Ammonia (AMM) Diagnostic Reagent Kit (Glutamate Dehydrogenase Method) Product Instruction

Product name
Generic Name: Ammonia (AMM) Diagnostic Reagent Kit (Glutamate Dehydrogenase Method)
Abbreviation: AMM

Package Specifications

Reagent
20ml×2
30ml×2
40ml×2

Calibrator (lyophilized):
Specification 1 (1.0mL×1; 1 level);
Quality control (lyophilized):
Specification 1 (1.0mL×1; 1 level).

Intended use
For in vitro quantitative determination of ammonia ions in serum or plasma.

Clinical significance
The ammonia content in the normal human blood circulation is very low due to oxidative deamination and transamination of dietary and amino acids. The liver is the main organ involved in ammonia removal. The clinical indicator of nervous system damage is usually an elevated blood ammonia concentration.

Principle
Under the action of lactate dehydrogenase (LDH), pyruvate in serum that interferes with ammonia determination is removed in the pre-reaction. Ammonia reacts with α-KG and NADH under the action of glutamate dehydrogenase, and the ammonia content in serum can be calculated by comparing with the calibration solution treated in the same way.

Main ingredient

Name	Ingredient	Concentration
Reagent	Tris buffer (ph=9)	50mmolL
	Lactate dehydrogenase	>15.0KU/L
	α-Ketoglutarate (a-KG)	18.0mmolL
	NADH	0.25mmol/L
	Stabilizer	0.1%
Calibrator	Ammonium chloride	15-30/mgl
	Stabilizer	0.1%
QC	Ammonium chloride	40-90/mgl
	Stabilizer	0.1%

Storage and stability
This kit stays stable for 12 months when stored in a dark condition at 2-8°C (do not freeze). After being opened for the first time, the kit can be stored at 2-8°C in an anti-pollution environment and stays stable for 14 days.

Specimen preparation
Fresh serum.
2-8°C, stable for 3 days.
-70°C, stable for 3 months.

Assay procedure
1. Reagent preparation
This reagent is liquid and can be used totally.

Main wavelength	340nm	Sample	15μl
Subwavelength	405nm	Reagent	250μl
Reation temperature	37°C	Direction	Decreasing
Cuvette light path	1cm	Reaction type	Two point End

2. Operation steps

Add to the cuvette:	
Sample (S)	15μl
Reagent	250μl
Mix well, incubate at 37°C for 20 seconds, record absorbance A1, reaction for 2 minutes, record absorbance A2	

Calculations

$$\text{Conc. Am.} = \frac{\text{A(sample)- A(blank)}}{\text{A(Cal.) - A(blank)}} \times \text{Conc. Cal.}$$

Reference interval
10～47μmol/L
It is recommended that each laboratory should establish its own reference interval.

Quality control
The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the limits.

Performance characteristics
1. Measuring range：
0-300μmol/L
Samples above this concentration should be diluted 1+1 with 0.9% NaCl solution and the result multiplied by 2.
2. Sensitivity:

When the sample concentration is 88.0 μmol/L, the absorbance change value (△A) should be ≥0.0300.

Automation
Special adaptations for automatic analyzers can be made on request.

General precautions
For in vitro diagnostic use only.
Diagnosis should only be made after taking clinical symptoms and the results of other tests into consideration.
Exercise the normal precautions required for handling all laboratory reagents.
Disposal of all waste material should be in accordance with local guidelines.

Precautions for measurement
Specimens should be treated as potentially infectious (HIV, Hepatitis B virus, Hepatitis C virus, etc.) and handled with appropriate caution.
Reagents with different lot numbers should not be interchanged or mixed.
For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.
Material safety data sheet available for professional user on request.

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