EMIT Ethyl Alcohol Assays:
Answers to Frequently Asked Questions

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Global Division
Siemens Healthcare Diagnostics Inc.
1717 Deerfield Road
Deerfield, IL 60015-0778
USA
www.siemens.com/diagnostics

EMIT Ethyl Alcohol Assays: Answers for life.
Introduction

Analyzing blood and urine samples for ethyl alcohol levels is one of the most frequently performed tests for drugs-of-abuse. The results of these tests are used for medical and legal purposes that include determining impairment or legal intoxication, and diagnosing and treating alcohol dependency and alcohol poisoning.

After alcohol is ingested, it is distributed throughout the body tissues within an hour—its absorption rate is subject to the various influences on the emptying time of the stomach. Some alcohol is absorbed from the stomach, but most is absorbed through the upper part of the small intestine.

Alcohol is rapidly metabolized by the liver, and a moderate dose clears from the blood in approximately one hour. About 95% of the alcohol is metabolized, and the remainder is excreted unchanged by the lungs, kidneys, and in the feces. Because alcohol distributes evenly throughout the body water, concentration in blood following a known dose may be estimated indirectly by measuring concentrations in urine, serum, or plasma.

EMIT® Ethyl Alcohol Assays have been designed to accurately quantitate ethyl alcohol in urine, serum, and plasma. In clinical studies, EMIT tests proved to be accurate, and to correlate well with other methods of ethyl alcohol measurement such as, gas chromatography.

Syva has been a leading developer and manufacturer of drugs-of-abuse tests for more than 30 years.

Now part of Siemens Healthcare Diagnostics, Syva® boasts a long and successful track record in drugs-of-abuse testing, and leads the industry in the production of enzyme immunoassays. In addition to drugs-of-abuse assays, Syva has been a key player in the development and manufacture of therapeutic drug monitoring assays.

Syva products are sold in more than 45 countries worldwide.
Because of the evaporative and other properties of ethyl alcohol, testing for its presence requires special precautions and procedures during sample collection, handling, and analysis, to ensure the integrity of the results.

We have prepared this booklet to answer questions concerning ethyl alcohol testing, and to help you get the best possible performance from EMIT Ethyl Alcohol Assays.

**Urine Samples:**
Use clean, dry containers that have tightly fitting screw-caps with plastic or white rubber liners.

- In order to approximately relate urine ethyl alcohol to blood-alcohol concentration, it is recommended that the patient completely empty the bladder. Collect the sample one half hour later for the ethyl alcohol analysis.

**How long can samples be stored before analysis?**
Run samples as quickly as possible because ethyl alcohol in the samples may evaporate or oxidize, causing low results.

- If samples cannot be run immediately, store them tightly sealed with as little dead-air-space as possible in the containers. Store samples refrigerated at 4°C to slow microbial growth.

- Freeze samples that are to be stored longer than three days. Do not expose them to repeated freeze/thaw cycles.

**What precautions should be taken to preserve sample integrity during testing?**
Precautions against loss of ethyl alcohol through evaporation or gain from contamination should be taken at all times.

**Before running the analysis:**
- Use only alcohol-free substances to sterilize equipment. Disinfectants that contain alcohol could contaminate samples causing false results.

- Gently invert samples several times before opening to ensure sample homogeneity.

- Aliquot samples immediately before running the assay. Do not prepare them in advance.

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**Serum and Plasma Samples:**
- Clean the puncture site with only alcohol-free disinfectants. Disinfectants that contain alcohol could contaminate the sample, causing a false result. Use aqueous zephiran (benzalkonium chloride), iodine, or other suitable aqueous disinfectants.

- Collect samples into plain tubes or anticoagulants containing vacutainers. The anticoagulants citrate, EDTA, fluoride/oxalate, and heparin have all been tested, and may be used with these assays. Fluoride/oxalate containers are preferred for short-term storage of whole blood prior to analysis of plasma samples, because they preserve ethyl alcohol by preventing glycolysis.
• Open samples only when absolutely necessary. Minute amounts of ethyl alcohol escape each time the containers are opened.

• Avoid pipetting and analyzing samples in a drafty environment, or in an environment where the temperature fluctuates greatly.

**If centrifuging is necessary:**
• Centrifuge samples with stoppers in place.

• Following centrifugation, separate serum/plasma into appropriately sized containers with less than 10% dead-air-space volume. Stopper the supernatant immediately. Seal containers to prevent evaporation.

• Use a needle and syringe to withdraw serum or plasma after centrifugation (it is preferable not to open the tube at all). Use a different needle and syringe for each sample to prevent contamination from carryover.

**When pipetting is employed:**
• Pipette samples immediately before use. Do not pipette in advance.

• Use a different pipette tip for each sample to prevent contamination from carryover.

• Keep the sample tube stoppered; open only when absolutely necessary.

• Reseal containers during multiple pipetting steps to minimize evaporation. Seal tops of sample containers with plastic film before and after use.

**When running the analysis:**
• Perform all instrument set-up steps prior to readying the samples.

• Load samples on rotors, racks, and sectors as rapidly as possible, and run the assay immediately upon loading.

• If using disposable cuvettes, make sure there are enough empty cuvettes to complete the run.

• Use sample tray-evaporation covers on analyzers that are so equipped.

• Follow samples with controls on long runs, or runs that involve switching rotors part way through.

• Complete the entire assay process within 90 minutes of filling the sample cups; i.e., no more than 90 minutes should elapse between pipetting the sample and completing the analysis.

**Note:**
Be sure to use ample volume. In general, a good rule of thumb is to use dead volume plus a minimum of 25 μL.

**Why do EMIT Ethyl Alcohol Assays have two reagents?**
Unlike many other ethyl alcohol assays, EMIT Ethyl Alcohol reagents are adaptable to an extensive number of clinical analyzers. The reagents have been fully optimized to achieve maximum stability and performance. The pH of the reaction (pH 8.9) is precisely controlled by Reagent 1 or Reagent A. The 12 week stability of reconstituted Reagent 2 or Reagent B is also achieved by the buffering process. What is the best way to handle reagents on a daily basis?

• Use fresh deionized water to reconstitute reagents. Swirl gently to mix. Do not shake violently or use a sonicator.

• Store enzyme reagents (Reagent 2 or Reagent B) at 4°C before and after reconstitution.

**Note:**
If your analyzer stores reagents at an ambient temperature, subaliquot a portion of reagent for use during your shift for “topping off.” Ensure temperature equilibration prior to analysis. If your analyzer has a refrigerated compartment, always store reagents in that compartment.
**What is the best way to handle the calibrator and controls on a daily basis?**

- Discard vials if moisture has penetrated the seals.
- Refrigerate and tightly stopper calibrator and controls, while allowing them to reach room temperature before use. Do not freeze.
- Do not expose opened calibrator or controls to unnecessary refrigeration-to-room-temperature cycles.
- Keep calibrator and controls stoppered and tightly capped during, and after use, to prevent evaporation of ethyl alcohol. If calibrator and controls are to be used repeatedly throughout the day, seal them tightly with plastic film, and keep them at room temperature.
- Use controls daily to monitor the performance of the assay, reagents, instrument, and technique.

**Note:**

Be sure to use ample volume of calibrator and controls.

**What should I do if controls fall outside the acceptable range?**

If the controls fall outside the acceptable range, follow these steps:

1. Repeat part of the run with fresh aliquots of calibrator and control.
2. If control values are now acceptable, compare patient results with original results for precision, or repeat the entire run with new and old controls.
3. Recalibrate if control values are still unacceptable.
4. If values remain unacceptable, check for equipment failure, expired or improperly handled reagents or materials, and follow troubleshooting procedures.

You may also call the Siemens Technical Solutions Center:

1-800-227-8994 in USA

**Why are EMIT Ethyl Alcohol Assays run as a kinetic rate method?**

There are several advantages to running EMIT Ethyl Alcohol Assays as a kinetic rate method:

- Relatively short reaction times required to obtain results
- Reduces interference from other alcohols and alcohol-like substances
- Eliminates the need for individual sample blanking

**Can disease conditions affect urine ethyl alcohol concentrations?**

Not directly. However, liver or renal diseases affect ethyl alcohol elimination from the body, and may lead to ethyl alcohol concentrations in urine that do not correlate with blood alcohol levels. Diabetes, accompanied by the presence of glucose and ketone bodies in the urine, does not affect ethyl alcohol measurement in urine.

The presence of glucose and certain kinds of bacteria and yeast may lead to the generation of ethyl alcohol during sample storage. Ethyl alcohol-producing organisms include: *Escherichia coli*, *Streptococci*, *Enterobacter*, *Candida albicans*, and *Proteus vulgaris*. 
Should chain-of-custody procedures be observed for all ethyl alcohol assays?

Ethyl alcohol tests are performed for medical as well as legal purposes. Chain-of-custody procedure is unnecessary if the result is not to be used for a legal action. However, standard laboratory procedures for sample identification should be in place.

Note:

Chain of custody is a legal procedure to ensure that an item, such as a blood alcohol specimen, is properly identified and has not been tampered with. Each individual handling the item certifies that it was properly identified; and in his or her possession, or locked in a secure place, from the time the item is received to the time of transfer.

References: