產品型號: BC-0028
V2.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑尿酸試劑（UA）- Enzymatic colorimetric test (uricase-PAP)

效能：

用於臨床實驗體外定量分析人體血清或血漿中尿酸的含量。

臨床意義：

尿酸是核酸中嘌呤分解代謝的終產物。尿酸增高可見痛風、白血病、多發性骨髓瘤、真性紅細胞增多、腎功能障礙、溶血性貧血、氯仿中毒等。

方法學原理：

$$\text{Uric acid} + O_2 + 2H_2O \xrightarrow{\text{Uricase}} \text{allantoin} + CO_2 + H_2O_2$$

$$2H_2O_2 + \text{4-aminoantipyrine} + \text{DHBS} \longrightarrow \text{quinoneimine dye} + 4H_2O$$

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	DHBS	0.01 mmol/L
	Phosphate buffer, pH6.7	150 mmol/L
R_2	Uricase	200 U/L
	Peroxidase	1000 U/L
	4-aminoantipyrine	0.3 mmol/L

保存溫度：

2-8℃避光保存，請勿冰凍。

檢體：

新鮮無溶血的血清；用肝素或 EDTA 抗凝血漿。

操作步驟：

1. 測定主波長：546 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。

■ 一步法（雙試劑）

加入物（ml）	空白管	標準管	檢體管
樣 本	---	---	0.02
標準液	---	0.02	---
去離子水	0.02	---	---
R1	0.8	0.8	0.8
混合, 37℃ 下培育 5 分鐘			
R2	0.2	0.2	0.2

立即混勻，於 37℃放置 5 分鐘，以空白管調"零"點，分別在 546nm 及 700nm 處檢測各管吸光值 A，$A = A_{546} - A_{700}$。

結果計算

檢體中的尿酸（mg/dL）

$$= \frac{A_{\text{檢體}}}{A_{\text{標準}}} \times \text{尿酸標準濃度（mg/dL）}$$

參考值：

1.5-7.0 mg/dL (90-420 µmol/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． **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，檢體中如果有膽紅素的干擾會影響尿酸的測定。**

5． **本試劑線性可達 30mg/dL。若檢體中尿酸濃度大於 30mg/dL 時，可用生理食鹽水稀釋後重測，結果乘以稀釋倍數。**

6． **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。**

7． **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)**

8． **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)**

9． **有效期限見試劑盒上標籤所示。**

10． **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。**

11． **試劑特性及參數設定請參見第四頁。**

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产品型号: BC-0028
V2.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑尿酸试剂（UA）- Enzymatic colorimetric test (uricase-PAP)

效能：

用于临床实验体外定量分析人体血清或血浆中尿酸的含量。

临床意义：

尿酸是核酸中嘌呤分解代谢的终产物。尿酸增高可见痛风、白血病、多发性骨髓瘤、真性红细胞增多、肾功能障碍、溶血性贫血、氯仿中毒等。

方法学原理：

$$\text{Uric acid} + O_2 + 2H_2O \xrightarrow{\text{Uricase}} \text{allantoin} + CO_2 + H_2O_2$$

$$2H_2O_2 + \text{4-aminoantipyrine} + \text{DHBS} \longrightarrow \text{quinoneimine dye} + 4H_2O$$

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	DHBS	0.01 mmol/L
	Phosphate buffer, pH6.7	150 mmol/L
R_2	Uricase	200 U/L
	Peroxidase	1000 U/L
	4-aminoantipyrine	0.3 mmol/L

保存温度：

2-8℃避光保存，请勿冰冻。

检体：

新鲜无溶血的血清；用肝素或 EDTA 抗凝血浆。

操作步骤：

1. 测定主波长：546 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。

■ 一步法（双试剂）

加入物（ml）	空白管	标准管	检体管
样 本	---	---	0.02
标准液	---	0.02	---
去离子水	0.02	---	---
R1	0.8	0.8	0.8
混合, 37℃ 下培育 5 分钟			
R2	0.2	0.2	0.2

立即混匀，于 37℃放置 5 分钟，以空白管调"零"点，分别在 546nm 及 700nm 处检测各管吸光值 A，$A = A_{546} - A_{700}$。

结果计算

检体中的尿酸（mg/dL）

$$= \frac{A_{\text{检体}}}{A_{\text{标准}}} \times \text{尿酸标准浓度（mg/dL）}$$

参考值：

1.5-7.0 mg/dL (90-420 µmol/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． **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，检体中如果有胆红素的干扰会影响尿酸的测定。**

5． **本试剂线性可达 30mg/dL。若检体中尿酸浓度大于 30mg/dL 时，可用生理食盐水稀释后重测，结果乘以稀释倍数。**

6． **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。**

7． **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)**

8． **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)**

9． **有效期限见试剂盒上标签所示。**

10． **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。**

11． **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 URIC ACID TEST (UA) - Enzymatic colorimetric test (uricase-PAP)

INTENDED USE

For the quantitative determination of uric acid in serum or plasma.

CLINICAL SIGNIFICANCE

Uric acid is the end-product of urine metabolism in human. It circulates and is filtered from the blood by the glomentuli. The determination of serum uric acid for detecting hyperuricemia is helpful in the diagnosis of gout, increased metabolism of nucleoproteins, such as in leukemia and polycythemia. Serum uric acid levels also increase with the decrease of renal function.

PRINCIPLE

$$\text{Uric acid} + O_2 + 2H_2O \xrightarrow{\text{Uricase}} \text{allantoin} + CO_2 + H_2O_2$$

$$2H_2O_2 + \text{4-aminoantipyrine} + \text{DHBS} \longrightarrow \text{quinoneimine dye} + 4H_2O$$

REAGENT

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

	Component	Conc.
R_1	DHBS	0.01 mmol/L
	Phosphate buffer pH6.7±0.25	150 mmol/L
R_2	Uricase	200 U/L
	Peroxidase	1000 U/L
	4-aminoantipyrine	0.3 mmol/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 un-hemolyzed serum, plasma are the choice of specimen. Serum uric acid is stable 3 days at room temperature, one week when refrigerated; 6 months when frozen. Avoid bacteria contamination.

PROCEDURES

1. Main wavelength：546 nm
Sub. wavelength：700nm
Reaction Temperature：37℃
Optical path length：1.0 cm
2. This kit contains two reagents, ready to use.

	Control	Specimen	Control
Specimen(ml)	——	0.02	——
Control(ml)	0.02	——	——
ddH_2O(ml)	——	——	0.02
R1（ml）	0.8	0.8	0.8
Mix, 37℃ incubate 5min			
R2（ml）	0.2	0.2	0.2

Mix, incubate at 37℃ for 5 min, and read the absorbance against reagent blank. $A = A_{546}-A_{700}$

CALCULATION

With standard or calibrator

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

REFERENCE RANGE

1.5-7.0 mg/dL (90-420 µmol/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. Bilirubin might interfere with the test result.**
5. **The test is developed to determine uric acid concentrations up to 30mg/dL. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.**
6. **The above-mentioned procedures are suitable either for the general semi-automatic, full-automatic biochemical analysis instrument or manual operation.**
7. **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.**

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Product number: BC-0028
V2.0

IVD For *In Vitro* Diagnostic

MeDiPro URIC ACID TEST (UA) - Enzymatic colorimetric test (uricase-PAP)

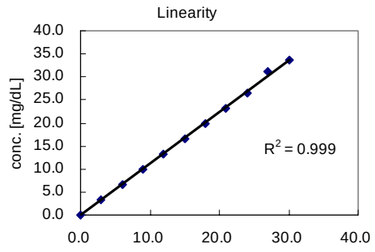
8. **Waste management please refers to the local legal requirements.**
9. **Please refer to the manufacturer's safety data sheet and the product labeling for information on potentially hazardous components. (MSDS could be obtained from local dealer.)**
10. **According to the technical suggestion, the 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.**
11. **Validity please see the reagent box label shown.**

REAGENT CHARACTERS

1. Precision (Within run)

N=15	Mean[mg/dL]	SD [mg/dL]	CV[%]
Sample1	5.21	0.06	1.09
Sample2	9.99	0.09	0.88
Sample3	9.90	0.09	0.95

2. Linearity



This kit has a good linearity up to 35mg/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 40mg/dL
Bilirubin (free form)	No interference was observed by bilirubin up to 24mg/dL
Bilirubin (conjugate form)	Not suitable when jaundice occur
Intrafat	No interference was observed by intrafat up to 2.0%

4. Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

1. Kabasakalian P, Kalliney S, Wescott A. Determination of uric acid in serum, with the use of uricase and a tribromophenol- aminoantipyrine chromogen. Clin. Chem. 1973. 19: 522.
2. Gochman N, Schmitz JM. Automated determination of uric acid with use of a uricase-peroxidase system. Clin. Chem. 1971. 17: 1154.

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[UA]
ASSAY CODE	[2 POINT]: [16]-[34]
SAMPLE VOLUME	[4]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH(nm)	[700][546]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[UA]
ASSAY CODE	[2 POINT]: [24]-[50]
SAMPLE VOLUME	[6]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH(nm)	[700][546]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0028M	MeDiPro URIC ACID TEST	R1 6×20ml R2 3×10ml
BC-0028A	MeDiPro URIC ACID TEST	R1 4×60ml R2 2×30ml
BC-0028B	MeDiPro URIC ACID TEST	R1 4×100ml R2 2×50ml
BC-0028C	MeDiPro URIC ACID TEST R1	R1 4×300ml
BC-0028D	MeDiPro URIC ACID TEST R1	R1 4×500ml
BC-0028G	MeDiPro URIC ACID TEST R2	R2 4×200ml

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