MAGNESIUM (15-25ºC)
(XYLIDYL BLUE)

CATALOGUE NUMBER	KIT SIZE (mL)
MPRMAG2	3x50ml / 1x5ml

Intended Use:
For *In Vitro* diagnostic use by trained professionals only.
This reagent is intended for the quantitative determination of Magnesium in human serum, plasma and urine.

Clinical Significance:
Magnesium is one of the major intracellular cations in the body. Its action is closely related to that of calcium. Magnesium deficiency, hypomagnesaemia can result in various neuromuscular disorders, weakness, tremors, tetany and convulsions. It is associated with hypocalcaemia, intravenous therapy, diabetes mellitus, alcoholism, dialysis and pregnancy.
Increased serum magnesium levels are associated with dehydration, severe diabetic acidosis and Addison's Disease. Conditions that interfere with glomerular filtration as in renal failure result in retention of magnesium and hence elevation of serum levels.

Test Principle:
Magnesium ions react with xylidyl blue in an alkaline medium to form a water soluble purple-red chelate, the colour intensity of which is proportional to the concentration of magnesium in the sample. Calcium is excluded from the reaction by complexing with EGTA.

Reagent Composition

REAGENT	COMPONENT	CONCENTRATION
Xylidyl Blue Reagent R1	Xylidyl Blue	1.0 mmol/l
	Tris Buffer	250 mmol/l
	Detergent	15 g/l
Magnesium Standard	Magnesium	2.5 mg/dl

Reagent Preparation and Stability:
R1: Liquid, ready to Use
R2: Liquid, ready to Use
R1 and Standard are stable to the stated expiry date when stored unopened at 15 - 25ºC and protected from light. Dispose of reagents carefully in line with local guidelines.

Sample / Sample Preparation / Sample Stability:
Collect serum and Li-heparin plasma by standard venepuncture technique.
Magnesium will be stable in serum and plasma for up to 7 days at 2 - 8ºC or 20 - 25ºC.
For longer term storage keep up to 12 months at -20ºC.
Urine is to be collected in a metal free container without preservative. Add acid to samples to pH 3 – 4 before assay. Dilute urine 1+4 with DDH_2O. Multiply the result by 5. Centrifuge samples containing precipitate before performing the assay.

Assay Procedure:

WAVELENGTH	546nm (520nm)
TEMPERATURE	25ºC
CUVETTE	1cm Path Length
BLANK	Reagent Blank

	Blank	Standard	Sample
Sample	-	-	10 µl
Standard	-	10 µl	-
Reagent	1000 µl	1000 µl	1000 µl
Mix and incubate for 5 minutes at assay temperature. Read the absorbance (Δ Abs) of Sample/Standard against the Reagent Blank within 60 minutes.			

Calculation:

$$\text{Concentration (mmol/l)} = \frac{\Delta\text{Abs Sample}}{\Delta\text{Abs Standard}} \times 1.028$$

To convert from mmol/l to mg/dl multiply by 2.43.
Standard concentration: 2.5 mg/dl (1.028 mmol/l)

Performance Characteristics:

Measuring range:
0.04mmol/l - 2.055 mmol/l (5mg/dl)
Dilute samples with higher concentrations with Normal saline 1+3 and rerun the assay. Multiply the result by the dilution factor (for 1+3 dilution, the dilution factor is 4)

Analytical Sensitivity: (Lower detection limit):
0.04 mmol/l (0.09 mg/dl)

Imprecision
Intra-Assay Precision:

Sample	Mean (mmol/l)	SD (mmol/l)	CV %
Pool 1	1.06	0.012	1.13
Pool 2	1.28	0.013	1.02
Pool 3	1.79	0.010	0.56

Inter-Assay Precision:

Sample	Mean (mmol/l)	SD (mmol/l)	CV %
Pool 1	1.03	0.023	2.28
Pool 2	1.27	0.023	1.28
Pool 3	1.81	0.062	3.43

Method Comparison:
Prestige Diagnostics Magnesium reagent (y) was compared with another commercially available reagent (x) and gave the following results:
y = 0.903x + 0.121, r = 0.986

Interferences:
Criterion: Recovery within +/- 10% of initial value.
Icterus: No significant interference up to 10 mg/dl of Bilirubin.
Haemolysis: Haemolysis interferes with the assay – do not use haemolysed samples.
Lipaemia: No significant interference up to 950 mg/dl of Triglycerides. There is poor correlation between turbidity and triglycerides concentration.

Reference Range:

Adult Serum/Plasma	1.3 – 2.1 mmol/l	1.59 – 2.56 mg/dl
5 months – 6 years	1.4 – 1.9 mmol/l	1.71 – 2.29 mg/dl
12-20 years	1.3 – 1.8 mmol/l	1.59 – 2.20 mg/dl
Urine	1.0 – 24.0 mmol/24h	12.2 – 292 mg/24h

Each laboratory should establish its own mean reference range according to the population.

Automated systems:
Contact Prestige Diagnostics Technical Department for applications on a wide range of automated analysers.
For automation we recommend the use of a serum based calibrator.

Quality Control and Calibration Material:
Calibration Serum: **QCCCAL1 / QCCCAL2**
Human Assayed Control Normal: **QCCHAN1 / QCCHAN2**
Human Assayed Control Elevated: **QCCHAE1 / QCCHAE2**

References:

1. Bablok W et al. A General Regression Procedure for method transformation. J.Clin Chem Clin Biochem 1988, 26:783-790.
2. Erhardt V, Apel W, Paschen K et al., Evakulerung elnes Xylidyl Blau-Reagent Zur Bestimmung von Magnesium. Wien Klin Wschr 1992: 104: 5-11.
3. Zumkley N, Spleker C (ed). Die Magneslumfibel, reinbeck: Einhorn-Pressie.
4. Tietz N.W (ed). Clinical Guide to Laboratory Tets. 3rd ed. Philadelphia, Pia: W.B Saunders Company, 1995; 380-382.
5. Passing H, Bablok W., A New Biometrical Procedure for Testing the Equality of Measurements from Two different Analytical Methods. J Clin Chem Clin Biochem 1983; 21: 709-720.

REF	Catalogue number		Temperature limitation
	Consult instructions for use	LOT	Batch code
IVD	*In vitro* diagnostic medical device		Use by Date
	Manufacturer		Keep away from sunlight

CE

Prestige Diagnostics UK Ltd 40 Ballymena Business Centre, Galgorm, Co. Antrim, BT42 1FL, United Kingdom. Tel: +44 (0) 28 2564 2100
www.prestigediagnostics.co.uk info@prestigediagnostics.co.uk

V4: rev Aug 2020