Total

Bilirubin Test Kit

REF B2A101

Four 30 mL bottles of Diluent
One 3 mL bottle of 5 mg/dL Bilirubin Equivalent
One 3 mL bottle of 20 mg/dL Bilirubin Equivalent
100 cuvettes

IVD

Intended Use

For *In Vitro* Diagnostic Use

Advanced Instruments Total Bilirubin Test Kit has been developed for use exclusively with the Advanced Instruments BR2 Bilirubin Stat-Analyzer™ Photometer for the determination of TOTAL (TBR) 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. The BR2 test kit has been specially formulated so that no recalibration is necessary between TBR and DBR determinations.

WARNING: Refer to the User 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 the User 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

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).

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.

	Storage	Stability
Unopened	2 - 30° C (36 - 86 °F)	Stable for two (2) years
Opened	2 - 30°C (36 - 86°F)	Stable for two (2) years

Interference

- Hemolysis will not significantly interfere with TBR determinations. The instrument corrects for oxyhemoglobin concentrations up to 600 mg/dL.
- 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[2] is greater than 0.99 for TBR.

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. Jendrassik, L. and Grof, P., Biochem. A. 297, 81 (1938)

For Sales and Service

Contact your Advanced Instruments Distributor.

For In vitro Diagnostic Use

Content


Manufacturer


Temperature Limit


Consult Instructions for Use

Catalog Number

Lot Number


Use By

Sufficient for [x] Tests

Do Not Re-Use

Diluent


Toxic

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