產品型號: BC-0025
V2.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑磷試劑（PHOS）- Phosphomolydbate method

效能：

用於臨床實驗體外定量分析人體血清或血漿中磷離子的含量。

臨床意義：

血清無機磷增高常見於副甲狀腺機能減退、腎功能衰竭、維生素 D 過多、多發性骨髓瘤及骨折癒合期。血清無機磷減低常見於副甲狀腺機能亢進、佝僂病、維生素 D 缺乏、糖尿病。

方法學原理：

血清中無機磷在酸性溶液中與鉬酸銨作用形成磷鉬酸複合物，可直接用 340nm 處檢測吸光值；其吸光度與樣本中的無機磷濃度成正比。

$$H_3PO_4 + Mo(VI) \xrightarrow{H^+} \text{phosphomolybdate complex}$$

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
Sulfuric acid	10 mmol/L
Ammonium molybdate	3.4 mmol/L

保存溫度：

2-8℃保存，請勿冰凍。

檢體：

新鮮無溶血的血清或是 heparin 抗凝血漿，避免使用含 EDTA、oxalate、citrate 血漿檢體。檢體採集後儘快分離以免細胞內的磷酸鹽混入，而對檢測結果產生干擾。

操作步驟：

1. 測定主波長：340 nm　測定副波長：405nm
   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 340nm 及 405nm 處檢測各管吸光值 A，A＝A_{340}-A_{405}。

結果計算

檢體中的磷（mg/dL）

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

參考值：

成人：2.5~4.5 mg/dL (0.81-1.45 mmol/L)

兒童：4.0~5.5 mg/dL (1.29-2.26 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 13 mg/dL。當檢體的磷濃度大於 13 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。檢體中若有溶血、ascorbic acid 及膽紅素，會影響其測定的數值，應儘量避免。**
6. **所用實驗器皿應避免磷污染，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-0025
V2.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑磷试剂（PHOS）- Phosphomolydbate method

效能：

用于临床实验体外定量分析人体血清或血浆中磷离子的含量。

临床意义：

血清无机磷增高常见于副甲状腺机能减退、肾功能衰竭、维生素 D 过多、多发性骨髓瘤及骨折愈合期。血清无机磷减低常见于副甲状腺机能亢进、佝偻病、维生素 D 缺乏、糖尿病。

方法学原理：

血清中无机磷在酸性溶液中与钼酸铵作用形成磷钼酸复合物，可直接用 340nm 处检测吸光值；其吸光度与样本中的无机磷浓度成正比。

$$H_3PO_4 + Mo(VI) \xrightarrow{H^+} \text{phosphomolybdate complex}$$

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
Sulfuric acid	10 mmol/L
Ammonium molybdate	3.4 mmol/L

保存温度：

2-8℃保存，请勿冰冻。

检体：

新鲜无溶血的血清或是 heparin 抗凝血浆，避免使用含 EDTA、oxalate、citrate 血浆检体。检体采集后尽快分离以免细胞内的磷酸盐混入，而对检测结果产生干扰。

操作步骤：

1. 测定主波长：340 nm　测定副波长：405nm
   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 340nm 及 405nm 处检测各管吸光值 A，A＝A_{340}-A_{405}。

结果计算

检体中的磷（mg/dL）

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

参考值：

成人：2.5~4.5 mg/dL (0.81-1.45 mmol/L)

儿童：4.0~5.5 mg/dL (1.29-2.26 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 13 mg/dL。当检体的磷浓度大于 13 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。检体中若有溶血、ascorbic acid 及胆红素，会影响其测定的数值，应尽量避免。**
6. **所用实验器皿应避免磷污染，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 PHOSPHORUS TEST (PHOS) - Phosphomolydbate method

INTENDED USE
For the quantitative determination of inorganic phosphorus in serum or plasma.

CLINICAL SIGNIFICANCE
Phosphorus is an abundant element in the body and plays an important role in the intermediary metabolism, skeletal formation, dentition and acid-base balance.

PRINCIPLE
$H_3PO_4 + Mo(VI) \xrightarrow{H^+}$ phosphomolybdate complex

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

Component	Conc.
Sulfuric acid	10 mmol/L
Ammonium molybdate	3.4 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
Fasting blood should be used since glucose ingestion will lower the inorganic phosphorus level. Fresh serum and heparin-treated plasma are the choices. Fresh unhemolyzed serum should be separated as soon as possible from the red blood cells. Hemolyzed serum should be avoided since it contains organic phosphorus compounds which may be hydrolyzed and interferes with inorganic phosphorus. If the serum is properly separated, the phosphorus is stable for 1 week when stored refrigerated.

PROCEDURES
1. Main wavelength：340 nm
   Sub. wavelength：405nm
   Reaction Temperature：37℃
   Optical path length：1.0 cm
2. This kit contains single reagent, ready to use.

	Blank	Control	Specimen
ddH_2O	0.01	---	---
Control	---	0.01	---
Specimen	---	---	0.01
R1	1.0	1.0	1.0

Mix, incubate at 37℃ for 5 min, and read the absorbance against reagent blank. $A = A_{340}-A_{405}$

CALCULATION
With standard or calibrator

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

REFERENCE RANGE

Age	Conc.（mg/dL）
Child	4.0~5.5 mg/dL
Adult	2.5~4.5 mg/dL

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. Hemolysis, ascorbic acid, and bilirubin might interfere with the result.**
5. **Each instrument, material and distilled water should avoid calcium contamination.**
6. **The test is developed to determine phosphorus concentrations up to 13mg/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.**
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.)**

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Product number: BC-0025
V2.0

IVD For *In Vitro* Diagnostic

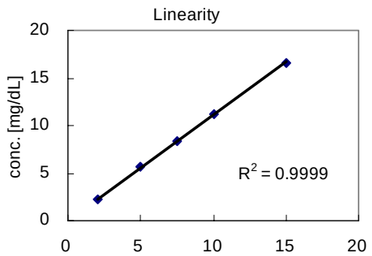
MeDiPro PHOSPHORUS TEST (PHOS) - Phosphomolydbate method

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	4.22	0.09	2.18
Sample2	8.14	0.08	0.96
Sample3	8.88	0.09	0.97

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 100mg/dL
Ascorbic acid	No interference was observed by ascorbic acid up to 30mg/dL
Bilirubin (free form)	Not suitable when jaundice occur
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. Concustell E, Cortes M, Ferragut A, Gener J. Inorganic phosphorus measurement: an improved method. Clin Chim Acta. 1977 Dec 15;81(3):267-72.
2. Bishop M.L., Duben-Engelkirk J.L., Fody E.P. Clinical Chemistry Fourth edition.

PARAMETER SETUP
Hitachi 7170/917 Applications

TEST	[PHOS]
ASSAY CODE	[1 POINT]:[34]-[0]
SAMPLE VOLUME	[2]
R1 VOLUME	[200]
R2 VOLUME	[0]
WAVELENGTH(nm)	[405][340]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[PHOS]
ASSAY CODE	[1 POINT]:[50]-[0]
SAMPLE VOLUME	[3]
R1 VOLUME	[300]
R2 VOLUME	[0]
WAVELENGTH(nm)	[405][340]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0025M	MeDiPro PHOSPHORUS TEST	R1 6×20ml
BC-0025A	MeDiPro PHOSPHORUS TEST	R1 4×60ml
BC-0025B	MeDiPro PHOSPHORUS TEST	R1 4×100ml
BC-0025C	MeDiPro PHOSPHORUS TEST	R1 3×250ml
BC-0025D	MeDiPro PHOSPHORUS TEST	R1 2×500ml

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