MISPA CCXL / CX4 / CXL PRO

AGAPPE

MAGNESIUM

2 x 30 mL
12019028

Intended Use
This reagent is intended for *in vitro* quantitative determination of Magnesium in serum ,plasma and urine.
- Xylidyl Blue with ATCS
- Linear up to 5 mg/dL

Clinical Significance
Magnesium is the second most abundant intracellular cation of the human body after potassium, being essential in a great number of enzymatic and metabolic processes. It is a co-factor of all the enzymatic reactions that involve ATP and found in the membranes that maintain the electrical excitability of muscular and nervous cells. A low magnesium level is found in malabsorption syndrome, diuretics aminoglucoside therapy, and hyperparathyroidism or diabetic acidosis.

Elevated concentration of magnesium is found in uremia, chronic renal failure, glomerulo nephritis, Addison's disease or intensive anti acid therapy. Clinical diagnosis is should not be made on a single test result; it should integrate clinical and other laboratory data.

Principle
Magnesium reacts with xylidyl Blue to form a colored compound in alkaline solution. The intensity of the color formed is proportional to the magnesium in the sample.

Kit Components

Reagent/ Component	Product Code 12019028	Description	
Magnesium Reagent	2 x 30 mL	Xylidyl Blue	110 mmol/L
		Ethanolamine (pH 11.0)	1 mol/L
		GEDTA	60mmol/L

Risk & Safety
Material Safety data sheets (MSDS) will be provided on request

Reagent Preparation
Magnesium Reagent is ready to use.

Reagent Storage and Stability
The sealed reagents are stable upto the expiry date stated on the label, when stored at 2-8^{o}C.

Open Vial Stability
Once opened the reagents are stable up to 90 days if contamination is avoided.

On-board Calibration Stability
Calibration is stable for 3 days.

Reagent Deterioration
Turbidity or precipitation in any kit component indicates deterioration and the component must be discarded. Values outside the recommended acceptable range for the Agappe Qualicheck Norm & Path control may also be an indication of reagent instability and associated results are invalid. Sample should be retested using fresh vial of reagent.

Precaution
To avoid contamination, use clean laboratory wares. Close reagent bottles immediately after use. Avoid direct exposure of reagent to light. Do not blow into the reagent bottles.

This reagent is only for IVD use and follow the normal precautions required for handling all laboratory reagents.

Waste Management
Reagents must be disposed off in accordance with local regulations.

Sample
Serum (free of haemolysis) Heparinized Plasma (do not use oxalates or EDTA as anticoagulant) / Urine (should be acidified to pH 3-4 with concentrated HCl then dilute sample 1/5 with distilled water and multiply the result by 5)

Materials provided
Magnesium Reagent

Reagents required but not provided
Multicalibrator (Product Code: 11610001), Qualicheck Norm (Product Code: 11601003), Qualicheck Path (Product Code: 11601002)

Unit Conversion

Traditional Unit	SI Unit	Conversion from Traditional to SI
mg/dL	mmol/L	x 0.4114

Calibration
Agappe Multicalibrator (Product Code: 11610001) is recommended for calibration of the assay.

Quality Control
It is recommended to use Qualicheck Norm (Product Code: 11601003) or Qualicheck Path (Product Code: 11601002) to verify the performance of the measurement procedure. Each Laboratory has to establish its own internal quality control scheme and procedures for corrective action if controls do not recover within the acceptable tolerance.

Reference Range
It is recommended that each laboratory should establish its own reference values. The following value may be used as guide line.

Serum : New born (2-4 days) :1.5 - 2.2 mg/dL
5 months-6 Years :1.7 - 2.3 mg/dL
6-12 Years :1.7 - 2.1 mg/dL
>12 Years :1.6 - 2.6 mg/dL

CSF : 2.1 - 3.3 mg/dL

Urine : 73 - 122 mg/24 h

Results obtained for patient samples are to be correlated with clinical findings of patient for interpretation and diagnosis.

Performance
1. Linearity

The reagent is linear up to 5 mg/dL. If the concentration is greater than linearity (5 mg/dL), dilute the sample with normal saline and repeat the assay. Multiply the result with dilution factor.

2. Comparison

A comparison study has been performed between Agappe reagent and another internationally available reagent yielded a correlation coefficient of r^2= 0.955 and a regression equation of y = 0.9975x.

3. Precision

	Intra Run		Inter Run	
Control	Level 1	Level 2	Level 1	Level 2
n	20	20	20	20
Mean (mg/dL)	1.9	3.6	1.84	3.66
SD	0.06	0.17	0.06	0.16
CV(%)	3.15	4.67	3.20	4.39

Accuracy (mg/dL)		
Control	Expected Value	Measured Value
Control Level 1	1.89 ± 0.29	2
Control Level 2	4.0 ± 0.6	3.7
Qualicheck Norm	1.85 ± 0.46	2
Qualicheck Path	3.10 ± 0.45	3.3

4. Sensitivity

Lower detection Limit is 0.05 mg/dL

Bibliography

1. Farrel, E. C.; Magnesium.in Kaplan, A., *et al.*; Clin chem. The CV Mosby Co. St. Louis, Torento, Princeton 1984; 1064-69
2. Brutis, C. A., *et al.* TIETZ Text book of Clinical chemistry, 3 rd edition W. B Saunders company; 1999, P.1395-1457
3. Young, D. S.; Effects of disease on clinical lab tests, 4th edition, AACC Press, 2001.
4. Burtis, Ashwood, Bruns & Saunders : Tietz Text Book of Clinical Chemistry 4th Edition -2006.

SYMBOLS USED ON THE LABELS

IVD IN VITRO DIAGNOSTIC USE | SEE PACKAGE INSERT FOR PROCEDURE | LOT LOT NUMBER | MANUFACTURER'S ADDRESS | MANUFACTURING DATE | EXPIRY DATE | TEMPERATURE LIMIT

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REV. NO.: ADL/IFU/MG/CCXL/R01

CE ISO 9001:2015
EN ISO 13485:2016