產品型號: BC-0022
V2.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑乳酸脫氫酶試劑（LDH）- LDH-P method

效能：

用於臨床實驗體外定量分析人體血清中乳酸脫氫酶的活性。

臨床意義：

乳酸脫氫酶主要存在於心、腎、肝和肌肉組織中，這些組織損害時會導致血清乳酸脫氫酶活性升高，目前常用於急性心肌梗塞、肝病、阻塞性黃疸和某些惡性腫瘤的輔助診斷。

方法學原理：

$$\text{Pyruvate + NADH + H}^+ \xrightarrow{\text{LDH}} \text{L-lactate + NAD}^+$$

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:	Buffer	(pH8.95)±0.3
	Pyruvate	55 mmol/L
R_2:	NADH	7.5 mmol/L

保存溫度：

2-8℃避光保存，請勿冰凍。

檢體：

新鮮無溶血的血清。

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	測定管
檢體 ml	0.02
R_1 ml	0.8
混勻，37℃保溫 5 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 1 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

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

Vt: 反應總體積 1.02ml, 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：

200 ~ 480 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. 當檢體的乳酸脫氫酶濃度大於 1000 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. 試劑變混濁或初始吸光度<0.6，則不能使用。

6. 檢體最好在兩小時內分離，汞、硼酸鹽及抗凝劑 (heparin 除外)大都會抑制其活性。

7. 紅血球的乳酸脫氫酶含量爲血清之 100-400 倍，因此檢體應避免溶血，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。

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)

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。

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产品型号: BC-0022
V2.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑乳酸脱氢酶试剂（LDH）- LDH-P method

效能：

用于临床实验体外定量分析人体血清中乳酸脱氢酶的活性。

临床意义：

乳酸脱氢酶主要存在于心、肾、肝和肌肉组织中，这些组织损害时会导致血清乳酸脱氢酶活性升高，目前常用于急性心肌梗塞、肝病、阻塞性黄疸和某些恶性肿瘤的辅助诊断。

方法学原理：

$$\text{Pyruvate + NADH + H}^+ \xrightarrow{\text{LDH}} \text{L-lactate + NAD}^+$$

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	(pH8.95)±0.3
	Pyruvate	55 mmol/L
R_2:	NADH	7.5 mmol/L

保存温度：

2-8℃避光保存，请勿冰冻。

检体：

新鲜无溶血的血清。

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	测定管
检体 ml	0.02
R_1 ml	0.8
混匀，37℃保温 5 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 1 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

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

Vt: 反应总体积 1.02ml, 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：

200 ~ 480 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. 当检体的乳酸脱氢酶浓度大于 1000 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. 试剂变混浊或初始吸光度<0.6，则不能使用。

6. 检体最好在两小时内分离，汞、硼酸盐及抗凝剂 (heparin 除外)大都会抑制其活性。

7. 红血球的乳酸脱氢酶含量为血清之 100-400 倍，因此检体应避免溶血，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。

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)

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。

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MeDiPro LACTATE DEHYDROGENASE TEST (LDH) - LDH-P method

INTENDED USE
For the quantitative determination of lactate dehydrogenase activity in serum.

CLINICAL SIGNIFICANCE
Lactate dehydrogenase (LDH) is widely distributed in mammalian tissues, being rich in myocardium, kidney, liver and muscle. Determination of serum LDH activity is one of the most frequently performed assays in the diagnosis of myocardial and pulmonary infarction. Other conditions, such as metaloblasic anemia, extensive carcinomatosis, severe shock and hypoxia, granulocytic or acute anemia, hemolytic anemia, infectious mononucleosis, progressive muscular dystrophy, hepatitis, cirrhosis, obstructive jaundice, and in delirium tremens all will cause the increased activity of LDH.

PRINCIPLE

$$\text{Pyruvate + NADH} \xrightarrow{\text{LDH}} \text{Lactic acid + NAD}^+$$

The rate of NADH formation is proportional to the activity of LDH

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

	Component	Conc.
R_1:	Buffer	(pH8.95)±0.3
	Pyruvate	55 mmol/L
R_2:	NADH	7.5 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 is the choice for the assay but heparin and EDTA which will inhibit the LDH activity should not be used. Hemolysis should be avoided. Serum LDH is reported to be stable for 1 week at room temperature, and for 3 weeks at 2~8 ℃. Specimen frozen should be avoided since the activities of LDH-4 and LDH-5 decrease significantly after frozen.

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 5min	
R_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

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

$$= (A_2 - A_1)/\text{min} \times 8199$$

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
200 ~ 480 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. Cause lots of LDH in red cell, so hemolysis should be avoided.**
5. **The test is developed to determine LDH concentrations up to 1000U/L. When values exceed this range, samples should be diluted with normal saline and calculate the results by multiplying the dilution factor.**
6. **Do not use if reagents become turbid or initial blank OD less than 0.6.**
7. **Fresh serum must be separated in 2 hours, Hg, sodium borate, and most anticoagulant, except heparin, might inhibit LDH activity.**
8. **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-0022
V2.0

IVD For *In Vitro* Diagnostic

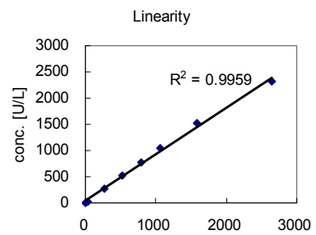
MeDiPro LACTATE DEHYDROGENASE TEST (LDH) - LDH-P method

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.**

REAGENT CHARACTERS
1. Precision (Within run)

N=15	Mean[U/L]	SD [U/L]	CV[%]
Sample1	290	2.53	0.87
Sample2	845	2.06	0.24
Sample3	9656	6.04	0.63

2. Linearity



This kit has a good linearity up to 2000U/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 1.6%

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 3. 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	[LDH]
ASSAY CODE	[Rate A]: [19]-[30]
SAMPLE VOLUME	[4]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH (nm)	[405][340]
CALIB. METHOD	[Linear]

Hitachi 7150 / 717 Applications

TEST	[LDH]
ASSAY CODE	[Rate A]: [30]-[45]
SAMPLE VOLUME	[6]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH (nm)	[405][340]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0022M	MeDiPro LACTATE DEHYDROGENASE TEST	R1 6×20ml R2 3×10ml
BC-0022A	MeDiPro LACTATE DEHYDROGENASE TEST	R1 4×60ml R2 2×30ml
BC-0022B	MeDiPro LACTATE DEHYDROGENASE TEST	R1 4×100ml R2 2×50ml
BC-0022C	MeDiPro LACTATE DEHYDROGENASE TEST R1	R1 2×300ml
BC-0022D	MeDiPro LACTATE DEHYDROGENASE TEST R1	R1 2×500ml
BC-0022G	MeDiPro LACTATE DEHYDROGENASE TEST R2	R2 2×200ml

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