產品型號: BC-0009
V1.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑澱粉酶試劑（AMY）- colorimetric test-CNPG3 method

效能：

本試劑僅供體外定量分析人血清、血漿或尿液中的 α-澱粉酶活性。

臨床意義：

血清澱粉酶上升可用於診斷急性胰腺炎、腮腺炎等；澱粉酶下降則對肝臟疾病，如肝炎、阻塞性黃疸、肝癌、肝硬化、肺炎、胰腺機能不全等有診斷意義。

方法學原理：

$$\text{Gal-G}_2\text{-α-CNP} \xrightarrow{\text{α-AMY}} \text{Gal-G}_2 + \text{CNP}$$

CNP（2-氯-4-硝基苯酚）的形成會造成波長 405nm 處吸光度上升，上升的速率與 α-AMY 活性成正比。

試劑：

1. 規格：
   詳見外盒包裝標示。
2. 成份：

成份	濃度
Gal-G2-α-CNP	0.3 mmol/L
Buffer	50 mmol/L

試劑穩定性：

在 2-8℃避光保存，請勿冰凍。

檢體：

新鮮無溶血血清，用肝素抗凝血漿。尿檢體測定前請保存於冰箱內。

操作步驟：

1. 測定主波長：405 nm　測定副波長：660nm
   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
檢體 ml	---	---	0.02
標準液 ml	---	0.02	---
去離子水 ml	0.02	---	---
試劑 ml	1.0	1.0	1.0

取試劑 1ml 於各管中，置 37℃保溫 5 分鐘。以去離子水調"零"點，分別在 405 及 660nm 下測吸光值 A，A＝A_{405}-A_{660}。加 0.02ml 檢體，1 分鐘後測定吸光值 A_1。準確間隔 1 分鐘，再檢測終末吸光值 A_2，A_2-A_1=△A/min。

結果計算：

$$\text{血清澱粉酶（U/L）} = \frac{(A_2\text{-}A_1)/\text{min}\times Vt\times 1000}{Lp\times\varepsilon\times Vs} = \frac{\Delta A/\text{min}\times 3806}{}$$

Vt: 反應總體積 1.02 ml, Vs: 樣品體積 0.02 ml
1000: 將 IU/ml 轉換完成 IU/L, Lp: 比色光徑（1cm）
ε: CNP 摩爾吸光係數 13.4

參考值：

血清：< 220 U/L
新鮮尿液：< 1000 U/L
收集尿液：< 900 U / 24 h

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. **草酸鹽、檸檬酸鈉、EDTA-2Na 及氟化物對澱粉酶活性有抑制現象，肝素無明顯抑制效果。檢體若有乳糜血的現象可能會影響測定。由於唾液中含有大量的澱粉酶，因此試劑必須注意避免唾液的污染。**
5. **本試劑線性可達 2000U/L。當血清中澱粉酶活性大於 2000U/L 時，應將血清用生理食鹽水稀釋，結果乘上稀釋倍數。尿液測定時建議將樣本以生理食鹽水稀釋 1 倍測定，再將結果乘以 2 。**
6. **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。**
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)**
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-0009
V1.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑淀粉酶试剂（AMY）- colorimetric test-CNPG3 method

效能：

本试剂仅供体外定量分析人血清、血浆或尿液中的 α-淀粉酶活性。

临床意义：

血清淀粉酶上升可用于诊断急性胰腺炎、腮腺炎等；淀粉酶下降则对肝脏疾病，如肝炎、阻塞性黄疸、肝癌、肝硬化、肺炎、胰腺机能不全等有诊断意义。

方法学原理：

$$\text{Gal-G}_2\text{-α-CNP} \xrightarrow{\text{α-AMY}} \text{Gal-G}_2 + \text{CNP}$$

CNP（2-氯-4-硝基苯酚）的形成会造成波长 405nm 处吸光度上升，上升的速率与 α-AMY 活性成正比。

试剂：

1. 规格：
   详见外盒包装标示。
2. 成份：

成份	浓度
Gal-G2-α-CNP	0.3 mmol/L
Buffer	50 mmol/L

试剂稳定性：

在 2-8℃避光保存，请勿冰冻。

检体：

新鲜无溶血血清，用肝素抗凝血浆。尿检体测定前请保存于冰箱内。

操作步骤：

1. 测定主波长：405 nm　测定副波长：660nm
   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
检体 ml	---	---	0.02
标准液 ml	---	0.02	---
去离子水 ml	0.02	---	---
试剂 ml	1.0	1.0	1.0

取试剂 1ml 于各管中，置 37℃保温 5 分钟。以去离子水调"零"点，分别在 405 及 660nm 下测吸光值 A，A＝A_{405}-A_{660}。加 0.02ml 检体，1 分钟后测定吸光值 A_1。准确间隔 1 分钟，再检测终末吸光值 A_2，A_2-A_1=△A/min。

结果计算：

$$\text{血清淀粉酶（U/L）} = \frac{(A_2\text{-}A_1)/\text{min}\times Vt\times 1000}{Lp\times\varepsilon\times Vs} = \frac{\Delta A/\text{min}\times 3806}{}$$

Vt: 反应总体积 1.02 ml, Vs: 样品体积 0.02 ml
1000: 将 IU/ml 转换完成 IU/L, Lp: 比色光径（1cm）
ε: CNP 摩尔吸光系数 13.4

参考值：

血清：< 220 U/L
新鲜尿液：< 1000 U/L
收集尿液：< 900 U / 24 h

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. **草酸盐、柠檬酸钠、EDTA-2Na 及氟化物对淀粉酶活性有抑制现象，肝素无明显抑制效果。检体若有乳糜血的现象可能会影响测定。由于唾液中含有大量的淀粉酶，因此试剂必须注意避免唾液的污染。**
5. **本试剂线性可达 2000U/L。当血清中淀粉酶活性大于 2000U/L 时，应将血清用生理食盐水稀释，结果乘上稀释倍数。尿液测定时建议将样本以生理食盐水稀释 1 倍测定，再将结果乘以 2 。**
6. **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。**
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)**
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 α-AMYLASE TEST (AMY) - colorimetric test-CNPG3 method

INTENDED USE

For the quantitative determination of α-amylase activity in serum, plasma or urine.

CLINICAL SIGNIFICANCE

α-Amylase catalyzes the hydrolysis of oligosaccharides, polysaccharides, starches and glycogen with formation of maltose and dextrin. The human serum α-amylase activity is therefore clinically related to the diseases of the pancreas and for evaluation of pancreatic function. α-amylase activity increased considerably in acute pancreatitis and obstruction of the pancreatic ducts. α-amylase activity also increase in acute abdominal pain associated with peptic ulcer, empyema of the gallbladder and intestinal obstruction.

PRINCIPLE

Substrate Gal-G_2-α-CNP is hydrolyzed by α-amylase to Gal-G_2 and CNP stochiometrically. The rate of CNP formation due to substrate hydrolysis by α-amylase is proportionally correlated with α-amylase activity which is measured by following the rate of absorbance increase at 410nm. The reaction is shown as follows:

$$\text{Gal-G}_2\text{-α-CNP} + \text{H}_2\text{O} \xrightarrow{\text{α-amylase}} \text{Gal-G}_2 + \text{CNP}$$

REAGENT

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

Component	Conc.
Gal-G2-α-CNP	0.3 mmol/L
Buffer	50 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

Serum, heparin-treated plasma, or urine samples may be used. Anticoagulant such as citrate, oxalate or EDTA must be avoided. α-Amylase activity in serum or urine sample, without bacterial contamination, are stable for 7 days at room temperature and several months at 4℃.

PROCEDURES

1. Main wavelength：405 nm
   Sub. wavelength：660nm
   Reaction Temperature：37℃
   Optical path length：1.0 cm
2. This kit contains single reagent, ready to use.

	Blank	Control	Specimen
Specimen ml	---	---	0.02
Control ml	---	0.02	---
ddH_2O ml	0.02	---	---
Reagent ml	1.0	1.0	1.0

Mix, incubate at 37℃ for 5 min, and read the initial absorbance A_1 against reagent blank, then read end absorbance A_2 in every 1 min. $A = A_{405}-A_{660}$

CALCULATION

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

$$= (A_2 - A_1)/\text{min} \times 3806$$

Vt: Reaction total volume 1.02 ml, Vs: sample volume 0.02 ml
ε: CNP molar absorptivity 13.4,
1000: transfer U/ml to U/L, Lp: Optical path length（cm）

REFERENCE RANGE

Serum < 220 U/L
Fresh urine < 1000 U/L
Collect urine < 900 U / 24 h

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 test is developed to determine α-amylase concentrations up to 2000U/L. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.**
6. **Anticoagulant such as citrate, oxalate or EDTA must be avoided because of binding of calcium ion, which is essential for α-amylase activity. Specimen lipemia might be affect test result. Saliva contains very high α-amylase activity; avoid bringing any saliva into the substrate.**
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.)**
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.**

FORMOSA BIOMEDICAL TECHNOLOGY CORP.
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Product number: BC-0009
V1.0

IVD For *In Vitro* Diagnostic

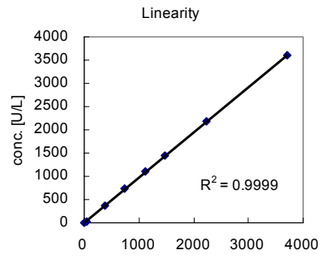
MeDiPro α-AMYLASE TEST (AMY) - colorimetric test-CNPG3 method

REAGENT CHARACTERS

1. Precision (Within run)

N=15	Mean[U/L]	SD [U/L]	CV[%]
Sample1	57.90	1.29	2.22
Sample2	384.00	2.91	0.76
Sample3	380.40	3.06	0.81

2. Linearity



This kit has a good linearity up to 3000U/L.

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 40mg/dL
Bilirubin (conjugate form)	No interference was observed by bilirubin up to 40mg/dL
Intrafat	No interference was observed by intrafat up to 0.2%

4. Stability

Expire day	1 year
Open vial stability	14 day

REFERENCE

1. Winn-Deen E.S., David H., Sigler G., Chavez R. Development of a direct assay for α-amylase. 1988. Clin. Chem. 34:2005-2008.
2. Foo A.Y., Bias R. Amylase measurement with 2-chliro-4-nitrophenyl maltotrioside as substrate. 1998. Clin. Chim. Acta. 272:137-147.

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[AMY]
ASSAY CODE	[RateA]:[3]-[10]
SAMPLE VOLUME	[4]
R1 VOLUME	[200]
R2 VOLUME	[0]
WAVELENGTH(nm)	[660][405]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[AMY]
ASSAY CODE	[RateA]:[5]-[15]
SAMPLE VOLUME	[6]
R1 VOLUME	[300]
R2 VOLUME	[0]
WAVELENGTH(nm)	[660][405]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0009M	MeDiPro α-AMYLASE TEST	R1 6×20ml
BC-0009A	MeDiPro α-AMYLASE TEST	R1 4×60ml
BC-0009B	MeDiPro α-AMYLASE TEST	R1 4×100ml
BC-0009C	MeDiPro α-AMYLASE TEST	R1 2×250ml
BC-0009D	MeDiPro α-AMYLASE TEST	R1 2×500ml

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