| Alcohol, Medical |
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| **Purpose** | This procedure provides instructions for performing ALCOHOL, MEDICAL using the ETOH method, an *in vitro* diagnostic test for the quantitative measurement of ethyl alcohol in human serum and plasma on the Dimension Vista® System. Ethyl alcohol test results may be used in the diagnosis and treatment of alcohol intoxication and poisoning. |
| **Policy Statements** | This procedure applies to all personnel who run the Siemens Dimension Vista®**This procedure is not intended for use in legal testing and is for medical use only.** |
| **Principle** | The ETOH method is based on an enzymatic reaction. Reagent 1 contains the buffering system. Reagent 2 contains alcohol dehydrogenase (ADH), the coenzyme nicotinamide adenine dinucleotide (NAD), buffer, preservatives, and stabilizers. The ADH catalyzes the oxidation of ethyl alcohol to acetaldehyde. During this reaction, NAD is reduced to NADH. The absorbance due to NADH (and thus the alcohol concentration) is determined using a two-filter (340–383 nm) bichromatic rate technique. |
| **Clinical Significance** | Ethanol (ethyl alcohol) is the most common toxic substance encountered and the most widespread and heavily consumed drug in human experience. It produces a loss of equilibrium, a sense of euphoria and loss of inhibition. The rate of ethanol absorption is dependent on the emptying time of the stomach. While some ethanol is absorbed through the stomach, the primary site of absorption is the small intestine. The presence of food in the stomach results in a smaller peak concentration being reached. Since ethanol distributes evenly throughout the body water, its concentration in blood following a known dose may be estimated indirectly by measuring concentrations in serum, plasma or urine. Ethanol readily crosses the blood-brain barrier. In addition, ethanol crosses the placenta of pregnant women, a phenomenon that may cause a potentially serious disorder known as fetal alcohol syndrome. Other deleterious effects are cardiac conditions, high blood pressure, liver disease and mental deterioration. Ethyl alcohol is metabolized to acetaldehyde and then to acetic acid by liver enzymes. About 95% of a dose undergoes metabolism by the liver. Ethanol is rapidly metabolized so that a moderate dose will clear from the blood in approximately one hour.Ethyl alcohol test results may be used in the diagnosis and treatment of alcohol intoxication and poisoning. The pharmacological response to blood alcohol levels may vary from individual to individual. The fatal concentration has been reported to be greater than 400 mg/dL.  |
| **Instrument**  | **PRIMARY METHOD:** Siemens Dimension Vista® 500 System**SECONDARY (BACKUP) METHOD:** Siemens Dimension Vista® 500 on opposite campus |
| **Sunquest Test Code** | ALCO Alcohol (Medical) in plasma or serum |
| **Specimen** | **Special Collection Procedure:****Use non-alcohol germicidal solution to cleanse the skin. Povidone Iodine preparation pads are recommended.** Do not use alcohol-containing germicidal. Serum and plasma can be collected using recommended procedures for collection of diagnostic blood specimens by venipuncture. See Specimen Collection Manual.Plasma (lithium heparin) preferred, or Serum. Plasma (Sodium heparin and EDTA) are also acceptable specimens. Refer to specimen collection procedures.**Minimum volume:**0.2 mL, plasma/ serum, 4 uL actual test volume**Stability**:The specimen tube should be completely filled and stored unopened under refrigeration until analyzed if there is a delay in testing. RT / not recommended, 2-8 °C / 3 days, < -20°C / stable indefinitely**Rejection criteria:**  Unlabelled specimens, samples other than serum or plasma, improper storage, or collection using alcohol to cleanse the skin.**Preparation**1. Do not open the sample tube to make an aliquot until ready to test the sample.
2. Complete clot formation should take place before centrifugation. Serum or plasma should be physically separated from cells with a maximum limit of 2 hours from the time of collection. Specimens should be free of particulate matter.
3. Whole blood specimens should be centrifuged according to Specimen Processing procedures prior to analysis. See Processing Procedure Manual.
4. Transfer serum or plasma to a properly labeled Siemens SSC nested on a bar-coded pilot tube. Minimum labeling includes sample accession ID, and/ or patient name, medical record number, collection date and time.
5. To minimize the loss of alcohol in a sample due to evaporation, open and process samples in **STAT** mode.
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| **Reagents** |

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| ***Product Description*** | ***Product Code*** | ***Stability*** |
| ETOH Flex Reagent Cartridge (Vista)Liquid, ready to use | K5022 | **Store at:** 2 - 8 °C.**Unopened:** Refer to carton for expiration date of individual unopened reagent cartridges. **On-board:** Sealed wells on the instrument are stable for 30 days.**Open well stability:** 5 days for all wells |
| CHEM 3 CAL | KC130A | **Store at:** 2 - 8 °C.**Unopened:** Refer to carton for expiration date.**On-board:** Once the vial stopper is punctured, assigned values are stable for 24 hours when stored on board the Dimension Vista® System**Opened:** Once the cap is removed, the assigned values are stable for 30 days when recapped immediately and stored at 2 - 8 °C. Do not use this vial on board. |

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| **Risk and Safety:** | CHEM 3 CAL is an Irritant. Contains a mixture of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1)* May cause sensitization by skin contact.
* Avoid contact with skin.
* Wear suitable gloves

Used cuvettes contain human body fluids; handle with appropriate care to avoid skin contact or ingestion |
| **Calibration** |

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| Assay Range: | 10 - 300 mg/dL |
| Reference Material: | CHEM 3 CAL, Cat. No. KC130A |
| Typical Calibration Levels: | Level 1 (Calibrator A): 0 mg/dLLevel 2 (Calibrator B): 303 mg/dL |
| Calibration Scheme: | Two levels, n=3 |
| Calibration Frequency: | * For each new lot of Flex® reagent cartridges
* Every 30 days for any one lot.
* After major maintenance or service, if indicated by QC results
* As indicated in laboratory quality control procedures
* When required by government regulations
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| Analytical Measuring Range | 10 - 300 mg/dL |

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| **Analytical Measuring Range (AMR)** | * Cal Verification and AMR verification are performed at least once every six (6) months.
* Touch Advanced 🡪 Calibrations 🡪 Calibrations by Lot, select method ETOH and “Order a Linearity Study”
* See iGuide “Calibration by Lot” for more information.
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| **Quality Control** | Bio-Rad Liquichek™ Ethanol/Ammonia Control, Level 1 & 3, contained in Vista Vials**Frequency:** Two levels each day of use**Stability:** Refer to the current lot product insert**Sunquest Control names:** Level 1 = C-NHL, Level 3 = C-NHH**Acceptable ranges:** * Ranges are current in Sunquest and the instrument. Refer to the Quality Control Procedure for QC exception codes.
* If a control value is outside the confidence interval, the determination must be repeated. If the repeated determination confirms the deviation, a new reference curve should be established.
* Do not release patient results until the cause of deviation has been identified and corrected
* When a new lot of control is received, validate the manufacturer’s insert range by running the new lot in parallel with the current lot, and confirming that the results obtained are within the stated range
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| **Calculations** | The State of Minnesota defines alcohol concentration as grams of alcohol per 100 milliliters of blood, or grams of alcohol per 210 liters of breath. These two concentrations are roughly equivalent to alleviate confusion. To convert milligrams/dL to grams/dL (may be referred to as % for legal needs, i.e. driving statutes) divide the Siemens Dimension Vista® final result in mg/dL by 1000. Then for example, 80 mg/dL would be the same as .08%. Children’s method is for medical purposes only. |
| **Interferences** | ETOH Hemolysis, Icterus & Lipemia (HIL) Index Values:

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No interference was found for:HIL:* Hemoglobin (free) up to 1000 g/dL
* Bilirubin (conjugated or unconjugated) up to 80 mg/dL
* Lipemia (Intralipid®) up to 3000 mg/dL

Refer to the Siemens IFU for a list of non-interfering substances.**Specificity**n-butanol, and n-propanol are substances that cross react with the ethyl alcohol result. See product insert for more information. |
| **Reference Range** | < 10 mg/dL |
| **Critical Values** | None specified |
| **Limitations** | Linear range of detection: 10– 300 mg/dLThe instrument reporting system contains flags and comments to provide the user with information regarding instrument processing errors, instrument status information and potential errors in Ethyl Alcohol results. Refer to the Dimension Vista® iGuide for the meaning of report flags and comments. Any report containing flags and/or comments should be addressed and not reported. |
| **Dilutions** |

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| Initial Vista Dilution: | None |
| Maximum Dilution: | 1:4 |
| Surplus Rack: | Samples with results >300 mg/dL reflex to a 1:4 automatically.  |
| Limited Rack: | Samples with results >300 mg/dL should be repeated as an Add-On Test with a Special Dilution of 1:4.  |
| Manual Dilution: | DO NOT PREPARE MANUAL DILUTIONS. |

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| **Result Reporting** | * Results between **10 – 300 mg/dL** without error messages are released.
* Results below **10 mg/dL** are reported as **<10 mg/dL**. The Vista may give a numerical result less than 10 mg/dL, such as 5 mg/dL. Report **<10** instead of the numerical value.
* Results > 300 mg/dL without error messages following dilution may be reported.
* Results >1200 mg/dL after autodilution or Special Dilution should be reported as **>1200 mg/dL.**
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| **Specimen Storage** | Promptly stopper tested specimen and store upright in numbered specimen rack by accession number. Every 8 hours remove specimens to refrigerator/freezer storage. Samples are retained 7 days in specimen storage freezer. |
| **References** | 1. Siemens Dimension Vista ® ETOH Flex® reagent cartridge Instructions for Use, Siemens Healthcare Diagnostics, PN 781022.001 Issued 2013-04-29, REV G
2. Siemens Dimension Vista ® CHEM CAL 3 Instructions for Use, Siemens Healthcare Diagnostics, 6/1/2014
3. Jacobs & DeMott Laboratory Test Handbook, Lexi-Comp, Inc, Hudson, OH, 5th Edition, 2001

Bio-Rad Liquichek Ethanol/Ammonia Control Product Insert, Bio-Rad Laboratories, Irvine, CA 92618 © 2013 |
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| **Historical Record** | **Version** | **Written/Revised by:** | **Effective Date:** | **Summary of Revisions** |
|  | D. Riedel | 04/1999 | Initial Version |
|  | L. Lichty | 5/15/2005 |  |
|  | L. Lichty | 12/11/06 |  |
|  | L. Lichty | 08/19/09 | Package insert revisions |
|  | D. Helfinstine/L. Lichty | April 1, 2011 | New format, renumbered from CH 3.06 |
|  | L. Lichty | February 22, 2013 | Clarify maximum dilution reporting |
|  | L. Lichty | October 22, 2013 | Revised for ETOH reagent |
|  | L. Lichty | 12/17/2013 | Siemens CLSI Procedure for ETOH on the Dimension Vista |
|  | D. Helfinstine | 7/28/2014 | Replaces Alcohol, Medical on Siemens Dimension RxL. |
|  |  | K. Brown/S. Gripentrog | June 19, 2017 | Removed no gel requirements from serum sample. Removed repeating of results <3 mg/dL by checking sample quality/quantity. |
|  |  | Erin Bartos | January 18, 2018 | Corrected typo: Povidone Iodine Prep Pads |
|  |  | Erin Bartos | July 27, 2018 | Changed lower reportable range to 10. Added comment to not remove top unless ready to test to avoid evaporation. |
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