產品型號: BC-0013
V1.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑鈣試劑（CA）- Arsenazo III method

效能：

用於臨床實驗體外定量分析人體血清或血漿中鈣離子的含量。

臨床意義：

人體中之無機元素以鈣含量最多。血清鈣的增高可見於於副甲狀腺機能亢進、代謝性酸中毒、多發性骨髓瘤、攝取過量維生素 D 等。血清鈣的降低則可見於原發性和繼發性副甲狀腺機能減退、維生素 D 缺乏、腎病綜合症、佝僂病、吸收性或代謝性鹼中毒等。

方法學原理：

鈣與 ArsenazoⅢ反應形成藍色的錯合物，在波長 660 nm 可以測得吸光值。

Ca + Arsenazo III ⟶ Ca – Arsenazo III complex

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
Imidazole	28 mmol/L
8-HQ	2 mmol/L
Arsenazo III	0.2 mmol/L

保存溫度：

2-8℃保存，請勿冰凍。

檢體：

新鮮無溶血血清或肝素抗凝血漿，避免使用 EDTA 或 oxalate 抗凝的檢體。

操作步驟：

1. 測定主波長：660 nm　測定副波長：700nm
   溫度：37℃　比色杯光徑：1.0 cm
2. 本試劑盒爲液態單試劑，可直接上機使用。

加入物(ml)	空白管	標準管	檢體管
去離子水	0.01	---	---
標準液	---	0.01	---
檢體液	---	---	0.01
R1	1.0	1.0	1.0

分別混合均勻，37℃保溫 5 分鐘，以空白管調"零"點，分別在 660nm 及 700nm 處檢測各管吸光值 A，A＝A_{660}-A_{700}。

結果計算

檢體中的鈣（mg/dL）

$$= \frac{A_{檢體}}{A_{標準}} \times \text{鈣標準液濃度（mg/dL）}$$

參考值：

8.7-11.0 mg/dL (2.18-2.74 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．本試劑線性可達 0~14 mg/dL。當檢體的鈣濃度大於 14 mg/dL 時，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。

6．所用實驗器皿應避免鈣污染，如用玻璃吸管、試管，請用 4N HCl 洗滌。並以蒸餾水沖淨，乾燥後用之。

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．本品操作時請穿戴手套及必要之防護措施，操作中若不慎沾上，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．試劑特性及參數設定請參見第四頁。

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产品型号: BC-0013
V1.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑钙试剂（CA）- Arsenazo III method

效能：

用于临床实验体外定量分析人体血清或血浆中钙离子的含量。

临床意义：

人体中之无机元素以钙含量最多。血清钙的增高可见于于副甲状腺机能亢进、代谢性酸中毒、多发性骨髓瘤、摄取过量维生素 D 等。血清钙的降低则可见于原发性和继发性副甲状腺机能减退、维生素 D 缺乏、肾病综合症、佝偻病、吸收性或代谢性碱中毒等。

方法学原理：

钙与 ArsenazoⅢ反应形成蓝色的错合物，在波长 660 nm 可以测得吸光值。

Ca + Arsenazo III ⟶ Ca – Arsenazo III complex

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
Imidazole	28 mmol/L
8-HQ	2 mmol/L
Arsenazo III	0.2 mmol/L

保存温度：

2-8℃保存，请勿冰冻。

检体：

新鲜无溶血血清或肝素抗凝血浆，避免使用 EDTA 或 oxalate 抗凝的检体。

操作步骤：

1. 测定主波长：660 nm　测定副波长：700nm
   温度：37℃　比色杯光径：1.0 cm
2. 本试剂盒为液态单试剂，可直接上机使用。

加入物(ml)	空白管	标准管	检体管
去离子水	0.01	---	---
标准液	---	0.01	---
检体液	---	---	0.01
R1	1.0	1.0	1.0

分别混合均匀，37℃保温 5 分钟，以空白管调"零"点，分别在 660nm 及 700nm 处检测各管吸光值 A，A＝A_{660}-A_{700}。

结果计算

检体中的钙（mg/dL）

$$= \frac{A_{检体}}{A_{标准}} \times \text{钙标准液浓度（mg/dL）}$$

参考值：

8.7-11.0 mg/dL (2.18-2.74 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．本试剂线性可达 0~14 mg/dL。当检体的钙浓度大于 14 mg/dL 时，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。

6．所用实验器皿应避免钙污染，如用玻璃吸管、试管，请用 4N HCl 洗涤。并以蒸馏水冲净，干燥后用之。

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．本品操作时请穿戴手套及必要之防护措施，操作中若不慎沾上，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．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 CALCIUM TEST (CA) - Arsenazo III method

INTENDED USE

For the quantitative determination of calcium in serum or plasma.

CLINICAL SIGNIFICANCE

The metabolism of calcium and that of phosphorus are very closely related. More than 99% of the calcium in the body are present in bone as calcium phosphate, the remains of the calcium, although in very small amount, has various and significant functions in the body. For example, calcium ions will decrease neuromuscular excitability, participate in blood coagulation, and activate some enzymes, such as succinate dehydrogenase and adenosine triphosphatase.
Hypercalcemia occurs in hyperparathyroidism, hyper-vitaminosis, sarcoidosis, multiple myeloma and certain cancers of bone. Hypocalcemia is observed in hypothyroidism, rickets, nephrosis, nephritis, steaorrhea and pancreatitis. Serum calcium level, is slightly dependent upon protein concentration, especially albumin. Hypoalbuminemia is usually accompanied by the decreased serum calcium level.

PRINCIPLE

Calcium, reacts with ArsenazoIII to form a bluish-purple colored chromophore which with an absorbance at 650 nm. Magnesium and iron are excluded from the reaction by complexing with 8-hydroxyquinoline. The reaction equation is shown as following:

2 ArsenazoIII + Ca^{2+} ⟶ Ca^{2+}-ArsenazoIII complex (blusih-purple)

REAGENT

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

Component	Conc.
Imidazole	28 mmol/L
8-HQ	2 mmol/L
Arsenazo-III	0.2 mmol/L

STORE TEMPERATURE

The standard is stable up to the end of the indicated expiration date. If stored at **2 – 8 °C**., 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 calcium due to increased erythrocyte permeability to calcium. Serum calcium separated from clot is stable at least 24 hours at room temperature, 1 week under refrigeration and up to 1 year in the freezer.

PROCEDURES

1. Main wavelength：660 nm
   Sub. wavelength：700nm
   Reaction Temperature：37℃
   Optical path length：1.0 cm
2. This kit contains single reagent, ready to use.

	Blank	Control	Specimen
ddH_2O (ml)	0.01	---	---
Control (ml)	---	0.01	---
Specimen (ml)	---	---	0.01
R1 (ml)	1.0	1.0	1.0

Mix, incubate at 37℃ for 5 min, and read the absorbance against reagent blank. $A = A_{660}-A_{700}$

CALCULATION

With standard or calibrator

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

REFERENCE RANGE

8.7-11.0 mg/dL (2.18-2.74 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.**
5. **The instrument, material and distilled water shall avoid calcium contamination.**
6. **The test is developed to determine calcium concentrations up to 14mg/dL. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.**
7. **The above-mentioned procedures are suitable either for the general semi-automatic, full-automatic biochemical analysis instrument or manual operation.**
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.**

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Product number: BC-0013
V1.0

IVD For *In Vitro* Diagnostic

MeDiPro CALCIUM TEST (CA) - Arsenazo III method

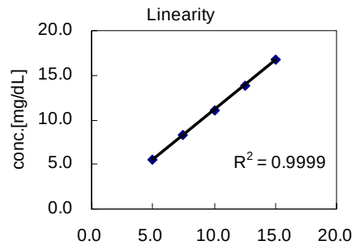
10. **Please refer to the manufacturer's safety data sheet and the product labeling for information on potentially hazardous components. (MSDS could be obtained from local dealer.)**
11. **According to the technical suggestion, the volume of reagent and specimen could be adjusted in a ratio for full-automatic 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	8.27	0.10	1.20
Sample2	11.64	0.13	1.13
Sample3	11.87	0.11	0.96

2. Linearity



This kit has a good linearity up to 15mg/dL.

3. Interference

Interference	Influence effect
Hemoglobulin	No interference was observed by hemoglobulin up to 500mg/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 32mg/dL
Bilirubin (conjugate form)	No interference was observed by bilirubin up to 40mg/dL
Intrafat	No interference was observed by intrafat up to 1.8%

4. Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

1. Janssen J.W. and Helbing A.R. Arsenazo III: An improvement of the routine calcium determinationin serum. Eur. J. Clin Chem. Clin. Biochem. 1991, 29:197-201.
2. Leary N.O., Pembroke A., Duggan P. F. Single stable reagent (Arsenazo III) for optically robust measurement of calcium in serum and plasma. Clin. Chem. 1992, 38: 904-908

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[CA]
ASSAY CODE	[1 POINT]:[6]-[0]
SAMPLE VOLUME	[2]
R1 VOLUME	[200]
R2 VOLUME	[0]
WAVELENGTH(nm)	[700][660]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[CA]
ASSAY CODE	[1POINT]:[10]-[0]
SAMPLE VOLUME	[3]
R1 VOLUME	[300]
R2 VOLUME	[0]
WAVELENGTH(nm)	[700][660]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0013M	MeDiPro CALCIUM TEST	R1 6×20ml
BC-0013A	MeDiPro CALCIUM TEST	R1 4×60ml
BC-0013B	MeDiPro CALCIUM TEST	R1 4×100ml
BC-0013C	MeDiPro CALCIUM TEST	R1 3×250ml
BC-0013D	MeDiPro CALCIUM TEST	R1 2×500ml

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