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URINE ALCOHOL TEST

REF

Catalog No. R13-472

INTENDED USE

Immunospec Urine Alcohol Test is intended for use as a rapid method to detect the presence of alcohol in urine.

The test is intended for the screening 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.

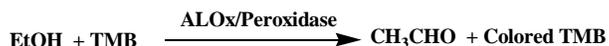
EXPLANATION OF THE TEST

Alcohol intoxication can lead to loss of alertness, coma, death and as well as birth defects. The BAC at which a person becomes impaired is variable. The United States Department of Transportation (DOT) has established a BAC of 0.02% (0.02g/dL) as the cut-off level at which an individual is considered positive for the presence of alcohol.

Determination of ethyl alcohol in blood, saliva and urine 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. Rapid Urine Alcohol Test is designed as the screen tool to rapidly determine if the alcohol level is higher than 0.04% by testing urine specimen.

PRINCIPLE OF THE PROCEDURE

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



The distinct color on reactive pad could be observed in less than 1 minute after the tip was contacted with urine samples with the ethyl alcohol concentration greater than 0.04%. It should be pointed out that other alcohols such as methyl, propyl and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in urine.

MATERIALS PROVIDED

1. Instruction for use
2. Immunospec Urine Alcohol Test
Each test contains these materials:

Tetramethylbenzidine (TMB)	0.12mg
Alcohol oxidase (EC)	0.05 IU
Peroxidase(EC)	35 IU
Proteins	0.15mg

MATERIALS REQUIRED BUT NOT PROVIDED

1. Timer or clock

PRECAUTIONS

1. For in vitro 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 clean container.
2. Avoid contact with skin by wearing gloves and proper laboratory attire.

QUALITY CONTROL

Good laboratory Practice recommends the daily use of control material to validate the reliability of device. Commercially available controls that contain sodium azide or other preservatives that will inhibit the enzyme activity cannot be used with Immunospec Urine Alcohol Test.

Immunospec Urine Alcohol Test may be qualitatively verified by using a test solution prepared by adding 10 drops of ethanol alcohol into 8 oz of distill water. This solution should show a distinct positive result.

PROCEDURE

1. Bring all materials and specimens to room temperature.
2. Remove the test strip from the foil pouch.
3. Dip the strip into the urine specimen with the arrow pointing toward the sample. The sample level should not be higher than the arrow pointed maximum line.
4. Hold the strip until liquid reaches the reaction pad (about 30 seconds).
5. Withdraw the strip and place it face up on a clean, non-absorptive surface or leave the strip in urine if the urine level is not higher than arrow pointed maximum line.
6. Immediately start timer and at 4 minutes, compare the reactive pad with the provided colored chart.

INTERPRETATION OF RESULTS

Negative: Almost no color change by comparing with the background. The negative result indicates that the urine alcohol level 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

Immunospec Urine 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 the list of substances that will interfere the test results.

EXPECTED RESULTS

Immunospec Urine Alcohol Test. is a semi-quantitative assay. It identifies alcohol in human urine at a concentration of 0.04% BAC.

PERFORMANCE CHARACTERISTICS

A. Detection limit

Detection limit is 40 mg/dL (0.04g/dL)

B Interference

The following substances may interfere with Immunospec Urine Alcohol Test:

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

These compounds are not normally present in sufficient amount in urine to interfere with the test. However, the precautious step must be taken so that these materials are not introduced into the urine during the period proceeding to conduct the test.

REFERENCES;

1. National highway traffic safety administration NHTSA), DOT, Federal Register. 59:147, August 1994, pp 22382-90
2. Bergemeyer, H.U., et.al, Methods of Enzyme Analysis, 3rd ed. Vol. II, 1983, p143
3. Jones A.W., Clin. Exp. Pharmacol. Physiol. Vol. 6, 1979, pp 53-59
4. McCall K.E.L., et.al, Clin. Sce. Vol. 56, 1979, pp 283-286



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