產品型號: BC-0006
V1.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑鹼性磷酸酶試劑（ALP）- IFCC method

效能：

用於臨床實驗體外定量分析人體血清中鹼性磷酸酶的活性。

臨床意義：

鹼性磷酸酶活性測定常用爲肝膽疾病和骨骼疾病等臨床輔助診斷之指標，其活性增加可見於阻塞性黃疸、急性或慢性黃疸型肝炎、肝癌、肝硬化、佝僂病、癌於骨骼中的轉移、骨軟化症等病症。

方法學原理：

$$\text{p-nitrophenylphosphate}+H_2O \xrightarrow[Mg^{2+}]{ALP} \text{p-nitrophenol (yellow)} + \text{phosphate}$$

磷酸硝基苯基質在鹼性磷酸酶作用下，釋放出對硝基酚從而引起波長 405nm 處吸光值的上升。吸光值的上升與血清中的鹼性磷酸酶活性成正比。

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
R1	AMP（buffer）pH10.2	413 mmol/L
	$MgCl_2$	1.25 mmol/L
R2	p-nitrophenylphosphate	32.5 mmol/L

保存溫度：

2-8℃避光保存，請勿冰凍。

檢體：

新鮮無溶血之血清，不可使用 EDTA、oxalate、citrate 抗凝的血漿。

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 405nm 及 660nm 處測吸光值 A，$A=A_{405}-A_{660}$。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

$$ALP（U/L）= \frac{(A_2-A_1)/\text{min}\times Vt\times 1000}{Lp\times\varepsilon\times Vs} = (A_2-A_1)/\text{min}\times 2742$$

Vt: 反應總體積 1.02 ml, Vs: 檢體體積 0.02 ml
ε: 對-硝基酚的毫摩爾吸光係數 18.6,
1000: 將 U/ml 轉換成 U/L, Lp: 光徑（cm）

參考值：

年齡	濃度（U/L）
小孩	30-130
成人	20-70

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・ 當檢體的鹼性磷酸酶活性大於 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 R_2 工作液後應是淡黃色透明液體，如放置一段時間後，發生混濁或試劑空白吸光值>0.7 時請勿使用。

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・ 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。溶血的檢體可能會使測定值上升，因爲鹼性磷酸酶在紅血球中的濃度爲血清中的六倍。

8・ 本品操作時需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)

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-0006
V1.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑碱性磷酸酶试剂（ALP）- IFCC method

效能：

用于临床实验体外定量分析人体血清中碱性磷酸酶的活性。

临床意义：

碱性磷酸酶活性测定常用为肝胆疾病和骨骼疾病等临床辅助诊断之指标，其活性增加可见于阻塞性黄疸、急性或慢性黄疸型肝炎、肝癌、肝硬化、佝偻病、癌于骨骼中的转移、骨软化症等病症。

方法学原理：

$$\text{p-nitrophenylphosphate}+H_2O \xrightarrow[Mg^{2+}]{ALP} \text{p-nitrophenol (yellow)} + \text{phosphate}$$

磷酸硝基苯基质在碱性磷酸酶作用下，释放出对硝基酚从而引起波长 405nm 处吸光值的上升。吸光值的上升与血清中的碱性磷酸酶活性成正比。

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
R1	AMP（buffer）pH10.2	413 mmol/L
	$MgCl_2$	1.25 mmol/L
R2	p-nitrophenylphosphate	32.5 mmol/L

保存温度：

2-8℃避光保存，请勿冰冻。

检体：

新鲜无溶血之血清，不可使用 EDTA、oxalate、citrate 抗凝的血浆。

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 405nm 及 660nm 处测吸光值 A，$A=A_{405}-A_{660}$。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

$$ALP（U/L）= \frac{(A_2-A_1)/\text{min}\times Vt\times 1000}{Lp\times\varepsilon\times Vs} = (A_2-A_1)/\text{min}\times 2742$$

Vt: 反应总体积 1.02 ml, Vs: 检体体积 0.02 ml
ε: 对-硝基酚的毫摩尔吸光系数 18.6,
1000: 将 U/ml 转换成 U/L, Lp: 光径（cm）

参考值：

年龄	浓度（U/L）
小孩	30-130
成人	20-70

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・ 当检体的碱性磷酸酶活性大于 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 R_2 工作液后应是淡黄色透明液体，如放置一段时间后，发生混浊或试剂空白吸光值>0.7 时请勿使用。

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・ 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。溶血的检体可能会使测定值上升，因为碱性磷酸酶在红血球中的浓度为血清中的六倍。

8・ 本品操作时需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)

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 ALKALINE PHOSPHATASE（ALP）- IFCC method

INTENDED USE
For the quantitative determination of alkaline phosphatase activity in serum.

CLINICAL SIGNIFICANCE
Alkaline phosphatases(ALP) in serum is derived primarily from the liver, intestine and with little amount from bone. Increase of ALP activities are, therefore, indicators of hepatobiliary or bone disorder. In hepatobiliary disease, billary cirrhosis produces exceptionally high levels of serum ALP. Infiltrative disease and cholangiolitic hepatitis are accompanied by significant elevations of ALP. Widely elevated ALP level may also occur in infectious mononucleosis.
Among the bone diseases, the highest level of serum ALP activity happens in Paget's disease and bone cancer. Moderate rises are observed in osteomalacia, rickets, Faconi syndrome, primary hyperparathyroidism and secondary hyperparathyroidism. An increase of alkaline phosphatase up to 2 to 3 times of normal is observed in women in the third trimester of pregnancy, this enzyme is placental original.
Moderate elevations of ALP may be observed in several disorders that do not involve the liver or bone. Among these are Hodgkin's disease, congestive heart failure, ulcesative colitis, regional enteritis, and intraabdominal bacterial infections.

PRINCIPLE
p-nitrophenylphosphate+H_2O $\xrightarrow[Mg^{2+}]{ALP}$ p-nitrophenol + phosphate (yellow)

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

	Component	Conc.
R1	AMP（buffer）pH10.2	413 mmol/L
	$MgCl_2$	1.25 mmol/L
R2	p-nitrophenyl phosphate	32.5 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
Freshly drawn serum is the specimen of choices. Avoid stasis or hemolysis. Heparinized plasma may also be used. Fluoride and anticoagulants such as citrate, oxalate or EDTA should be avoided in the collection of specimens due to their ability to be chelated with Mg^{2+}. Alkaline phsphatase in serum is stable for at least 7 days at 4℃ and longer when frozen.

PROCEDURES
1. Main wavelength：405 nm
   Sub. wavelength：660nm
   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 5 min	
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. $A = A_{405}-A_{660}$.

CALCULATION

$$ALP\ (U/L) = \frac{(A_2-A_1)/min \times Vt \times 1000}{Lp \times \varepsilon \times Vs} = (A_2 - A_1)/min \times 2742$$

Vt: Reaction total volume 1.02 ml, Vs:sample volume 0.02 ml
ε: p-nitrophenyl phosphate molar absorptivity 18.6,
1000: transfer U/ml to U/L, Lp: Optical path length（cm）

REFERENCE RANGE

Age	Conc. (U/L)
Child	30-130
Adult	20-70

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. Red cells contains lots of alkaline phosphatase than serum, if specimen hemolyzed, it will interfere with the result.**
5. **The test is developed to determine alkaline phosphatases 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.**
6. **Reagent R2 shall be clear light yellow solution. Please don't use when it becomes muddy or blank OD over 0.7.**

FORMOSA BIOMEDICAL TECHNOLOGY CORP.
F-5F, No. 201, Tunghua N. Rd, Taipei, 105, Taiwan Website: http://www. fbc.com.tw/
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Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan

Product number: BC-0006
V1.0

IVD For *In Vitro* Diagnostic

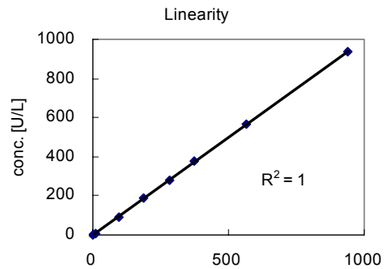
MeDiPro ALKALINE PHOSPHATASE（ALP）- IFCC method

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	85.80	0.63	0.74
Sample2	378.8	3.61	0.95
Sample3	382.1	3.11	0.81

2. Linearity



This kit has a good linearity up to 900U/L.

3. Interference

Interference	Influence effect
Hemoglobulin	No interference was observed by hemoglobulin up to 150mg/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	14 day

REFERENCE
1. Posen S, Doherty E. The measurement of serum alkaline phosphatase in clinical medicine. Adv. Clin. Chem. 1981. 157: 1441.
2. Fleisher GA, Eickelberg ES, Elveback LR, Alkaline phosphatase activity in the plasma of children and adolescents. Clin. Chem. 1977. 23: 469.

PARAMETER SETUP
Hitachi 7170/917 Applications

TEST	[ALP]
ASSAY CODE	[Rate A]: [19]-[34]
SAMPLE VOLUME	[4]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH (nm)	[660][405]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[ALP]
ASSAY CODE	[Rate A]: [30]-[50]
SAMPLE VOLUME	[6]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH (nm)	[660][405]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0006M	MeDiPro ALKALINE PHOSPHATASE TEST	R1 6×20ml R2 3×10ml
BC-0006A	MeDiPro ALKALINE PHOSPHATASE TEST	R1 4×60ml R2 2×30ml
BC-0006B	MeDiPro ALKALINE PHOSPHATASE TEST	R1 4×100ml R2 2×50ml
BC-0006C	MeDiPro ALKALINE PHOSPHATASE TEST R1	R1 2×300ml
BC-0006D	MeDiPro ALKALINE PHOSPHATASE TEST R1	R1 2×500ml
BC-0006G	MeDiPro ALKALINE PHOSPHATASE TEST R2	R2 2×200ml

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