

DrugCheck® Alcohol Rapid Test

For the rapid semi-quantitative determination of alcohol level in human urine

INTENDED USE

The DrugCheck® Alcohol Rapid Test is intended for the rapid semi-quantitative determination of ethyl alcohol level in human urine. The test is a rapid enzymatic method to detect the presence of alcohol in urine greater than 0.04%. The tests are designed to obtain a visual, semi-quantitative result and are intended for professional use only. They are not intended for quantitative results, nor for over-the-counter sale. The Alcohol Rapid Test provides only preliminary analytical data. A more specific, alternative method is required to obtain a confirmed analytical result. To confirm the concentration of positive specimens, an alternate, non-enzymatic technology such as headspace gas chromatography should be used. Clinical considerations and professional judgment should be applied to any test result, particularly when preliminary positive results are indicated.

SUMMARY AND EXPLANATION OF 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. 1-3 Determination of ethyl alcohol in blood 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. The TM Alcohol Rapid Test is designed as the screen method to rapidly determine if the alcohol level in urine is higher than 0.04%.

PRINCIPLE OF THE PROCEDURE

The DrugCheck® Alcohol Rapid 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:
It should be pointed out that other alcohols such as methyl, propanol and allyl alcohol would develop the similar color on the reactive pad. However, these alcohols are not normally present in urine.

PROCEDURE

1. Add urine to cup
2. Read Results

IMPORTANT: Results after more than 2 minutes may be not accurate. In order to prevent an incorrect reading, do not read the test results after more than 5 minutes. After 5 minutes, the intensity of the colored pad may change. To avoid confusion, discard the test device after interpreting the result.

INTERPRETATION OF RESULTS

Negative: Almost no color change on test pad by comparing with the background of the provided colored chart. The negative result indicates that the concentration of ethyl alcohol in urine is less than 0.04%.

Positive: A distinct color developed all over the pad. The positive result indicates that the concentration of ethyl alcohol in urine 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.

PROCESS AND 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 this test. The TM Alcohol Rapid 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.

AFTER TESTING

Urine specimens may be potentially infectious. Avoid contact with skin by wearing gloves and proper laboratory attire. Properly handle and dispose of all used test devices in an approved biohazard container. Residual urine should be disposed of in a medically approved manner after the completion of all testing, including the confirmatory assay.

PERFORMANCE CHARACTERISTICS

SENSITIVITY: The DrugCheck® Alcohol Rapid Tests have been designed for detection of alcohol in urine at the detection sensitivity of 40mg/dL (0.04g/dL). In sensitivity studies performed, samples with concentrations of alcohol equal to or higher than 40mg/dL were identified as positive results for all

samples. Thus, the cut-off level of the DrugCheck® Alcohol Rapid Test was determined to be 40mg/dL. Tests, within-lot and inter-lot reproducibility studies were performed. Results of the within-lot reproducibility studies clearly showed excellent repeatability for all positive and negative urine samples using one lot of DrugCheck® Alcohol Rapid Tests. The results of inter-lot reproducibility studies clearly demonstrated that there was no appreciable inter-lot variation when testing both positive and negative samples across three different lots of DrugCheck® Alcohol Rapid Test.

INTERFERENCE: The following substances were added to the sample, which had alcohol levels of 0 and 0.08%. None of the substances at concentration tested interfered in the DrugCheck® Alcohol Rapid Tests.

Acetaminophen	20 mg/dl
Caffeine	20 mg/dl
Glucose	2,000 mg/dl
Hemoglobin	1 mg/dl
Human Serum Protein	2,000 mg/dl

The following substances may interfere with the test:

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

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

ASSAY COMPARISONS & EQUIVALENCY

Accuracy and equivalency comparisons of DrugCheck® Alcohol Rapid Test was evaluated as well as against 86 individual external SAMHSA-certified clinical laboratory samples. The results have been tabulated below.

Alcohol Strip	GC (+)	GC (-)	Row Totals
(+)	41	2	43
(-)	3	40	43
Col.Totals	44	42	86

When compared to the GC data, the relative sensitivity or percent agreement of DrugCheck® Alcohol Test positive samples with the external clinical study was 41/44 or 93.2%. Negative samples recovered a relative specificity of agreement of 40/42 or 95.2%. The overall relative accuracy obtained was 81/86 or 94.2%.

LIMITATIONS OF PROCEDURE

- The DrugCheck® Alcohol Rapid Test is designed for in vitro detection 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.
- This diagnostic test provides a semi-quantitative screening for alcohol in urine. It is not to be used for quantitative determination of alcohol concentration in urine. To confirm the concentration of positive specimens, an alternate, non-enzymatic technology such as headspace gas chromatography should be used.
- Adulterants, such as bleach or other strong oxidizing agents, may produce erroneous test results when added to urine specimens, regardless of the analysis method used. If an adulteration is suspected, a fresh urine specimen should be used.

EXPECTED RESULTS

The DrugCheck® Alcohol Rapid Test is a semi-quantitative assay. It identifies alcohol in human urine at a concentration of 0.04% BAC.

BIBLIOGRAPHY

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