

**AMMONIA**

**PLASMA**

**ABBOTT ARCHITECT**

**Intended Use**

The MULTIGENT Ammonia Ultra assay is intended for the quantitative enzymatic determination of ammonia in human plasma on the ARCHITECT *c* Systems.

**Clinical Significance**

Ammonia, derived from the catabolism of amino acids and from the action of intestinal bacteria on dietary protein, is converted to urea in the liver hepatocytes and so rendered non-toxic. Studies have shown that excess ammonia can have a toxic effect on the central nervous system and clinical manifestations are typically neurological disturbances. Elevated ammonia may also be observed in severe liver failure, as may occur in Reye’s Syndrome, viral hepatitis, or cirrhosis. Hyperammonemia occurs with genetic defects of the urea cycle and some other hereditary disorders. Therefore, elevated plasma ammonia may occur in the pediatric population. Elevated ammonia has also been reported due to administration of valproic acid.

**Principle**

Ammonia, in the presence of glutamate dehydrogenase (GLDH), combines with α-ketoglutarate and NADH to yield glutamate and NAD+. The decrease in absorbance (NADH to NAD+) at 340 nm is proportional to the ammonia concentration in the examined plasma. The reagent contains lactate dehydrogenase (LDH) in excess, to rapidly reduce endogenous pyruvate so that it does not interfere with the assay system.

**Methodology:** Glutamate Dehydrogenase

**Specimen Collection and Handling**

***Plasma***

• Use nonhemolyzed plasma collected by standard venipuncture techniques. Hemolyzed samples should not be used as erythrocytes contain ammonia levels approximately three times that of plasma.

• The acceptable anticoagulant is EDTA. **Do not use ammonium heparin**.

• The collection tube must be completely filled with blood and immediately placed on ice.

• Centrifuge the cold sample as quickly as possible and separate the plasma from blood cells according to the specimen collection tube manufacturer’s instructions. Ensure centrifugation is adequate to remove platelets.

**NOTE:** Rapid separation of plasma from blood cells is critical for obtaining reliable results. The standard recommendation is no more than 15 minutes from sample collection to the start of centrifugation. Timing is especially critical for patients with liver disease. Delays exceeding 15 minutes have been shown to increase ammonia concentration even at 0°C.1 Follow the plasma ammonia protocol established for your laboratory. Sources of contamination include (but are not restricted to) cigarette smoking (patient and phlebotomy staff), air in the laboratory, and laboratory glassware.

**Specimen Storage**



**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**

 6K89-30 MULTIGENT Ammonia Ultra Kit

**MATERIALS REQUIRED BUT NOT PROVIDED**

• Refer to the Chemistry Quality Control Procedure for specific QC products

• Saline (0.85% to 0.90% NaCl) for specimens that require dilution

**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.

• Do not mix fresh reagents with in-use reagents.

**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.



**Reagent Handling**

• R1 Ready for use.

• R2 Ready for use.

• 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.

**Reagent Storage**

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

• Reagent stability is 15 days if the reagent is uncapped and onboard.

• Opened calibrator is stable for 120 days at 2 to 8°C if contamination is avoided and vials are recapped immediately after use.

Reagent Preparation:

6K89-30 MULTIGENT Ammonia Ultra is supplied as a two-component kit which contains: **R1 & CAL**



**Calibrator:** Included in the reagent kit

**Quality Control:** Minimum 2 levels of ChemistryControl (Normal and Abnormal)

**Calibration**

**Frequency:**

Calibration is stable for 24 hours for any one lot and must be recalibrated with each change in reagent lot.

**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:** 5P04-01 TDM Multiconstituent Calibrator (TDM MCC)

**Reagents:**

* Unopened calibrators are stable until the expiration date indicated on the package when stored at 2-8 °C.
* Opened calibrator is stable for 120 days at 2 to 8°C if contamination is avoided and vials are recapped immediately after use.

**Calibrator Preparation:**

Ready to use - Calibrator must be clear – do not use if turbid

**Calibration Procedure:**

For a detailed description of how to calibrate an assay, refer to *Section 6* of the **ARCHITECT System Operations Manual**.

Calibrator value is verified using an internal standard obtained from ammonium sulfate puriss (ultrapure).

**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**.

**Reporting Results**

The result unit for the ARCHITECT Ammonia assay are reported as μmol/L.

**Specific Performance Characteristics**

**Reference Ranges**

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

**Plasma:**

Adult: 18-72 umol/L

**Critical Values: N/A**

**Performance Characteristics**

**Reportable Range**

The reportable range for MULTIGENT Ammonia Ultra is 8 to 1,700 μg/dL (4.70 to 997.90 μmol/L).

**Limit of Detection (LOD)**

The LOD for MULTIGENT Ammonia Ultra is 8 μg/dL (4.70 μmol/L).

**Dilution:**

**Plasma:** Specimens with ammonia values exceeding 1,700 μg/dL (997.90 μmol/L) are flagged and may be diluted by following either the Automated Dilution Protocol or the Manual Dilution Procedure.

***Automated Dilution Protocol***

If using an Automated Dilution Protocol, the system performs a 1:1.85 dilution of the specimen and automatically corrects the concentration by multiplying the result by the appropriate dilution factor.

***Manual Dilution Procedure***

• Use saline (0.85% to 0.90% NaCl) to dilute the sample.

• The operator must enter the 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.

• If the operator does not enter the dilution factor, the result must be multiplied by the appropriate dilution factor before reporting the result.

**NOTE:** If a diluted sample result is flagged indicating it is less than the linear low limit, do not report the result. Rerun using an appropriate dilution.

For detailed information on ordering dilutions, refer to *Section 5* of the **ARCHITECT System Operations Manual**.

**Precision:**

The precision of the MULTIGENT Ammonia Ultra assay is ≤ 10% Total CV.



#### Limitations of Procedure

Instrument absorbance errors were observed with Intralipid concentrations greater than 100 mg/dL

**Interfering Substances**

Interference studies were conducted using an acceptance criteria of +/- 10% deviation from the target value. MULTIGENT Ammonia Ultra is not affected by the presence of the following interferents up to the concentrations indicated below.



Hemoglobin: hemolyzed samples should not be used as erythrocytes contain ammonia levels approximately 3 times that of plasma.

**References:**

1. ABBOTT ARCHITECT Ammonia package insert

Abbott Laboratories

Diagnostics Division

Abbott Park, IL 60064

May 2014 306526/R03

1. ABBOTT ARCHITECT TDM Multiconstituent Calibrator package insert

Abbott Laboratories

Diagnostics Division

Abbott Park, IL 60064

1. Abbott ARCHITECT Operator’s Guide