TRAINING UPDATE

Lab Location:	GEC	**Date Distributed:**	8/31/2016
Department:	Core	**Due Date:**	9/20/2016
		Implementation:	**9/20/2016**

DESCRIPTION OF PROCEDURE REVISION

Name of procedure:

Ethyl Alcohol by Dimension® Xpand Chemistry Analyzer GEC.C41 v2

Description of change(s):

Changes are minor (most involved updating to current SOP format)

Section	Reason
3.2	Specify anticoagulant
4,5,6	Remove labeling instructions and add general one
6.4, 6.5	Replace LIS with Unity Real Time
10.5	Move patient review from section 6
15	Update to new standard wording
17	Update PI revision dates

This revised SOP will be implemented on September 20, 2016

Document your compliance with this training update by taking the quiz in the MTS system.

Technical SOP

Title	**Ethyl Alcohol by Dimension® Xpand Chemistry Analyzer**
Prepared by	Ashkan Chini Date: 8/14/2013
Owner	Robert SanLuis Date: 8/14/2013

Laboratory Approval	**Local Effective Date:**	
Print Name and Title	**Signature**	**Date**
Refer to the electronic signature page for approval and approval dates.		

Review		
Print Name	**Signature**	**Date**

Form revised 2/02/2007

TABLE OF CONTENTS

1. TEST INFORMATION

Assay	Method/Instrument	Local Code
Ethyl Alcohol	Dimension® Xpand Chemistry Analyzer	ALCO

Synonyms/Abbreviations
Ethanol, ETOH

Department
Chemistry

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2. ANALYTICAL PRINCIPLE

The Ethyl Alcohol Assay 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 with a concomitant increase in absorbance at 340 nm proportional to the concentration of alcohol in the specimen.

$$\text{Ethyl Alcohol} + NAD^{+} \xleftarrow{\text{ADH}} \text{acetaldehyde} + NADH \text{ (absorbs at 340 nm)}$$

3. SPECIMEN REQUIREMENTS

3.1 Patient Preparation

Component	Special Notations
Fasting/Special Diets	N/A
Specimen Collection and/or Timing	Normal procedures for collecting and storing serum and plasma may be used for samples to be analyzed by this method.
Special Collection Procedures	Use non-alcohol germicidal solution to cleanse the skin.
Other	N/A

3.2 Specimen Type & Handling

Criteria		
Type -Preferred	Serum	
-Other Acceptable	Plasma (Lithium Heparin)	
Collection Container	Serum: Red top tube Plasma: Mint green top tube (PST)	
Volume - Optimum	1.0 mL	
- Minimum	0.5 mL	
Transport Container and Temperature	Collection container or Plastic vial at room temperature	
Stability & Storage Requirements	Room Temperature:	(18 – 28°C) 2 days
	Refrigerated:	(2 – 8 °C) 2 weeks
	Frozen:	(-20 °C or colder) stable indefinitely
Timing Considerations	Tubes that have been open for any great length of time are unacceptable. Open and process samples in STAT mode.	

Criteria	
Unacceptable Specimens & Actions to Take	Specimens that are unlabeled, improperly labeled, or those that do not meet the stated criteria are unacceptable. Request a recollection and credit the test with the appropriate LIS English text code for "test not performed" message. Examples: Quantity not sufficient-QNS; Wrong collection-UNAC. Document the request for recollection in the LIS.
Compromising Physical Characteristics	Gross hemolysis. Reject sample and request a recollection. Credit the test with the appropriate LIS English text code explanation of HMT (Specimen markedly hemolyzed)
Other Considerations	Allow Red Top tube to clot completely prior to centrifugation.

NOTE: Labeling requirements for all reagents, calibrators and controls include: (1) Open date, (2) Substance name, (3) Lot number, (4) Date of preparation, (5) Expiration date, (6) Initials of tech, and (7) Any special storage instructions. Check all for visible signs of degradation.

4. REAGENTS

The package insert for a new lot of kits must be reviewed for any changes before the kit is used. A current Package Insert is included as a Related Document.

4.1 Reagent Summary

Reagents	Supplier & Catalog Number
Ethyl Alcohol	Siemens, Flex® reagent cartridge, Cat. No. DF22

4.2 Reagent Preparation and Storage

Reagent	**Ethyl Alcohol**
Container	Reagent cartridge
Storage	Store at 2-8° C
Stability	• Reagent is stable until expiration date stamped on the reagent cartridges. • Sealed or unhydrated cartridge wells on the instrument are stable for 30 days. • Open well stability: 5 days for all wells
Preparation	All reagents are liquid and ready to use.

5. CALIBRATORS/STANDARDS

5.1 Calibrators/Standards Used

Calibrator	Supplier and Catalog Number
CHEM III Calibrator	Siemens Dimension®, Cat. No. DC130

5.2 Calibrator Preparation and Storage

Calibrator	CHEM III Calibrator
Preparation	Calibrator is ready for use. No preparation is required.
Storage/Stability	• Store at 2 – 8 °C • Unopened calibrators are stable until the expiration date printed on the label. • Once cap is removed, assigned values are stable for 30 days when recapped immediately after use and stored at 2 – 8 °C

5.3 Calibration Parameter

Criteria	Special Notations
Reference Material	CHEM III Calibrator
Assay Range	3 – 300 mg/dL
Suggested Calibration Level	See Reagent Package Insert for lot specific assigned values in mg/dL
Frequency	• Every new reagent cartridge lot. • Every 90 days for any one lot • When major maintenance is performed on the analyzer. • When control data indicates a significant shift in assay.
Calibration Scheme	Three levels in triplicate
Assigned Coefficients	C_0 0.10 C_1 3.3

5.4 Calibration Procedure

1. From Operating Menu press F5:Process Control press F1: Calibration Enter Password press F2: SETUP and RUN
2. Select the test method to be calibrated - if lot number is incorrect Press F1: Other Lot
3. Enter all information on screen

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4. Press F8: QC yes/no to change to yes
5. Press F4: Assign cups If additional methods need to be calibrated, select the method.
6. Press F7: Load/run
7. Load cups into assigned position
8. Press F4: RUN

5.5 Tolerance Limits

IF……	THEN……
If result fall within assay-specific specification, and QC values are within acceptable limits,	proceed with analysis
If result falls outside assay-specific specification, or QC values are out of Acceptable limits,	troubleshoot the assay and/or instrument and repeat calibration

6. QUALITY CONTROL

6.1 Controls Used

Controls	Supplier and Catalog Number
Liquichek™ Ethanol/Ammonia Control Levels 1, 2 and 3	Bio-Rad Laboratories Cat. No. 544, 545 and 546

6.2 Control Preparation and Storage

Control	Liquichek Ethanol/Ammonia Controls, Levels 1, 2 and 3
Preparation	Before sampling, allow this product to reach room temperature (18 - 25°C). Gently swirl the vial several times to ensure homogeneity. After each use, promptly replace the stopper and return to 2 - 8°C storage.
Storage/Stability	Once the control is opened, all analytes will be stable for 20 days at 2-8°C. Unopened controls are stable until the expiration date at 2-8° C.

6.3 Frequency

Analyze all levels of QC material after every calibration and each day of testing.

Refer to the Dimension Xpand® QC Schedule in the Laboratory policy Quality Control Program and in the Dimension Xpand® Quick Reference Guide.

6.4 Tolerance Limits and Criteria for Acceptable QC

Step	Action
1	Acceptable ranges for QC are programmed into the instrument's Quality Control software system and Unity Real Time, and may be posted near the instrument for use during computer downtime.
2	**Run Rejection Criteria** • Anytime the established parameters are exceeded (if one QC result exceeds 2 SD), the run is considered out of control (failed) and patient results must not be reported. • The technologist must follow the procedure in the Laboratory QC Program to resolve the problem.
3	**Corrective Action**: • All rejected runs must be effectively addressed through corrective action. Steps taken in response to QC failures must be documented. Patient samples in failed analytical runs must be reanalyzed according to the Laboratory QC Program. Supervisors may override rejection of partial or complete runs only with detailed documentation and criteria for overrides that are approved by the Medical Director. Consult corrective action guidelines in Laboratory QC Program. Follow corrective action guidelines in the Laboratory QC Program. • Corrective action documentation must follow the Laboratory Quality Control Program.
4	**Review of QC** • QC must be reviewed weekly by the Group Lead or designee and monthly by the Supervisor/Manager or designee. • If the SD and/or CV are greater than established ranges, investigate the cause for the imprecision and document implementation of corrective actions.

6.5 Documentation

- QC tolerance limits are programmed into the instrument and Unity Real Time; it calculates cumulative mean, SD and CV and stores all information for easy retrieval.
- Quality control records are reviewed daily at the bench, weekly by the Group Lead or designee, and monthly by the Supervisor/Manager or designee.
- Refer to complete policies and procedures for QC documentation and for record retention requirements in the Laboratory QC Program.

6.6 Quality Assurance Program

- Each new lot number of reagent or new shipment of the same lot of reagent must be tested with external control materials and previously analyzed samples. Performance of the new lot must be equivalent to the previous lot; utilize published TEA for acceptability criteria.
- Training must be successfully completed and documented prior to performing this test. This procedure must be incorporated into the departmental competency assessment program.
- The laboratory participates in CAP proficiency testing. All proficiency testing materials must be treated in the same manner as patient samples.
- Monthly QC must be presented to the Medical Director or designee for review and signature.
- Monthly QC mean and SD are sent to Bio-Rad Laboratories for peer group comparison.
- Consult the Laboratory QC Program for complete details.

7. EQUIPMENT and SUPPLIES

7.1 Assay Platform

Dimension Xpand® System

7.2 Equipment

- Refrigerator capable of sustaining 2–8°C.
- Freezer capable of sustaining range not to exceed -20 to -70°C.
- Centrifuge

7.3 Supplies

- Plastic serum tubes and serum cups
- Reagent Grade water (Millipore® or equivalent)
- Calibrated pipettes and disposable tips

8. PROCEDURE

ETOH Flex® reagent cartridge Cat. No. DF22 is required to perform this test.

Ethyl Alcohol is performed on the Dimension Xpand® clinical chemistry system after the method is calibrated (see Reference Material in Calibration section) and Quality Controls are acceptable.

NOTE: For all procedures involving specimens, buttoned lab coats, gloves, and face protection are required minimum personal protective equipment. Report all accidents to your supervisor.

8.1	Instrument Set-Up Protocol
1.	For instrument set up and operation: Refer to Startup and Maintenance, Siemens Dimension Xpand® procedure.
2.	Check reagent inventory
3.	Sampling, reagent delivery, mixing and processing of results are automatically performed by the Dimension Xpand® system. For details of the automated parameters, see below under "Test conditions."

8.2	Specimen/Reagent Preparation
1.	Centrifuge the specimens.
2.	Specimens are placed in Dimension® Xpand segments for analysis by the instrument. Refer to the Sample Processing, Siemens Dimension® Xpand procedure. The sample container (if not a primary tube) must contain sufficient quantity to accommodate the sample volume plus 50 µL of dead volume. Precise container filling is not required.

8.3	Specimen Testing
1.	For QC placement and frequency, refer to the Dimension® Xpand QC Schedule in the Laboratory QC Program.
2.	Follow the instructions, outlined in the Dimension® Xpand Operators Manual
3.	The instrument reporting system contains error messages to warn the user of specific malfunctions. Results followed by such error messages should be held for follow-up. Refer to the Dimension Xpand® system manual "Error messages" section for troubleshooting.
4.	Follow protocol in Section 10.5 "Repeat criteria and resulting" for samples with results above or below the Analytical Measurement Range (AMR). Investigate any failed delta result and repeat, if necessary.
5.	Append the appropriate English text code qualifier messages to any samples requiring a comment regarding sample quality and/or any other pertinent factors.

Test Conditions	
Sample Volume:	9 µL
Buffer Volume:	225 µL
Enzyme Reagent Volume:	121 µL
Temperature:	37° C
Wavelength:	340 and 383 nm
Type of measurement:	Bichromatic rate

NOTE: In the event that the test system becomes inoperable, notify supervision or designee for further direction. Patient specimens must be stored in a manner that maintains the integrity of the specimen.

9. CALCULATIONS

The instrument automatically calculates the concentration of Ethyl Alcohol in mg/dL.

10. REPORTING RESULTS AND REPEAT CRITERIA

10.1 Interpretation of Data

None required

10.2 Rounding

No rounding is necessary. Instrument reports results as a whole number.

10.3 Units of Measure

mg/dL

10.4 Clinically Reportable Range (CRR)

3 - 900 mg/dL

10.5 Review Patient Data

Technologist must review each result with error messages. Refer to the Dimension Xpand® system manual "Error messages" section for troubleshooting. Check for unusual patterns, trends, or distributions in patient results (such as an unusually high percentage of abnormal results). Resolve any problems noted before issuing patient reports.

10.6 Repeat Criteria and Resulting

All repeats must replicate the original result within the total allowable error (TEa) of the assay. Refer to TEa listing for specific information.

Values that fall within the AMR or CRR may be reported without repeat. Values that fall outside these ranges must be repeated.

IF the result is …	THEN…
< 3 mg/dL	Assure there is sufficient sample devoid of bubbles, cellular debris, and/or fibrin clots. Report as: < 3 mg/dL
≥ 300 mg/dL	**On Board Automated Dilution:** Results ≥ 300 mg/dL will automatically have repeat testing performed into the instrument using dilution factor of 1.5. No multiplication is necessary.

IF the result is …	THEN…
> 450 mg/dL	**Manual Dilution:** Using the primary tube, make the smallest dilution possible to bring the raw data within the AMR. Maximum allowable dilution: x 3 **Diluent**: Reagent Grade Water Enter dilution factor as a whole number on the "Enter Sample Data" screen.
> 900 mg/dL	If the recommended dilution does not give results within the clinically reportable range, report as: "> 900 mg/dL-REP" Bring to the attention of your supervisor prior to releasing result.

Message	Code
Verified by repeat analysis	Append –REP to the result.

11. EXPECTED VALUES

11.1 Reference Ranges

< 5 mg/dL

11.2 Critical Values

> 400 mg/dL

11.3 Standard Required Messages

None established

12. CLINICAL SIGNIFICANCE

Alcohol (ethyl alcohol, ethanol) is the most frequently performed medico legal test, and is the most common toxic substance encountered. In addition to beverages, products containing alcohol in significant amounts include mouthwashes, colognes, and medicinal preparations. Measurements of alcohol levels are used to determine legal impairment, for forensic purposes, in the diagnosis and treatment of alcohol dependency and in emergency settings to detect alcohol poisoning.

Alcohol's deleterious effects are well documented. It has been linked with birth defects (fetal alcohol syndrome), cardiac conditions, high blood pressure, liver disease, and mental deterioration. It is by far the leading cause of death from hepatic failure. Additionally, alcohol-induced behavior is a contributing factor in the majority of accidents and murders.

Within approximately one hour of ingestion, alcohol will have permeated all tissues of the body in proportion to water content. Some alcohol is absorbed while in the stomach, but the principal site of absorption is the upper portion of the small intestine. Rate of absorption is dependent upon emptying time of the stomach, which is subject to various influences. Since alcohol distributes evenly throughout the body water, its concentration in blood following a known dose may be estimated indirectly by measuring concentrations in urine, serum, or plasma.

About 95% of the elimination of alcohol from the body is accomplished by metabolism in the liver. The remainder is excreted unchanged by the lungs, kidneys, and in the feces. Alcohol is rapidly metabolized so that a moderate dose will clear from the blood in approximately one hour.

13. PROCEDURE NOTES

- **FDA Status:** FDA Approved/cleared
- **Validated Test Modifications:** None

The instrument reporting system contains error messages to warn the operator of specific malfunctions. Any report slip containing such error messages should be held for follow-up. Refer to your Dimension Xpand Operator's Guide.

A system malfunction may exist if the following 5-test precision is observed:

Activity	S.D.
100 mg/dL	> 3 mg/dL
300 mg/dL	> 6 mg/dL

14. LIMITATIONS OF METHOD

14.1 Analytical Measurement Range (AMR)

3 – 300 mg/dL

14.2 Precision

Material	Mean mg/dL	Standard Deviation (%CV)	
		Repeatability	Within-Lab
Bio-Rad Ethalnol/Ammonia			
Level 1	39	0.3 (0.8)	1.0 (2.6)
Level 2	98	0.7 (0.8)	2.4 (2.5)
Level 3	255	1.5 (0.6)	5.4 (2.1)
Plasma Pool	246	1.4 (0.6)	3.0 (1.2)
Serum Pool	102	1.2 (1.2)	1.4 (1.4)

14.3 Interfering Substances

HIL Interference:
The ETOH method was evaluated for interference according to CLSI/NCCLS EP7-A2. Bias, defined as the difference between the control sample (does not contain interferent) and the test sample (contains interferent), is shown in the table below. Bias exceeding 10% is considered "interference".

Substance tested	Substance Concentration SI Units	ETOH mg/dL	Bias %
Hemoglobin (hemolysate)	1000 mg/dL	100	<10
Bilirubin (unconjugated)	80 mg/dL	96	<10
Bilirubin (conjugated)	80 mg/dL	97	<10
Lipemia Intralipid®	3000 mg/dL	102	<10

14.4 Clinical Sensitivity/Specificity/Predictive Values

Not available

15. SAFETY

Refer to your local and corporate safety manuals and Safety Data Sheet (SDS) for detailed information on safety practices and procedures and a complete description of hazards.

16. RELATED DOCUMENTS

1. Dimension Xpand® Clinical Chemistry System Operator's Manual
2. Calibration / Verification Siemens Dimension® Xpand procedure
3. Dimension Xpand® Cal Accept Guidelines
4. Dimension Xpand® Calibration summary
5. Sample Processing, Siemens Dimension® Xpand procedure
6. Start up and Maintenance, Siemens Dimension® Xpand procedure
7. Laboratory Quality Control Program
8. QC Schedule for Siemens Dimension Xpand®
9. Laboratory Safety Manual
10. Safety Data Sheets (SDS)
11. Siemens Dimension Xpand® Limits Chart (AG.F143)
12. Quest Diagnostics Records Management Procedure
13. Dimension Xpand® System Error Messages Chart
14. Centrifuge Use, Maintenance and Functions Checks (Lab policy)
15. Hemolysis, Icteria and Lipemia Interference (Lab policy)
16. Repeat Testing Requirements (Lab policy)
17. Critical Values (Lab policy)
18. Current Allowable Total Error Specifications at http://questnet1.qdx.com/Business_Groups/Medical/qc/docs/qc_bpt_tea.xls
19. Current package insert ETOH Flex® Reagent Cartridge DF22

17. REFERENCES

1. Package Insert, ETOH Flex® Reagent Cartridge DF22, Siemens Healthcare Diagnostics Inc., 6/5/2013.
2. Package Insert, CHEM III Calibrator, Siemens Healthcare Diagnostics Inc., 01/2016.
3. Package Insert, Liquichek Ethanol/Ammonia Control, Bio-Rad Laboratories, 08/2015.

18. REVISION HISTORY

Version	Date	Section	Reason	Reviser	Approval
000	7/15/14	5, 17	Revised to reflect new CHEM III calibrator	A Chini	R SanLuis
000	7/15/14	Footer	Version # leading zero's dropped due to new EDCS in use as of 10/7/13	L Barrett	R SanLuis
1	8/24/16	3.2	Specify anticoagulant	J Negado	R SanLuis
1	8/24/16	4,5,6	Remove individual section labeling instructions and add general one	L Barrett	R SanLuis
1	8/24/16	6.4, 6.5	Replace LIS with Unity Real Time	L Barrett	R SanLuis
1	8/24/16	10.5	Move patient review from section 6	L Barrett	R SanLuis
1	8/24/16	15	Update to new standard wording, add reagent warning	L Barrett	R SanLuis
1	8/24/16	17	Update PI revision dates	J Negado	R SanLuis

19. ADDENDA

None