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.

α-ketoglutarate + NH4 + + reduced cofactor $\xrightarrow{\text{GLDH}}$ L-glutamate +cofactor + H2O

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 µg/dL

STORAGE AND STABILITY.

- Store at 2-8ºC
- 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……37ºC
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

EC REP	Authorized Representative		Expiration date
IVD	For in-vitro diagnostic use		CAUTION, consult instructions for use
REF	Catalogue number		
LOT	Lot number		Manufactured by
	Consult instructions for use		Temperature Limit

CALCULATIONS

A blank = Blank A1 - Blank A2
A sample = Sample A1 - Sample A2

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

REFERENCE VALUES

EDTA plasma

	µmol/L	µg/mL
Adults Females	11-51 µmol/L	19- 87 µg/dL
Males	16-60 µmol/L	27-102 µg/dL
Children	< 48 µmol/L	< 81.5 µg/dL
Neonates(1- 6 days)	< 228 µg/dL	< 134 µmol/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 µmol/L (0.15 – 20.0 µg/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 µmol/L (0.07 µg/ml).

Precision

Intra-assay n = 20	Mean [µmol/L]	SD [µmol/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 [µmol/L]	SD [µmol/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 µmol/L
- At lower ammonia levels, Triglycerides interfere in even minimal concentrations.

BIBLIOGRAPHY

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

GENESIS LAB FOR DIAGNOSTIC REAGENTS
1st industrial area, Obour City, Cairo, Egypt
(+202) 44891632 Fax : (+202) 44891632
www.genesis-egy.com
info@genesis-egy.com

IFU-AMM-06
Rev. (2) 17/09/2023

ISO 13485:2016 Medical Devices

CE

EC REP CMC Medical device, C/ Horacio Lengo n18 C.P 29006, Málaga-Spain