AMMONIUM Liquid

Diagnostic reagent for determination of Ammonium concentration.

Liquid. Dual Reagents. Store at +4°C and +22°C. For in Vitro Diagnostic Use. Do not freeze

Ref No	Pack	Ref No	Pack	Ref No	Pack	Ref No	Pack
ZA57	6*25						

INTENDED USE

The test is applied for the quantitative determination of Ammonium concentration in serum.

TEST PRINCIPLE

The major source of circulating ammonia is the GI tract. Under normal conditions, ammonia is metabolized to urea by liver enzymes. Several diseases, both inherited and acquired, cause elevated ammonia (hyperammonemia). The inherited deficiencies of urea cycle enzymes are the major cause of hyperammonemia in infants. The acquired hyperammonemia diseases are caused by liver disease, renal failure and Reye's Syndrome. Elevated ammonia is toxic to the central nervous system.

In presence of LDH pyruvate is removed from the serum via a prereaction. Thereafter, ammonium is measured - in presence of α-KG and NADH - under optimized conditions by adding GLDH. If carried out manually the procedure of the test takes 10 min.

TEST PARAMETERS

Method	: Colorimetric, Endpoint
Wavelength	: 340nm (334-365 nm)
Temperature	: 37°C
Sample	: Serum
Linearity	: 300 µg/dL.

REAGENT COMPOSITION

Reagent 1&2: (liquid)

Composition	Final Concentration
LDH	≤ 3 KU/l
α-KG	≤ 24.0 mmol/l
Sodium Azide	≤ 0.2 %
TRIS pH 8.0	≤ 90 mmol/l
NADH	≤ 0.68 mmol/l
GLDH	≤ 45.0 KU/l
EDTA	≤ 8.3 mmol/l

Standard: 150 µg/dl Liquid

REAGENT PREPARATION

No need to preparation. Dual reagents liquid are stable.
Keep reagent at: 30 days at 4 - 8°C (Fridge), away from light sources.

Reagents should be clear, do not use turbid reagents.

REAGENT STABILITY AND STORAGE

Once opened vials are stable minimum 30 days at 2-8°C at optimum conditions. On board stability is strongly related to auto analyzers cooling specification and carry-over values.

SAMPLE

Serum (preferred) are collected by standard procedures.
Blood is collected from a stasis-free vein and stored in an ice bath. The plasma is then separated within 30 min.
Ammonia assay should be carried out immediately. The plasma may be stored for 2 hours at +2 to +8°C.
Sample should be clear. Don't use turbid samples with hemolysis.

Use disposable test tubes (in photometers also disposable reaction cuvets.) and glassware washed with HCL 1N solution and then distillated water.

TEST PROCEDURE

Sample Start
There have many ready application procedures dedicated to different kind of photometers and ready manual working process can be supplied on request.

There have many ready application procedures dedicated to different kind of biochemistry auto analyzers can be supplied on request.

CALCULATION

Ammonium µg/dL = Ax/As x 150 (standard value)

Unit Conversion

µmol/dL= 0,587 µg/dL

REFERENCE INTERVAL (NORMAL VALUES)

Men	: ≤94 µg/dL
Women	: ≤82 µg/dL

*It is recommended that each laboratory establish its own reference range.

QUALITY CONTROL AND CALIBRATION

All control sera with Ammonium values determined by this method can be used. We recommend:

"ARCON N", Assayed Control Serum Normal
Cat.No. A3910

"ARCON P", Assayed Control Serum Abnormal
Cat.No. A3920

The use of a Ammonium Calibrator (for manuel Systems) is optional. We recommend ARCAL Calibrator ("Arcal Auto") **Cat. No.** A39050

*Calibration Stability: It is strongly depend of application to auto analyzers and auto analyzers specification. Calibration stability is 10 days.

*Each laboratory should establish its own internal Quality Control scheme and procedures for corrective action if controls do not recover within the acceptable tolerances.

Quality control is recommended every morning. Calibration is not recommended if QC control values are acceptable. Reagent should be calibrated after lot changes.

PERFORMANCE CHARACTERISTICS

Low linearity: 5 µg/dL.

High Linearity: The method is linear up to 300 µg/dL.

If the limit value is exceeded, it is suggested to dilute sample 1 + 9 with distilled water and to repeat the test and multiplying the result by 10.

Linearity may considerably vary depending on the instrument used.

Precision Studies

Repeatibility (within run) (Intra-assay)

Mean conc.	SD	CV	n
140.00 µg/dL	3.30	2.58%	10
191.50 µg/dL	2.20	2.07%	10

Sensitivity (LOD) (Based on CLSI EP17 document): The limit of detection is 2 µg/dL.

Trueness: Results obtained with this reagent did not show systematic differences when compared with reference reagents. Details of the comparison experiments are available on request.

Interferences:
Hemolysis interferes with the assay.

NOTES

1. For in vitro diagnostic use only. Do not pipette by mouth. Avoid contact with skin and mucous membranes.
2. All the calibrators, controls and some reagents must be considered as human & animal sample, so potentially infectious; all the protection actions must be applied to avoid any potential biological risk.
3. Material safety data sheet will be supplied on request.
4. Exercise the normal precautions required for handling laboratory reagents.
5. After measurements are taken, reagent bottles should cap and kept at 2-8°C. Caps of the reagents bottles cannot be used between two different kind of reagent and between R1 & R2.
6. Reagents with different lot numbers should not be interchanged or mixed.
7. The linearity limit depends on the sample to reagent ratio.

PRECAUTIONS AND WASTE DISPOSAL

Solutions R1&R2 and CAL contain Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
This product is made to be used in professional laboratories and by professional operators. Perform the test according to the general "Good Laboratory Practice" (GLP) guidelines.
R36/38 : Irritating to eyes and skin.
S20/21 : When using, do not eat, drink or smoke.
S26 : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S28 : After contact with skin wash immediately with plenty of water.
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.
S45 : In case of accident or if you feel unwell, seek medical advice immediately.
S56 : Dispose of this material and its container at hazardous or special waste collection point.

S57 : Use appropriate container to avoid environmental contamination.
S61 : Avoid release in environment. Refer to special instructions/safety data sheets.
Please consult local regulations for a correct waste disposal.

ABBREVIATIONS

CLSI : Clinical and Laboratory Standards Institute
CV% : Coefficient of Variation Percentage
EP : Evaluation Protocols
GLP : Good Laboratory Practice
IU : International Unit
mA : miliabsorbance
mL : mililiter
NCCLS : National Committee for Clinical Laboratory Standards
QC : Quality Control

REFERENCES

1. Young DS. Effects of Drugs on Clinical Laboratory Tests. 3rd ed. Washington: AACC Press (1990).
2. Tietz Textbook of Clinical Chemistry, Second Edition, Burtis-Ashwood (1994).
3. Clin.Chem. 35/4, 552-554 (1989)
4. Clinical and Laboratory Standards Institute (formerly NCCLS). Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline - Second Edition. Wayne, PA: Clinical and Laboratory Standards Institute; 2004. NCCLS Document EP05-A2.
5. K.Ueno, T.Imamura, K.L.Cheng - Handbook of organic analytical reagents - CRC Press (1992).
6. International Federation of Clinical Chemistry, Committee on Reference Systems for Enzymes, Chem Clin Lab Med 2002; 40 (7):718–724.

SYMBOLS

IVD	Only for invitro diagnostic use
LOT	Lot of manufacturing
R1	Reagent 1
R2	Reagent 2
CONC	Concentration
INGRED	Reagent Ingredients
REF	Reference Number (Catalog No)
SN	Serial Number
	Expiration date
	Storage temperature interval
	Read the directions
	Biological risk

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