TECO DIAGNOSTICS
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MAGNESIUM COLORIMETRIC METHOD TC MATRIX

INTENDED USE
For the quantitative determination of magnesium concentration in serum or plasma on TC Matrix analyzers.

SUMMARY AND EXPLANATION OF THE TEST
Magnesium is one of the most abundant cations in the body involved in many biochemical reactions. Many enzymes such as alkaline phosphatese, ALP require magnesium as activator. Magnesium is also necessary for the stability of conformational structure for many macromolecules such as DNA, RNA, etc.

Although little is know about the regulation of magnesium levels in blood, it has been reported that para-thyroid gland is involved. Increased level of magnesium has been shown in Addison's disease, diabetic acidosis, renal failure and vitamin D intoxication, and decreased level of magnesium are observed in diabetes, diuretics, hyperthyroidism, hyperalimentation, alcoholism, myocardial infarction, congestive heart failure and liver cirrhosis.

Magnesium forms a colored complex with calmagite in alkaline medium to produce a red complex that is measured spectrophotometrically at 520 nm. EGTA serves to complex and prevent calcium interference, and a surfactant eliminates the effect of protein. The color produced is proportional to the magnesium concentration.

The TC Matrix System automatically proportions the appropriate sample and reagent volumes into the cuvette. The system monitors the change in absorbance at 520 nanometers. This change in absorbance is directly proportional to the concentration of magnesium in the sample and is used by the TC Matrix System to calculate and express the magnesium concentration.

$$\text{Calmagite} + Mg^{2+} \xrightarrow{OH^-} Mg^{2+}\text{ - Calmagite complex}$$

REAGENT CONTENTS:
Each kit contains: Four Magnesium Reagent 1(Colorless, 4×20 ml)
Four Magnesium Reagent 2(Purple, 4×36 ml)
Instruction Insert.

REAGENT PREPARATION
No preparation is required.

REAGENT COMPOSITION
2-Ethylaminoethanol : 6% w/v
Calmagite : 0.15 mmol/L
pH: >13.0
Also non-reactive chemicals for optimal system performance.

REAGENT STORAGE AND STABILITY
Magnesium reagent stored unopened at 2-8°C is stable until the expiration date shown on the bottle label. Once opened, magnesium reagent is stable for 7 days, unless the expiration date is exceeded.
DO NOT FREEZE.

SPECIMEN COLLECTION AND HANDLING
1. The test can be performed on serum or plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and is allowed to clot. The serum is then separated from the clot. A maximum limit of two hours from the time of collection is recommended.
2. Separated serum or plasma should not remain at room temperature longer than 8 hours. If assays are not completed within 8 hours, serum and plasma should be stored at 2°C to 8°C. If assays are not completed within 48 hours, or the separated sample is to be stored beyond 48 hours, samples should be frozen at -15°C to -20°C. Frozen samples should be thawed only once. Analyte deterioration may occur in samples that are repeatedly frozen and thawed.
3. For plasma, add whole blood directly into a tube containing anticoagulant. Acceptable anticoagulants are listed in the "LIMITATIONS" section.

CALIBRATION
1. Calibrator required: TECO MULTI Calibrator.
2. The system must have a valid calibration in memory before controls or patient samples can be run.
3. The TC Matrix system will automatically perform checks on the calibration and produce data at the end of calibration.

Note: Refer to the TC Matrix manual for further instructions on calibrating the instrument

MATERIALS NEEDED BUT NOT SUPPLIED WITH REAGENT KIT
TECO MULTI Calibrator
At least two levels of control material.

LIMITATIONS
1. The anticoagulants EDTA, Potassium Oxalate, Sodium Fluoride and Sodium Citrate were found to be incompatible with this method.
2. The anticoagulants Ammonium Heparin, Lithium Heparin and Sodium Heparin were found to be compatible with this method.

INTERFERENCE
1. Hemoglobin levels up to 400 mg/dl, Triglyceride levels up to 1000 mg/dl and Bilirubin levels up to 30 mg/dl were found to exhibit negligible interference.
2. A number of drugs and substances affect the concentration of magnesium. See Young, et.al.[10]

EXPECTED VALUE
1.7 to 2.8 mg/dL or 0.70 to 1.15 mmol/L

PRECAUTIONS:
1. For in vitro diagnostic use only.
2. Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.
3. Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.
4. Recommended to test alone.

PROCEDURES

TEST NAME:	MG	R1:	180
TEST NO.		R2:	220
FULL NAME:	Magnesium	SAMPLE VOLUME:	4
REFERENCE NO.:		R1 BLANK:	/
ANALY.TYPE:	Endpoint	MIX REAG. BLANK:	0.1 - 1.5
PRI. WAVE :	546 nm	CONCENTRATION:	/
SECON. WAVE:	630 nm	LINEARITY LIMIT:	0.1 – 7.0
TREND:	Ascending	SUBSTRATE LIMIT:	/
REACT. TIME:	0 - 10	FACTOR:	/
INCUBATE TIME:	4	PROZONE CHECK:	/
UNIT:	mg/dl	Q1: / Q2: / Q3: / Q4: /	
PRECISION:	0.1	PC: / ABS.: /	
Calibration Type: Calib + Reag. Blank		Calibration Rule: Two-point Linear	

PERFORMANCE CHARACTERISTICS

Analytical Range: 0.1- 7.0 mg/dL
For magnesium analyte by Magnesium Reagent on TC Matrix System, this method has been demonstrated to be linear from 0.1-7.0 mg/dL

Accuracy: Comparison study was performed on TC Matrix System from 40 samples. Beckman Coulter Magnesium Reagent was used to compare with Magnesium Reagent. The results of this study in yield a correlation coefficient of 0.99 with a regression equation of y=1.001X -0.06.

Precision: Within Run precision for Magnesium Reagent Set was determined following a modification of NCCLS EP5-A.Two commercial human serum were assayed on TC Matrix System for 25 times.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	2.1	4.5
Standard Deviation (mg/dl)	0.03	0.1
Coefficient of Variation (%)	1.4	2.2

Run-Day precision for Magnesium Reagent was determined following a modification of NCCLS EP5-A.Two commercial human serum were assayed on TC Matrix Systems five times per day for five days for the total of 25 values.

Sample	Sample 1	Sample 2
N	25	25
Mean (mg/dl)	2.1	4.4
Standard Deviation (mg/dl)	0.03	0.09
Coefficient of Variation (%)	1.4	2.0

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