產品型號: BC-0011
V1.0

IVD 供體外診斷使用
For *In Vitro* Diagnostic

台塑直接膽紅素試劑（DBIL）- Diazo-DPD method

效能：

用於臨床實驗體外定量分析人血清或血漿中直接膽紅素的含量。

臨床意義：

直接膽紅素的測定對於阻塞性黃疸、先天性非溶血性黃疸和肝炎後間接膽紅素過高血症的診斷具有重要意義。

方法學原理：

在酸性的環境下，重氮劑 (3,5-dichlorophenyl diazonium, 3,5-DCPD)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。

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

試劑：

1. 型號規格:
   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
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、肝素抗凝血漿樣本。檢體採集後應置於暗處，避光 2-8℃保存，並儘速測定完成。

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	0.04	---	---
標準液 ml	---	0.04	---
樣品 ml	---	---	0.04
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

樣品中直接膽紅素濃度(mg/dL)

$$= \frac{A_{樣品} - A_{樣品空白}}{A_{標準} - A_{標準空白}} \times C_{標準液濃度}（mg/dL）$$

參考值：

0.2-0.7 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. **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；檢體若有乳糜血的現象也會影響測定。**
5. **本試劑線性可達 6 mg/dL。當樣品中直接膽紅素含量高於 6 mg/dL 時，用生理食鹽水稀釋後再測，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。**

台塑生醫科技股份有限公司
台北市敦化北路 201 號前棟五樓
TEL：+886-2-2712-2211 #7822
製造廠：台塑生醫宜蘭廠

Website: http://www. fbc.com.tw/
FAX：+886-2-2717-8381
廠址：宜蘭縣礁溪鄉龍潭村龍泉路 3 號

产品型号: BC-0011
V1.0

IVD 供体外诊断使用
For *In Vitro* Diagnostic

台塑直接胆红素试剂（DBIL）- Diazo-DPD method

效能：

用于临床实验体外定量分析人血清或血浆中直接胆红素的含量。

临床意义：

直接胆红素的测定对于阻塞性黄疸、先天性非溶血性黄疸和肝炎后间接胆红素过高血症的诊断具有重要意义。

方法学原理：

在酸性的环境下，重氮剂 (3,5-dichlorophenyl diazonium, 3,5-DCPD)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。

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

试剂：

1. 型号规格:
   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
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、肝素抗凝血浆样本。检体采集后应置于暗处，避光 2-8℃保存，并尽速测定完成。

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	0.04	---	---
标准液 ml	---	0.04	---
样品 ml	---	---	0.04
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

样品中直接胆红素浓度(mg/dL)

$$= \frac{A_{样品} - A_{样品空白}}{A_{标准} - A_{标准空白}} \times C_{标准液浓度}（mg/dL）$$

参考值：

0.2-0.7 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. **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；检体若有乳糜血的现象也会影响测定。**
5. **本试剂线性可达 6 mg/dL。当样品中直接胆红素含量高于 6 mg/dL 时，用生理食盐水稀释后再测，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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制造厂：台塑生医宜兰厂

Website: http://www. fbc.com.tw/
FAX：+886-2-2717-8381
厂址：宜兰县礁溪乡龙潭村龙泉路 3 号

MeDiPro DIRECT BILIRUBIN TEST (DBIL) - Diazo-DPD method

INTENDED USE

For the quantitative determination of direct bilirubin in serum or plasma.

CLINICAL SIGNIFICANCE

An increase in the formation or retention of bilirubin in the body results in the increased level of serum bilirubin and jaundice. This hyperbilirubinemia is classified as either pre-hepatic, hepatic or post-hepatic depending on the major cause of condition. Therefore, the determination of the total bilirubin and its conjugated (direct) bilirubin is important for the diagnosis of hyperbilirubinemia.

PRINCIPLE

$$\text{Bilirubin+ 3,5-DCPD} \xrightarrow{\text{HCl}} \text{azobilirubin (Purplish-red)}$$

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
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 should be avoided. **Do not freeze the reagent!**

SPECIMEN COLLECTION AND PREPARATION

Fresh serum and heparin-treated plasma are the choices. The sample should be collected without hemolysis, since hemoglobin will inhibit 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)	0.04	---	---
control (ml)	---	0.04	---
Specimen(ml)	---	---	0.04
Max, 37℃ incynate 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

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

REFERENCE RANGE

0.2-0.7 mg/dL

WARNINGS AND PRECAUTIONS

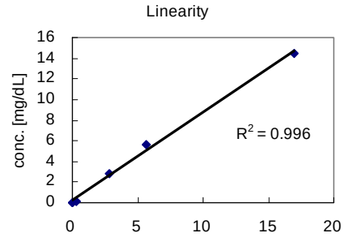
1. **This kit offers an optional calibrator, which is sold individually. Bio-Rad Lyphochek control is recommended to use as serum control.**
2. **Each laboratory has to perform the quality control test to assure the results being reliable before running the specimen tests.**
3. **This kit is for professionals and *in vitro* diagnostic use only.**
4. **To ensure the accuracy of result, the absorbance should be measured within 30 minutes after sample addition. Hemolysis and lipemia specimen should be avoided.**
5. **The test is developed to determine direct bilirubin concentrations up to 6mg/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.**
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	0.54	0.01	2.27
Sample2	2.48	0.02	0.71
Sample3	2.36	0.03	1.45

2. Linearity



This kit has a good linearity up to 12mg/dL.

3. Interference

Interference	Influence effect
Hemoglobulin	Not suitable when hemolysis occur
Ascorbic acid	No interference was observed by ascorbic acid up to 35mg/dL
Intrafat	Not suitable when lipemia occur

4. Stability

Expire day	1 year
Open vial stability	30 day

REFERENCE

1. Doumas BT, Wu TW. The measurement of bilirubin fractions in serum. Crit Rev Clin Lab Sci 1991; 28(5-6): 415-445.
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	[DBIL]
ASSAY CODE	[2POINT]: [16]-[34]
SAMPLE VOLUME	[8]
R1 VOLUME	[160]
R2 VOLUME	[40]
WAVELENGTH(nm)	[700][570]
CALIB. METHOD	[Linear]

Hitachi 7150/717 Applications

TEST	[DBIL]
ASSAY CODE	[2POINT]: [24]-[50]
SAMPLE VOLUME	[12]
R1 VOLUME	[240]
R2 VOLUME	[60]
WAVELENGTH(nm)	[700][570]
CALIB. METHOD	[Linear]

ORDERING INFORMATION

Cat. No.	Product	Package
BC-0011M	MeDiPro DIRECT BILIRUBIN TEST	R1 6×20ml R2 3×10ml
BC-0011A	MeDiPro DIRECT BILIRUBIN TEST	R1 4×60ml R2 2×30ml
BC-0011B	MeDiPro DIRECT BILIRUBIN TEST	R1 4×100ml R2 2×50ml
BC-0011C	MeDiPro DIRECT BILIRUBIN TEST R1	R1 2×300ml
BC-0011D	MeDiPro DIRECT BILIRUBIN TEST R1	R1 2×500ml
BC-0011G	MeDiPro DIRECT BILIRUBIN TEST R2	R2 2×200ml

FORMOSA BIOMEDICAL TECHNOLOGY CORP.
F-5F, No. 201, Tunghua N. Rd, Taipei, 105, Taiwan Website: http://www. fbc.com.tw/
TEL: +886-2-2712-2211 #7822 FAX: +886-2-2717-8381
Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan

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IVD For *In Vitro* Diagnostic

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F-5F, No. 201, Tunghua N. Rd, Taipei, 105, Taiwan Website: http://www. fbc.com.tw/
TEL: +886-2-2712-2211 #7822 FAX: +886-2-2717-8381
Factory: No. 3, Longchuan Rd, Longtang Village, Jiaosi, Yilan County, 262, Taiwan