DXC (ETOH) ALCOHOL

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PURPOSE

To provide instructions for the quantitative determination of ethyl alcohol on the DXC 600/800.

PRINCIPLE

ETOH reagent, when used in conjunction with UniCel® DxC 600/800 System(s) and SYNCHRON® Systems ETOH Calibrator, is intended for quantitative determination of ethyl alcohol concentration in human serum, plasma, or urine.

BACKGROUND

Clinical Significance

Testing for alcohol is common in medical/legal cases concerning toxic or abused substances. Alcohol can be lethal by itself or can contribute to accidents of all types. Measurements obtained are used in the diagnosis and treatment of alcohol intoxication and poisoning.

Methodology

Alcohol reagent is used to measure ethyl alcohol concentration by an enzymatic rate method. In the reaction, alcohol dehydrogenase (ADH) catalyzes the oxidation of ethanol to acetaldehyde with the concurrent reduction of Nicotinamide Adenine Dinucleotide (NAD) to NADH.
The SYNCHRON® System(s) automatically proportions the appropriate sample and reagent volumes into a cuvette. The ratio used is one part sample to 27.5 parts reagent. The system monitors the rate of change in absorbance at 340 nanometers. The rate of change in absorbance due to NADH is directly proportional to the concentration of ethyl alcohol in the sample and is used by the System to calculate and express the ethyl alcohol concentration based upon a two-point calibration curve.

RELATED DOCUMENTS

R-PO-CH0810	Quality Control Program General Laboratory
R-PO-CH0809	Quality Control Westgard Rules Statistics
R-PR-AD0540	Specimen Rejection/Cancellation Protocol
J-F-CH0820	DXC 800 Controls
M-F-CH0820	Chemistry Controls
J-F-CH0826	DXC 800 Calibrators
M-F-CH0826	Chemistry Calibrators
M-F-CH1940	DXC 600 (AMR) Analytical Measurement Range
J-F-CH1940	DXC 800 (AMR) Analytical Measurement Range

SPECIMEN

Type of Specimen

Biological fluid samples should be collected in the same manner routinely used for any laboratory test. Freshly drawn serum, plasma collected in sodium fluoride/potassium oxalate tubes, or freshly collected urine are the preferred specimens. Acceptable anticoagulants for plasma are listed in the PROCEDURAL NOTES section of this chemistry information sheet. Nonalcoholic germicidal solution should be used to swab the venipuncture site or to clean the equipment used to collect the specimen.

Specimen Storage and Stability

1. Tubes of blood are to be kept closed at all times and in a vertical position. It is recommended that the serum or plasma be physically separated from contact with cells within two hours from the time of collection.

2. Samples should be analyzed without delay and immediately after opening the sample tube. Precautions should be taken to prevent alcohol evaporation from calibrators, controls and samples.

Sample Type	Volume	Sample Stability
Plasma/Serum/Urine	0.5mL	• 8 hours at 18-26°C • 48 hours at 2-8°C • After 48 hours, freeze at -15 to -20°C

Criteria for Unacceptable Specimens

Refer to the PROCEDURAL NOTES section of this chemistry information sheet for information on unacceptable specimens.

Sample Volume

A filled 0.5 mL sample cup is the optimum volume. For optimum primary sample tube volumes in primary tube samples and minimum volumes, refer to the Primary Tube Sample Template for your system.

REAGENTS

Contents

Each kit contains the following items:
Two ETOH Reagent Cartridges (2 x 150 tests)

Volume per Test	
Sample Volume	10 µL
Total Reagent Volume	275 µL
Cartridge Volumes	A 200 µL B 75 µL C – –

Reactive Ingredients	
Tris reaction buffer (0.2 M)	41 mL
Alcohol dehydrogenase (yeast) (35 KU/L)	16 mL
NAD (9 mmol/L) in Tris buffer	

Also non-reactive chemicals necessary for optimal system performance.

Reagent Preparation

No preparation is required.

Acceptable Reagent Performance

The acceptability of a reagent is determined by successful calibration and by ensuring that quality control results are within your facility`s acceptance criteria.

Reagent Storage and Stability

ETOH reagent when stored unopened at +2°C to +8°C, will obtain the shelf-life indicated on the cartridge label. Once opened, the reagent is stable for 60 days at +2°C to +8°C. Do not use beyond the manufacturer's expiration date. DO NOT FREEZE.

CALIBRATION

Calibrator Required

SYNCHRON® Systems ETOH Calibrator

Calibrator Preparation

No preparation is required.

Calibrator Storage and Stability

SYNCHRON® Systems ETOH Calibrator when stored unopened at +2°C to +8°C will remain stable until the expiration date printed on label. Opened calibrators that are recapped and stored at +2°C to +8°C are stable until the expiration date.

Calibration Information

1. The system must have valid calibration factors in memory before controls or patient samples can be run.

2. Under typical operating conditions the ETOH reagent cartridge must be calibrated every 30 days and also with certain parts replacements or maintenance procedures, as defined in the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual. This assay has within-lot calibration available. Refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual for information on this feature.

3. For detailed calibration instructions, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

4. The system will automatically perform checks on the calibration and produce data at the end of calibration. In the event of a failed calibration, the data will be printed with error codes and the system will alert the operator of the failure. For information on error codes, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

Traceability

For Traceability information refer to the Calibrator instructions for use.

QUALITY CONTROL

See Related Documents J-F-CH0820 DXC 800 Controls & M-F-CH0820 Chemistry Controls

STEPS

1. Load the reagent onto the system.

2. After reagent load is completed, calibration may be required.

3. Program controls for analysis.

4. After loading controls onto the system, follow the protocols for system operation. To load samples manually refer to the FHS DXC Series Manual Sample Programming procedure. For detailed testing procedures, refer to the UniCel DxC 600/800 System *Instructions For Use* (IFU) manual.

CALCULATIONS

SYNCHRON® System(s) perform all calculations internally to produce the final reported result. The system will calculate the final result for sample dilutions made by the operator when the dilution factor is entered into the system during sample programming.

ANTICOAGULANT TEST RESULTS

The following anticoagulants were assessed by Deming regression analysis with a minimum of 50 paired serum and plasma samples. Values of serum (X) ranging from 4.8 to 540 mg/dL were compared with the values from plasma (Y) yielding the following results:

Anticoagulant	Level of Anticoagulant Tested	Deming Regression Analysis
Sodium Heparin	14 Units/mL	Y = 0.998X - 1.44; r = 0.999
Sodium Fluoride/Potassium Oxalate	2.5 / 2.0 mg/mL	Y = 0.983X + 0.71; r = 0.998
Lithium Heparin	14 Units/mL	Y = 0.996X - 1.25; r = 0.999

PERFORMANCE CHARACTERISTICS

Reference Range

Serum/Plasma/Urine	Conventional Units
Normal	< 5 mg/dL
Abnormal	5 mg/dL-300 mg/dL
Toxic	> 300 mg/dL

Analytic Range

The SYNCHRON® System(s) method for the determination of ethyl alcohol provides the following analytical range:

Sample Type	Conventional Units
Serum, Plasma or Urine	5-600 mg/dL

Serum, plasma or urine samples with concentrations exceeding the high end of the analytical range should be diluted with ETOH Calibrator Level 1 and reanalyzed.

Reporting results outside of analytical range

Lower limit of detection	5 mg/dL	Results below 5; Report as <5 mg/dL
Upper limit of detection	600mg'dL	Results >600 mg/dL should be diluted with ETOH Calibrator 1, reanalyzed and dilution factor applied. The maximum allowable dilution is X2. Results >1200 are reported as >1200 mg/dL.

Sensitivity

Sensitivity is defined as the lowest measurable concentration which can be distinguished from zero with 95% confidence. Sensitivity for ETOH determination is 4 mg/dL.

LIMITATIONS

1. Adulteration of the urine sample may cause erroneous results. Alteration of a urine specimen may be detected by checking the appearance, temperature, pH specific gravity, and creatinine levels of a sample.

2. An effort should be made to keep pipetted samples free from gross debris. It is recommended that highly turbid specimens be centrifuged before analysis.

Interferences

1. The following substances were tested for interference with this methodology:

Substance		Source	Level Tested	Observed Effect
Serum	Hemoglobin	RBC hemolysate	500 mg/dL INDEX of 10	NSI (within ± 4.8 mg/dL or 6%)
	Bilirubin	Porcine	30 mg/dL INDEX of 20	NSI (within ± 4.8 mg/dL or 6%)
	Lipemia	Human	500 mg/dL INDEX of 10	NSI (within ± 4.8 mg/dL or 6%)
	LDH and Lactate	Porcine NA	1890 U/L 14 mM	+4 mg/dL
Urine	Acetaldehyde	NA	2000 mg/dL	NSI (within ± 4.8 mg/dL or 6%)
	Acetone	NA	2000 mg/dL	NSI (within ± 4.8 mg/dL or 6%)
	n-Butanol	NA	2000 mg/dL	+22.1 mg/dL @ 7.6 mg/dL
	Ethylene Glycol	NA	2000 mg/dL	NSI (within ± 4.8 mg/dL or 6%)
	Glycerol	NA	2000 mg/dL	NSI (within ± 4.8 mg/dL or 6%)
	Isopropanol	NA	2000 mg/dL	+7.2 @ 7.6 mg/dL
	Methanol	NA	2000 mg/dL	NSI (within ± 4.8 mg/dL or 6%)
	n-Propanol	NA	2000 mg/dL	+198.5 mg/dL @ 7.6 mg/dL

2. Increased levels of lactic acid and LDH in post mortem samples may cause elevated alcohol results. Both LDH and Lactate must be greater than, or equal to, the values listed for interference to occur (8).

3. Refer to References (9,10) for other interferences caused by drugs, disease and preanalytical variables.

ADDITIONAL INFORMATION

For more detailed information on UniCel DxC Systems, refer to the appropriate system manual.

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Updated formatting, added index to interfering substances, added maximum dilution, removed references to whole blood testing.			
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