Ammonia

14010710207 **2*50ml R1**

Intended Use

System reagent for the quantitative determination of Ammonia in human plasma on the clinical chemistry analyzers. FOR IN VITRO DIAGNOSTIC USE ONLY.

Summary

The bulk of ammonia in the body is generated in the gastrointestinal system by action of bacterial enzymes on the contents of the colon and from hydrolysis of glutamine. It is removed in the liver and converted to urea through a series of enzymatic reactions in the Krevs-Henseleit cycle. Among other conditions, advanced liver disease and hepatic encephalopathy result in elevated levels of ammonia in blood. Hyperammonemia is also common in inherited deficiencies of the enzymes involved in the conversion of ammonia to urea. The determination of ammonia is very useful in the diagnosis and prognosis of Reye's syndrome. Elevated blood ammonia exerts toxic effects on the central nervous system.

Methodology

The enzymatic determination of ammonia allows a direct measurement of the compound in the plasma which avoids the long and laborious methods of separation employed in older methodologies. The enzymatic assay gives a highly sensitive and specific method. The assay is based on the following reaction :

$$NH_4^+ + \alpha\text{-KG} + NADPH \xrightarrow{GLDH} \text{L-glutamate} + NADP^+ + H_2O$$

Reagents

Ready to use

Final concentration of reactive ingredients:

Buffer	100 mmol/L
EDTA	2 mmol/L
a-Ketoglutarate	3.4 mmol/L
Adenosine diphosphate	0.5 mmol/L
NADPH	0.3 mmol/L
GLDH	400 KU/L

Also contains preservatives

Storage and stability

1. The unopened reagents are stable, up to the stated expiry date when stored at 2 to 8°C.

2. Opened bottles of reagent are stable for 30 days when stored in the refrigerated compartment of the analyzer.

Specimen Collection and Preparation

EDTA plasma is the specimen of choice. The use of heparin as an anticoagulant is not recommended. Collect blood from a stasis-free vein into an EDTA evacuated tube; release residual vacuum in the tube; mix gently, place on ice and deliver to the laboratory without delay. Separate the plasma from the cells immediately. Do not use hemolyzed samples. The analysis should be performed within 30 minutes.

sample Storage and Stability

A maximum of 2 hours delay with the plasma on ice is permissible

Discard contaminated sera!

Assay Procedure for Analyzers

Application sheets for automated systems are available on request.

Calibration

The frequency of calibration for the Ammonia procedure is every day. Calibration of this Ammonia procedure is accomplished by use of the Duocal Ammonia.

Recalibrate the assay every day, or when the following occur:

1. Change in reagent lot or significant shift in control values, 2. Major preventative maintenance was performed on the analyzer or a critical part was replaced.

Following calibration, the resulting curve should be visually reviewed, on the analyzer, for acceptability. Quality control procedures should be undertaken immediately following calibration in accordance with good laboratory practice

Quality Control

During operation of the analyzer, at least one level of Duotrol Ammonia should be tested a minimum of once a day. In addition, controls should be performed after calibration, with each new lot of reagent, and after specific maintenance or troubleshooting steps described in the appropriate User's Guide. Quality control testing should be performed in accordance with regulatory requirements and each laboratory's standard procedure.

Results

Results are automatically printed out for each sample in µg/dL.

Reference Range

Adults f < 82 µg/dL

M < 94 µg/dL

Each laboratory should check if the reference ranges are transferable to its own patient population and determine own reference ranges if necessary.

Measuring Range

This assay is linear up to 1500 µg/dL. For samples with a higher concentration, dilute 1:5 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 6.

Precision

Intra Assay precision (n=21)	Mean µg/dL	SD µg/dL	CV%
Sample 1	86.2	4.5	5.22
Sample 2	500	11.1	2.22

Inter Assay precision (n=21)	Mean µg/dL	SD µg/dL	CV%
Sample 1	88.3	5.1	5.77
Sample 2	485	11.9	2.45

Ammonia

Interference

The major interference for this assay is from contamination by ammonia in the air and water. Analytical and physiological variables including drugs and other substances which influence ammonia concentrations have been listed by Young.

Method Comparison

A comparison of Biomed Ammonia (y) to a commercially available test (x) using 52 samples gave following results: y = 0.991 x – 0.561; r= 0.999

References

1. Textbook of Clinical Chemistry Edited by N.W. Tietz, W.B. Saunders Company, Philadelphia, p. 1409, 1986.

2. Ratcliff, C.R. and Hall, F.F. in Selected Methods of Clinical Chemistry, volume 9, p. 85. Edited by Willard R. Faulkner and Samuel Meites. American Association for Clinical Chemistry. Washington, D.C., 1982.

3. Da Fonseca-Wollheim F., J. Clin. Chem. Clin. Biochem. 11, 421, 1973.

4. Young, D.S., Effects of Pre-analytical Variables on Clinical Laboratory Tests, First Edition, AACC Press, Washington, D.C., 3.20-3.21, 1993.

5. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, Third Edition, AACC Press, Washington, D.C., 3.30-3.32, 1990.

6. Young, D.S., Effects of Drugs on Clinical Laboratory Tests, 1991 Supplement to the Third Edition, AACC Press, Washington, D.C., 3.9-3.10, 1991.

Manufacturer

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