Total and Direct

Bilirubin Test Kit

REF B2A102 Four 30mL bottles of Diluent
One 3mL bottle of 5 mg/dL Bilirubin Equivalent
One 3mL bottle of 20 mg/dL Bilirubin Equivalent
One 25 mL bottle of Sulfanilic Acid Solution
One 25 mL bottle of 0.2N Hydrochloric Acid
One 50 mg Sodium Nitrite Tablet
100 cuvettes

CE IVD

INTENDED USE

For *In Vitro* Diagnostic Use

Advanced Instruments Total and Direct Bilirubin Test Kit has been developed for use exclusively with the Advanced Instruments BR2 Bilirubin Stat-Analyzer™ Photometer for the determination of TOTAL (TBR) and DIRECT (DBR) bilirubin in neonatal serum or plasma.

PRINCIPLE OF OPERATION

The BR2 is a dual-wavelength, narrow-bandpass photometer that measures TBR from its differential absorbance at 454 nm and 540 nm (1). Since oxyhemoglobin, a common contaminant of neonatal serum, has equal absorbance at 454 and 540 nm, TBR readings on the BR2 are not appreciably affected by concentrations of up to 600 mg/dL oxyhemoglobin. Thirty (30) µL of serum is diluted with 1 mL of pH adjusted diluent in a disposable, polystyrene cuvette for this measurement.

DBR is measured on the same sample with a two-minute timed modification of the Malloy-Evelyn method (2,3). The previously diluted sample is acidified, and then reacted with diazotized sulfanilic acid. Under these conditions, bilirubin glucuronides react to form azobilirubin. The BR2 Bilirubin Stat-Analyzer Photometer measures the formation of azobilirubin at 540 nm. The BR2 test kit has been specially formulated so that no recalibration is necessary between TBR and DBR determinations.

WARNING

Refer to the User's Guide for additional information. Contact manufacturer for safety data sheets.

INSTRUCTIONS FOR USE

Instrument Setup:

The BR2 requires at least 30 minutes to warm up when its power is first turned on. See User's Guide for instrument setup and operational checks.

Calibration Procedure:

A great variety of normal and elevated bilirubin sera products are commercially available. The Advanced BR2 Bilirubin Stat-Analyzer Photometer was designed for calibration with any industry-accepted serum-based product. Results obtained with the BR2 can thus be directly compared with whatever method you have previously used, provided that both methods have been calibrated with the same product. Elevated bilirubin control material can be used to calibrate the BR2.

1. Verify the assigned bilirubin values on the product label/insert of the commercially available product, preferably using a manual method.
2. On the BR2, press the TOTAL button.
3. Add 1 mL diluent to a cuvette, place cuvette into the BR2 well so that the light beam passing from right to left passes through the clear (not ribbed) sides of the cuvette, close the cuvette chamber cover, and adjust the display to 00.0 with the ZERO knob.
4. Add 30 µL of the product that is to be used for calibration and mix thoroughly. (A positive displacement pipette is recommended.)
5. Adjust the display to the appropriate bilirubin value with the CALIBRATE knob.
6. Repeat steps 1 through 5 with additional aliquots of the product that is being used for calibration to verify the calibration values set on the BR2.
7. The BR2 is now calibrated and ready for testing unknown samples.

Note: The BR2 requires calibration upon installation and at least every six months, unless quality control data indicates the need for earlier calibration.

Quality Control, 5 mg/dL and 20 mg/dL Bilirubin Equivalent Solutions:

After the BR2 calibration is complete, check the calibration using products with known values, or the 5 mg/dL and 20 mg/dL Bilirubin Equivalent Solutions. Initially the Bilirubin Equivalent Solutions should be treated as if they were unknown sera. Immediately after calibrating with a primary serum-based product, determine a TBR value for each and write the value on its bottle. These values are directly related to the primary standard used to calibrate the instrument, and allow for frequent calibration checks. Now use the assigned Bilirubin Equivalent Solutions and follow the Calibration Procedure to conduct daily or more frequent calibration checks. The BR2 calibration should not drift more than +/- 0.2 mg/dL daily.

Testing Procedure:

DIAZO REAGENT PREPARATION

The diazo reagent for Direct Bilirubin determinations must be freshly prepared from reagents in the test kit, as follows:

1. Add 10 mL of distilled water to the vial containing the sodium nitrite and mix until completely dissolved. When refrigerated at 2-8ºC (35-46ºF), the solution can be used as needed until the expiration date on the kit box. After the solution has been in the refrigerator for 15 minutes, proceed to step 2.
2. Mix 1 part of the chilled sodium nitrite solution with 10 parts sulfanilic acid solution. By choosing appropriate volumes for these reagents, the total diazo reagent volume can be prepared according to the number of tests required. The resulting diazo solution is stable for at least three hours at 2-8ºC (35-46ºF) or one hour at 15-30ºC (59 - 86ºF).

TOTAL BILIRUBIN DETERMINATION

1. Press TOTAL button.
2. Pipette 1 mL diluent into cuvettes.
3. ZERO display with ZERO knob.
4. Add 30 µL sample and mix.
5. Read display for total bilirubin (TBR).

DIRECT BILIRUBIN DETERMINATION

6. Press DIRECT button.
7. Add 0.2 mL 0.2N HCl and mix.
8. ZERO display with ZERO knob.
9. Add 0.1 mL DIAZO and mix.
10. Press DIRECT TIMER button. Read display for direct bilirubin (DBR) when DIRECT TIMER light flashes.

Notes:

- Positive displacement pipettes are recommended for optimum accuracy. At high TBR concentrations, small pipetting errors can lead to significant, falsely low readings. It is suggested that the same pipettes be used each time to ensure sample-to-sample and day-to-day consistency.
- To prevent photodegradation of bilirubin, do not expose samples to light for long periods of time.
- Do *NOT* reuse the disposable cuvette.

STORAGE AND HANDLING

Do not freeze.

Description	Storage	Stability
Diluent Bilirubin Equivalent 5,20 Sulfanilic Acid Solution Hydrochloric Acid, 0.2N Sodium Nitrite Tablet	2 - 30°C (36 - 86°F)	Stable for two (2) years
Reconstituted Sodium Nitrite	2 - 8°C (36 - 46°F)	Stable for two (2) years when refrigerated
Diazo Reagent	2 - 8°C (36 - 46°F) 15 - 30°C (59 - 86°F)	Stable for three (3) hours when refrigerated Stable for one hour at room temperature

INTERFERENCE

1. Hemolysis will not significantly interfere with TBR determinations. The instrument corrects for oxyhemoglobin concentrations up to 600 mg/dL.
2. Turbidity associated with triglyceride levels up to 500 mg/dL will not significantly alter the BR2 readings.

LIMITATIONS

The Advanced BR2 is *not* intended for use on adult serum or plasma due to the presence of carotenoid pigments, which interfere with the photometric determination of bilirubin. In healthy adults, carotenoids have been shown to add from 0.4 - 1.0 mg/dL to the TBR determination. Pediatric serum carotenoid concentrations usually begin to increase with the onset of a normal diet; however, there is no clear cutoff at which point it becomes high enough to interfere with photometric TBR determinations. In serum or plasma of older children, the possible effect of carotenoids on the diagnostic value of TBR measured on the BR2 must be separately evaluated. It is necessary to measure parameters other than TBR for assessment of kernicterus development, or clinical management of jaundiced neonates.

LINEARITY

The BR2 is linear over a range of 0 - 30 mg/dL ± 0.2 mg/dL.

PERFORMANCE CHARACTERISTICS

Within-run and day-to-day reproducibility is better than 0.2 mg/dL (1 S.D.) over the entire range. Most of this variability, particularly at elevated levels, is due to error in sample pipetting. The same diluted sample can be read to a precision of 0.1 mg/dL (2 S.D.) over the entire range of the instrument. Correlation with manual methods based on the method of Jendrassik and Grof (4) is greater than 0.99 for TBR, and greater than 0.97 for DBR.

DISPOSING OF MATERIALS

Handle this product according to established good laboratory practices, using appropriate precautions. Dispose of materials according to your institution's practices. Discard all materials in a safe and acceptable manner that is in compliance with all country, state and local requirements.

REFERENCES

1. Jackson, S.H., Clin. Chem. 11, 1051 (1965)
2. Malloy, H.T. and Evelyn, K.A., J. Biol. Chem. 119, 481 (1937)
3. Henry, R.J., Cannon, D.C., and Winkelman, eds. Clinical Chemistry; Principles and Technics, 2nd edition, Harper & Row, New York (1974)
4. Jendrassik, L. and Grof, P., Biochem. A. 297, 81 (1938)

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IVD

For *In Vitro* Diagnostic Use
Pour un diagnostic in vitro
Zur In-vitro-Diagnose
Para diagnósticos in vitro
Para uso diagnóstico in vitro
Da utilizzarsi per diagnostica in vitro
För in vitro-diagnostik
Til diagnostisk brug in vitro
Για διάγνωση In Vitro

CE

European Conformity
Conformité européenne
Konformität mit EU-Normen
Conformidad europea
Conformidade com as directrizes europeias
Conformità europea
Uppfyllande av europeiska krav
Europæisk konformitet
Ευρωπαϊκή Συμμόρφωση

CONT

Content
Contenu
Inhalt
Contenido
Conteúdo
Contenuto
Innehåll
Indhold
–εριεχόμενο

Manufacturer
Fabricant
Hersteller
Fabricante
Fabricante
Fabbricante
Tillverkare
Producent
Κατασκευαστής

Temperature Limit
Limite de température
Temperaturgrenze
Límite de temperatura
Limite de temperatura
Limite di temperatura
Temperaturgräns
Temperaturgrænse
Όριο Θερμοκρασίας

Consult Instructions for Use
Consulter le mode d'emploi
Bedienungsanleitung lesen
Consulte las instrucciones de uso
Consulte as Instruções de Utilização
Leggere le istruzioni per l'uso
Läs bruksanvisningarna
Læs Brugsanvisningen
Συμβουλευτείτε τις Οδηγίες Χρήσης

EC REP

Authorized Representative
Représentant autorisé
Autorisierter Vertreter
Representante autorizado
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Auktoriserad representant
Autoriseret repræsentant
Εξουσιοδοτημένος Αντιπρόσωπος

REF

Catalog Number
Référence
Best.-Nr.
Número de catálogo
Número de Catálogo
Numero catalogo
Katalognummer
Katalognummer
Αριθμός Καταλόγου

LOT

Lot Number
Numéro de lot
Losnummer
Número de lote
Número do Lote
Numero lotto
Partinummer
Lotnr.
Αριθμός –αρτίδας

Use By
Date limite de conservation
Verfalldatum
Fecha de vencimiento
Utilizar até
Scadenza
Använd senast
Anvendes inden
Χρήση Έως

Sufficient for [x] Tests
Quantité suffisante pour [x] tests
Ausreichend für [x] Tests
Suficiente para [x] pruebas
Suficiente para [x] testes
Sufficiente per [x] test
Tillräckligt för [x] tester
Nok til [x] tests
Για [x] δοκιμές

Do Not Re-Use
Ne pas réutiliser
Nicht wieder verwenden
No volver a usar
Não reutilizar
Non riutilizzare
Återanvänd inte
Må ikke genbruges
Μην το Επαναχρησι μ οποιείτε

SAMP DIL

Diluent
Diluant
Verdünnungsmittel
Diluyente
Diluente
Diluente
Utspädningsmedel
Fortynder
Διαλύτης

Toxic
Toxique
Toxisch
Tóxico
Tóxico
Tossico
Giftig
Toksisk
Τοξικό

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