IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑肌酸激酶試劑（CK）- UV kinetic, NAC method

效能：
用於臨床實驗體外定量分析人體血清或血漿中肌酸激酶的活性。

臨床意義：
肌酸激酶主要存在於骨骼肌和心肌、腦組織中，肌酸激酶增高常見於：各種類型進行性肌萎縮症、急性心肌梗塞（2-4 小時開始增高，可高達正常上限的 10-12 倍）、病毒性心肌炎、腦血管意外、腦膜炎、甲狀腺機能低下。

方法學原理：

$$\text{Creatine phosphate + ADP} \xrightarrow{\text{CK}} \text{creatine + ATP}$$

$$\text{ATP + D-glucose} \xrightarrow[\text{Hexokinase}]{} \text{glucose-6-phosphate + ADP}$$

$$\text{glucose-6-phosphate + NAD}^+ \xrightarrow{\text{G6PDH}} \text{6-phosphogluconate + NADH + H}^+$$

G6PDH 催化 NAD^+到 NADH 的還原反應，利用在 340nm NADH 吸光值的上升，來檢測肌酸激酶之活性。

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	Imidazole pH7.0±0.3	10 mmol/L
	Mg^{2+}	10 mmol/L
	AMP	5.0 mmol/L
	Hexokinase	3000 U/L
	G6PDH	2500 U/L
	Creatine phosphate	30 mmol/L
R_2	D-glucose	20 mmol/L
	ADP	5 mmol/L

保存溫度：
2-8℃保存，請勿冰凍。

檢體：
新鮮無溶血血清、肝素抗凝血漿。避免使用 EDTA 抗凝的檢體。因血清中肌酸激酶不穩定，檢體採集後要避光並儘快分析。

操作步驟：
1. 主波長：340 nm　副波長：405nm
   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。

二步法（雙試劑）：

加入物	測定管
檢體 ml	0.02
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 340nm 及 405nm 處檢測各管吸光度 A，$A = A_{340} - A_{405}$。混勻檢體管，37℃保溫 3 分鐘。檢測檢體管初始吸光值 A_1，準確間隔 1 分鐘，再檢測終末吸光值 A_2。

結果計算

$$CK\ (U/L) = \frac{(A_2 - A_1)/\min \times Vt \times 1000}{Lp \times \varepsilon \times Vs} = (A_2 - A_1)/\min \times 8199$$

Vt: 反應總體積 1.02m, Vs:檢體體積 0.02ml
ε: NADH 的毫摩爾吸光係數 6.22
1000: 將 U/ml 轉換完成 U/L, Lp: 光徑（1.0cm）

參考值：
男性： 24-195 U/L
女性： 24-170 U/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 800 U/L。當檢體的肌酸激酶濃度大於 800 U/L 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. **在室溫下，肌酸激酶只能穩定 4 小時，故檢體收集後應盡快分析，且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。受測結果會受測試血清或血漿中的溶血影響數值，應避免。**
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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IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑肌酸激酶试剂（CK）- UV kinetic, NAC method

效能：
用于临床实验体外定量分析人体血清或血浆中肌酸激酶的活性。

临床意义：
肌酸激酶主要存在于骨骼肌和心肌、脑组织中，肌酸激酶增高常见于：各种类型进行性肌萎缩症、急性心肌梗塞（2-4 小时开始增高，可高达正常上限的 10-12 倍）、病毒性心肌炎、脑血管意外、脑膜炎、甲状腺机能低下。

方法学原理：

$$\text{Creatine phosphate + ADP} \xrightarrow{\text{CK}} \text{creatine + ATP}$$

$$\text{ATP + D-glucose} \xrightarrow[\text{Hexokinase}]{} \text{glucose-6-phosphate + ADP}$$

$$\text{glucose-6-phosphate + NAD}^+ \xrightarrow{\text{G6PDH}} \text{6-phosphogluconate + NADH + H}^+$$

G6PDH 催化 NAD^+到 NADH 的还原反应，利用在 340nm NADH 吸光值的上升，来检测肌酸激酶之活性。

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	Imidazole pH7.0±0.3	10 mmol/L
	Mg^{2+}	10 mmol/L
	AMP	5.0 mmol/L
	Hexokinase	3000 U/L
	G6PDH	2500 U/L
	Creatine phosphate	30 mmol/L
R_2	D-glucose	20 mmol/L
	ADP	5 mmol/L

保存温度：
2-8℃保存，请勿冰冻。

检体：
新鲜无溶血血清、肝素抗凝血浆。避免使用 EDTA 抗凝的检体。因血清中肌酸激酶不稳定，检体采集后要避光并尽快分析。

操作步骤：
1. 主波长：340 nm　副波长：405nm
   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。

二步法（双试剂）：

加入物	测定管
检体 ml	0.02
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 340nm 及 405nm 处检测各管吸光度 A，$A = A_{340} - A_{405}$。混匀检体管，37℃保温 3 分钟。检测检体管初始吸光值 A_1，准确间隔 1 分钟，再检测终末吸光值 A_2。

结果计算

$$CK\ (U/L) = \frac{(A_2 - A_1)/\min \times Vt \times 1000}{Lp \times \varepsilon \times Vs} = (A_2 - A_1)/\min \times 8199$$

Vt: 反应总体积 1.02m, Vs:检体体积 0.02ml
ε: NADH 的毫摩尔吸光系数 6.22
1000: 将 U/ml 转换完成 U/L, Lp: 光径（1.0cm）

参考值：
男性： 24-195 U/L
女性： 24-170 U/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 800 U/L。当检体的肌酸激酶浓度大于 800 U/L 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. **在室温下，肌酸激酶只能稳定 4 小时，故检体收集后应尽快分析，且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。受测结果会受测试血清或血浆中的溶血影响数值，应避免。**
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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MeDiPro CREATINE KINASE TEST (CK) - UV kinetic, NAC method

INTENDED USE

For the quantitative determination of creatine kinase activity in serum or plasma.

CLINICAL SIGNIFICANCE

Creatinine kinase (CK) catalyzes the reversible reaction of creatine and ATP to form creatine phosphate and ADP which plays a very important role in the function of energy storage in the human tissue. It presents mostly in skeletal muscle, heart and brain. Damage of muscle and heart tissues will release CK to the blood stream and result in the increase of CK activity. Determination of CK activity in serum or plasma is a good diagnostic marker of muscular dystrophy, myocardial infarction, renal damage and dysfunction and other skeletal muscle diseases.

PRINCIPLE

Creatine phosphate + ADP $\xrightarrow{CK}$ creatine + ATP

ATP + D-glucose $\xrightarrow{Hexokinase}$ glucose-6-phosphate + ADP

glucose-6-phosphate + NAD^+ $\xrightarrow{G6PDH}$ 6-phosphogluconate + NADH + H^+

The rate of NADH formation is directly proportional to the CK activity.

REAGENT

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

	Component	Conc.
R_1	Imidazole pH7.0±0.3	10 mmol/L
	Mg^{2+}	10 mmol/L
	AMP	5.0 mmol/L
	Hexokinase	3000 U/L
	G6PDH	2500 U/L
	Creatine phosphate	30 mmol/L
R_2	D-glucose	20 mmol/L
	ADP	5 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

Serum and heparin-treated plasma are the choices for the assay. Avoid from hemolysis since glucose-6-phosphate dehydrogenase, adenylate kinase, ATP liberated from red cells will interfere with the result. CK is reportedly stable for 4 hrs at room temperature, 8~12 hours at 4℃, and 2~3 days when frozen. Analyze as soon as possible after sampling is recommended.

PROCEDURES

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

	Volume (ml)
sample	0.02
R_1	0.8
Mix, 37℃ incubate 3min	
R_2	0.2

Mix, incubate at 37℃ for 3 min, and read the initial absorbance A_1 against reagent blank, then read end absorbance A_2 in every 1 min. $A = A_{340} - A_{405}$.

CALCULATION

$$CK\ (U/L) = \frac{(A_2 - A_1)/\min \times Vt \times 1000}{Lp \times \varepsilon \times Vs} = (A_2 - A_1)/\min \times 8199$$

Vt: Reaction total volume 1.02 ml, Vs: sample volume 0.02 ml
ε: NADH molar absorptivity 6.22,
1000: transfer U/ml to U/L, Lp: Optical path length（cm）

REFERENCE RANGE

Sex	Conc.（U/L）
Male	24-195 U/L
Female	24-170 U/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. Hemolysis specimen shall be avoided.**
5. **The test is developed to determine creatine kinase concentrations up to 800U/L. 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.**

FORMOSA BIOMEDICAL TECHNOLOGY CORP.
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Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan

Product number: BC-0015
V1.0

IVD For *In Vitro* Diagnostic

MeDiPro CREATINE KINASE TEST (CK) - UV kinetic, NAC method

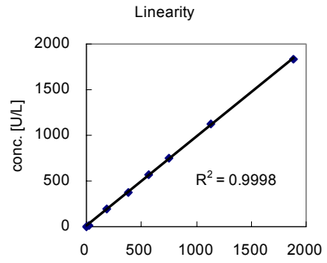
7. **Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related to the safety precautions of such materials.**
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[U/L]	SD [U/L]	CV[%]
Sample1	124	1.11	0.89
Sample2	417	2.12	0.51
Sample3	452	4.37	0.97

2. Linearity



This kit has a good linearity up to1600U/L.

3. Interference

Interference	Influence effect
Hemoglobulin	Not suitable when hemolysis occur
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	No interference was observed by intrafat up to 1.4%

4. Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

1. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37℃, Part 2. Clin. Chem. Lab. Med. 2002, 40: 631.
2. New IFCC reference procedures for the determination of catalytic activity concentrations of five enzymes in serum: preliminary upper reference limits obtained in hospitalized subjects. Clinica Chimica. Acta. 2003, 327: 69.

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[CK]
ASSAY CODE	[RateA]:[24]-[34]
SAMPLE VOLUME	[4]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH(nm)	[405][340]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[CK]
ASSAY CODE	[RateA]:[35]-[50]
SAMPLE VOLUME	[6]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH(nm)	[405][340]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0015M	MeDiPro CREATINE KINASE TEST	R1 6×20ml R2 3×10ml
BC-0015A	MeDiPro CREATINE KINASE TEST	R1 4×60ml R2 2×30ml
BC-0015B	MeDiPro CREATINE KINASE TEST	R1 4×100ml R2 2×50ml
BC-0015C	MeDiPro CREATINE KINASE TEST R1	R1 2×300ml
BC-0015D	MeDiPro CREATINE KINASE TEST R1	R1 2×500ml
BC-0015G	MeDiPro CREATINE KINASE TEST R2	R2 2×200ml

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