AMMONIA SYSTEM PACK

(KINETIC METHOD)

B Auto 200, Unicorn 230, Unicorn 120 , Bonavera Chem 200 , Beaconic chem 200, Beaconic B200, Beaconic analyzer 120 & Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA204	Ammonia System Pack	1x16 + 1x4 ml

INTENDED USE

The reagent kit is intended for the *In Vitro* quantitative determination of Ammonia.

SUMMARY

Ammonia (NH_3) is a reagent kit used for the quantitative determination of ammonia in plasma, based on enzymatic method using glutamate dehydrogenase (GLDH) enzyme.

PRINCIPLE

Ammonia reacts with α-ketoglutarate to form glutamate in presence of glutamate dehydrogenase. NADH is oxidized to NAD+ in this reaction, which is measured as decrease in absorbance at 340 nm. The rate of decrease in absorbance at 340 nm is directly proportional to plasma ammonia concentration.

$$NH_3 + \alpha\text{-ketoglutarate} + NAD \xrightarrow{GLDH} \text{Glutamate} + NAD^+$$

REAGENT COMPOSITION

Reagent 1 : Ammonia Reagent 1
Reagent 2 : Ammonia Reagent 2
Reagent 3 : Ammonia Standard (500 µg/dl)

REAGENT PREPARATION

Ready to use

STORAGE & STABILITY

The reagent kit should be stored at +2 - +8°C and is stable till the expiry date indicated on the label.
On board stability: Min. 30 days if refrigerated (+8-+14°C) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

EDTA plasma or Heparinized plasma.
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 hour at +2-+8°C.

LINEARITY

This procedure is linear up to 1500 µg/dl. If value exceeds this limit dilute the sample with normal saline (NaCl 0.9%) and repeat the assay Multiply result by dilution factor.

CALIBRATION

Calibration with the Ammonia Standard provide in the kit is recommended.

QUALITY CONTROL

For accuracy, it is advised to run known controls with each assay.

LIMITATION

1. Anticoagulants having ammonium ions should not be used because of extreme sensitivity of the color reaction to ammonia.
2. Reaction is linear up to 1500 µg/dl. For higher values, dilute the sample with normal saline and perform the assay. Multiply the final result by dilution factor to get the real value.
3. The working reagent is considered unsatisfactory and should not be used if the absorbance is less than 0.700 at 340 nm against distilled water.
4. Do not use strongly hemolysed samples.

UNIT CONVERSION

Ammonia (µg/dl)x 0.588= Ammonia (µmol/L)

EXPECTED VALUES

Plasma : 17-90 µg/dl

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon. Data obtained in your laboratory may differ from these values.

Limit of quantification : 10 µg/dl
Linearity : 1500 µg/dl
Measuring range : 10-1500 µg/dl
Precision

Intra-assay precision Within run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	104.95	1.96	1.87
Sample 2	152.10	1.52	1.00

Inter-assay precision Run to run (n=20)	Mean (U/L)	SD (U/L)	CV (%)
Sample 1	97.33	1.23	1.27

COMPARISON

A comparison between Ammonia System Pack (y) and commercially available tests (x) using 40 samples gave following results:
y =1.0174x - 1.3868 µg /dl
r = 0.999

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INTERFERENCES

Following substances do not interfere:

Ascorbic acid UP TO 40 mg/dl ,Bilirubin up to 20 mg/dl,triglyceride up to 700 mg/dl & hemolysed samples should not be used as erythrocytes contain level of ammonia 3 times that of plasma .

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handled by entitled and professionally educated person. MSDS will be provided on request.

WASTE MANAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 200, Unicorn 230, Unicorn 120 , Bonavera Chem 200, Beaconic chem 200, Beaconic B200, Beaconic analyzer 120 & Bonavera chem 100
(Fully Auto Biochemistry Analyzer)

Test Name	Ammonia
Full Name	Ammonia
Pri Wave	340 nm
Sec Wave	630 nm
Assay/point	Fixed Time
Start	20
End	30
Decimal	1
Unit	µg/dL
Linearity Range Low	10
Linearity Range High	1500 µl
Sample Volume	20 µl
Reagent 1 (r1) Volume	160 µl
Reagent 2 (r2) Volume	40 µl
Subsatrate Depleted	-
Linearity	1500 µg/dl
Out Of Linearity Range	-
Calibration Type	2 Point linear
Points	2
Blank Type	Water
Concentration Blank	0.00
Concentration Std	500 µg/dl

NOTES

Clinical diagnosis should not be made on findings of a single test result, but should integrate both clinical and laboratory data.

BIBLIOGRAPHY

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Symbols Used On Labels

REF	Catalogue Number		Manufacturer
	See Instruction for Use	LOT	Lot Number
CONT	Content		Storage Temperature
	Expiry Date	IVD	In Vitro Diagnostics

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