

Ana-Chek® MAGNESIUM

METHOD – XYLIDYL BLUE

PRODUCT CODE – LM01



INSTRUCTIONS FOR USE

INTENDED USE: Test for estimation of Magnesium in serum / plasma using Xylidyl Blue method.

SUMMARY AND PRINCIPLE

Magnesium is an essential nutrient which is involved in many biochemical functions. Low levels of Magnesium are associated with prolonged diarrhoea and impairment of neuromuscular function. High magnesium levels are found in patients with renal glomerular failure and diabetic coma. Ana-Chek® Magnesium is a reagent set for determination of magnesium in human serum / plasma using Xylidyl blue dye.



KIT COMPONENTS

Reagent 1 : Magnesium Reagent
Reagent 2 : Magnesium Standard (2 mg/dL)

REAGENT PREPARATION, STORAGE & STABILITY

Ana-Chek® Magnesium is single ready to use reagent. The reagent kit should be stored at 2-8 °C and is stable till the expiry date indicated on the label.

PRECAUTIONS & HANDLING

The reagents/samples should be handled by qualified personnel only. Discard reagent/sample as per good laboratory practices and local regulatory requirements. Read the instructions given on the labels and instructions for use carefully before using the kit. The kit is intended for in-vitro diagnostic use only. Don't freeze the reagent. Do not shake the reagent vigorously. Discard the reagent if the absorbance of the reagent exceeds 1.000 O.D. against D/W at 546 nm. Contamination of the reagent should be avoided.

TEST PARAMETERS

Name	Magnesium	Reagent Volume	1000 µl
Reaction Type	End Point	Sample Volume	10 µl
Primary Wavelength	546 nm	Incubation Time	10 Min
Flow Cell Temp.	37 °C	Incubation Temperature	37 °C
Blank setting	Reagent	Standard Conc.	2 mg/dL
Blank abs. limit	> 1.000	Linearity	5 mg/dL

MATERIALS REQUIRED BUT NOT PROVIDED

Test tubes, Micropipette with tips, Analyzer, Controls, Incubation chamber.

SPECIMEN COLLECTION & PRESERVATION

Blood should be collected in a clean dry container. Serum is preferred. Heparinized plasma can be used. Do not use EDTA plasma. Haemolysed samples should not be used. Magnesium in serum/plasma is stable for 7 days at 2-8 °C and for 1 year at -20 °C.

COMPONENTS OF REAGENT

Component	Concentration
Tris Buffer	200 mmol/L
EGTA	60 mmol/L
Xylidyl Blue	110 mmol/L
Stabilizers, inactive ingredients and surface-active agents.	-

ASSAY PROCEDURE

	Blank	Standard	Test
Reagent	1000 µl	1000 µl	1000 µl
Standard	NA	10 µl	NA
Sample	NA	NA	10 µl
Mix the reagent and sample/standard in the above-mentioned ratio.			
Incubate the assay mixture for 10 mins at 37°C.			

CALCULATION

$$\text{Magnesium (mg/dL)} = \frac{\text{Abs. of sample} \times 2}{\text{Abs. of standard}}$$

REFERENCE VALUES FOR NORMAL PEOPLE

Men : 1.8 – 2.6 mg/dL.
Women : 1.9 – 2.5 mg/dL.
Children : 1.5 – 2.3 mg/dL.
Neonates : 1.2 – 2.6 mg/dL.

PERFORMANCE CHARACTERISTICS

Measuring Range: The assay is linear between 0.1 - 5 mg/dL. If the Magnesium value exceeds linearity limit (above 5 mg/L), dilute the specimen suitably with normal saline and repeat the assay. In that case, assay value should be multiplied with the dilution factor to obtain correct Magnesium value of the specimen.

Interference: There is no significant interference in samples containing Bilirubin upto 20 mg/dL.

Precision: Precision studies has been carried out using quality control sera as shown below:

(n=10)	Within Run			Between Run		
Specimen Material	Mean (mg/dL)	SD (mg/dL)	CV %	Mean (mg/dL)	SD (mg/dL)	CV %
Low Value Serum	2.12	0.07	3.1	2.29	0.10	4.3
High Value Serum	4.33	0.04	0.9	3.88	0.04	1.1

Note: We recommend all the laboratories to establish its own accuracy and precision data.

QUALITY CONTROL

Inclusion of a normal value and abnormal value chemistry control serum in each test run ensures optimum quality control. Consistent use of same type and methodology of control serum provides between run precision and accuracy data for Magnesium. We recommend to produce such data on daily basis for greater accuracy

in assay system which include reagents, instrument, apparatus and operator.

PRECAUTIONS

If the Magnesium value exceeds 5 mg/dL then dilute the specimen suitably with normal saline and repeat assay. In such case multiply the result obtained with dilution factor to obtain correct Magnesium value.

BIBLIOGRAPHY

1. Endres DB, Rude RK, Mineral and Bone Metabolism In : Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry, 3rd ed. Philadelphia: WB Saunders Company 1999, p.1395 -1457.
2. Mann CK, Yoe JH. Spectrophotometric Determination of Magnesium with 1-Azo-2-hydroxy-3-(2,4-dimethyl-carboxanilido)-naphthalene-1'-(2-hydroxy benzene) Anal. Chem. Acta 1957 ; 16 : 155 - 60.

Symbol	Explanation	Symbol	Explanation
	Manufactured By		In Vitro Diagnostic Use
	Lot Number		Read Instructions Before Use
	Catalogue Number		Storage Temperature
	Manufacturing Date		Number of Tests / Volume
	Expiry Date		Do Not Reuse
	Protect from Sunlight		Keep Dry

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ISO 9001: 2015
ISO 13485: 2016
GMP
CE