產品型號: BC-0007
V2.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑丙胺酸轉胺酶試劑（ALT）-UV-IFCC method

效能：

用於臨床實驗體外定量分析人體血清中丙胺酸轉胺酶的活性。

臨床意義：

血清丙胺酸轉胺酶活性的檢測對中毒性肝炎、病毒性肝炎、肝癌、肝硬化活動期、脂肪肝、阻塞性黃疸、膽管炎和膽囊炎、心血管疾病、心肌梗塞、心肌炎、骨骼肌疾病、內臟和肌肉炎症性壞死等病症的診斷具有重要的價值。

方法學原理：

L-alanine+α-ketoglutaric acid $\xrightarrow{ALT}$ pyruvate+ glutamate

pyruvate + NADH + H^+ $\xrightarrow{LDH}$ lactate + 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
	LDH	>1200 U/L
	L-alanine	500 mmol/L
R_2	α-ketoglutaric acid	15 mmol/L
	Tris Buffer	100 mmol/L
	NADH	0.18 mmol/L

保存溫度：

2-8℃避光保存，請勿冰凍。

檢體：

新鮮無溶血血清。

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	檢體
檢體 ml	0.05
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 下測吸光，$A = A_{340}-A_{405}$。混勻檢體管，37℃保溫 1 分鐘，檢測檢體管初始吸光值 A1，準確間隔 1 分鐘再檢測終末吸光值 A2。

結果計算

$$ALT（U/L）= \frac{（A_2 - A_1）/ min \times Vt \times 1000}{Lp \times \varepsilon \times Vs} = (A_2 - A_1)/min \times 3376$$

Vt: 反應總體積 1.05 ml, Vs: 檢體體積 0.05 ml
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（1cm）

參考值：

< 40U/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． **當檢體的丙胺酸轉胺酶活性大於 800U/L 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。**

5． **試劑空白吸光度小於 1.000 時，勿用。**

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，且避免用溶血的檢體做檢測，溶血的檢體可能會使測定值上升 10 倍。**

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-0007
V2.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑丙胺酸转胺酶试剂（ALT）-UV-IFCC method

效能：

用于临床实验体外定量分析人体血清中丙胺酸转胺酶的活性。

临床意义：

血清丙胺酸转胺酶活性的检测对中毒性肝炎、病毒性肝炎、肝癌、肝硬化活动期、脂肪肝、阻塞性黄疸、胆管炎和胆囊炎、心血管疾病、心肌梗塞、心肌炎、骨骼肌疾病、内脏和肌肉炎症性坏死等病症的诊断具有重要的价值。

方法学原理：

L-alanine+α-ketoglutaric acid $\xrightarrow{ALT}$ pyruvate+ glutamate

pyruvate + NADH + H^+ $\xrightarrow{LDH}$ lactate + 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
	LDH	>1200 U/L
	L-alanine	500 mmol/L
R_2	α-ketoglutaric acid	15 mmol/L
	Tris Buffer	100 mmol/L
	NADH	0.18 mmol/L

保存温度：

2-8℃避光保存，请勿冰冻。

检体：

新鲜无溶血血清。

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. 本试剂盒为液态双试剂，可直接上机使用。

加入物	检体
检体 ml	0.05
R_1 ml	0.8
混匀，37°C保温 5 分钟	
R_2 ml	0.2

以去离子水调"零"点，分别在 340nm 及 405nm 下测吸光，$A = A_{340}-A_{405}$。混匀检体管，37°C保温 1 分钟，检测检体管初始吸光值 A1，准确间隔 1 分钟再检测终末吸光值 A2。

结果计算

$$ALT（U/L）= \frac{（A_2 - A_1）/ min \times Vt \times 1000}{Lp \times \varepsilon \times Vs} = (A_2 - A_1)/min \times 3376$$

Vt: 反应总体积 1.05 ml, Vs: 检体体积 0.05 ml
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（1cm）

参考值：

< 40U/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． **当检体的丙胺酸转胺酶活性大于 800U/L 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。**

5． **试剂空白吸光度小于 1.000 时，勿用。**

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，且避免用溶血的检体做检测，溶血的检体可能会使测定值上升 10 倍。**

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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MeDiPro ALANINE AMINOTRANSFERASE (ALT) - UV-IFCC method

INTENDED USE

For the quantitative determination of alanine aminotransferase activity in serum.

CLINICAL SIGNIFICANCE

Alanine aminotransferase (ALT) is widely distributed in animal tissue, with the highest concentration present in liver and kidney. Acute destruction of tissue results in the release of ALT into the blood. Serum ALT level up to 1000 times normal has been observed in cases of acute hepatitis. Less elevated values have been associated with infectious mononucleosis, extra-hepatic, obstructive jaundice and cirrhosis.

PRINCIPLE

L-Alanine+α-ketoglutaric acid $\xrightarrow{ALT}$ pyruvate+ glutamate

pyruvate + NADH + H^+ $\xrightarrow{LDH}$ lactate + NAD^+ + H_2O

REAGENT

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

	Component	Conc.
R_1	Tris Buffer	100 mmol/L
	LDH	>1200 U/L
	L-alanine	500 mmol/L
R_2	α-ketoglutaric acid	15 mmol/L
	Tris Buffer	100 mmol/L
	NADH	0.18 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

Fresh serum is suitable for ALT assay. Avoid hemolysis. Hemolysis could cause false elevation of the ALT activity. Serum should be removed from the clot or cells without delay.

Serum ALT activity is not stable and should be kept at 4℃ for short period or stored frozen at -20℃ or lower for longer periods.

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	0.05
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

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

$$= (A_2 - A_1)/min \times 3376$$

Vt: Reaction total volume 1.05 ml, Vs: sample volume 0.05 ml
ε: NADH molar absorptivity 6.22,
1000: transfer U/ml to U/L, Lp: Optical path length（cm）

REFERENCE RANGE

<40U/L

WARNINGS AND PRECAUTIONS

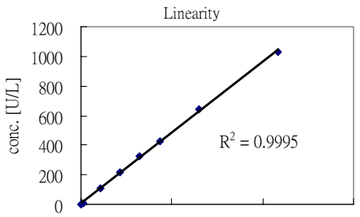
1. **This kit offers an optional calibrator, which is sold individually. Bio-Rad Lyphochek control is recommended to use as serum control.**
2. **Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.**
3. **This kit is for professionals 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. **Do not use when reagent blank OD less than 1.0.**
6. **The test is developed to determine alanine aminotransferase 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.**
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.**

REAGENT CHARACTERS

1. Precision (Within run)

N=15	Mean[U/L]	SD [U/L]	CV[%]
Sample1	32.90	0.74	2.24
Sample2	97.40	0.70	0.72
Sample3	97.40	0.70	0.72

2. Linearity



This kit has a good linearity up to 1000U/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 30mg/dL
Bilirubin (free form)	No interference was observed by bilirubin up to 12mg/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. IFCC primary reference procedures for the measurement of catalytic activity concentrations of enzymes at 37℃, Part 4. 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	[ALT]
ASSAY CODE	[Rate A]: [19]-[34]
SAMPLE VOLUME	[10]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH(nm)	[405][340]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[ALT]
ASSAY CODE	[Rate A]: [30]-[50]
SAMPLE VOLUME	[15]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH(nm)	[405][340]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0007M	MeDiPro ALANINE AMINOTRANSFERASE TEST	R1 6×20ml, R2 3×10ml
BC-0007A	MeDiPro ALANINE AMINOTRANSFERASE TEST	R1 4×60ml, R2 2×30ml
BC-0007B	MeDiPro ALANINE AMINOTRANSFERASE TEST	R1 4×100ml, R2 2×50ml
BC-0007C	MeDiPro ALANINE AMINOTRANSFERASE TEST R1	R1 4×300ml
BC-0007D	MeDiPro ALANINE AMINOTRANSFERASE TEST R1	R1 4×500ml
BC-0007G	MeDiPro ALANINE AMINOTRANSFERASE TEST R2	R2 4×200ml

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IVD For *In Vitro* Diagnostic

MeDiPro ALANINE AMINOTRANSFERASE (ALT) - UV-IFCC method

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