ELITechGroup
CLINICAL SYSTEMS

ELITech Clinical Systems
Selectra Pro Series Analyzers
MAGNESIUM XYLIDYL

References : ***Kit composition :***

☛*MAGX-0230* *8 x 8.8 mL* ***R*** *8 x 8.8 mL*

***In vitro* diagnostic reagent, for professional use only**

CAUTION: Federal Law restricts this device to sale by or on the order of a licensed healthcare practitioner (Rx ONLY)

INTENDED USE

ELITech Clinical Systems MAGNESIUM XYLIDYL is intended for the quantitative *in vitro* diagnostic determination of magnesium in human serum and plasma on ELITech Clinical Systems Selectra Pro Series Analyzers. Magnesium measurements are used in the diagnosis and treatment of hypomagnesemia (abnormally low plasma levels of magnesium) and hypermagnesemia (abnormally high plasma levels of magnesium).
It is not intended for use in Point of Care settings*.

CLINICAL SIGNIFICANCE [1-2]

In blood, approximately 55% of the magnesium is free, 30% is protein-bound (mainly associated with albumin) and 15% is complexed with various anions. Magnesemia measures total magnesium but only free magnesium is biologically active. Hence protein levels must be considered for the proper interpretation of total serum magnesium levels. Magnesium serves as a cofactor and activator of numerous enzyme systems and plays an active role in bone mineral homeostasis and the neuromuscular function. Hypomagnesemia can result from malabsorption or losses associated with chronic renal failure (alcoholism, diabetes, some drugs, increased sodium or calcium excretion) or intestinal disorders such as severe diarrhea. Hypermagnesemia is usually associated with excessive intake resulting from therapy.

METHOD

Colorimetric - Xylidyl Blue
End Point

PRINCIPLE [3]

Xylidyl blue in the reagent combines with the magnesium from the sample to form a red-purple chelate. Calcium is bound by glycoletherdiamine-N,N,N',N'-tetraacetic acid (EGTA) and is prevented from interfering with the test. The simultaneous increase in absorbance at 505-510 nm and decrease of the 620-630 nm absorbance is proportional to the magnesium concentration in the sample.

REAGENTS COMPOSITION

Reagent : R

Xylidyl blue	110 µmol/L
EGTA	60 µmol/L
Ethanolamine	750 mmol/L

MATERIAL REQUIRED BUT NOT PROVIDED

- ELICAL 2, calibrator, ref.CALI-0580, 4 x 3 mL.
- ELITROL I, control serum, ref.CONT-0080, 10 x 5 mL.
- ELITROL II, control serum, ref.CONT-0180, 10 x 5 mL.
- General Laboratory equipment.

PRECAUTIONS AND WARNING

- This reagent is for professional *in vitro* diagnostic use only.
- Reagent R is classified as hazardous:

DANGER.Causes serious eye damage. Causes skin irritation. Wear protective gloves/protective clothing/eye protection/face protection. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor. IF ON SKIN: Wash with plenty of soap and water. If skin irritation occurs: Get medical advice/attention. Take off contaminated clothing and wash it before reuse.

- For more information, refer to the Safety Data Sheet (SDS).
- Take normal precautions and adhere to good laboratory practice.
- Use clean or single use laboratory equipment only to avoid contamination.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local, state and Federal regulatory requirements.

STABILITY OF REAGENTS

Store at 2-8 °C and protect from light.

The reagent is stable until the expiry date stated on the label.

On board stability: Refer to § PERFORMANCE DATA.

PREPARATION

The reagent is ready to use.

REAGENT DETERIORATION

The reagent solution should be clear. Cloudiness would indicate deterioration.

SAMPLES [4]

- Specimen

Serum free from hemolysis.
Lithium heparinized plasma.

☛- Warnings and precautions

Venipuncture should be performed prior to the administration of drugs.

- Storage

Samples are stable for 7 days at room temperature or 2-8 °C, and 1 year at -20 °C.

REFERENCE VALUES [5]

Serum, plasma: 1.53 - 2.55 mg/dL (0.63 - 1.05 mmol/L)

Note : *It is recommended for each laboratory to establish and maintain its own reference values. The data given here are only for information.*

Conversion factor : mg/dL x 0.4114 = mmol/L

☛PROCEDURE

See application included in the barcode indicated at the end of the insert.

Important set-up information:

MAGNESIUM XYLIDYL reagent can be weakly contaminated by TOTAL PROTEIN PLUS on Selectra ProM.

In order to avoid contamination on Selectra ProM, program the following incompatibilities :

Software	Menu	Parameter
TouchPro	Probe incompatibilities	incompatibility / PROTEIN - MAGNESIUM
Other	Needle incompatibility	PROTEIN : MAGNESIUM

CALIBRATION

For calibration, multiparametric calibrator Elical 2 must be used. Its value is traceable to the atomic absorption reference method.

Calibration frequency: refer to § PERFORMANCE DATA.

QUALITY CONTROL

To ensure adequate quality, control sera such as ELITROL I (normal control) and ELITROL II (abnormal control) should be used. These controls must be performed and validated before the patient samples are assayed. The control frequency must be at least once a day, after each calibration and should be adapted to Quality Control procedures of each laboratory and the regulatory requirements. Results should be within the defined ranges. If values fall outside of the defined ranges, each laboratory should take corrective measures. Quality control materials should be used in accordance with local, state, and/or federal guidelines.

PERFORMANCE DATA at 37 °C on ELITech Clinical Systems Selectra ProM Analyzers

- Measuring range

Determined according to CLSI EP6-A[6] protocol, the measuring range is from 0.20 to 5.00 mg/dL (0.08 to 2.06 mmol/L).

- Limit of Detection (LoD) and Limit of Quantification (LoQ)

Determined according to CLSI EP17-A[7] protocol.

LoD = 0.06 mg/dL (0.02 mmol/L)
LoQ = 0.20 mg/dL (0.08 mmol/L)

- Precision

Determined according to CLSI EP5-A2[8] protocol.

		Mean		Within-run	Total
	n	mg/dL	mmol/L	CV (%)	
Level 1	80	1.44	0.59	0.7	2.7
Level 2	80	2.56	1.05	0.7	3.7
Level 3	80	3.83	1.58	0.6	3.7

- Correlation

A comparative study has been performed between an ELITech Clinical Systems Selectra ProM Analyzer and another FDA-Approved system equipment (Xylidyl Blue method) on 118 human serum samples according to CLSI EP9-A2[9] protocol.
The sample concentrations were between 0.26 and 4.55 mg/dL (0.11 and 1.87 mmol/L).

The parameters of the linear regressions are as follows:

Correlation coefficient: (r) = 0.993
Linear regression: y = 1.008 x + 0.01 mg/dL

☛- Limitations, Interferences

- Due to potentiel contamination by TOTAL PROTEIN PLUS refer to § PROCEDURE.

- Do not report results outside of the usable range.

- Studies have been performed to determine the level of interference from different compounds according to CLSI EP7-A2[10] protocol. Recovery is within ±10% of initial value of magnesium concentration of 1.50 mg/dL, 2.50 mg/dL and 3.90 mg/dL.

Unconjugated Bilirubin:	No significant interference up to 30 mg/dL (513 µmol/L).
Conjugated Bilirubin:	No significant interference up to 29.5 mg/dL (504 µmol/L).
Triglycerides:	No significant interference up to 2000 mg/dL (22.60 mmol/L).
Calcium:	No significant interference up to 20 mg/dL (4.99 mmol/L).
Acetylsalicylic acid:	No significant interference up to 200 mg/dL.
Ascorbic acid:	No significant interference up to 20.0 mg/dL (1136 µmol/L).
Acetaminophen:	No significant interference up to 30 mg/dL.

- In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgM type (Waldenstrom's macroglobulinemia) can cause unreliable results.[11]

- Many other substances and drugs may interfere. Users should refer to the literature references. [12,13]

- The results of this assay should be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

- On board stability/Calibration frequency

On Board Stability: 7 days
Calibration frequency: 2 days

Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

.../...

* : US FDA only
☛: Modification from previous version

(04/2016)
FTNA-MAGX-v3

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PERFORMANCE DATA at 37 °C on ELITech Clinical Systems Selectra ProS Analyzers

- Measuring range

Determined according to CLSI EP6-A[6] protocol, the measuring range is from 0.20 to 5.00 mg/dL (0.08 to 2.06 mmol/L).

- Limit of Detection (LoD) and Limit of Quantification (LoQ)

Determined according to CLSI EP17-A[7] protocol.

LoD = 0.08 mg/dL (0.03 mmol/L)
LoQ = 0.20 mg/dL (0.08 mmol/L)

- Precision

Determined according to CLSI EP5-A2[8] protocol.

		Mean		Within-run	Total
	n	mg/dL	mmol/L	CV (%)	
Level 1	80	1.43	0.59	1.3	3.7
Level 2	80	2.49	1.02	1.4	3.9
Level 3	80	4.09	1.68	1.1	3.8

- Correlation

A comparative study has been performed between an ELITech Clinical Systems Selectra ProS Analyzer and another FDA-Approved system equipment (Xylidyl Blue method) on 120 human serum samples according to CLSI EP9-A2[9] protocol.
The sample concentrations were between 0.2 and 4.99 mg/dL (0.08 and 2.05 mmol/L).

The parameters of the linear regressions are as follows:

Correlation coefficient: (r) = 0.998
Linear regression: y = 1.016 x - 0.05 mg/dL (0.2 mmol/L)

☛- Limitations, Interferences

- Do not report results outside of the usable range.

- Studies have been performed to determine the level of interference from different compounds according to CLSI EP7-A2[10] protocol. Recovery is within ±10% of initial value of magnesium concentration of 1.50 mg/dL, 2.50 mg/dL and 3.90 mg/dL.

Unconjugated Bilirubin:	No significant interference up to 30 mg/dL (513 µmol/L).
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- The results of this assay should be interpreted in conjunction with other diagnostic test results, clinical findings and the patient's medical history.

- On board stability/Calibration frequency

On Board Stability: 7 days

Calibration frequency: 2 days

Recalibrate when reagent lots change, when quality control results fall outside the established range, and after a maintenance operation.

☛SYMBOLS

- IVD In vitro diagnostic medical device
- Consult instruction for use
- Manufacturer
- REF Catalogue number
- CE European Conformity
- Temperature limitation
- LOT Batch code
- Use by
- R Reagent

☛BIBLIOGRAPHY

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☛ **IMPORTANT NOTE/see § PROCEDURE:**
- Contamination risk

Magnesium Xylidyl 0
550 FTNA-MAGX

(04/2016)
FTNA-MAGX-v3

☛: Modification from previous version

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