產品型號: BC-0032
V1.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑葡萄糖試劑（GLU-HK）- Enzymatic UV test without deproteinisation

效能：
用於臨床實驗體外定量分析人體血清或血漿中葡萄糖的含量。

臨床意義：
血糖濃度受神經系統和激素的調節而保持相對穩定，當這些調節失去原有的相對平衡，則出現病理性的高血糖或低血糖。

方法學原理：

$$\text{Glucose + ATP} \xrightarrow{\text{HK}} \text{glucose-6-phosphate + ADP}$$

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

試劑：
1. 產品規格:
   詳見外盒包裝標示。I
2. 成份與濃度：

	成份	濃度
R_1:	Buffer pH6.5	
	ATP	2 mmol/L
	NAD^+	2 mmol/L
R_2:	G6PDH	1500 U/L
	Hexokinase	1500 U/L

保存溫度：
2-8℃保存，請勿冰凍。

檢體：
無溶血血清、肝素或 EDTA 抗凝血漿。檢體採集後必須儘快離心處理，或用氟化物抑制醣解作用。

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. 本試劑盒爲液態雙試劑，可直接上機使用。

加入物	空白管	標準管	檢體管
檢體(ml)	---	---	0.01
標準品 (ml)	---	0.01	---
ddH_2O (ml)	0.01	---	---
R_1 (ml)	0.8	0.8	0.8
混勻，37℃保溫 5 分鐘			
R_2 (ml)	0.2	0.2	0.2

以去離子水調"零"點，分別在 340nm 及 405nm 處檢測各管吸光值 A，$A=A_{340}-A_{405}$。。混勻、保溫 1 分鐘，檢測檢體管初始吸光值 A_1，準確間隔 1 分鐘後再檢測終末吸光值 A_2。

結果計算
葡萄糖（mg/dL）

$$= \frac{\text{檢體管吸光值}}{\text{標準管吸光值}} \times \text{葡萄糖標準液濃度（mg/dL）}$$

參考值：
70-105 mg/dL (3.9-5.8 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．本試劑線性可達 400 mg/dL。當檢體的葡萄糖濃度大於 400 mg/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。

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．本品操作時請穿戴手套及必要之防護措施，操作中若不慎沾上，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-0032
V1.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑葡萄糖试剂（GLU-HK）- Enzymatic UV test without deproteinisation

效能：
用于临床实验体外定量分析人体血清或血浆中葡萄糖的含量。

临床意义：
血糖浓度受神经系统和激素的调节而保持相对稳定，当这些调节失去原有的相对平衡，则出现病理性的高血糖或低血糖。

方法学原理：

$$\text{Glucose + ATP} \xrightarrow{\text{HK}} \text{glucose-6-phosphate + ADP}$$

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

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:	Buffer pH6.5	
	ATP	2 mmol/L
	NAD^+	2 mmol/L
R_2:	G6PDH	1500 U/L
	Hexokinase	1500 U/L

保存温度：
2-8℃保存，请勿冰冻。

检体：
无溶血血清、肝素或 EDTA 抗凝血浆。检体采集后必须尽快离心处理，或用氟化物抑制醣解作用。

操作步骤：
1. 测定主波长：340 nm　测定副波长：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。

加入物	空白管	标准管	检体管
检体(ml)	---	---	0.01
标准品 (ml)	---	0.01	---
ddH_2O (ml)	0.01	---	---
R_1 (ml)	0.8	0.8	0.8
混匀，37℃保温 5 分钟			
R_2 (ml)	0.2	0.2	0.2

以去离子水调"零"点，分别在 340nm 及 405nm 处检测各管吸光值 A，$A=A_{340}-A_{405}$。。混匀、保温 1 分钟，检测检体管初始吸光值 A_1，准确间隔 1 分钟后再检测终末吸光值 A_2。

结果计算
葡萄糖（mg/dL）

$$= \frac{\text{检体管吸光值}}{\text{标准管吸光值}} \times \text{葡萄糖标准液浓度（mg/dL）}$$

参考值：
70-105 mg/dL (3.9-5.8 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．本试剂线性可达 400 mg/dL。当检体的葡萄糖浓度大于 400 mg/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。

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．本品操作时请穿戴手套及必要之防护措施，操作中若不慎沾上，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 GLUCOSE TEST-Hexokinase method (GLU-HK) - Enzymatic UV test without deproteinisation

INTENDED USE

For the quantitative determination of glucose in serum or plasma.

CLINICAL SIGNIFICANCE

The most common disease associated with abnormal carbohydrate metabolism is diabetes mellitus, with its accompanying high blood glucose levels. Other conditions which may also result in abnormal blood glucose levels include: disorders of the pituitary gland, hyperthyroidism, Cushing 's disease, traumatic injury, convulsive disorders, mental stress and phenochromocytoma. Acute and chronic infection, eclampsia, hypertension and severe liver disease may also exhibit transitory elevation of blood glucose level. On the other hand, hyperinsulinism from either exogenous insulin overdose or from lesions of the pancreas can result in low level of blood glucose.

PRINCIPLE

The reagent used here is based on the hexokinase (HK) – glucose-6-phosphate dehydrogenase (G6PDH) U.V. end point method. The reactions are as follows:

$$\text{Glucose + ATP} \xrightarrow{HK} \text{glucose-6-phosphate + ADP}$$

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

The increase in NADH concentration is directly proportional to the glucose concentration.

REAGENT

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

	Component	Conc.
R_1:	Buffer pH6.5	
	ATP	2 mmol/L
	NAD^+	2 mmol/L
R_2:	G6PDH	1500 U/L
	Hexokinase	1500 U/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

Both serum and plasma samples can be used. For serum samples, collect whole blood and allow it to clot in clean test tube at room temperature. Separate and then transfer the serum without delay to a clean test tube. Do the test as soon as possible or store at 2~8℃ to avoid degradation. For plasma specimens, collect whole blood into a tube containing a suitable anticoagulant, (EDTA, heparin, etc.), separate and transfer the plasma into a clear test tube. To prevent degradation from glycolysis, fluoride (up to 10 mg/dl) may be added with no effect on the test results.

PROCEDURES

1. Main wavelength：340 nm
Sub. wavelength：400nm
Reaction Temperature：37℃
Optical path length：1.0 cm
2. This kit contains two reagents, ready to use.

	Blank	Control	Sample
Sample(ml)	---	---	0.01
Control (ml)	---	0.01	---
ddH_2O (ml)	0.01	---	---
R_1 (ml)	0.8	0.8	0.8
Mix, 37℃ incubate 5min			
R_2 (ml)	0.2	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 1 min. $A = A_{340}-A_{405}$.

CALCULATION

With standard or calibrator

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

REFERENCE RANGE

70-105 mg/dL (3.9-5.8 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. **The test is developed to determine glucose concentrations up to 400mg/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.**

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Product number: BC-0032
V1.0

IVD For *In Vitro* Diagnostic

MeDiPro GLUCOSE TEST-Hexokinase method (GLU-HK) - Enzymatic UV test without deproteinisation

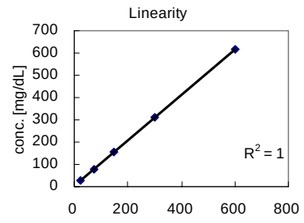
7. **Since all specimens are potentially infectious, they should be handled with appropriate precautions and practices in accordance with Biosafety level 2 as recommended by USA NIH manual Biosafety in Microbiological and Biomedical Laboratories, and in accordance with National or local regulations related 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[mg/dL]	SD [mg/dL]	CV[%]
Sample1	89	0.94	1.06
Sample2	281	1.64	0.58
Sample3	277	1.75	0.63

2. Linearity



This kit has a good linearity up to 600mg/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 2.0%

4. Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

1. Henry, J.B., "Clinical Diagnosis and Management by Laboratory Method." W.B. Saunders and Company Philadelphia, PA, p. 153 (1979).
2. Barthelmai, W., and Czek, R., Klin. Wochenscht., 40:585 (1962).
3. Tietz, N.W., Fundamentals of Clinical Chemistry, 2 nd. Ed., W.B. Saunders Co., Philadelphia, PA243 (1976).

PARAMETER SETUP

Hitachi 7170 / 917 Applications

TEST	[GLU-HK]
ASSAY CODE	[2 POINT]: [16]-[34]
SAMPLE VOLUME	[2]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH (nm)	[405][340]
CALIB. METHOD	[Linear]

Hitachi 7150 / 717 Applications

TEST	[GLU-HK]
ASSAY CODE	[2 POINT]: [24]-[50]
SAMPLE VOLUME	[3]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH (nm)	[405][340]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0032M	MeDiPro GLUCOSE TEST - Hexokinase Method	R1 6×20ml R2 3×10ml
BC-0032A	MeDiPro GLUCOSE TEST - Hexokinase Method	R1 4×60ml R2 2×30ml
BC-0032B	MeDiPro GLUCOSE TEST - Hexokinase Method	R1 4×100ml R2 2×50ml
BC-0032C	MeDiPro GLUCOSE TEST - Hexokinase Method R1	R1 4×300ml
BC-0032D	MeDiPro GLUCOSE TEST - Hexokinase Method R1	R1 4×500ml
BC-0032G	MeDiPro GLUCOSE TEST - Hexokinase Method R2	R2 4×200ml

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