



GENESIS

Instructions For Use

Ammonia (Kinetic Enzymatic Method)

Cat no.	size
1306 101	2*25
1306 102	4*25

INTENDED USE

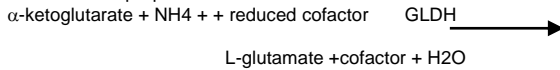
Ammonia reagent is intended for in-vitro quantitative determination of Ammonia in human plasma.

DIAGNOSTIC CHARACTERISTICS

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

PRINCIPLE OF THE METHOD

Ammonia reacts with α -ketoglutarate and reduced cofactor to form L-glutamate and the cofactor. The reaction is catalyzed by glutamate dehydrogenase. The decrease in absorbance due to the oxidation of the reduced cofactor can be monitored at 340 or 380 nm and is proportional to the ammonia concentration.



COMPOSITION

Reagent (R)	Buffer, pH 8.0	
	alpha-ketoglutarate	10 mmol/L
	GLDH (microbial)	≥ 24 KU/L
	NADPH analogue	0.2 mmol/L
	stabilizers, preservative, detergent	
Standard (S)		521 $\mu\text{g/dL}$

STORAGE AND STABILITY.

- Store at 2-8°C
- The kit are stable until the expiration date on the label when stored tightly closed.
- Once opened, the reagent is stable for 1 month at the specified temperature.

REAGENT PREPARATION

- Reagent Ready to use.

ADDITIONAL EQUIPMENT

- Analyzer, spectrophotometer able to read at 340 nm

SPECIMEN

- EDTA plasma or heparinized plasma (not ammonium heparin!) (serum is not recommended)

PROCEDURE

1. Assay conditions:

Wavelength: 340 nm
 Optical path: 1 cm
 Assay type: Fixed Rate
 Constant temperature: 37°C
 Delay time 30 seconds
 read time 150 seconds

2. Pipette into a cuvette:

	Reagent Blank	Standard	Sample
Reagent (R)	1.0 mL	1.0 mL	1.0 mL

3. incubate reagent at 37 °C for 3 minutes ,then add sample and standard

Standard	-----	0.1 mL	-----
Sample	-----	-----	0.1 mL

4. Mix and after 30 seconds read the absorbance A1 of the reagent blank, standard and specimen . Exactly 150 Second later, read absorbance A2 of reagent blank, standard and specimen.

Symbols in Product Labeling			
	Authorized Representative		Expiration date
	For in-vitro diagnostic use		CAUTION, consult instructions for use
	Catalogue number		Manufactured by
	Lot number		Temperature Limit
	Consult instructions for use		

CALCULATIONS

A blank = Blank A1 - Blank A2

A sample = Sample A1 - Sample A2

A sample – A blank

Conc. of Ammonia = $\frac{\text{A sample – A blank}}{\text{A standard – A blank}} \times \text{Standard conc}$

REFERENCE VALUES

EDTA plasma

	$\mu\text{mol/L}$	$\mu\text{g/mL}$
Adults Females	11-51 $\mu\text{mol/L}$	19- 87 $\mu\text{g/dL}$
Males	16-60 $\mu\text{mol/L}$	27-102 $\mu\text{g/dL}$
Children	< 48 $\mu\text{mol/L}$	< 81.5 $\mu\text{g/dL}$
Neonates(1- 6 days)	< 228 $\mu\text{g/dL}$	< 134 $\mu\text{mol/L}$

QUALITY CONTROL

It is recommended to use the Control Serum level I And II to verify the performance of the measurement procedure.

Each laboratory should establish its own internal Quality Control.

METROLOGICAL CHARACTERISTICS

Linearity: The assay is linear from 8.8 to 1174 $\mu\text{mol/L}$ (0.15 – 20.0 $\mu\text{g/mL}$). A sample with an ammonia level exceeding the linearity limit should be diluted with 0.9% saline and reassayed multiplying the result by the dilution factor.

Sensitivity: The lower limit of detection is 4.1 $\mu\text{mol/L}$ (0.07 $\mu\text{g/ml}$).

Precision

Intra-assay n = 20	Mean [$\mu\text{mol/L}$]	SD [$\mu\text{mol/L}$]	CV [%]
Sample 1	28.2	1.06	3.7
Sample 2	139.7	1.82	1.3
Sample 3	298.3	1.64	0.5

Inter-assay n = 20	Mean [$\mu\text{mol/L}$]	SD [$\mu\text{mol/L}$]	CV [%]
Sample 1	29.4	1.12	3.7
Sample 2	92.8	1.23	1.3
Sample 3	298.2	2.11	0.7

INTERFERENCES

no interference up to:

Ascorbic acid 3 mg/dL ,Bilirubin 40 mg/dL ,Triglycerides* 600 mg/dL , Pyruvate 6.6 mg/dL , Lactate 200 mg/dL and At ammonia concentration 121.5 $\mu\text{mol/L}$

- At lower ammonia levels, Triglycerides interfere in even minimal concentrations.

BIBLIOGRAPHY

- Conway, E.J., Biochem J. 29:27 (1935).
- Kingsley, G.R., and Tager H.S., Standard Methods of Clinical Chemistry 6:115, Washington D.C. 1970, American Assoc. of Clinical Chemistry.
- Ratcliff, C.R., and Hall, F.F. Selected Methods of Clinical Chemistry 9:85, Edited by Willard R. Faulkner and Samuel Meites, American Association for Clinical Chemistry, Washington D.C. (1982).
- U.S. Patent No. 5,801,006.
- Tietz, N.W., Fundamentals of Clinical Chemistry, 3rd Edition, W.B. Saunders, Philadelphia, PA (1999).
- CLSI Guidelines and Standards, Clinical and Laboratory Standards Institute, Wayne, PA.
- Young, D.S., Effects of Drugs on Clinical Laboratory Tests, AACC Press, Washington, Third Edition (1990).

