MAGNESIUM SYSTEM PACK

(XB METHOD)

B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic Chem 400 (Fully Auto Biochemistry Analyzer)

BEACON

Code	Product Name	Pack Size
UNI27	Magnesium System Pack	4 x 20 ml

INTENDED USE

Diagnostic reagent for quantitative *in vitro* determination of Magnesium in human serum.

CLINICAL SIGNIFICANCE

Magnesium is an essential nutrient which is involved in many biochemical functions. It has a structural role in nucleic acids and ribosomal particles, required as an activator for many enzymes and has a role in energy producing oxidative phosphorylation.

Hypomagnesaemia results in the impairment of neuromuscular functions and may develop in severe prolonged diarrhoea, malabsorption syndromes, primary aldosteronism and diuretic therapy. Hypermagnesaemia is seen in renal glomerular failure and diabetic coma.

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 concentration in the specimen.

REAGENT COMPOSITION

Reagent 1 : Magnesium Reagent

Tris Buffer	< 200 mmol/l
Xylidyl Blue (l)	>0.05 mmol/l

REAGENT PREPARATION

Reagents are liquid. ready to use.

STABILITY AND STORAGE

The unopened reagents are stable till the expiry date stated on the bottle and kit label when stored at +2-+8°C.

On board stability: Min. 7 days if refrigerated (+8-+14°C) and not contaminated.

SPECIMEN COLLECTION AND HANDLING

Use unheamolyse serum.
It is recommended to follow NCCLS procedures (or similar standardized conditions).

Stability in serum

7 days	at+4 - +8°C
1 year	at –20°C

Discard contaminated specimens.

CALIBRATION

Calibration with the Beacon Multicalibrator is recommended.

QUALITY CONTROL

It's recommended to run normal and abnormal control sera to validate reagent performance

UNIT CONVERSION

mg/dl x 0.4114 = mmol/L

EXPECTED VALUES

Serum

Men	1.8 - 2.6 mg/dl
Women	1.9 - 2.5 mg/dl
Children	1.5 - 2.3 mg/dl
New Born	1.2 - 2.6 mg/dl

It is recommended that each laboratory verify this range or derives reference interval for the population it serves.

PERFORMANCE DATA

Data contained within this section is representative of performance on Beacon systems.

Data obtained in your laboratory may differ from these values.

Limit of quantification: 0.16 mg/dl
Linearity: 5.00 mg/dl
Measuring range: 0.16 – 5.00 mg/dl

PRECISION

Intra-assay precision Within run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	2.15	0.03	1.23
Sample 2	3.93	0.05	1.30

Inter-assay precision Run to run (n=20)	Mean (mg/dl)	SD (mg/dl)	CV (%)
Sample 1	3.80	0.070	1.83

COMPARISON

A comparision between Magnesium System Pack (y) and commercially available test (x) using 20 samples gave following results:

y = 0.982x + 0.005 mg/dl
r = 0.992

INTERFERENCES

Following substances do not interfere:
Bilirubin up to 40 mg/dl, triglycerides up to 2000 mg/dl.
Haemoglobin interferes because magnesium is relesed by erythrocytes.

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. To be handles by entitled and professionally educated person.

WASTE MENAGEMENT

Please refer to local legal requirements.

Parameter For B Auto 400, Unicorn 480, Bonavera Chem 400, Beaconic B400 & Beaconic Chem 400
(Fully Auto Biochemistry Analyzer)

TEST NAME	Magnesium
FULL NAME	Magnesium
PRI WAVE	546 nm
SEC WAVE	-
ASSAY/POINT	1 Point end
START	-
END	33
DECIMAL	2
UNIT	mg/dl
LINEARITY RANGE LOW	0.16
LINEARITY RANGE HIGH	5
SAMPLE VOLUME	2 µ l
REAGENT 1 (R1) VOLUME	200 µl
REAGENT 1 (R2) VOLUME	-
SUBSTRATE DEPLETED	-
LINEARITY	5 mg/dl
OUT OF LINEARITY RANGE	-
CALIBRATION TYPE	2 Point linear
POINTS	2
BLANK TYPE	Reagent
CONCENTRATION BLANK	0.00
CONCENTRATION STD	Refer calibrator value sheet.

NOTE

The program is made as per the in house testing, it can be modified as per requirements.

REFERENCES

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4. Bohoun C. Microdosage du magnesium dans divers milileux biologiques. Cliln Chim Acta 1962;7:811-7.
5. Sitzmann FC. Normalwerte. Munchen: Hans Marseille Verlag GmbH: 1986.p.166.
6. Tietz Textbook of Clinical Chemistry and Molecular Diagnostics. Burtis, C.A., Ashwood, E.R., Bruns, D.D.; 5th edition, WB Saunders Comp., 2012

SYMBOLS USED ON LABELS

REF Catalogue Number | Manufacturer | See Instruction for Use

LOT Lot Number | CONT Content | Storage Temperature

Expiry Date | IVD In Vitro Diagnostics

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