LiquiMAX Ammonia

Order information

Ref. No.	Pack size	Presentation
AVAMM - 10	10 ml	Liquid Stable Mono Reagent with
AVAMM - 25	25 ml	Calibrator

INTENDED USE :
Kit for the quantitative determination of ammonia (NH3) in human plasma Semi automated systems.

PRODUCT FEATURES
1. Liquid stable , Ready to use Mono reagents
2. UV Fixed Rate (Initial Rate) method.
3. 180 Sec. Fixed time reaction (60 Sec. Delay +120 sec. Measuring)
4. Measuring Wavelength 340nm.
5. Aqueous calibrator provided (calibrator conc. 200 mg/dl).
6. Linearity 1700 µg/dl
7. EDTA plasma is only the specimen.
8. Available as multipurpose reagents and dedicated system packs

CLINICAL SIGNIFICANCE :
Ammonia , derived from the catabolism of amino acids and from the action of intestinal bacteria on dietary protein , is coverted to urea in the liver hepatocytes and so rendere non toxic . Under normal circumstances the Conc.of ammonia in the circulation remains low, typically less then 90µg/dl. Studies have shown that excess ammonia can have a toxic effect on the central nervous system and clinical manifestations are typically neurological disturbances. Elevated levels ammonia may be either due to :(i) inborn errors of metabolism ; or (ii) secondary to other conditions. Inborn errors of the metabolism are the major cause of elevated ammonia in infants usually the result of urea cycle enzyme enzyme deficiencies. Inherited disorders affecting the metabolism of the dibasic amino acids (lysine and ornithine) and those involving the metabolism of organic acids may also produce elevated levels of circulating ammonia .Elevated ammonia may also observed in severe liver failure as may occur in Reye's syndrome,viral hepatitis or cirrhosis.

PRINCIPLE
A number of methods Hve been developed for the estimation of plasma ammonia and these can be broadly classified into either indirect or direct methods. In the indirect ,procedures Ammonia is first of all isolated, for example addition of alkali or the use of cation exchange resin,after which it is measured colorimetrically by nesslerization or Berthelot reaction .These procedure are not easily automated equipment .Direct procedures such as enzymatic method ,are more widely used in laboratories as they do not require the the separation of ammonia from the specimen prior to the analytical step .direct procedures are therefore more easily automated .The LiquiMAX ammonia Reagent is a direct enzymatic procedure based on the following reaction sequence;
NH_4+a-ketogulatrate +NADH Analouge (GLDH) Glutamate +NAD^4+H_2O
The reagent contains LDH in excess ,to rapidly reduce endogenous pyruvate so that it does not interfere with the assay system.The LiquiMAX Ammonia reagent also incorporates patented stabilization process this renders the reagent stable in the liquid phase.

STABILITY AND STORAGE
When stored at 2-8°c the regents are stable until the expiration date stated on the bottle and kit box labels .
It is recommended that when the reagent is not in use for prolonged periods of the reagent be capped and stored at 2-8°c.

KIT COMPONENTS

1.Ammonia Reagent

2. Ammonia Standard : Concentration as stated on the label

COMPOSITION

Active Ingredient	Concentration
a-ketoglutarate	7.5mmol/L
NADH	>0.2mmol/L
GLDH(Micro-organism)	>4000u/L
LDH(Micro-organism)	>3000u/L
Tris buffer	100mmol/L
pH	8.7± 0.1 at 20°c

REAGENT RECONSTITUTION & STABILITY

Reagent are liquid stable no need for reconstitution.

When the reagent is stored properly at 2-8°C & the contamination avoided, it is stable up to the expiry date mention on the label & kit box.

MATERIAL REQUIRED BUT NOT PROVIDED

Laboratory Instrumentation, Spectrophotometer UV/VIS with thermostatic cuvette holder or clinical chemistry analyzer: semi auto, calibrated micropipettes, glass or high quality polystyrene cuvettes, test tube/rack, heating bath controls, saline.

REAGENT DETERIORATION
- Discard any turbid reagent or reagent absorbance less than 0.8 at 340 nm against distilled water.
- Keep the standard vial plugged after use, in order to avoid deterioration.

WARNING & PRECAUTIONS
- Reagent may contain some non reactive and preservative components. It is recommended to handle carefully, avoiding contact with skin and ingestion.
- Specimen should be considered infectious and handled appropriately.
- Contamination by soap or glycerol will affect this assay.
- Perform the test according to the general " Good Laboratory Practice" GLP guidelines.

SPECIMEN
1. Heparin plasma or EDTA plasma are the only specimens Serum should not be used.
2. EDTA plasma : Use K3 EDTA or K2 EDTA vaccutainers for whole blood collection.
3. Heparin Plasma : use Lithium heparin or sodium Heparin vaccutainers (with or without Gel barrier)for blood collection .Do not use ammonia heparin
4. Do not use liquid EDTA or Liquid for Blood collection.
5. Ideally, the collection tube should be completely filled with blood and immediately placed on ice centrifuge the sample as soon as possible and separate plasma and store at 2-4°c until analysis.
6. Do not keep the plasma with RBC once centrifuged. Plasma should be immediately separated. Heamolysed sample should not be used as erythrocytes contain level of ammonia Approximately 3 times that of plasma.

STORAGE: Ammonia sample are stable for 3 hours at 2-4°c or 24 hours at -20°c.

SYSTEM PARAMETERS
The following system parameters are recommended. Individual instrument applications are available upon request form the Technical support Group.

Assay Type	:	Fixed type
Reaction Direction	:	Decreasing
Temperature	:	37°C
Wavelength	:	340nm
Working reagent Volume	:	500 µl
Sample Volume	:	25 µl
Calibrator Conc	:	200 µg/dl
Delay time	:	60 sec
Measuring Time	:	120 sec
Linearity	:	1700µg/dl

TEST PROCEDURE

Reagent	Calibrator	Sample
Ammonia Reagent	500 µl	500 µl
Calibrator	25 µl	-----
Plasma	-----	25 µl

Mix well and start the stop watch. Record the first absorbance (A1) at 60 seconds after adding the calibrator /sample.
Exactly 120 sec .after the first reading record the absorbance (A2) at 37°c.

CALCULATIONS

$$\text{Concentration of Ammonia (µg/dl)} = \frac{\text{A1-A2 (sample)}}{\text{A1-A2(calibrator)}} \times 200 \text{ (calibratorconc.)}$$

NOTES

1. The reagent and sample volume may be altered proportionally to accommodate different spectrophotometer requirements.
2. Specimen with ammonia concentration greater then 1700µg/dl should be diluted with ammonia free water reassayed . Multiply results by diluation factor.

EXPECTED VALUES

The quoted values were derived from a normal population and should serve as a guide only. (17-110µg/dl)

QUALITY CONTROL & CALIBRATION

It is recommend to perform internal quality control with assayed normal (BioNorm) and assayed abnormal (BioPath), to confirm the validity of the test and assure the accuracy of patient result.
Using the recommended calibrator (Avecon) or the standard included, calibrate the assay:
a) When using a new reagent or lot.
b) When QC values are out of range.

PERFORMANCE CHARACTERISTICS

1. Linearity

Linearity : 1700 µg/dl

2. Sensitivity/ Limit of Detection (LOD)

The lower limit of detection is 13µg/dl

3. Interferences

No significant interference was observed from Bilirubin upto 20mg/dl (Both conjugated and unconjugated Bilirubin), Lipema as Triglycerides upto 2000mg/dl,Ascorbic acid upto 30mg/dl.

4. Precision

Intra-assay precision	mean	SD	CV
N=76	(µg/dl)	(µg/dl)	(%)
Sample 1	61.1	3.6	6.0
Sample 2	115.5	8.5	7.4

Inter-assay precision	mean	SD	CV
N=76	(µg/dl)	(µg/dl)	(%)
Sample 1	103.9	3.61	6.0
Sample 2	196.4	14.5	7.4

5. Method Of Comparison

Studies were carried out using another similar commercially available ammonia reagent .plasma samples were assayed in parallel and the results compared by least square regression. The following statistics were obtained.

Numbers if sample pairs	:	42
Range of sample results	:	(13-600µg/dl)
Meqan of reference method results	:	(530µg/dl)
Mean of LiquiMAX Ammonia results	:	(536µg/dl)
Slope	:	1.002
Correlation coefficient	:	0.9974

Ver. : 05/01-26

LIMITATIONS

1. Perform the test with 1.0 ml as it will not leave any space in the flow cell and give reliable ammonia results.
2. Performing Ammonia test with 0.5 ml may result inconsistent results if there is carry over in the Analyzer result the air gap.
3. Heamolysed samples should not be used as erythrocytes contain level of ammonia approximately 3 times that of plasma.
4. No interference from pyruvate was 0bserved up to a level of 20 mg/dl.
5. Reliable estimations of ammonia can only be achieved If steps are taken to avoid contamination from ammonia sources of contamination include ,but are not restricted to ,cigarette smoking (patient and collection staff),laboratory atmosphere and laboratory glassware.

WASTE DISPOSAL

Reagents must be disposed off in accordance with local regulations.

REFERENCES

1. Clinical chemistry infobase : A scientific c & Management cyclopedia pesce-kaplan publishers 1996; 2246-2320.

Symbols Used on Pack

REF	Catalogue Number	⚠	Warning/Caution
LOT	Batch No.	IVD	In vitro diagnostic device
	Manufacturing Date		Storage Limit
	Expiry Date		Consult instruction for use
	Manufacturer		Keep away from sunlight
	Keep Dry		Do not use if package is damaged
Σ	Contains sufficient no. of test		

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