產品型號: BC-0010
V 1.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑總膽紅素試劑（TBIL）- Diazo-DPD method

效能：

用於臨床實驗體外定量分析人體血清或血漿中總膽紅素的含量。

臨床意義：

總膽紅素的測定對於急性肝炎、慢性肝炎、肝硬化、膽管炎、膽石症、急性膽囊炎等肝膽疾病和溶血性貧血的診斷具有重要意義。

方法學原理：

在酸性的環境下，重氮劑可以與膽紅素形成偶氮膽紅素(azobilirubin)，具有指示劑的性質，可以在 OD_{546nm} 讀值

$$\text{Bilirubin+ 3,5-DCPD} \xrightarrow{\text{HCl, DMSO}} \text{azobilirubin（紅紫色）}$$

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	Sulfamic acid	70 mmol/L
	HCl	70 mmol/L
	DMSO	5 mol/L
R_2	3.5-DCPD	5mmol/L

保存溫度：

2-8℃避光保存，請勿冰凍。

檢體：

新鮮無溶血血清、肝素抗凝血漿檢體。檢體採集後應置於暗處，避光 2-8℃保存。

操作步驟：

1. 測定主波長：546 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	空白管	標準管	樣品管
R_1 ml	0.8	0.8	0.8
去離子水 ml	0.02	---	---
標準液 ml	---	0.02	---
樣品 ml	---	---	0.02
37℃保溫 5 分鐘後，再加入 R_2			
R_2 ml	0.2	0.2	0.2

分別混勻，37℃保溫 5 分鐘，以去離子水調"零"點，分別在 546nm 及 660nm 處檢測各管吸光值 A，$A=A_{546}-A_{660}$。

結果計算

檢體中膽紅素總量濃度 mg/dL

$$= \frac{A_{\text{檢體}}}{A_{\text{標準}}} \times \text{TBIL}_{\text{標準液濃度}}\text{（mg/dL）}$$

參考值：

成人　< 1.2 mg/dL
新生兒　< 12 mg/dL

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． **本試劑線性可達 18 mg/dL。當血清中總膽紅素濃度高於 18 mg/dL 時，用生理食鹽水稀釋檢體後重測，結果乘以稀釋倍數。**

5． **若 R_2 變黃，則不能使用。**

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，且避免使用溶血的檢體，血中的血紅素會造成負偏差。**

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)**

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-0010
V 1.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑总胆红素试剂（TBIL）- Diazo-DPD method

效能：

用于临床实验体外定量分析人体血清或血浆中总胆红素的含量。

临床意义：

总胆红素的测定对于急性肝炎、慢性肝炎、肝硬化、胆管炎、胆石症、急性胆囊炎等肝胆疾病和溶血性贫血的诊断具有重要意义。

方法学原理：

在酸性的环境下，重氮剂可以与胆红素形成偶氮胆红素(azobilirubin)，具有指示剂的性质，可以在 OD_{546nm} 读值

$$\text{Bilirubin+ 3,5-DCPD} \xrightarrow{\text{HCl, DMSO}} \text{azobilirubin（红紫色）}$$

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	Sulfamic acid	70 mmol/L
	HCl	70 mmol/L
	DMSO	5 mol/L
R_2	3.5-DCPD	5mmol/L

保存温度：

2-8℃避光保存，请勿冰冻。

检体：

新鲜无溶血血清、肝素抗凝血浆检体。检体采集后应置于暗处，避光 2-8℃保存。

操作步骤：

1. 测定主波长：546 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	空白管	标准管	样品管
R_1 ml	0.8	0.8	0.8
去离子水 ml	0.02	---	---
标准液 ml	---	0.02	---
样品 ml	---	---	0.02
37℃保温 5 分钟后，再加入 R_2			
R_2 ml	0.2	0.2	0.2

分别混匀，37℃保温 5 分钟，以去离子水调"零"点，分别在 546nm 及 660nm 处检测各管吸光值 A，$A=A_{546}-A_{660}$。

结果计算

检体中胆红素总量浓度 mg/dL

$$= \frac{A_{\text{检体}}}{A_{\text{标准}}} \times \text{TBIL}_{\text{标准液浓度}}\text{（mg/dL）}$$

参考值：

成人　< 1.2 mg/dL
新生儿　< 12 mg/dL

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． **本试剂线性可达 18 mg/dL。当血清中总胆红素浓度高于 18 mg/dL 时，用生理食盐水稀释检体后重测，结果乘以稀释倍数。**

5． **若 R_2 变黄，则不能使用。**

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，且避免使用溶血的检体，血中的血红素会造成负偏差。**

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)**

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 TOTAL BILIRUBIN TEST（TBIL）- Diazo-DPD method

INTENDED USE
For the quantitative determination of total bilirubin in serum or plasma.

CLINICAL SIGNIFICANCE
Bilirubin, is derived primarily in bile,from the breakdown of hemoglobin when senescent red blood cells are phagocytized. Normally, about 6 to 6.5 g of hemoglobin in aged red blood cells are broken down daily in an adult to form about 220 mg of bilirubin; another 50 to 60 mg of bilirubin originates from other sources. The detail mechanism of bilirubin formation is not well understood. But it is known that the heme group of hemoglobin is converted to bilirubin in reticuloendothelial system, which binds to albumin in plasma and is esterified to bilirubin diglucuromide (BDG), which is secreted from liver as a waste product. It presents in serum in the free and conjugated forms. An increase in the formation or retention of bilirubin in the body results in the increased levels of serum bilirubin and jaundice. This hyperbilirubinemia is classified as prehepatic, hepatic or posthepatic depending on the major cause of condition. Therefore, the determination of total bilirubin and its conjugated (direct) bilirubin is important for the diagnosis of hyperbilirubinemia.

PRINCIPLE

Bilirubin+ 3,5-DCPD $\xrightarrow{\text{HCl, DMSO}}$ azobilirubin
（Reddish-purple）

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

	Component	Conc.
R_1	Sulfamic acid	70 mmol/L
	HCl	70 mmol/L
	DMSO	5 mol/L
R_2	3.5-DCPD	5mmol/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 is avoided.
Do not freeze the reagent!

SPECIMEN COLLECTION AND PREPARATION
Fresh serum and plasma are the choices. The sample be collected without hemolysis, since hemoglobin inhibits the diazo reaction.
Avoid direct light exposure to the specimen since Bilirubin values may decrease as much as 50 % in one hour. Serum specimen may be kept in dark in 2-8℃ for up to one week, and in freezer for 3 months without appreciable change in the Bilirubin levels.

PROCEDURES
1. Main wavelength：546 nm
   Sub. wavelength：660nm
   Reaction Temperature：37℃
   Optical path length：1.0 cm
2. This kit contains two reagents, ready to use.

	Blank	Control	Specimen
R_1 (ml)	0.8	0.8	0.8
ddH_2O(ml)	0.02	---	---
Control (ml)	---	0.02	---
Specimen(ml)	---	---	0.02
mix, 37℃ incubate 5min			
R_2 (ml)	0.2	0.2	0.2

Mix, incubate at 37℃ for 5 min, and read the absorbance against reagent blank. $A = A_{546}-A_{660}$

CALCULATION
With standard or calibrator

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

REFERENCE RANGE

Age	Conc.（mg/dL）
Newborn	< 12
Adult	< 1.2

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 if reagent 2 turns yellow.**
6. **The test is developed to determine bilirubin concentrations up to 18mg/dL. 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.**

FORMOSA BIOMEDICAL TECHNOLOGY CORP.
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Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan

Product number: BC-0010
V1.0

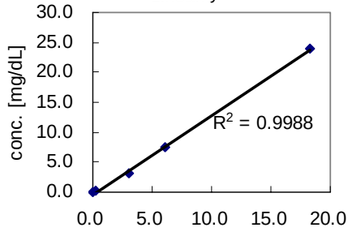
IVD For *In Vitro* Diagnostic

MeDiPro TOTAL BILIRUBIN TEST（TBIL）- Diazo-DPD method

REAGENT CHARACTERS
1. Precision (Within run)

N=15	Mean[mg/dL]	SD [mg/dL]	CV[%]
Sample1	0.74	0.01	1.78%
Sample2	4.89	0.10	1.97%
Sample3	4.77	0.08	1.67%

2. Linearity



This kit has a good linearity up to 20mg/dL.

3. Interference

Interference	Influence effect
Hemoglobulin	Not suitable when hemolysis occur
Ascorbic acid	No interference was observed by ascorbic acid up to 50mg/dL
Intrafat	Not suitable when lipemia occur

4. Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE
1. Basll T.D., Billy W.P., Edward A.S., Jon V.S. Standardization in bilirubin assays: evaluation of selected methods and stability of bilirubin solutions. 1973, 19: 984-993.
2. Billy W.P., Basll T.D., etc. A candidate reference method for determination of bilirubin in serum. Test for transferability. Clin. Chem. 1983, 29: 297-301.

PARAMETER SETUP

Hitachi 7170/917 Applications

TEST	[TBIL]
ASSAY CODE	[2POINT]: [16]-[34]
SAMPLE VOLUME	[4]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH(nm)	[660][546]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[TBIL]
ASSAY CODE	[2POINT]: [24]-[50]
SAMPLE VOLUME	[6]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH(nm)	[660][546]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0010M	MeDiPro TOTAL BILIRUBIN TEST	R1 6×20ml R2 3×10ml
BC-0010A	MeDiPro TOTAL BILIRUBIN TEST	R1 4×60ml R2 2×30ml
BC-0010B	MeDiPro TOTAL BILIRUBIN TEST	R1 4×100ml R2 2×50ml
BC-0010C	MeDiPro TOTAL BILIRUBIN TEST R1	R1 2×300ml
BC-0010D	MeDiPro TOTAL BILIRUBIN TEST R1	R1 2×500ml
BC-0010G	MeDiPro TOTAL BILIRUBIN TEST R2	R2 2×200ml

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