
3. Handle all specimens as potentially infectious.
4. The product is sensitive to the presence of alcohol and moisture. After open the package, the test device should be used immediately.

SPECIMEN COLLECTION AND PREPARATION

1. Urine specimen can be collected in a sputum cup or a clean container.
2. Avoid contact with skin by wearing gloves and proper laboratory attire.

PROCEDURE

1. Open the foil package and remove the test strip.
2. Dipping the strip into the urine specimen collected in a sputum cup.
3. **After wetting the reaction pad by urine specimen, immediately remove it.**
4. At 2 minutes, compare the reactive pad with the provided color chart.
   Results after more than 5 minutes may be not accurate



INTERPRETATION OF RESULTS

Negative: Almost no color change by

comparing with the background. The negative result indicates that the alcohol concentration is less than 0.04%.
Positive: A distinct color developed all over the pad. The positive result indicates that the urine alcohol concentration is 0.04% or higher.
Invalid: *The test should be considered invalid if only the edge of the reactive pad turned color that might be ascribed to insufficient sampling.* The subject should be re-tested.

LIMITATION OF PROCEDURE

Alcohol Test is designed for use with human urine only. A positive result indicates only the presence of alcohol and does not indicate or measure intoxication.
There is a possibility that technical or procedure error as well other substances in certain foods and medicines may interfere with the test and cause false results. Please refer to " Interference" section for list of substances that will interfere the test results.

EXPECTED RESULTS

Alcohol Test is a semi-quantitative assay. It identifies alcohol in human urine specimens at a concentration of 0.04% or higher.

PERFORMANCE CHARACTERISTICS

A. Accuracy

The following data were obtained based on 56 clinical urine samples.

	GC(+)	GC(-)	Row Total
Strip Test(+)	26	0	26
Strip Test(-)	1	29	30
Col. Total	96%	100%	98%
	Sensitivity	Specificity	Agreement

B. Detection Limit

Detection limit at 20mg/dL (0.02g/dL)

C. Interference

The following substances may interfere with the Alcohol Test:

Strong oxidizers	Ascorbic acid
Tannic acid	Polyphenolic compopunds
Mercaptans	Uric acid
Bilirubin	Oxalic acid

These compounds are not normally present in sufficient amount in urine to interfere with the test.

REFERENCES;

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