

**ETHANOL**

**SERUM, PLASMA OR URINE**

**ABBOTT ARCHITECT**

**Intended Use**

The MULTIGENT Ethanol assay is intended for the quantitative determination of ethanol in human urine, serum, or plasma on the ARCHITECT *c* Systems.

**Clinical Significance**

In addition to beverages, ethanol (ethyl alcohol 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 (e.g., 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. These techniques either require specimen pretreatment or require incubation periods ranging from 10 to 60 minutes. Administration of pure alcohol to fasting men produced the following average maximal concentrations at the times indicated:



These concentrations decreased at an average rate of 18.9 mg/dL/h. At concentrations greater than 20 mg/dL, the rate of metabolism is independent of concentration, i.e., zero-order

**Principle**

MULTIGENT Ethanol assay is a liquid, ready-to-use, kinetic assay based on the high specificity of alcohol dehydrogenase (ADH) for ethyl alcohol. In the presence of ADH and nicotinamide adenine dinucleotide (NAD), ethanol is readily oxidized to acetaldehyde and NADH.



The enzymatic reaction can be monitored spectrophotometrically at 340/412 nm (416 nm for *c* 4000 and *c* 16000).

**Methodology:** Alcohol Dehydrogenase

**Specimen Collection and Handling**

• Serum, plasma, and urine can be used for this assay.

• Anticoagulants such as EDTA, citrate, fluoride/oxalate, and heparin can be used for collection of plasma samples.

• Collect urine specimens in plastic or glass containers. Testing of fresh urine specimens is suggested. Samples within a pH range of 3 to 11 are suitable for testing with this assay.

• Do not use alcohol as a disinfectant when collecting or storing blood specimens.

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

**Specimen Storage**

**Serum and Plasma:**



**Urine**:



**NOTE:** Stored specimens must be inspected for particulates. If present, mix and centrifuge the specimen to remove particulates prior to testing.

**Materials and Equipment Required**

**TEST INSTRUMENT**: Abbott ARCHITECT System

**MATERIALS PROVIDED**

 3L36 Ethanol Reagent Kit

**MATERIALS REQUIRED BUT NOT PROVIDED**

* 3L36-01 MULTIGENT Ethanol Neg Cal
* 3L36-02 MULTIGENT Ethanol 100 Cal
* 3L36-10 MULTIGENT Ethanol 50 Control
* 3L36-12 MULTIGENT Ethanol 300 Control
* Control Material

**Reagent Handling and Storage:**

***CAUTION*:**

1. For in vitro diagnostic use.

2. Do not use components beyond the expiration date.

3. Do not mix materials from different kit lot numbers.

**CAUTION:** This product requires the handling of human specimens.

It is recommended that all human sourced materials be considered

potentially infectious and be handled in accordance with the OSHA

Standard on Bloodborne Pathogens. Biosafety Level 2 or other appropriate biosafety practices should be used for materials that contain or are suspected of containing infectious agents.

• The following warning and precaution apply to R1 and R2:

Contains sodium azide.

EUH032 Contact with acids liberates very toxic gas.

These materials and their containers must be disposed of in a safe way.

**Reagent Handling**

•R1 Ready for use. Before use, invert several times, avoiding the formation of bubbles.

•R2 Ready for use. Before use, invert several times, avoiding the formation of bubbles.

Remove air bubbles, if present in the reagent cartridge, with a new applicator stick. Alternatively, allow the reagent to sit at the appropriate storage temperature to allow the bubbles to dissipate.

To minimize volume depletion, do not use a transfer pipette to remove the bubbles.

**CAUTION:** Reagent bubbles may interfere with proper detection of reagent level in the cartridge, causing insufficient reagent aspiration that could impact results.

• When either the R1 orR2 the reagent cartridge becomes empty, replace both cartridges and validate the system by analyzing controls.

**Reagent Storage**

• Reagent stability is 56 days if the reagent is uncapped and onboard.

• Unopened reagents are stable until the expiration date when stored at 2 to 8°C.

Reagent Preparation:

3L36-20 MULTIGENT Ethanol is supplied as a liquid, ready-to-use, two-reagent kit which contains:

**R1 & R2**



**Calibrator:**

3L36-01 MULTIGENT Ethanol Neg Cal

3L36-02 MULTIGENT Ethanol 100 Cal

**Quality Control:**

3L36-10 MULTIGENT Ethanol 50 Control

3L36-12 MULTIGENT Ethanol 300 Control

**Calibration**

**Frequency:**

Calibration is stable for 13 days (312 hours) for any one lot. Calibration is required with each change in reagent lot number.

**A new calibration is required:**

1. If quality control results do not meet acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory. Recalibration may be necessary.
2. Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

**Calibrator Required:**

3L36-01 MULTIGENT Ethanol Neg Cal

3L36-02 MULTIGENT Ethanol 100 Cal

**Reagents:**

The MULTIGENT Ethanol Calibrators and Controls are liquid and ready-to-use. The MULTIGENT Ethanol Neg Cal consists of TRIS buffer with sodium azide as a preservative. The MULTIGENT Ethanol 100 Cal, MULTIGENT Ethanol 50 Control, and the MULTIGENT Ethanol 300 Control are prepared by spiking the MULTIGENT Ethanol Neg Cal with a known quantity of ethanol. The MULTIGENT Ethanol Neg Cal and MULTIGENT Ethanol 100 Cal are used to calibrate the assay.

The MULTIGENT Ethanol 50 Control and MULTIGENT Ethanol 300 Control are used to validate assay performance. The MULTIGENT Ethanol Neg Cal can also be used for dilution of samples with ethanol concentrations greater than 600 mg/dL.

**Calibrator Preparation:**

The MULTIGENT Ethanol Calibrators and Controls are ready-to-use.

**Calibration Procedure:**

Before performing the assay, refer to the ASSAY PARAMETERS which are included in the MULTIGENT Ethanol reagent package insert. The parameters contain additional instructions for using a quantitative protocol. For further instructions refer to the CALIBRATION and QUALITY CONTROL sections of the MULTIGENT Ethanol reagent package insert.

1. Verify that the calibrator values are correct in the instrument parameter files.

2. Mix bottles by gentle inversion several times.

3. Open the bottles, place appropriate amounts of the required calibrators and/or controls in separate sample cups, and place in the assigned positions.

**NOTE:** Immediately cap bottles tightly and return to refrigerated storage. Always return each cap to its original bottle.

4. Calibrate as outlined in *Section 6* of the **ARCHITECT System Operations Manual**.

5. Follow the established quality control procedures for your laboratory and the instructions found in *Section 5* of the **ARCHITECT System** **Operations Manual**.

6. Verify control results are within acceptable limits before reporting patient results.

**Troubleshooting and Overall Acceptance Criteria Failure**

See ARCHITECT Operations Manual for further calibration troubleshooting.

**Quality Control:**

Abbott recommends, refer to your laboratory standard operating procedure(s) and/or quality assurance plan for additional quality control requirements and potential corrective actions:

• Two levels of controls (normal and abnormal) are to be run every 24 hours.

• If more frequent control monitoring is required, follow the established quality control procedures for your laboratory.

• If quality control results do not meet the acceptance criteria defined by your laboratory, patient values may be suspect. Follow the established quality control procedures for your laboratory.

Recalibration may be necessary.

• Review quality control results and acceptance criteria following a change of reagent or calibrator lot.

**Procedure**

For a detailed description of how to run an assay, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

**Calculations**

Refer to *Appendix C* of the **ARCHITECT System Operations Manual** for information on results calculations.

**Reporting Results**

Results for the MULTIGENT Ethanol assay can be reported as mg/dL, mmol/L, or percentage (%).

**Specific Performance Characteristics**

**Reference Ranges**

It is recommended that each laboratory determine its own reference range based upon its particular locale and population characteristics.

 **Serum/Plasma**

The rate of alcohol metabolism and excretion varies among individuals and is dependent upon factors such as gender, age, body weight, stomach content, concurrent use of medication, and health condition.

The legal definition of intoxication varies.

**Urine**

Urine ethanol concentrations are often used to estimate blood concentrations. During the elimination phase, the urine/blood ratio of 1.3 applies and provides a valid estimate in most cases

**Serum/Plasma: 0.0 – 0.010 g/dL**

**Critical Values: >0.081 g/dL**

**Performance Characteristics**

**Sensitivity**

Sensitivity, defined as the lowest concentration that can be differentiated from the negative calibrator with 99% confidence, is 10.0 mg/dL.

**Linearity**

The MULTIGENT Ethanol assay can accurately quantitate alcohol concentrations within a range of 10.0 mg/dL (0.01%) to 600.0 mg/dL (0.6%).

**Dilution:**

Samples exceeding 600.0 mg/dL may be manually diluted with MULTIGENT Ethanol Neg Cal and rerun.

The dilution must be performed so the diluted test results read greater than the assay sensitivity of 10.0 mg/dL.

The operator must enter the manual dilution factor in the patient or control order screen. The system uses this dilution factor to automatically correct the concentration by multiplying the result by the entered factor. The printed result is the reportable result if no errors are present.

**NOTE:** If the operator does not enter the manual dilution factor, the printed result must be multiplied by the manual dilution factor before reporting the result.



For detailed information on ordering dilutions, refer to *Section 5* of the

**ARCHITECT System Operations Manual**.

**Specificity**

The following data were generated using the same reagent on a commercially available clinical chemistry analyzer.

Various structurally related organic compounds were tested for cross reactivity in the assay. The following table summarizes the results:



**Precision:**

Precision on an ARCHITECT *c* System is ≤ 5% total CV.



#### Limitations of Procedure

• Legal alcohol intoxication levels vary. The test result should be interpreted in light of clinical signs and symptoms.

• The test is designed for use with human urine, serum, and plasma only.

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

• It is possible that other substances and/or factors (e.g., technical or procedural errors) not listed in the Specificity table may interfere with the test and cause false results.

**Interfering Substances**

The following data were generated using the same reagent on a commercially available clinical chemistry analyzer. Grossly hemolyzed (800 mg/dL hemoglobin), icteric (30 mg/dL bilirubin), and lipemic (1,000 mg/dL triglycerides) samples were found to have no interference with the assay.

**References:**

1. ABBOTT ARCHITECT Ethanol package insert

Abbott Laboratories

Diagnostics Division

Abbott Park, IL 60064

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1. ABBOTT ARCHITECT Ethanol Calibrator package insert

Abbott Laboratories

Diagnostics Division

Abbott Park, IL 60064

1. Abbott ARCHITECT Operator’s Guide

**Related Documents:**

**Attachments:**