# **MAGNESIUM SYSTEM PACK**

# (XB METHOD)

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200, Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

Code	Product Name	Pack Size
BA227	Magnesium System Pack	4x20 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 diarrhea, 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 (I) >0.05 mmol/l

# REAGENT PREPARATION

Reagents are liquid. ready to use.

# STABILITY AND STORAGE

The unopened reagents are stable til the expiry date stated on the bottle and Kit label when stored at +2-+8  $^{\circ}$ 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 1year 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

 $\begin{array}{ll} \mbox{Limit of quantification:} & 0.16 \ mg/dl \\ \mbox{Linearity:} & 5.00 \ mg/dl \\ \mbox{Measuring range:} & 0.16 - 5.00 \ mg/dl \\ \end{array}$ 

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

y = 0.982x + 0.005 mg/dlr = 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 released by erythrocytes.

# WARNING AND PRECAUTIONS

For in vitro diagnostic use. To be handles by entitled and professionally educated person. MSDS will be provided on request.

# WASTE MANAGEMENT

Please refer to local legal requirements.

B Auto 200, Unicorn 230, Unicorn 120 & Bonavera Chem 200, Beaconic chem 200, Beaconic B200, Beaconic analyzer 120, Bonavera chem 100 (Fully Auto Biochemistry Analyzer)

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Test Name	MAGNESIUM			
Full Name	MAGNESIUM			
Pri Wave	546 nm			
Sec Wave	-			
Assay/point	1 Point End			
Start	-			
End	17			
Decimal	2			
Unit	mg/dl			
Linearity Range Low	0.16			
Linearity Range High	5			
Sample Volume	2 μΙ			
Reagent 1 (R1) Volume	200 μΙ			
Reagent 2 (R2) Volume	=			
Subsatrate 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.

Clinical diagnosis should not be made on findings of a single test results, but both clinical and laboratory data.

# REFERENCES

- 1. Thomas L. Clinical Laboratory Diagnostics. 1sted. Frankfurt: TH-Books Verlagsgeselischaft, 1998.p.231-41.
- 2. Endres DB, Rude RK. Mineral and bone metabolism. In: Burtis CA, Ashwood ER, editors. Tietz Textbook of Clinical Chemistry. 3rd ed. Philadelphia: W.B Saunders Company; 1999. p. 1395-1457.

- 3. Mann CK, Yoe JH. Spectrophotometric determination of magnesiumwith 1- Az0-2-hydroxy-3-(2.4-dimethyl-carboxanilido)-naphthalene-1-(2- hydroxybenzene). Anal ChimActa 1957:16:155-60.
- 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 Textbookof Clinical Chemistry and Molecular Diagnostics. Buttis, C.A., Ashwood, E.R., Bruns, D.D.; 5th edition, W8 Saunders Comp., 2012.

# Symbols Used On Labels

REF Catalogue Number \*\*\*

Manufacturer

See Instruction for Use

LOT

Lot Number

CONT

Content

Expiry Date

IVD

Storage Temperature
In Vitro Diagnostics

BEA/24/MAG/SB/IFU Ver-03 BSCIC ISO 900



