



BILIRUBIN D- DPD

Direct Bilirubin

DPD. Colorimetric

Quantitative determination of direct bilirubin**IVD**

Store at 2-8°C

PRINCIPLE OF THE METHOD

Direct bilirubin (conjugated) couples with the diazo reagent in the presence of sulfamic acid to form azobilirubin. The intensity of color formed is proportional to the bilirubin concentration in the sample tested. The increase of absorbance at 546 nm is directly proportional to the direct bilirubin concentration.

CLINICAL SIGNIFICANCE

Bilirubin is caused by the degradation of hemoglobin and exists in two forms. Unconjugated bilirubin is transported to the liver bound by albumin where it becomes conjugated (direct) with glucuronic acid and excreted.

Hyperbilirubinemia is the result of an increase of bilirubin in plasma. Possible causes: **Total bilirubin:** Increase hemolysis, genetic, neonatal jaundice, ineffective erythropoiesis and presence of drugs.

Direct bilirubin: Hepatic cholestasis, genetic, hepatocellular damage.

Clinical diagnosis should not be made based on a single test result; it should integrate clinical and other laboratory data.

REAGENTS

R 1	Sulfamic acid	100 mM
R 2	2,4-DPD Hydrochloric acid (HCl)	0,5 mM 0,3 M

PRECAUTIONS

R1: H314 - Irritation or skin corrosion. / R2: H290- Corrosive to metals. H335 - May cause respiratory irritation. H314 - Irritation or skin corrosion.

R2: contains HCl and 2,4-DPD.

Follow the safety advice given in MSDS and product label.

PREPARATION

The reagents are provided in a ready to use format.

STORAGE AND STABILITY

The reagents are stable until the expiry date stated on the label when stored at

2-8°C, protected from light and contaminations are prevented during their use. Do not use reagents over the expiration date.

Signs of reagent deterioration:

- Presence of particles and turbidity.

ADDITIONAL EQUIPMENT

- SPIN640 / SPIN640Plus Autoanalyzer.
- General laboratory equipment.

SAMPLES

Serum or plasma, free of hemolysis. Protect samples from light.

Stability of the sample: 4 days at 2-8°C or 2 month at -20°C.

QUALITY CONTROL

Control sera are recommended to monitor the performance of assay procedures: SPINTROL H Normal and Pathologic (Ref. 1002120 and 1002210). If control values are found outside the defined range, check the instrument, reagents and calibrator for problems.

Each laboratory should establish its own Quality Control scheme and corrective actions if controls do not meet the acceptable tolerances.

BARCODED REAGENTS LOAD MUST BE PRECEDED OF A SPINREACT "DATABASE" COPY INTO THE ANALYZER SOFTWARE. IT IS AVAILABLE UNDER REQUEST TO SPINREACT.

SPIN640 APPLICATION

TEST INFORMATION		REAGENT VOLUME	
Nº	**	Vol. R1	240
Test	BILI D	Vol. R2	60
Full Name	BILIRUBIN D	Vol. R3	
Standard nº	1	Vol. R4	
SAMPLE VOLUME		RESULT SETUP	
Vol. Sample Stand.	15	Decimal Unit	0.01 mg/dL
Vol. Sample Increas.		Slope Inter.	1 0
Vol. Sample Dec			
REACTION PARAMETERS			
Reac. Type	End Point	Direction	Increase
Pri. Wave.	546	Reagent Blank	41-42
Sec. Wave.		React. Time	76-77

SPIN640Plus APPLICATION

EDIT PARAMETERS			
Test	BILI D	No. Print name	** BILI D
Full name	BILI D		
Reac. Type	End Point	Direction	Increase
Pri. Wave.	546	Sec. Wave.	
Unit	mg/dL	Decimal	0.01
Reagent Blank	47 - 48	React. Time	81 - 82
Vol. Sample	15 ul	R1	240 ul
Increased		R2	60 ul
Decreased		R3	
Sample blank		R4	

The Calibration is stable until 7 days. After this period the Calibration must be performed again in order to obtain good results.

REFERENCE VALUES

Direct bilirubin 0 – 0,2 mg/dL (0 – 3,42 µmol/L)

These values are for orientation purpose; each laboratory should establish its own reference range.

PERFORMANCE CHARACTERISTICS

Measuring range: From *detection limit* of 0,03 mg/dL to *linearity limit* of 9 mg/dL.

If the results obtained are greater than the linearity limit, dilute the sample 1/2 with NaCl 9 g/L and multiply the result by 2.

Precision:

	Inter assay (n= 40)	Intra assay (n= 80)
Mean (mg/dL)	0,7458	2,444
SD	0,05868	0,0550
CV (%)	7,9	2,2

Sensitivity: 1 mg/dL = 0,040 Abs. units

Accuracy: Results obtained using SPINREACT reagents (y) did not show systematic differences when compared with other commercial reagents (x) on a Spintech 240 analyzer. The results obtained using 53 samples ranging from 0,06 a 9 mg/dL (1,02 to 153,9 µmol/L) were:

Correlation coefficient (r): 0,9986

Regression equation: $y = 1,0056 x - 0,1046$

The results of the performance characteristics depend on the analyzer used.

BIBLIOGRAPHY

1. David G Levitt and Michael D Levitt. Quantitative assessment of the multiple processes responsible for bilirubin homeostasis in health and disease. Clin Exp Gastroenterol. 2014; 7: 307–328.
2. Malloy H T. et al. The determination of bilirubin with the photoelectric colorimeter. J. Biol Chem 1937; 112, 2: 481-491.
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6. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
7. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

PACKAGING

Ref: MD1001047	Cont.	R 1: 4 x 40 mL
		R 2: 2 x 20 mL





BILIRUBIN D- DPD

Bilirrubina Directa

DPD. Colorimétrico

Determinación cuantitativa de bilirrubina directa**IVD**

Conservar a 2-8°C

PRINCIPIO DEL MÉTODO

La bilirrubina directa (conjugada) se combina con la sal de diazonio en presencia de un ácido sulfámico para formar el compuesto coloreado, azobilirrubina. La intensidad del color formado es proporcional a la concentración de bilirrubina presente en la muestra ensayada. El aumento de la absorbancia a 546 nm es directamente proporcional a la concentración de bilirrubina directa.

SIGNIFICADO CLÍNICO

La bilirrubina se origina por la degradación de la hemoglobina y existe en dos formas. La bilirrubina no conjugada se transporta al hígado, unida por la albúmina, donde se convierte en conjugada (directa) con el ácido glucurónico y se excreta. La hiperbilirrubinemia es el resultado de un incremento de la bilirrubina en plasma. Causas más probables de la hiperbilirrubinemia:

Bilirrubina Total: Aumento de la hemólisis, alteraciones genéticas, anemia neonatal, alteraciones eritropoyéticas, presencia de drogas.

Bilirrubina Directa: Colestasis hepática, alteraciones genéticas y alteraciones hepáticas.

El diagnóstico clínico debe realizarse teniendo en cuenta todos los datos clínicos y de laboratorio.

REACTIVOS

R 1	Ácido sulfámico	100 mM
R 2	2,4-DPD Ácido clorhídrico (HCl)	0,5 mM 0,3 M

PRECAUCIONES

R1: H314-Irritación o corrosión / R2: H290- Corrosivo para los metales. H335 - Puede irritar las vías respiratorias. H314-Irritación o corrosión.

R2: contiene HCl and 2,4-DPD.

Seguir los consejos de prudencia indicados en la FDS y etiqueta del producto.

PREPARACIÓN

Todos los reactivos están listos para su uso.

CONSERVACIÓN Y ESTABILIDAD

Los reactivos son estables hasta la fecha de caducidad indicada en la etiqueta, cuando se mantienen los viales bien cerrados a 2-8°C, protegidos de la luz y se evita la contaminación durante su uso. No usar reactivos fuera de la fecha indicada.

Indicadores de deterioro de los reactivos:

- Presencia de partículas y turbidez.

MATERIAL ADICIONAL

- Autoanalizador SPIN640 / SPIN640Plus.
- Equipamiento habitual de laboratorio.

MUESTRAS

Suero o plasma libre de hemólisis¹. Proteger de la luz.

Estabilidad de la muestra: 4 días a 2-8°C o 2 meses a -20°C.

CONTROL DE CALIDAD

Es conveniente analizar junto con las muestras sueros control valorados:

SPINTROL H Normal y Patológico (Ref. 1002120 y 1002210).

Si los valores hallados se encuentran fuera del rango de tolerancia, revisar el instrumento, los reactivos y el calibrador.

Cada laboratorio debe disponer su propio Control de Calidad y establecer correcciones en el caso de que los controles no cumplan con las tolerancias.

PARA LA CARGA DE REACTIVOS MEDIANTE EL CÓDIGO DE BARRAS SE DEBE PRECARGAR LA "BASE DE DATOS" DISPONIBLE BAJO SOLICITUD A SPINREACT.

APLICACIÓN AL SPIN640

TEST INFORMATION		REAGENT VOLUME	
Nº	**	Vol. R1	240
Test	BILI D	Vol. R2	60
Full Name	BILIRRUBINA D	Vol. R3	
Standard nº	1	Vol. R4	
SAMPLE VOLUME		RESULT SETUP	
Vol. Sample Stand.	15	Decimal Unit	0.01 mg/dL
Vol. Sample Increas.		Slope Inter.	1 0
Vol. Sample Dec			
REACTION PARAMETERS			
Reac. Type	End Point	Direction	Increase
Pri. Wave.	546	Reagent Blank	41-42
Sec. Wave.		React. Time	76-77

APLICACIÓN AL SPIN640Plus

EDIT PARAMETERS			
Test	BILI D	No. Print name	** BILI D
Full name	BILI D		
Reac. Type	End Point	Direction	Increase
Pri. Wave.	546	Sec. Wave.	
Unit	mg/dL	Decimal	0.01
Reagent Blank	47 - 48	React. Time	81 - 82
Vol. Sample	15 ul	R1	240 ul
Increased		R2	60 ul
Decreased		R3	
Sample blank		R4	

La Calibración es estable hasta 7 días. Pasado este período es necesario solicitar de nuevo la Calibración para la obtención de buenos resultados.

VALORES DE REFERENCIA

Bilirrubina Directa 0-0,2 mg/dL (0-3,42 µmol/L)

Estos valores son orientativos. Es recomendable que cada laboratorio establezca sus propios valores de referencia.

CARACTERÍSTICAS DEL MÉTODO

Rango de medida: Desde el límite de detección de 0,03 mg/dL hasta el límite de linealidad de 9 mg/dL.

Si la concentración de la muestra es superior al límite de linealidad, diluir 1/2 con NaCl 9 g/L y multiplicar el resultado final por 2.

Precisión:

	Interserie (n= 40)	Intraserie (n= 80)
Media (mg/dL)	0,7458	2,444
SD	0,05868	0,0550
CV (%)	7,9	2,2

Sensibilidad analítica: 1 mg/dL = 0,040 Abs.

Exactitud: Los resultados obtenidos usando reactivos SPINREACT (y) no muestran diferencias sistemáticas significativas cuando se comparan con otros reactivos comerciales (x) con el analizador Spintech 240. Los resultados obtenidos con 53 muestras con valores de entre 0,06 a 9 mg/dL (1,02 a 153,9 µmol/L) fueron los siguientes:

Coeficiente de correlación (r): 0,9986.

Ecuación de la recta de regresión: $y = 1,0056 x - 0,1046$

Las características del método pueden variar según el analizador utilizado.

BIBLIOGRAFÍA

1. David G Levitt and Michael D Levitt. Quantitative assessment of the multiple processes responsible for bilirubin homeostasis in health and disease. Clin Exp Gastroenterol. 2014; 7: 307-328.
2. Malloy H T. et al. The determination of bilirubin with the photoelectric colorimeter. J. Biol Chem 1937; 112, 2; 481-491.
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6. Burtis A et al. Tietz Textbook of Clinical Chemistry, 3rd ed AACC 1999.
7. Tietz N W et al. Clinical Guide to Laboratory Tests, 3rd ed AACC 1995.

PRESENTACIÓN

Ref: MD1001047	Cont.	R 1: 4 x 40 mL
		R 2: 2 x 20 mL



Détermination quantitative de bilirubine directe**IVD**

Conserver à 2 - 8°C.

PRINCIPE DE LA MÉTHODE

La bilirubine directe (conjuguée) s'associe au sel de diazonium en présence d'un acide sulfamique pour former le composé coloré, azobilirubine. L'intensité de la couleur formée est proportionnelle à la concentration de bilirubine présente dans l'échantillon testé. L'augmentation de l'absorption à 546 nm est directement proportionnelle à la concentration de bilirubine directe.

SIGNIFICATION CLINIQUE

La bilirubine est créée par la dégradation de l'hémoglobine et existe sous deux formes. La bilirubine non conjuguée est transportée vers le foie, unie par l'albumine, où elle se transforme en conjuguée (directe) avec l'acide glucuronique et elle est excrétée. L'hyperbilirubinémie est le résultat d'une augmentation de la bilirubine dans le plasma. Les causes les plus probables de l'hyperbilirubinémie :

Bilirubine totale : Augmentation de l'hémolyse, altérations génétiques, anémie néonatale, altérations érythropoïétiques, présence de médicaments.

Bilirubine directe : Cholestase hépatique, altérations génétiques et altérations hépatiques.

Le diagnostic clinique doit être réalisé en prenant en compte toutes les données cliniques et de laboratoire.

RÉACTIFS

R 1	Acide sulfamique	100 mM
R 2	2,4-DPD Acide chlorhydrique (HCl)	0,5mM 0,3 M

PRÉCAUTIONS

R1 : H314-Irritation ou corrosion / R2: H290- Corrosif pour les métaux. H335 - Peut irriter les voies respiratoires. H314-Irritation ou corrosion
R2 : contient HCly 2,4-DPD.

Suivre les conseils de prudence indiqués sur la FDS et sur l'étiquette du produit.

PRÉPARATION

Tous les réactifs sont prêts à être utilisés.

CONSERVATION ET STABILITÉ

Les réactifs sont stables jusqu'à la date d'expiration indiquée sur l'étiquette, quand ils sont conservés bien fermés à 2-8°C, à l'abri de la lumière et que leur contamination est évitée pendant leur utilisation. Ne pas utiliser des réactifs au-delà de la date indiquée.

Indicateurs de détérioration des réactifs :

- La présence de particules et de turbidité.

MATÉRIEL SUPPLÉMENTAIRE

- Auto-analyseur SPIN640 / SPIN640Plus.
- Équipement habituel de laboratoire.

ÉCHANTILLONS

Sérum ou plasma sans hémolyse. Protéger de la lumière.

Stabilité de l'échantillon : 4 jours à 2-8°C ou 2 mois à -20°C.

CONTROLE DE QUALITÉ

Il convient d'analyser avec les échantillons de sérum de contrôle évalués :

SPINTROL H Normal et pathologique (Réf. 1002120 et 1002210).

Si les valeurs trouvées sont en dehors de la gamme de tolérance, il faut vérifier l'instrument, les réactifs et le calibrage.

Chaque laboratoire doit disposer de son propre Contrôle de qualité et établir des corrections dans le cas où les contrôles ne sont pas conformes aux tolérances exigées.

POUR TRAVAILLER AVEC CODES A BARRES, IL FAUT CHARGER LA BASE DE DONNEES QUE VOUS DEVEZ SOLICITER PREALABLEMENT A SPINREACT.

APPLICATION AU SPIN640

TEST INFORMATION		REAGENT VOLUME	
Nº	**	Vol. R1	240
Test	BILI D	Vol. R2	60
Full Name	BILIRUBIN D	Vol. R3	
Standard nº	1	Vol. R4	
SAMPLE VOLUME		RESULT SETUP	
Vol. Sample Stand.	15	Decimal	0.01
Vol. Sample Increas.		Slope	1
Vol. Sample Dec		Unit	mg/dL Inter.
			0
REACTION PARAMETERS			
Reac. Type	End Point	Direction	Increase
Pri. Wave.	546	Reagent Blank	41-42
Sec. Wave.		React. Time	76-77

APPLICATION AU SPIN640Plus

EDIT PARAMETERS		**	
Test	BILI D	No. Print name	BILI D
Full name	BILI D		
Reac. Type	End Point	Direction	Increase
Pri. Wave.	546	Sec. Wave.	
Unit	mg/dL	Decimal	0.01
Reagent Blank	47 - 48	React. Time	81 - 82
Vol. Sample	15 ul	R1	240 ul
Increased		R2	60 ul
Decreased		R3	
Sample blank		R4	

L'étalonnage est stable jusqu'à 7 jours. Passé ce délai, ou en cas d'obtention de résultats insatisfaisants, doit étalonner de nouveau pour obtenir de bons résultats.

VALEURS DE RÉFÉRENCE

Bilirubine directe 0- 0,2 mg/dL (0 -3,42 μ mol/L)

Ces valeurs sont indicatives. Il est conseillé que chaque laboratoire établisse ses propres valeurs de référence.

CARACTÉRISTIQUES DE LA MÉTHODE

Gamme de mesure: Depuis la limite de détection de 0,03 mg/dL jusqu'à la limite de linéarité de 9mg/dL.

Si la concentration de l'échantillon est supérieure à la limite de linéarité, diluer 1/2 avec CINA 9 g/L et multiplier le résultat final par 2.

Précision :

	Inter-série (n= 40)	Intra-série (n= 80)
Moyenne (mg/l/L)	0,7458	2,444
SD	0,05868	0,0550
CV (%)	7,9	2,2

Sensibilité analytique : 1 mg/dL = 0,040Abs.

Exactitude : Les résultats obtenus en utilisant les réactifs SPINREACT (y) ne montrent pas de différences systématiques significatives quand ils sont comparés à d'autres réactifs commerciaux (x). avec l'analyseur Spintech 240. Les résultats obtenus avec 53 échantillons avec des valeurs de 0,06 à 9 mg/dL (1,02 a 153,9 μ mol/L) furent les suivants :

Coefficient de corrélation (r) : 0,9986.

Equation de la droite de régression : $y = 1,0056x - 0,1046$

Les caractéristiques de la méthode peuvent varier selon l'analyseur utilisé.

BIBLIOGRAPHIE

1. David G Levitt and Michael D Levitt. Quantitative assessment of the multiple processes responsible for bilirubin homeostasis in health and disease .Cin Exp Gastroenterol. 2014; 7: 307-328.
2. Malloy H T. et al. The determination of bilirubin with the photoelectric colorimeter. J. Biol Chem 1937; 112, 2; 481-491.
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PRÉSENTATION

Ref: MD1001047	Cont.	R 1: 4 x 40 mL
		R 2: 2 x 20 mL



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CLINICAL SIGNIFICANCE

Bilirubin is caused by the degradation of hemoglobin and exists in two forms. Unconjugated bilirubin is transported to the liver bound by albumin where it becomes conjugated (direct) with glucuronic acid and excreted.

Hyperbilirubinemia is the result of an increase of bilirubin in plasma. Possible causes: **Total bilirubin:** Increase hemolysis, genetic, neonatal jaundice, ineffective erythropoiesis and presence of drugs.

Direct bilirubin: Hepatic cholestasis, genetic, hepatocellular damage.

Clinical diagnosis should not be made based on a single test result; it should integrate clinical and other laboratory data.

REAGENTS

R 1	Sulfamic acid	100 mM
R 2	2,4-DPD Hydrochloric acid (HCl)	0,5 mM 0,3 M

PRECAUTIONS

R1: H314 - Irritation or skin corrosion. / R2: H290- Corrosive to metals. H335 - May cause respiratory irritation. H314 - Irritation or skin corrosion.

R2: contains HCl and 2,4-DPD.

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PREPARATION

The reagents are provided in a ready to use format.

STORAGE AND STABILITY

The reagents are stable until the expiry date stated on the label when stored at

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- Presence of particles and turbidity.

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- General laboratory equipment.

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Serum or plasma, free of hemolysis. Protect samples from light.

Stability of the sample: 4 days at 2-8°C or 2 month at -20°C.

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Nº	**	Vol. R1	240
Test	BILI D	Vol. R2	60
Full Name	BILIRUBIN D	Vol. R3	
Standard nº	1	Vol. R4	
SAMPLE VOLUME		RESULT SETUP	
Vol. Sample Stand.	15	Decimal Unit	0.01 mg/dL
Vol. Sample Increas.		Slope Inter.	1 0
Vol. Sample Dec			
REACTION PARAMETERS			
Reac. Type	End Point	Direction	Increase
Pri. Wave.	546	Reagent Blank	41-42
Sec. Wave.		React. Time	76-77

SPIN640Plus APPLICATION

EDIT PARAMETERS			
Test	BILI D	No. Print name	** BILI D
Full name	BILI D		
Reac. Type	End Point	Direction	Increase
Pri. Wave.	546	Sec. Wave.	
Unit	mg/dL	Decimal	0.01
Reagent Blank	47 - 48	React. Time	81 - 82
Vol. Sample	15 ul	R1	240 ul
Increased		R2	60 ul
Decreased		R3	
Sample blank		R4	

The Calibration is stable until 7 days. After this period the Calibration must be performed again in order to obtain good results.

REFERENCE VALUES

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Accuracy: Results obtained using SPINREACT reagents (y) did not show systematic differences when compared with other commercial reagents (x) on a Spintech 240 analyzer. The results obtained using 53 samples ranging from 0,06 a 9 mg/dL (1,02 to 153,9 µmol/L) were:

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Regression equation: $y = 1,0056 x - 0,1046$

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PACKAGING

Ref: MD1001047	Cont.	R 1: 4 x 40 mL
		R 2: 2 x 20 mL

