

MAGNESIUM ENVOY

REF **MAGX-0850**



PIEVY-MAGX-2-v4 (12/2018)

ENGLISH - EN

For *in vitro* diagnostic use, for professional use only

INTENDED USE

MAGNESIUM ENVOY is an *in vitro* diagnostic reagent intended for the quantitative determination of magnesium in human serum and plasma samples using the Envoy Analyzers.

CLINICAL SIGNIFICANCE

In blood, approximately 55% of the magnesium is free, 30% is protein-bound (mainly associated with albumin) and 15% is complexed with various anions. Magnesium 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 AND PRINCIPLE

Colorimetric - Xylidyl blue -End Point
Xylidyl blue in the reagent combines with the magnesium from the sample to form a red-purple chelate. Calcium is bound by glycoethyrdiamine-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

MAGNESIUM ENVOY Reagent R contains:

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

WARNINGS AND PRECAUTIONS

- This reagent kit 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.

PREPARATION

The reagent is ready to use.

REAGENT DETERIORATION

The reagent solution should be clear. Cloudiness would indicate deterioration. Do not use reagent if there is visible evidence of biological, chemical or physical deterioration.

DAMAGED PACKAGING

Do not use the reagent if the damages of packaging might have an effect on the product performance (leakages, pierced boat).

STORAGE AND STABILITY

Store these reagents at 2 to 8 °C. Do not freeze. Do not use after expiration dates indicated on the bottle labels.

On board stability : Refer to § PERFORMANCE DATA.

SAMPLES

SPECIMENS

- Serum free from hemolysis.

- Lithium heparinized plasma.

- Do not use other specimens.

WARNING AND PRECAUTIONS

- According to Good Laboratory Practice, venipuncture should be performed prior to the administration of drugs.

STORAGE AND STABILITY

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

EXPECTED VALUES

Published reference ranges for magnesium are listed below:

Reference Range	Conventional Units	SI Units
Serum, plasma :	1.53 - 2.55 mg/dL	0.63 - 1.05 mmol/L

Note: *The quoted range should serve as a guide only. It is recommended that each laboratory verifies this range or establishes a reference interval for the intended population.*

PROCEDURE

MATERIALS PROVIDED

The MAGNESIUM ENVOY Kit includes the following components:

- 8 x 33.2 mL boats of MAGNESIUM ENVOY Reagent

MATERIALS REQUIRED BUT NOT PROVIDED

- CALI-0550 ELICAL 2 4 x 3 mL
- CONT-0060 ELITROL I 10 x 5 mL
- CONT-0160 ELITROL II 10 x 5 mL
- WASH SOLUTION ENVOY (product ref. SLWE-0850)*.

- Envoy Analyzer

- General Laboratory Equipment

- Do not use materials that are not required as indicated above

* required only if CHOLESTEROL ENVOY Kit (product ref.CHSL-0850) is on-board.

REAGENT INSTALLATION AND USE

Refer to the Operator Manual for information on installing reagents, and programming the analyzer, and running, calibrators, controls and samples. The test parameters are available at the end of this Instructions For Use.

If **CHOLESTEROL ENVOY Kit** (product ref.CHSL-0850) is on-board, **Wash Solution ENVOY** (product ref.SLWE-0850) must be installed in the **Basic wash position** and **Additional Wash** must be programmed as indicated on § **APPLICATION PARAMETERS**.

Before installing, record the installation date on the label. Mix the reagents by gently inverting reagent bottles several times, open the bottles and insert the unit into the designated position on the reagent tray. Let reagents equilibrate on the instrument for at least 30 minutes before use.

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 guidelines.

CALCULATION

All calculations are performed by the instrument. To calculate the result in SI units (mmol/L), multiply the result in conventional units (mg/dL) by 0.4114.

WASTE MANAGEMENT

Disposal of all waste material should be in accordance with local and legal requirements.

PERFORMANCE DATA ON ENVOY 500+ ANALYZER

MEASURING RANGE

Determined according to CLSI⁽⁶⁾ EP6-A 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⁽⁷⁾ EP17-A protocol:

LoD = 0.15 mg/dL (0.06 mmol/L)
LoQ = 0.20 mg/dL (0.08 mmol/L).

PRECISION

Determined according to CLSI⁽⁹⁾ EP5-A2 protocol.

Sample	n	Mean		Within-run CV (%)	Total CV (%)
		mg/dL	mmol/L		
Level 1	80	1.52	0.63	2.1	4.6
Level 2	80	2.37	0.97	1.2	3.8
Level 3	80	3.36	1.38	0.8	3.6

CORRELATION

A comparative study has been performed between an Envoy 500 Analyzer and an FDA-approved system equipment (colorimetric method) on 120 human serum samples according to CLSI⁽⁸⁾ EP9-A2 protocol. The sample concentrations were between 0.23 and 4.92 mg/dL (0.09 and 2.02 mmol/L).

The parameters of the linear regressions are as follows :
Correlation coefficient: (r) = 0.996
Linear regression: y = 1.070 x - 0.18 mg/dL (0.07 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⁽¹⁰⁾ EP7-A2 protocol. Recovery is within ± 10% of initial value at magnesium concentration of 1.50 mg/dL, 2.50 mg/dL and 3.90 mg/dL for low, medium and high concentration accordingly.

Unconjugated bilirubin:	No significant interference up to 30.0 mg/dL (513 µmol/L).
Conjugated bilirubin:	No significant interference up to 29.5 mg/dL (504 µmol/L).
Calcium:	No significant interference up to 20 mg/dL
Triglycerides:	No significant interference up to 3000 mg/dL (33.90 mmol/L).
Ascorbic acid:	No significant interference up to 20.0 mg/dL (1136 µmol/L).
Acetylsalicylic Acid:	No significant interference up to 200 mg/dL.
Acetaminophen:	No significant interference up to 30 mg/dL.

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

- Many other substances and drugs may interfere. Some of them are listed in Young.^(12,13)

- The results of this assay should only 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 : 10 days

Calibration frequency: 5 days

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

ESPAÑOL - ES

Para el diagnóstico *in vitro*, de uso exclusivo profesional

USO PREVISTO

MAGNESIUM ENVOY es un reactivo de diagnóstico *in vitro* diseñado para la determinación cuantitativa de magnesio en muestras de suero y plasma humanos en los equipos Envoy.

SIGNIFICADO CLÍNICO

En la sangre, aproximadamente el 55% del magnesio es libre, 30% está unido a proteínas (principalmente asociado con albúmina) y 15% en complejo con diversos aniones. La magnesemia representa el magnesio sanguíneo total, pero solamente el magnesio libre que es biológicamente activo. Por lo tanto los niveles de proteína deben ser considerados para la interpretación correcta de los niveles totales de magnesio en suero. El magnesio sirve como un cofactor y activador de numerosos sistemas enzimáticos y desempeña un papel activo en la homeostasis mineral ósea y la función neuromuscular. La hipomagnesemia puede ser resultado de la mala absorción o pérdidas asociadas a la insuficiencia renal crónica (alcoholismo, diabetes, algunos medicamentos, el aumento de la excreción de sodio o calcio) o trastornos intestinales, como diarrea severa. La hipermagnesemia se asocia generalmente con la ingesta excesiva resultante de un tratamiento terapéutico.

MÉTODO Y PRINCIPIO

Colorimétrico - Azul Xylidyl - Punto final.

El azul Xylidyl en el reactivo se combina con el magnesio de la muestra para formar un quelato de color rojo púrpura. El calcio es retenido por el ácido glicoleterdiamina-N, N, N', N'-tetraacético (EGTA) para no interferir con la prueba. El aumento simultáneo en la absorbancia a 505-510 nm y la disminución de la absorbancia a 620- 630 nm es proporcional a la concentración de magnesio en la muestra.

REACTIVOS

COMPOSICIÓN

MAGNESIUM ENVOY Reactivo R contiene:

Azul Xylidyl	110	µmol/L
EGTA	60	µmol/L
Etanolamina	750	mmol/L



