



台塑肌酐試劑（CREA）- Picric acid test

效能：
用於臨床實驗體外定量分析人體血清或尿液中肌酐的含量。

臨床意義：
肌酐經腎小球濾過後不被腎小管再吸收通過腎小管排泄。在腎臟疾病初期，血清肌酐值通常不升高，直至腎臟實質性損害血清肌酐值才增高。肌酐值增加於腎機能不全、尿路阻塞、甲狀腺高能症。

方法學原理：
$$\text{creatinine} + \text{Picric acid} \xrightarrow{\text{Alkali}} \text{reddish colored complex}$$

試劑：

- 型號規格：
詳見外盒包裝標示。
- 成份與濃度：

	成份	濃度
R ₁ :	NaOH	2.67 mmol/L
R ₂ :	Picric acid	6.5 mmol/L

試劑穩定性：
在 2-8℃ 避光保存，有效期內穩定，請勿冰凍。

檢體：
新鮮無溶血血清或尿液檢體。（尿液樣本應在分析前作 100 倍稀釋）

操作步驟：

- 測定主波長：505 nm 測定副波長：570nm
溫度：37 比色杯光徑：1.0 cm
- 本試劑盒為液態雙試劑，可直接上機使用。

加入物	標準管	樣品管	空白管
樣本 (ml)	---	0.1	---
標準液(ml)	0.1	---	---
ddH ₂ O (ml)	---	---	0.1
R1 (ml)	0.8	0.8	0.8
混合，37 培養 5 分鐘			
R2 (ml)	0.2	0.2	0.2

在 505nm 處，以去離子水調零點，於 30 秒讀第一個吸光值 A₁，準確間隔 30 秒時，讀取第二吸光值 A₂。

結果計算
$$\text{肌酐 (mg/dL)} = \frac{(\text{A}_2 - \text{A}_1)_{\text{樣本}}}{(\text{A}_2 - \text{A}_1)_{\text{標準}}} \times \text{肌酐標準濃度 (mg/dL)}$$

參考值：
血清：男 0.6-1.1 mg/dL (53-97 μmol/L)
 女 0.5-0.9 mg/dL (44-80 μmol/L)
收集尿液：0.5-1.5g/24hr

注意事項：

- 本試劑請用專用標準品(calibrator)，不另外提供質控血清(control)，建議質控血清為 Bio-Rad Lyphochek control。
- 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。
- 本檢驗試劑限由醫師或醫檢師臨床使用。
- 本試劑線性可達 10 mg/dL，當樣本的肌酐濃度大於 10 mg/dL 時，應將樣本用生理食鹽水稀釋後再分析，結果乘以稀釋倍數。
- 為保證結果的準確性，必須在檢體加入後 30 分鐘內檢測吸光值。
- 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。
- 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）
- 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）
- 有效期限見試劑盒上標籤所示。
- 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。
- 試劑特性及參數設定請參見第四頁。



台塑肌酐试剂（CREA）- Picric acid test

效能：
用于临床实验体外定量分析人体血清或尿液中肌酐的含量。

临床意义：
肌酐经肾小球滤过后不被肾小管再吸收通过肾小管排泄。在肾脏疾病初期，血清肌酐值通常不升高，直至肾脏实质性损害血清肌酐值才增高。肌酐值增加于肾功能不全、尿路阻塞、甲状腺高能症。

方法学原理：
$$\text{creatinine} + \text{Picric acid} \xrightarrow{\text{Alkali}} \text{reddish colored complex}$$

试剂：

- 型号规格：
详见外盒包装标示。
- 成份与浓度：

	成份	浓度
R ₁ :	NaOH	2.67 mmol/L
R ₂ :	Picric acid	6.5 mmol/L

试剂稳定性：
在 2-8℃ 避光保存，有效期内稳定，请勿冰冻。

检体：
新鲜无溶血血清或尿液检体。（尿液样本应在分析前作 100 倍稀释）

操作步骤：

- 测定主波长：505 nm 测定副波长：570nm
温度：37 比色杯光径：1.0 cm
- 本试剂盒为液态双试剂，可直接上机使用。

加入物	标准管	样品管	空白管
样本 (ml)	---	0.1	---
标准液(ml)	0.1	---	---
ddH ₂ O (ml)	---	---	0.1
R1 (ml)	0.8	0.8	0.8
混合，37 培养 5 分钟			
R2 (ml)	0.2	0.2	0.2

在 505nm 处，以去离子水调零点，于 30 秒读第一个吸光值 A₁，准确间隔 30 秒时，读取第二吸光值 A₂。

结果计算
$$\text{肌酐 (mg/dL)} = \frac{(\text{A}_2 - \text{A}_1)_{\text{样本}}}{(\text{A}_2 - \text{A}_1)_{\text{标准}}} \times \text{肌酐标准浓度 (mg/dL)}$$

参考值：
血清：男 0.6-1.1 mg/dL (53-97 μmol/L)
 女 0.5-0.9 mg/dL (44-80 μmol/L)
收集尿液：0.5-1.5g/24hr

注意事项：

- 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。
- 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。
- 本检验试剂限由医师或医检师临床使用。
- 本试剂线性可达 10 mg/dL，当样本的肌酐浓度大于 10 mg/dL 时，应将样本用生理食盐水稀释后再分析，结果乘以稀释倍数。
- 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。
- 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。
- 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）
- 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）
- 有效期限见试剂盒上标签所示。
- 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。
- 试剂特性及参数设定请参见第四页。



台塑生醫科技股份有限公司
台北市敦化北路 201 號前棟五樓
TEL：+886-2-2712-2211 #7822
製造廠：台塑生醫宜蘭廠

Website: <http://www.fbc.com.tw/>
FAX：+886-2-2717-8381
廠址：宜蘭縣礁溪鄉龍潭村龍泉路 3 號



台塑生医科技股份有限公司
台北市敦化北路 201 号前栋五楼
TEL：+886-2-2712-2211 #7822
制造厂：台塑生医宜兰厂

Website: <http://www.fbc.com.tw/>
FAX：+886-2-2717-8381
厂址：宜兰县礁溪乡龙潭村龙泉路 3 号

**MeDiPro CREATININE TEST (CREA) - Picric acid test****INTENDED USE**

For the quantitative determination of creatinine in serum or urine.

CLINICAL SIGNIFICANCE

Creatinine is excreted as a waste product by the kidneys. Increased serum creatinine level usually indicates impairment of renal function. Creatinine appears in the glomerular filtrate and is not reabsorbed by the tubule. Hence, any condition that reduces the glomerular filtration rate will result in the increase of creatinine concentration in plasma. Since the excretion rate of creatinine is relatively constant and its production rate is not influenced by protein catabolism or other external factors. The concentration of creatinine in serum is, therefore, a good measure of renal glomerular function

PRINCIPLE

Creatinine + picric acid $\xrightarrow{\text{Alkali}}$ Creatinine-picric acid
(Reddish colored complex)

REAGENT

- Package: please see the reagent box label shown.
- Components:

	Component	Conc.
R ₁ :	NaOH	2.67 mmol/L
R ₂ :	Picric acid	6.5 mmol/L

STORE TEMPERATURE

The standard is stable up to the end of the indicated expire 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

The choice of specimen is serum and the use of plasma is not recommended. Creatinine in serum is stable for 7 days at room temperature, 28 days in the refrigerator and at least 180 days when frozen. Hemolysis should be avoided.

For urine specimens, it should be diluted 1:100 with water. Avoid conditions which could allow bacterial growth. Add preservatives such as fluoride, thymol or boric acid during collection is recommended.

PROCEDURES

- Main wavelength : 505 nm
Sub. wavelength : 570nm
Reaction Temperature : 37°C
Optical path length : 1.0 cm
- This kit contains two reagents, ready to use.

	Control	Specimen	Blank
Specimen (ml)	---	0.1	---
Control (ml)	0.1	---	---
ddH ₂ O (ml)	---	---	0.1
R1 (ml)	0.8	0.8	0.8
Mix, 37°C incubate 5min			
R2 (ml)	0.2	0.2	0.2

Mix, incubate at 37°C for 30sec, and read the initial absorbance A₁ against reagent blank, then read end absorbance A₂ in every 30sec. A = A₅₀₅ - A₅₇₀.

CALCULATION

With standard or calibrator

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

REFERENCE RANGE

Age	Conc. (mg/dL)
Serum(male)	0.6-1.1
Serum(female)	0.5-0.9
Collected urine	0.5-1.5g/24hr

WARNINGS AND PRECAUTIONS

- This kit offers an optional calibrator, which is sold individually. Bio-Rad Lyphochek control is recommended to use as serum control.
- Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.
- This kit is for professionals and *in vitro* diagnostic use only.
- To ensure the accuracy of result, the absorbance should be measured within 30 minutes after sample addition.
- The test is developed to determine creatinine concentrations up to 10mg/dL. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.
- The above-mentioned procedures are suitable either for the general semi-automatic, full-automatic biochemical analysis instrument or manual operation.
- Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2

**MeDiPro CREATININE TEST (CREA) - Picric acid test**

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.

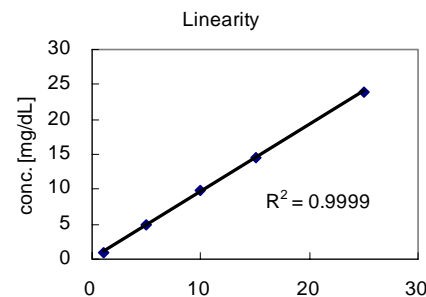
- Waste management please refers to the local legal requirements.
- Please refer to the manufacturer's safety data sheet and the product labeling for information on potentially hazardous components. (MSDS could be obtained from local dealer.)
- According to the technical suggestion, the volume of reagent and specimen could be adjusted in a ratio for full-automatic biochemical analysis instrument use. It won't affect the absorbance and the result.
- Validity please see the reagent box label shown.

REAGENT CHARACTERS

- Precision (Within run)

N=15	Mean[mg/dL]	SD [mg/dL]	CV[%]
Sample1	1.70	0.00	0.00
Sample2	7.10	0.00	0.00
Sample3	7.08	0.04	0.60

- Linearity



This kit has a good linearity up to 20mg/dL.

- Interference

Interference	Influence effect
Hemoglobin	No interference was observed by hemoglobin 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 16mg/dL
Bilirubin (conjugate form)	No interference was observed by bilirubin up to 4mg/dL
Intrafat	No interference was observed by intrafat up to 2.0%

- Stability

Expire day	1 year
Open vial stability	14 day

REFERENCE

Narayanan S, Appelton H. Creatinine: a review. Clin Chem 1980; 26: 1119.

PARAMETER SETUPHitachi 7170/917 Applications

TEST	[CREA]
ASSAY CODE	[RateA]:[19]-[23]
SAMPLE VOLUME	[14]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH (nm)	[570][505]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[CREA]
ASSAY CODE	[RateA]: [30]-[37]
SAMPLE VOLUME	[18]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH(nm)	[570][505]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0017M	MeDiPro CREATININE TEST	R1 6x20ml R2 3x10ml
BC-0017A	MeDiPro CREATININE TEST	R1 4x60ml R2 2x30ml
BC-0017B	MeDiPro CREATININE TEST	R1 4x100ml R2 2x50ml
BC-0017C	MeDiPro CREATININE TEST R1	R1 2x300ml
BC-0017D	MeDiPro CREATININE TEST R1	R1 2x500ml
BC-0017G	MeDiPro CREATININE TEST R2	R2 2x200ml

**FORMOSA BIOMEDICAL TECHNOLOGY CORP.**

F-5F, No. 201, Tunghua N. Rd, Taipei, 105, Taiwan Website: <http://www.fbc.com.tw/>
TEL: +886-2-2712-2211 #7822 FAX: +886-2-2717-8381
Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan

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F-5F, No. 201, Tunghua N. Rd, Taipei, 105, Taiwan Website: <http://www.fbc.com.tw/>
TEL: +886-2-2712-2211 #7822 FAX: +886-2-2717-8381
Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan