

ANA BIO ISP Magnesium

(Xylidyl blue Method)

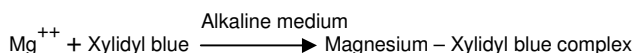
For Miura Instruments

Intended Use

Magnesium is used for the quantitative determination of magnesium concentration in serum and plasma based on the colorimetric Xylidyl blue method.

Principle

Magnesium ions react with xylidyl blue in an alkaline medium to form purple coloured complex. The intensity of the purple colour formed is directly proportional to the magnesium concentration.



Note: Calcium is excluded from the reaction by complexing with Ethylene Glycol Tetraacetic Acid.

Components & Concentration of Reagents

| Reagent | Component | Concentration |
|---------|---|---------------|
| Reagent | Tris Buffer | 200 mmol/L |
| | Xylidyl Blue | 0.10 mmol/L |
| | EDTA | 0.10 mmol/L |
| | Stabilizers, excipients & surface active agents | |

Reagent storage and stability

The reagent and standard are ready-to-use and are stable till expiry, when stored at 2° - 8°C. DO NOT FREEZE THE REAGENT.

Reagent Preparation

Ready to use liquid reagent. After opening the reagent is stable for 30 days if closed, stored at 2° - 8°C, and protect from direct light. Do not mix different batches.

Specimen collection and preservation

Blood should be collected in a clean dry container. Serum is preferred but heparinized plasma can also be used. EDTA plasma and haemolysed specimen should not be used. Magnesium is stable in serum or plasma for 7days when stored at 2-8°C and 1 year at - 20°C. Centrifuge samples containing precipitate before performing the assay.

Automation

This kit, though developed and manufactured to be used as manual assay and with I.S.E. Miura Analyzer, can be used also with other analyzers able to meet the specifications indicated in section "Reaction conditions – Test procedure" Application sheets are available for automatic instruments.

All applications not explicitly approved by KDPL. Cannot be guaranteed in terms of performance, and must there be established by the operator.

Calibration

For Calibration use the "Multicalibrator"

Calibration Stability

For the instrumentation series Miura, the calibration is recommended to be done every 10 days.

Materials required but not supplied in the kit

Calibrators and controls

Assay guidelines for Analyzer I.S.E. Miura

| | | |
|-------------------|-----------------|------|
| Analyte Name | Magnesium | |
| Method Code | MG | |
| Type | End-Point | |
| Unit | Mg/dl | |
| Filter F1 | 546 nm | |
| Blank in | Use | |
| Step | Reaction Volume | U.M. |
| Volume reagent R1 | 200 | µl |
| Sample Volume | 2 | µl |
| Final Incubation | 300 | Sec. |

Normal Range

| | |
|----------|-----------------|
| Men | 1.8 - 2.6 mg/dl |
| Women | 1.9 - 2.5 mg/dl |
| Children | 1.5 - 2.3 mg/dl |
| Neonates | 1.2 - 2.6 mg/dl |

Note: Expected range varies from population to population and each laboratory should establish its own normal range.

Limitation

Reaction is linear up to 5 mg/dl. For higher values, dilute the sample with normal saline and perform the assay. Multiply the final result by dilution factor to get the real value.

Quality Control

To ensure adequate quality control measures, it is recommended that each batch should include a normal and an abnormal commercial reference control serum. It should be realized that the use of quality control material checks both instrument and reagent functions together. Factors which might affect the performance of this test include proper instrument function, temperature control, cleanliness of glassware, Wavelength setting, Expiration date of reagents and accuracy of prob aspiration.

Accuracy-Recovery

Magnesium added to a serum matrix containing known amounts of glucose gave an average recovery of 101%.

Precision of the Method

| Within-run | | | | | |
|-------------|-------|------|-------|---------|---------|
| Range | U.M | Mean | S.D. | C.V.(%) | No. run |
| Low | mg/dl | 1.07 | 0.05 | 4.70 | 20 |
| High | mg/dl | 4.21 | 0.07 | 1.66 | 20 |
| Between run | | | | | |
| Range | U.M | Mean | S.D. | C.V.(%) | No. run |
| Low | mg/dl | 1.07 | 0.016 | 1.49 | 20 |
| High | mg/dl | 4.21 | 0.124 | 2.95 | 20 |














Sensitivity

At 546 nm a concentration of 0.1 mg/dl of Magnesium can estimate.


References

1. Tietz NW, ed. **Clinical Guide to Laboratory Tests**, 3rd ed. Philadelphia, Pa: W.B. Saunders Company, 1995:380-382.
2. Endres DB, Rude RK, Mineral and Bone Metabolism in; Burtis CA, Ashwood ER, editors, **Teitz Text book of Clinical Chemistry 3rd ed. Philadelphia**, Pa; W.B. Saunders Company 1999,p. 1395-1457.
3. Mann CK, Yoe JH. Spectrophotometric Determination of Magnesium with 1-Azo-2-hydroxy-3-(2,4-dimethyl-carboxanilido)-naphthalene-1-(2-hydroxy benzene) **Anal Chem. Acta** 1957; 16;155-60.
4. Farrell EC "Magnesium" in Clinical Chemistry. Theory, Analysis and Correlation. The CV Mosby Company. Kaplan LA, Pesce AJ (Ed) 1984; Chapter 55; 1065-70.
5. In-house test data. **Kee Diagnostics Pvt. Ltd.**

Symbols

| | | | |
|---|----------------------|---|--------------------------|
|  | In Vitro Diagnostics |  | Caution |
|  | Batch No. |  | Product Expiry Date |
|  | Content |  | Manufactured By |
|  | Read Instructions |  | Date of Manufacture |
|  | Storage Temperature |  | Keep Dry |
|  | Catalogue No. |  | Fragile |
| | |  | Keep away from sun light |



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