IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑血中尿素氮試劑（BUN）- Enzymatic UV test-urease-GLDH

效能：

用於臨床實驗體外定量分析人體血清或血漿中尿素氮的含量。

臨床意義：

血中尿素氮測定對腎功能不全的診斷具有重要的意義，通常在尿液排泄障礙，如腎小球功能降低、浮腫；尿素生成過剩，如高蛋白飲食，組織壞死情況下尿素測定結果均呈現上升趨勢。而在尿素排泄過多，如多尿；或是尿素生成減少，如低蛋白飲食呈下降趨勢。

方法學原理：

$$urea + H_2O \xrightarrow{urease} NH_4^+ + CO_2$$

$$NH_4^+ + \alpha\text{-KG} + NADH \xrightarrow{GLDH} glutamate + NAD^+ + H_2O$$

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:	Tris buffer	100 mmol/L
	α-KG	5 mmol/L
	ADP	0.6 mmol/L
	GLDH	>1500 U/L
	Urease	>20 U/L
R_2:	Tris buffer	100 mmol/L
	NADH	0.25 mmol/L

保存溫度：

在 2-8℃避光保存，請勿冰凍。

檢體：

無溶血的血清或 heparin 抗凝的血漿。

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. 二步法（雙試劑）：

加入物	標準管	測定管
R_1（ml）	0.8	0.8
標準液（ml）	0.01	----
檢體（ml）	----	0.01
混合, 37℃ 下培育 5 分鐘		
R_2（ml）	0.2	0.2

以去離子水調"零"點，混勻分別在 340nm 及 405nm 處檢測各管吸光度 A，A＝A_{340}-A_{405}。37℃預溫 60 秒，檢測初始光吸收值 A_1，準確間隔 30 秒後檢測終末光吸收值 A_2。

結果計算

檢體中的尿素氮（mg/dL）

$$= \frac{(A_2 - A_1)_{檢體}}{(A_2 - A_1)_{標準}} \times 尿素氮標準濃度（mg/dL）$$

參考值：

5~25 mg/dL (1.8~8.9 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. **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。**
5. **在測定過程中，各種器材和蒸餾水應無氨污染。**
6. **本試劑線性可達 150mg/dL。當檢體的 BUN 濃度大於 150mg/dL 時， 應將檢體用生理食鹽水稀釋後再分析，結果乘以稀釋倍數。**
7. **試劑空白吸光度小於 1.000，勿用。**
8. **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。**
9. **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)**
10. **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)**
11. **有效期限見試劑盒上標籤所示。**
12. **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。**
13. **試劑特性及參數設定請參見第四頁。**

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

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑血中尿素氮试剂（BUN）- Enzymatic UV test-urease-GLDH

效能：

用于临床实验体外定量分析人体血清或血浆中尿素氮的含量。

临床意义：

血中尿素氮测定对肾功能不全的诊断具有重要的意义，通常在尿液排泄障碍，如肾小球功能降低、浮肿；尿素生成过剩，如高蛋白饮食，组织坏死情况下尿素测定结果均呈现上升趋势。而在尿素排泄过多，如多尿；或是尿素生成减少，如低蛋白饮食呈下降趋势。

方法学原理：

$$urea + H_2O \xrightarrow{urease} NH_4^+ + CO_2$$

$$NH_4^+ + \alpha\text{-KG} + NADH \xrightarrow{GLDH} glutamate + NAD^+ + H_2O$$

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:	Tris buffer	100 mmol/L
	α-KG	5 mmol/L
	ADP	0.6 mmol/L
	GLDH	>1500 U/L
	Urease	>20 U/L
R_2:	Tris buffer	100 mmol/L
	NADH	0.25 mmol/L

保存温度：

在 2-8℃避光保存，请勿冰冻。

检体：

无溶血的血清或 heparin 抗凝的血浆。

操作步骤：

1. 测定主波长：340 nm　测定副波长：405nm
   温度：37°C　比色杯光径：1.0 cm
2. 二步法（双试剂）：

加入物	标准管	测定管
R_1（ml）	0.8	0.8
标准液（ml）	0.01	----
检体（ml）	----	0.01
混合, 37°C 下培育 5 分钟		
R_2（ml）	0.2	0.2

以去离子水调"零"点，混匀分别在 340nm 及 405nm 处检测各管吸光度 A，A＝A_{340}-A_{405}。37°C预温 60 秒，检测初始光吸收值 A_1，准确间隔 30 秒后检测终末光吸收值 A_2。

结果计算

检体中的尿素氮（mg/dL）

$$= \frac{(A_2 - A_1)_{检体}}{(A_2 - A_1)_{标准}} \times 尿素氮标准浓度（mg/dL）$$

参考值：

5~25 mg/dL (1.8~8.9 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. **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。**
5. **在测定过程中，各种器材和蒸馏水应无氨污染。**
6. **本试剂线性可达 150mg/dL。当检体的 BUN 浓度大于 150mg/dL 时， 应将检体用生理食盐水稀释后再分析，结果乘以稀释倍数。**
7. **试剂空白吸光度小于 1.000，勿用。**
8. **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。**
9. **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)**
10. **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)**
11. **有效期限见试剂盒上标签所示。**
12. **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。**
13. **试剂特性及参数设定请参见第四页。**

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

IVD For *In Vitro* Diagnostic

MeDiPro BLOOD UREA NITROGEN TEST (BUN) - Bromcresol green method

INTENDED USE

For the quantitative determination of urea nitrogen in serum or plasma

CLINICAL SIGNIFICANCE

Urea is a nitrogen-generated end-product of proteolysis. Urea is produced in the liver. It constitutes the majority of the NPN fraction of the blood, and is normally excreted by the kidney into urine. Blood Urea Nitrogen (BUN) levels are therefore related to the protein metabolism (Intake and catabolism) and kidney function.

PRINCIPLE

Urea is hydrolyzed by urease to produce ammonia. The ammonia is then coupled with α-ketoglutarate and NADH to produce glutamate and NAD^+. The rate of absorbance decrease is directly proportional to the amount of urea present in the sample. The reaction equation is as following:

$$\text{Urea} + 2H_2O \xrightarrow[\text{Glutamate dehydrogenase}]{\text{urease}} 2NH_3 + H_2CO_3$$

$$NH_3 + \alpha\text{-ketoglutarate} \longrightarrow \text{glutamate} + NAD^+$$

REAGENT

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

	Component	Conc.
R_1:	Tris buffer	100 mmol/L
	α-ketoglutarate	5 mmol/L
	ADP	0.6 mmol/L
	GLDH	>1500 U/L
	Urease	>20 U/L
R_2:	Tris buffer	100 mmol/L
	NADH	0.25 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

The test can be performed by using serum, plasma. For serum, blood is drawn into a tube which does not contain anticoagulant and allowed to form clotting. The serum is then separated from the clot. Samples are generally stable for 1 day at room temperature but can be stored for several days refrigerated or several months frozen without any appreciable loss of urea.
For plasma, add whole blood directly into a tube containing anticoagulant. Most common anticoagulants may be used except EDTA.

PROCEDURES

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

	Control	Specimen
R_1（ml）	0.8	0.8
Control ml）	0.01	----
Specimen（ml）	----	0.01
Mix, 37℃ incubate 5 min		
R_2（ml）	0.2	0.2

Mix, incubate at 37℃ for 1 min, and read the initial absorbance A_1 against reagent blank, then read end absorbance A_2 in every 30 sec. $A = A_{340} - A_{405}$.

CALCULATION

With standard or calibrator

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

REFERENCE RANGE

5~25 mg/dL (1.8~8.9 mmol/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.**
5. **Each instrument, material and distilled water used in the test procedures shall be confirmed without ammonium contamination.**
6. **The test is developed to determine blood urea nitrogen concentrations up to 150mg/dL. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.**
7. **Do not use if reagent blank less than 1.0.**
8. **The above-mentioned procedures are suitable either for the general semi-automatic, full-automatic biochemical analysis instrument or manual operation.**
9. **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.**
10. **Waste management please refers to the local legal requirements.**
11. **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.)**
12. **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.**
13. **Validity please see the reagent box label shown.**

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

Product number: BC-0012
V1.0

IVD For *In Vitro* Diagnostic

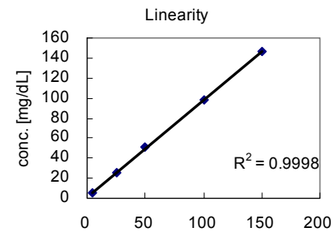
MeDiPro BLOOD UREA NITROGEN TEST (BUN) - Bromcresol green method

REAGENT CHARACTERS

1. Precision (Within run)

N=15	Mean[mg/dL]	SD [mg/dL]	CV[%]
Sample1	15.50	0.26	1.71
Sample2	48.29	0.29	0.61
Sample3	49.43	0.49	1.00

2. Linearity



This kit has a good linearity up to 150mg/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 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 1.8%

4. Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

Tiffany, TO, Jansen JM, Burtis CA, et.al. Enzymatic kinetic rate and endpoint analysis of substrate by use of GEMSAEC fast analyzer. Clin. Chem. 1972. 18:829.

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[BUN]
ASSAY CODE	[Rate A]: [19]-[22]
SAMPLE VOLUME	[2]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH(nm)	[405][340]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[BUN]
ASSAY CODE	[Rate A]: [30]-[35]
SAMPLE VOLUME	[3]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH(nm)	[405][340]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0012M	MeDiPro BLOOD UREA NITROGEN TEST	R1 6×20ml R2 3×10ml
BC-0012A	MeDiPro BLOOD UREA NITROGEN TEST	R1 4×60ml R2 2×30ml
BC-0012B	MeDiPro BLOOD UREA NITROGEN TEST	R1 4×100ml R2 2×50ml
BC-0012C	MeDiPro BLOOD UREA NITROGEN TEST R1	R1 2×300ml
BC-0012D	MeDiPro BLOOD UREA NITROGEN TEST R1	R1 2×500ml
BC-0012G	MeDiPro BLOOD UREA NITROGEN TEST R2	R2 2×200ml

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