Bioway Chemistry Reagent Series

The Serum Direct Bilirubin Detection Kit

Detection of Serum Direct Bilirubin in Human Serum on Chemistry Analyzers

Cat. No. R026K11 ***The Serum DBIL Detection Kit***

SUMMARY OF TEST PROCEDURE

Figure 1: Procedure Diagram

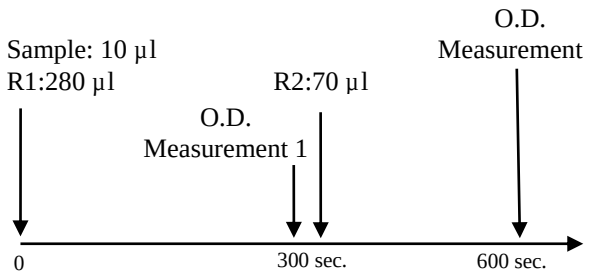

Table 1: Instrument Parameters*

Calibration method	2 point linear	Slope of reaction	Decrease
Wavelength	Dλ : 450 nm Sλ : 570 nm	Sample volume	10 µl
Test method	2 point end	R1 volume	280 µl
Reaction temperature	37℃	R2 volume	70 µl

*Refer to Figure 1 and the package insert for detail

INTENDED USE

Bioway Chemistry Reagent Series **Serum Direct Bilirubin Reagent Kit** (the Kit) is an oxidation assay intended for *in vitro* quantitative detection of serum total bilirubin in human serum on automated clinical chemistry analyzers.

SUMMARY AND EXPLANATION

Bilirubin is the ultimate breakdown product of heme catabolism and used as a diagnostic marker of liver and blood disorders. Bilirubin is released from live to bile and urine, also responsible for the yellow color of bruises and urine. An increased serum bilirubin level may be caused by chronic or acute hepatitis, liver cancer, pancreas carcinoma, heart failure, liver cirrhosis, cholangitis and acute or chronic alcoholism. For new-born babies unconjugated hyperbilirubinaemia can bring about consequent irreversible damages in brain and neuro system, makes seizures and abnormal eye movements. It is very sensitive to oxidation and light. The serum samples should be prevented from light and be analyzed as soon as possible.

TEST PRINCIPLES

The SCR oxidation method is used to measure the serum total bilirubin level in human serum. During the test, Bilirubin is oxidized to biliverdin under acidic condition. It causes the absorbance of yellow to decrease.

Bilirubin $\xrightarrow{\text{SCR oxidant}}$ Biliverdin

The change in absorbance is proportional to the level of serum total bilirubin in the sample. The actual concentration is obtained by comparing with a calibration curve with known concentrations.

MATERIALS PROVIDED

Reagents:

R1	Citrate buffer pH 2.9	100mmol/L
R2	Phosphate buffer pH 7.0 SCR oxidant	10mmol/L 4mmol/L

MATERIALS NEEDED BUT NOT PROVIDED

1. Automated chemistry analyzer.
2. DBIL calibrator set (available for purchase) and control set (commercially available).

INSTRUMENT

The Kit is applicable on most automated chemistry analyzers. Refer to specific instrument application for suggested settings.

STORAGE AND STABILITY

Store the reagents at 2-8℃. Avoid direct sunlight. The Kit is stable through the expiration date when stored properly. R1 and R2 reagents are stable for 1 month at 2-8℃ after opening.

PRECAUTIONS

1. The Kit is for *in vitro* diagnostic use only. Not for use in humans or animals.
2. The instructions must be followed to obtain accurate results.
3. Do not use the reagents beyond the expiration date.
4. Treat all specimens as infectious. Proper handling and disposal procedures of specimens and test materials should be strictly followed.
5. Samples containing levels of DBIL above the assay range should be diluted with saline and retested.

SPECIMEN COLLECTION AND HANDLING

Follow standard laboratory procedures to collect serum samples.
It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, store sample at 2-4° C for up to 3 days or at -20° C for up to 6 months. Avoid repeated freezing and thawing.

TEST PROCEDURE (see Figure 1)

No pretreatment required for reagents and samples.

Calibration: Recommend using commercially available calibrators for optimal results.

Test procedure: see Figure 1 and Table 1 for instrument parameter setup. Refer to specific instrument application for suggested setting.

1. Add 10 µl of sample and 280 µl of R1; mix well and incubate at 37℃ for 300 seconds.
2. Take optical density measurement OD 1 just before addition of R2.
3. Add 70 µl of R2, mix well and incubate at 37℃.
4. Take optical density measurement OD 2 at 546 seconds.
5. Calculate ΔOD = OD 2 – OD 1

RESULT

The DBIL value can be obtained by using the calculated ΔOD to find the corresponding value on a calibration curve prepared with known values.

$$\text{DBIL (µmol/L)} = \frac{\Delta A\text{test}}{\Delta A\text{standard}} \times \text{standard solution (µmol/L)}$$

EXPECTED VALUES

0~6.84 µmol/dL.

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It is recommended for each laboratory to establish its own expected values.

QUALITY CONTROL

Using commercially available controls with known concentration is recommended before each batch of tests to ensure the test is properly performed and all reagents and the instrument are functional as specified.

LIMITATIONS

1. The Kit is for *in vitro* use on automated chemistry analyzers only.
2. Hemolysis, jaundice and lipid containing samples may cause inconsistent results.
3. The test result from the Kit should not be used as the only basis for definite diagnosis.

PERFORMANCE CHARACTERISTICS

Linearity: 0~342 μmol/L (R≥0.990)

Accuracy: Bias proportion 90%~110%

Precision: Within Run: CV≤4%;
Run-to-Run: CV≤6%

Interference: no interference detected for: Hemoglobin (≤500mg/dl), lipid (≤2500NTU), glucose (≤1000mg/dl), urea (≤17.85mmol/L), urea nitrogen (≤50mg/dl), uric acid (≤1.19μmol/L), ascorbic acid (≤50mg/dl)

Reagent Blank Absorbance: at 450nm wavelength and 10 mm optical diameter, O.D. ≤ 0.10

REFERENCES

1. Simmi Kharb, World Journal of Medical Sciences 1(2):93-94 (2006)
2. Johan Fevery, Liver International 592-605 (2008)

Not Intended for Sale in the United States.

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