**INTENDED USE**

**Bioway Chemistry Reagent Series Serum Total 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 hyperbilirubinemia 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.

\[
\text{Bilirubin} \xrightarrow{\text{SCR oxidant}} \text{Biliverdin}
\]

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 8.2, 100mmol/L
  - R2: Phosphate buffer pH 7.0, SCR oxidant, 10mmol/L, 4mmol/L

**MATERIALS NEEDED BUT NOT PROVIDED**

1. Automated chemistry analyzer.
2. TBIL 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°C. 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°C 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 TBIL 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°C 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°C.
4. Take optical density measurement OD 2 at 546 seconds.
5. Calculate ΔOD = OD 2 – OD 1

**RESULT**

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

\[
\text{TBIL} (\mu\text{mol/L}) = \frac{\Delta\text{OD}_{\text{test}}}{\Delta\text{OD}_{\text{standard}}} \times \text{standard solution (µmol/L)}
\]

**EXPECTED VALUES**

3.4 – 17.1 µmol/dL.
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**: 1~684 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**

Not Intended for Sale in the United States.

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