產品型號: BC-0024
V2.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑鎂試劑(MG) - Calmagite test

效能：

用於臨床實驗體外定量分析人體血清中鎂離子的含量。

臨床意義：

鎂(MG)爲人體必需元素，和鈣共存於骨骼和肌肉細胞中，爲細胞內僅次於鉀的重要陽離子，爲醣類代謝重要的活化劑。健康人血中鎂的濃度非常穩定，但在利尿劑治療者、糖尿病及體內失調的情形，血中鎂會有變動。血清鎂減少和鈣一樣會造成心律不整；鎂增加會壓制心臟及呼吸中樞神經傳導。

方法學原理：

血清中鎂離子在鹼性條件下，與 calmagite 染料生成紫紅色錯合物，以 505nm 波長比色，顏色的深淺與血清中的鎂含量成正比。

試劑：

1. 產品規格:
   詳見外盒包裝標示。
2. 成份與濃度：

	成份	濃度
R_1:	EGTA	0.075mmol/L
	KCl	134 mmol/L
	KOH	176 mmol/L
R_2:	Calmagite	0.064mmol/L

保存溫度：

2-8℃避光保存，請勿冰凍。

檢體：

新鮮血清。

操作步驟：

1. 測定主波長：505 nm　　測定副波長：700nm
   溫度：37℃　　比色杯光徑：1.0 cm
2. 本試劑盒爲液態雙試劑，可直接上機使用。

加入物	測定管
檢體(ml)	0.01
R_1 (ml)	0.8
混勻，37℃保溫 3 分鐘	
R_2 (ml)	0.2

以去離子水調零點，分別在 505nm 及 700nm 處檢測各管吸光度 A，$A=A_{505}-A_{700}$。混勻、保溫 1 分鐘，檢測檢體管初始吸光值 A_1，準確間隔 1 分鐘後再檢測終末吸光值 A_2。

結果計算

樣本中鎂含量（mg/dL）

$$= \frac{A_{樣本}}{A_{標準}} \times \text{鎂標準濃度 mg/dL}$$

參考值：

1.6~2.6 mg/dL (0.65~1.05 mmol/L)

注意事項：

1. 本試劑請用專用標準品(calibrator)，不另外提供質控血清(control)，建議質控血清爲 Bio-Rad Lyphochek control。

2. 建議各實驗室建立獨立之品管系統，並定義專屬之參考值範圍。

3. 本檢驗試劑限由醫師或醫檢師臨床使用。

4. 當檢體的鎂濃度大於 6.0 mg/dL，應將檢體用生理食鹽水稀釋後再分析，結果乘以稀釋倍數。

5. 爲保證結果的準確性，必須在檢體加入後 30 分鐘內檢測吸光值，且含有乳糜血的檢體可能會影響測定值。

6. 若試劑變混濁或空白吸光值大於 1.0，請勿使用。

7. 以上操作步驟適用於手工操作及一般半自動及全自動生化分析儀。

8. 本品操作時需穿戴手套及必要之防護措施，若不慎沾上，應用水或肥皂水清洗。(詳細溶液物化性請洽詢經銷商索取物質安全資料表)

9. 用畢應按醫療事業廢棄物處理。(詳細溶液物化性請洽詢經銷商索取物質安全資料表)

10. 有效期限見試劑盒上標籤所示。

11. 經專業人員建議，試劑與檢體用量可根據所用分析儀的要求按比例調整，其吸光值不變，不影響監測結果。

12. 受測結果會受測試血清或血漿中的乳糜影響，應避免。

13. 試劑特性及參數設定請參見第四頁。

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产品型号: BC-0024
V2.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑镁试剂(MG) - Calmagite test

效能：

用于临床实验体外定量分析人体血清中镁离子的含量。

临床意义：

镁(MG)为人体必需元素，和钙共存于骨骼和肌肉细胞中，为细胞内仅次于钾的重要阳离子，为醣类代谢重要的活化剂。健康人血中镁的浓度非常稳定，但在利尿剂治疗者、糖尿病及体内失调的情形，血中镁会有变动。血清镁减少和钙一样会造成心律不整；镁增加会压制心脏及呼吸中枢神经传导。

方法学原理：

血清中镁离子在碱性条件下，与 calmagite 染料生成紫红色错合物，以 505nm 波长比色，颜色的深浅与血清中的镁含量成正比。

试剂：

1. 产品规格:
   详见外盒包装标示。
2. 成份与浓度：

	成份	浓度
R_1:	EGTA	0.075mmol/L
	KCl	134 mmol/L
	KOH	176 mmol/L
R_2:	Calmagite	0.064mmol/L

保存温度：

2-8℃避光保存，请勿冰冻。

检体：

新鲜血清。

操作步骤：

1. 测定主波长：505 nm　　测定副波长：700nm
   温度：37℃　　比色杯光径：1.0 cm
2. 本试剂盒为液态双试剂，可直接上机使用。

加入物	测定管
检体(ml)	0.01
R_1 (ml)	0.8
混匀，37℃保温 3 分钟	
R_2 (ml)	0.2

以去离子水调零点，分别在 505nm 及 700nm 处检测各管吸光度 A，$A=A_{505}-A_{700}$。混匀、保温 1 分钟，检测检体管初始吸光值 A_1，准确间隔 1 分钟后再检测终末吸光值 A_2。

结果计算

样本中镁含量（mg/dL）

$$= \frac{A_{样本}}{A_{标准}} \times \text{镁标准浓度 mg/dL}$$

参考值：

1.6~2.6 mg/dL (0.65~1.05 mmol/L)

注意事项：

1. 本试剂请用专用标准品(calibrator)，不另外提供质控血清(control)，建议质控血清为 Bio-Rad Lyphochek control。

2. 建议各实验室建立独立之品管系统，并定义专属之参考值范围。

3. 本检验试剂限由医师或医检师临床使用。

4. 当检体的镁浓度大于 6.0 mg/dL，应将检体用生理食盐水稀释后再分析，结果乘以稀释倍数。

5. 为保证结果的准确性，必须在检体加入后 30 分钟内检测吸光值，且含有乳糜血的检体可能会影响测定值。

6. 若试剂变混浊或空白吸光值大于 1.0，请勿使用。

7. 以上操作步骤适用于手工操作及一般半自动及全自动生化分析仪。

8. 本品操作时需穿戴手套及必要之防护措施，若不慎沾上，应用水或肥皂水清洗。(详细溶液物化性请洽询经销商索取物质安全数据表)

9. 用毕应按医疗事业废弃物处理。(详细溶液物化性请洽询经销商索取物质安全数据表)

10. 有效期限见试剂盒上标签所示。

11. 经专业人员建议，试剂与检体用量可根据所用分析仪的要求按比例调整，其吸光值不变，不影响监测结果。

12. 受测结果会受测试血清或血浆中的乳糜影响，应避免。

13. 试剂特性及参数设定请参见第四页。

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IVD For *In Vitro* Diagnostic

MeDiPro MAGNESIUM TEST (MG) - Calmagite test

INTENDED USE

For the quantitative determination of magnesium in serum.

CLINICAL SIGNIFICANCE

Magnesium is one of the most abundant cations in the body and is involved in many biochemical reactions. Many enzymes such as alkaline phosphatase, ALP require magnesium as an activator. Magnesium is also necessary for the stability of conformational structure of 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.

PRINCIPLE

Magnesium forms a colored complex with calmagite under alkaline conditions with an absorbance at 505 nm. The interference of calcium is eliminated by the addition of EGTA. The reaction equation is shown as following:

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

REAGENT

1. Package: please see the reagent box label shown.
2. Components:

	Component	Conc.
R_1:	EGTA	0.075mmol/L
	KCl	134 mmol/L
	KOH	176 mmol/L
R_2:	calmagite	0.064mmol/L

STORE TEMPERATURE

The standard is stable up to the end of the indicated expiration date. If stored at **2 – 8 °C**., reagent should be protected from light and contamination should be avoided.
Do not freeze the reagent!

SPECIMEN COLLECTION AND PREPARATION

Freshly drawn serum is the specimen of choice, plasma derived from specimen collection tubes containing EDTA, citrate, or oxalate must not be used in this test. Serum should be removed from the clot without delay to avoid loss of serum magnesium due to increased erythrocyte permeability to magnesium.

PROCEDURES

1. Main wavelength：505 nm
   Sub. wavelength：700nm
   Reaction Temperature：37℃
   Optical path length：1.0 cm
2. This kit contains two reagents, ready to use.

	Volume (ml)
Sample	0.01
R_1	0.8
Mix, 37℃ incubate 3min	
R_2	0.2

Mix, incubate at 37℃ for 1 min, and read the initial absorbance A_1 against reagent blank, then read end absorbance A_2 in every 1 min. $A = A_{505} - A_{700}$

CALCULATION

With standard or calibrator

$$MG(mg/dL) = \frac{A_{sample}}{A_{std./cali.}} \times \text{conc. Std./cali.（mg/dL）}$$

REFERENCE RANGE

1.6~2.6 mg/dL (0.65~1.05 mmol/L)

WARNINGS AND PRECAUTIONS

1. **This kit offers an optional calibrator, which is sold individually. Bio-Rad Lyphochek control is recommended to use as serum control.**
2. **Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.**
3. **This kit is for professionals and *in vitro* diagnostic use only.**
4. **To ensure the accuracy of result, the absorbance should be measured within 30 minutes after sample addition. Lipemia specimen should be avoided.**
5. **The test is developed to determine magnesium concentrations up to 6.0mg/dL. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.**
6. **Do not use if reagents become turbid or initial blank OD over 1.0.**
7. **The above-mentioned procedures are suitable either for the general semi-automatic, full-automatic biochemical analysis instrument or manual operation.**

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Product number: BC-0024
V2.0

IVD For *In Vitro* Diagnostic

MeDiPro MAGNESIUM TEST (MG) - Calmagite test

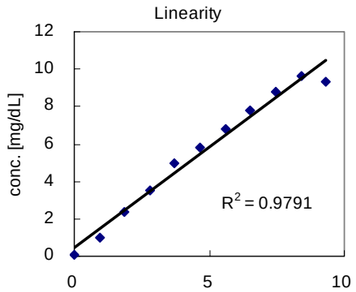
8. **Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.**
9. **Waste management please refers to the local legal requirements.**
10. **Please refer to the manufacturer's safety data sheet and the product labeling for information on potentially hazardous components. (MSDS could be obtained from local dealer.)**
11. **According to the technical suggestion, the volume of reagent and specimen could be adjusted in a ratio for full-automatic biochemical analysis instrument use. It won't affect the absorbance and the result.**
12. **Validity please see the reagent box label shown.**

REAGENT CHARACTERS

1. Precision (Within run)

N=15	Mean[mg/dL]	SD [mg/dL]	CV[%]
Sample1	2.61	0.10	3.64
Sample2	4.63	0.04	0.94
Sample3	4.47	0.02	0.46

2. Linearity



This kit has a good linearity up to 8.0mg/dL.

3. Interference

Interference	Influence effect
Hemoglobulin	No interference was observed by hemoglobulin up to 150mg/dL
Ascorbic acid	No interference was observed by ascorbic acid up to 50mg/dL
Bilirubin (free form)	No interference was observed by bilirubin up to 40mg/dL
Bilirubin (conjugate form)	No interference was observed by bilirubin up to 40mg/dL
Intrafat	Not suitable when lipemia occur

4. Stability

Expire day	1 year
Open vial stability	14 day

REFERENCE

1. Liedtke RJ., Kroon G. Automated calmagite complexim etric measurement of magnesium in serum, with sequential addition of EDTA to eliminate endogenous interference. Clin. Chem. 1984. 30:1801.
2. Polancic JE. Magnesium: metabolism, clinical importance, and analysis. Clin Lab Sci 1991; 4(2).

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[MG]
ASSAY CODE	[2 point end]:[16]-[34]
SAMPLE VOLUME	[2]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH(nm)	[700][505]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[MG]
ASSAY CODE	[2 point end]:[24]-[50]
SAMPLE VOLUME	[3]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH(nm)	[700][505]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0024M	MeDiPro MAGNESIUM TEST	R1 6×20ml R2 3×10ml
BC-0024A	MeDiPro MAGNESIUM TEST	R1 4×60ml R2 2×30ml
BC-0024B	MeDiPro MAGNESIUM TEST	R1 4×100ml R2 2×50ml
BC-0024C	MeDiPro MAGNESIUM TEST R1	R1 2×300ml
BC-0024D	MeDiPro MAGNESIUM TEST R1	R1 2×500ml
BC-0024G	MeDiPro MAGNESIUM TEST R2	R2 2×200ml

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