DRI® Ethyl Alcohol Assay

thermo scientific

IVD **For In Vitro Diagnostic Use**

Rx Only

REF 10016397 (3 x 18 mL Kit)
0037 (100 mL Kit)
0038 (500 mL Kit)

Intended Use
The DRI® Ethyl Alcohol Assay is intended for the quantitative determination of alcohol in human urine, serum or plasma.

Summary and Explanation of the Test
In addition to beverages, ethyl alcohol (ethanol or alcohol) can also be found in high concentrations in a variety of products such as mouthwashes, colognes, candies and medicinal preparations. When alcohol is ingested, it will permeate all tissues of the body within one hour. About 95% of the alcohol is metabolized in the liver, and the remainder is excreted unchanged.

Alcohol intoxication can lead to birth defects (eg, fetal alcohol syndrome), loss of alertness, stupor, coma and death. Determination of ethyl alcohol concentration is commonly used for measuring legal impairment, investigating forensic evidence, diagnosing and/or treating alcohol dependency, as well as detecting alcohol poisoning.

Gas chromatography techniques and several enzymatic methods are available for determination of ethyl alcohol.[1,2] These techniques either require specimen pretreatment or require incubation periods ranging from 10 to 60 minutes.[3]

DRI Ethyl Alcohol Assay is a liquid, ready-to-use, kinetic method based on the high specificity of alcohol dehydrogenase (ADH) for ethyl alcohol. In the presence of ADH and nicotinamide adenine dinucleotide (NAD), ethyl alcohol is readily oxidized to acetaldehyde and NADH. The enzymatic reaction can be monitored spectrophotometrically at 340 nm.

$$\text{Ethyl Alcohol} + \text{NAD} \xleftrightarrow{\text{ADH}} \text{NADH} + \text{Acetaldehyde}$$

Materials Provided
Buffer Reagent (A):
Contains Tris buffer with sodium azide as preservative.
Enzyme Reagent (E):
Contains alcohol dehydrogenase (ADH) and NAD in Phosphate buffer with stabilizer and sodium azide as a preservative.

Additional Material Required (sold separately):

DRI Ethyl Alcohol Calibrators and Controls:

REF	Kit Description
0311	Ethyl Alcohol Negative Calibrator, 5 mL
1405	Ethyl Alcohol Negative Calibrator, 25 mL
0239	Ethyl Alcohol 50 mg/dL Control, 5 mL
0241	Ethyl Alcohol 100 mg/dL Calibrator, 5 mL
1406	Ethyl Alcohol 100 mg/dL Calibrator, 25 mL
0243	Ethyl Alcohol 300 mg/dL Control, 5 mL

⚠ Precautions and Warnings
This test is for in vitro diagnostic use only. The components are harmful if swallowed.

DANGER: DRI Ethyl Alcohol Assay contains ≤2.0% bovine serum albumin (BSA).

Reagents used in the assay components contain ≤0.10 % sodium azide. Avoid contact with skin and mucous membranes. Flush affected areas with copious amounts of water. Get immediate medical attention for eyes, or if ingested. Sodium azide may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of such reagents, always flush with large volumes of water to prevent azide build-up. Clean exposed metal surfaces with 10% sodium hydroxide.

H317 - May cause allergic skin reaction.
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled.
EUH032 - Contact with acids liberates very toxic gas.

Avoid breathing mist or vapor. Contaminated work clothing should not be allowed out of the workplace. In case of inadequate ventilation wear respiratory protection. If on skin: Wash with plenty of soap and water. IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing. Specific treatment (see First Aid information on product label and/or Section 4 of the SDS). If skin irritation or rash occurs: Get medical advice/attention. If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. Dispose of contents/container to location in accordance with local/regional/national/international regulations.

Do not use the reagents beyond their expiration dates.

Do not leave either calibrators or controls uncapped longer than necessary. Store tightly capped inside a refrigerator whenever possible to prevent evaporation of alcohol.

Increased levels of lactic acid and lactic dehydrogenase (LDH) in postmortem samples may cause elevated ethyl alcohol results.

Reagent Preparation and Storage
The reagents are ready for use. No reagent preparation is required. All assay components, when stored properly at 2-8°C, are stable until the expiration date indicated on the label.

Specimen Collection and Handling
Collect urine, plasm or serum specimens in plastic or glass containers. Care should be taken to preserve the chemical integrity of the urine sample from the time it is collected until the time it is assayed.

Urine specimens kept at room temperature that do not receive initial test within 7 days[4] of arrival at the laboratory may be placed into a secure refrigeration unit at 2 to 8°C for up to two months.[4] For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20°C.[4, 5]

Plasma or serum specimens kept at room temperature that do not receive an initial test within 10 days[6] of arrival at the laboratory may be placed into a secure refrigeration unit at 2 to 8°C for up to 10 days[6]. For longer storage prior to analysis or for sample retention after analysis, urine specimens may be stored at -20°C.[5]

Samples within a pH range of 3 to 11 are suitable for testing with this assay.

Laboratories following the SAMHSA mandatory guidelines should refer to SAMHSA "Short-Term Refrigerated Storage" and "Long-Term Storage" requirements.[7]

To protect the integrity of the sample, do not induce foaming and avoid repeated freezing and thawing. An effort should be made to keep pipetted samples free of gross debris. It is recommended that grossly turbid specimens be centrifuged before analysis. Frozen samples should be thawed and mixed prior to analysis. Adulteration of the urine sample may cause erroneous results. If adulteration is suspected, obtain another sample and forward both specimens to the laboratory for testing.

Handle all urine specimens as if they were potentially infectious.

Assay Procedure
Analyzers capable of maintaining a constant temperature, pipetting samples, mixing reagents, measuring enzymatic rates at 340 nm and timing the reaction accurately can be used to perform this assay.

Refer to the specific application instructions of each analyzer for chemistry parameters before performing the assay.

Quality Control and Calibration
Good laboratory practices suggest the use of controls to ensure proper assay performance. Both 50 mg/dL and 300 mg/dL ethyl alcohol controls are available from Microgenics. Establish the acceptable control ranges for your own laboratory. Both negative and 100 mg/dL alcohol calibrators should be used to calibrate the assay. Controls should be used at least once a day to validate the assay performance. All quality control requirements should be performed in conformance with local, state and/or federal regulations or accreditation requirements.

Results
The rate of alcohol metabolism and excretion vary among individuals and are dependent upon factors such as gender, age, body weight, stomach content, concurrent use of medication and health condition. The DRI Ethyl Alcohol Assay can accurately quantitate alcohol concentrations within a range of 10 mg/dL (0.01%) to 600 mg/dL (0.6%).

The legal definition of intoxication varies. The following table is recommended as a general guideline for the significance of blood (serum and/or plasma) alcohol level:[8]

Blood Alcohol Level	Sporadic Drinkers	Chronic Drinkers
100 mg/dL or 0.1%	Legally intoxicated	Minimal signs
200-250 mg/dL or 0.2-0.25%	Alertness loss, lethargic	Effort needed to maintain control
300-350 mg/dL or 0.3-0.35%	Stupor to coma	Drowsy and slow
> 500 mg/dL or > 0.5%	Death possible	Coma

Urine alcohol concentrations are often used to estimate blood alcohol concentrations. During the elimination phase, the urine/blood alcohol ratio of 1.3 provides a valid estimate in most cases.[9]

Limitations

1. Legal alcohol intoxication levels vary. The test result should be interpreted in light of clinical signs and symptoms.
2. Ethyl alcohol is volatile. Precautions suggested in the Specimen Collection and Handling section are required to prevent alcohol evaporation from calibrators, controls and samples.
3. The test is designed for use with human urine, serum and plasma only.
4. Increased levels of lactic acid and LDH in postmortem samples may cause elevated ethyl alcohol results.

Typical Performance Characteristics

Performance results obtained on the Hitachi 717 analyzer are shown below.[10] The results obtained in your laboratory may differ from these data.

Precision

Within-run and run-to-run precision were evaluated with the following results:

	Within-Run Precision		
Sample	**n**	**Mean ± S.D. (mg/dL)**	**%CV**
50 mg/dL	12	48.6 ± 1.3	2.7
100 mg/dL	12	100.3 ± 1.2	1.2
300 mg/dL	12	290.2 ± 1.9	0.6

	Run-to-Run Precision		
Sample	**n**	**Mean ± S.D. (mg/dL)**	**%CV**
50 mg/dL	10	50.7 ± 4.5	4.5
250 mg/dL	10	253.7 ± 6.7	2.6

Sensitivity

Sensitivity, defined as the lowest concentration that can be differentiated from the negative sample, is 10 mg/dL (or 0.01%).

Linearity

The assay is linear up to a concentration of 600 mg/dL. Samples with an alcohol concentration greater than 600 mg/dL can be diluted with the negative calibrator. Repeat the assay and multiply the result with the dilution factor to obtain the true concentration.

Specificity

Grossly hemolyzed (800 mg/dL hemoglobin), icteric (30 mg/dL bilirubin) and lipemic (1000 mg/dL triglycerides) samples were found to have no interference with the assay. Various structurally related organic compounds were tested for cross-reactivity in the assay. The following table summarizes the results:

Compound	Level Tested (mg/dL)	% Cross Reactivity
Acetaldehyde	2000	0
Acetone	2000	0
n-Butanol	2000	1.7
Ethylene Glycol	2000	0
Isopropanol	2000	0
Methanol	2000	0
n-Propanol	2000	10.7

Correlation

One hundred and twenty-five clinical specimens were assayed for ethyl alcohol concentration by both DRI Ethyl Alcohol Assay (y) and a commercially available ethyl alcohol assay (x). A linear regression equation of y = 1.02x + 2.05 and a correlation coefficient (r) of 0.982 were obtained.

References

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2. Beutler HO: Ethanol. In: Bergmeyer HU, ed. Methods of Enzymatic Analysis, Vol. VI, 3rd ed. New York: Academic Press, 1984, pp 598 - 606.
3. Redetzki HM, Dees WL, Comparison of Four Kits for Enzymatic Determination of Ethanol in Blood. Clin Chem 22, 83 (1976).
4. Mandic-Radic S, Dzingalasevic G, Lukovic N. Stability of Ethanol in Blood and Urine Samples. *JMB* 26: 241-244, 2007.
5. C52-A2, Toxicology and Drug Testing in the Clinical Laboratory; Approved Guideline – Second Edition, *Clinical and Laboratory Standards Institute (CLSI)* (April 2007).
6. Penetar DM, McNeil JF, Ryan ET, Lukas, SE. Comparison Among Plasma, Serum, and Whole Blood Ethanol Concentrations: Impact of Storage Conditions and Collection Tubes. *J Anal Toxicol.* 2008 September: 32(7): 505-510.
7. *Notice of Mandatory Guidelines for Federal Workplace Drug Testing Program: Final Guidelines; Federal Register,* Substance Abuse and Mental Health Administration (SAMHSA), (1994) 110 (June 9):11983.
8. Ellenhorn MJ, and BG Barceloux: Medical Toxicology, New York, Elsevier Science Publishing Company, Inc. 1988, pp 525-6 and 782-96.
9. Heise HA. Concentrations of Alcohol in Samples of Blood and Urine Taken at The Same Time. J For Sci 12, 454 (1967).
10. Data on file at Microgenics, a part of Thermo Fisher Scientific.

Glossary:

http://www.thermofisher.com/symbols-glossary

Microgenics Corporation
46500 Kato Road
Fremont, CA 94538 USA
US Customer and
Technical Support:
1-800-232-3342

EC REP
B·R·A·H·M·S GmbH
Neuendorfstrasse 25
16761 Hennigsdorf, Germany

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