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 MAGNISIUM 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
In blood, approximately 50% of the magnesium is free, 30% is protein-bound (mainly associated with albumin) and 10% is complexed with various anions. Magnesium measurements 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 enzymes and plays an active role in bone mineral homeostasis and the neuromuscular function. Hypermagnesemia 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 - Xylydyl Blue
End Point

PRINCIPLE
Xylydyl blue in the reagent combines with the magnesium from the sample to form a red-purple chelate. Calcium is bound by glycolethamidene-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.

REAAGENTS COMPOSITION
Reagent:  R
Xylydyl blue 110 μmol/L
EGTA 60 μmol/L
Ethanolamine 750 mM

MATERIAL REQUIRED BUT NOT PROVIDED
- ELICAL 2, calibrator, ref.CALI-0580, 4 x 3 mL.
- ELICAL T, control serum, ref.CONT-0080, 10 x 5 mL.
- ELICAL 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 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 and 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.

STORAGE
- On board stability: Refer to § PERFORMANCE DATA.
- Stability of reagents:
  - ELICAL 2, calibrator, ref.CALI-0580, 4 x 3 mL.
  - ELICAL T, control serum, ref.CONT-0080, 10 x 5 mL.
  - ELICAL II, control serum, ref.CONT-0180, 10 x 5 mL.
  - General Laboratory equipment.

QUALITY CONTROL
- 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.

PERFORMANCE DATA at 37 °C on ELITech Clinical Systems Selectra ProM Analyzers
- Measuring range
  - Determined according to CLSI EP9-A2 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)
    - LoD = 0.06 mg/dL (0.02 mmol/L)
    - LoQ = 0.20 mg/dL (0.08 mmol/L)
  - Precision
    - Determined according to CLSI EP8-A2 protocol.

<table>
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<tr>
<th>n</th>
<th>Mean</th>
<th>Within-run CV (%)</th>
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- Correlation
  - A comparative study has been performed between an ELITech Clinical Systems Selectra ProM Analyzer and another FDA-Approved system equipment (Xylydyl blue method) on 118 human serum samples according to CLSI EP2-A 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:
      \[ y = 1.038 x + 0.01 \text{ mg/dL} \]

  - Limitations, Interferences
    - Due to potential 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 EP2-A2 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.
      - Uncompurated Bilirubin: No significant interference up to 30 mg/dL (513 μmol/L).
      - Compurated Bilirubin: No significant interference up to 20.5 mg/dL (304 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).
      - Anisaldehydic acid: No significant interference up to 200 mg/dL.
      - Ascorbic acid: No significant interference up to 20.0 mg/dL (1136 μmol/L).
      - Xylydyl blue: No significant interference up to 30 mg/dL.

    - In very rare cases, monoclonal gammopathies (multiple myeloma), in particular IgH type (Waldenstrom’s macroglobulinemia) can cause unreliable results.\(^{(1)}\)
    - Many other substances and drugs may interfere. Users should refer to the literature references.\(^{(10)}\)
    - 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.
**PERFORMANCE DATA at 37 °C on ELITech Clinical Systems Selectra ProS Analyzers**

- **Measuring range**
  Determined according to CLSI EP7-A2(9) protocol, the measuring range is from 0.20 to 2.60 mmol/L.
- **Limit of Detection (LoD) and Limit of Quantification (LoQ)**
  Determined according to CLSI EP7-A2(9) 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(6) protocol.

<table>
<thead>
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<th>Within-run</th>
<th>Total</th>
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- **Correlation**
  A comparative study has been performed between an ELITech Clinical Systems Selectra ProS Analyzer and another FDA-Approved system equipment (Xyldyl Blue method) on 120 human serum samples according to CLSI EP7-A2(9) protocol. The sample concentrations were between 0.2 and 4.99 mg/dL (0.08 and 2.06 mmol/L). The parameters of the linear regressions are as follows:
  - Correlation coefficient: \( r = 0.998 \)
  - Linear regression: \( y = 1.016 x - 0.05 \text{ mg/dL (0.2 mmol/L)} \)

- **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(9) 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.
  - Other substances and drugs may interfere. Users should refer to the literature references (12,13).
  - 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.

**BIBLIOGRAPHY**