Bioway Chemistry Reagent Series

# The Serum TBA Reagent Kit

***Detection of Total Bile Acids in Human Serum or Plasma on Chemistry Analyzers***

***Cat. No. R050K11*** ***The Serum TBA Reagent Kit***

## *SUMMARY OF TEST PROCEDURE*

**Figure 1: Procedure Diagram**

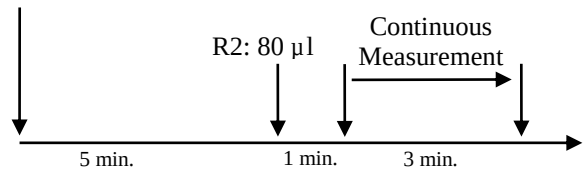



**Table 1: Instrument Parameters***

| | | | |
|---|---|---|---|
| Calibration method | 2-point linear | Slope of reaction | Increase |
| Testing wavelength | Dλ : 405 nm<br>Sλ : 660 nm | Sample volume | 4 µl |
| Test method | Rate Method | R1 volume | 240 µl |
| Reaction temperature | 37℃ | R2 volume | 80 µl |

*Refer to Figure 1 and the package insert for detail

## *INTENDED USE*

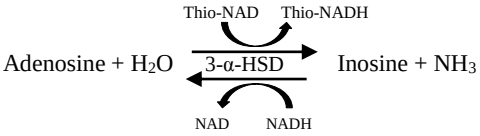
***Bioway Chemistry Reagent Series*** **TBA Reagent Kit** (the Kit) is an assay intended for *in vitro* quantitative detection of Total Bile Acids in human serum or plasma on automated clinical chemistry analyzers.

## *SUMMARY AND EXPLANATION*

Total Bile Acids are steroid acids in the bile. In human, it includes taurocholic acid, cholic acid, chenodeoxycholic acid, glycocholic acid, and so on. Bile acids are synthesized in liver and released to bile and then get to help body digesting lipids and absorbing fat-soluble vitamins. Monitoring serum TBA levels is useful for diagnosing liver diseases, such as cholestasis, portosystemic shunt, and hepatic microvascular dysplasia. Sometimes the elevated serum bile acids concentration indicates the development of colon cancer.

## *TEST PRINCIPLES*

The Kit utilizes enzymatic and kinetic reactions to measure the amount of TBA (µmol/L) in human serum or plasma.




3-α-hydroxysteroid dehydrogenase converts bile acids to 3-keto steroids and Thio-NADH in the presence of Thio-NAD. The reaction is reversible. With excess NADH, the cycling reaction enlarge the specific change of absorbance at 405 nm due to the formation of Thio-NADH. The rate of increase in absorbance at 405 nm is directly proportional to the TBA activity in the sample.

## *MATERIALS PROVIDED*

**Reagents:**

| | | |
|---|---|---|
| **R1** | Tris buffer pH=3.0<br>Thio-NAD | 30 mmol/L<br>2 mmol/L |
| **R2** | NADH<br>3-α-HSD | 2 mmol/L<br>≦5 U/L |

## *MATERIALS NEEDED BUT NOT PROVIDED*

1. Automated chemistry analyzer
2. TBA calibrator 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. The reagent is 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.

## *SPECIMEN COLLECTION AND HANDLING*

Follow standard laboratory procedures to collect serum preventing hemolysis.

It is recommended to perform test immediately after sample collection. If the test cannot be done immediately, specimens may be stored at 2~8℃ for 14 days.

## *TEST PROCEDURE (see Figure 1)*

Reagent 1 and 2 are liquid stable ready-to-use, no preparation needed.

**Calibration:** Recommend using commercially available calibrator set 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 4µl of sample and 240µl of R1; mix well and incubate at 37℃ for 5 minutes.
2. Add 80µl of R2; mix well and incubate at 37℃ for 1 minute.
3. Take continuous optical density measurement for 3 minutes.
4. Calculate average Δ A /min

## *RESULT*

The amount of TBA in µmol/L can be obtained by the following calculation:

$$\frac{\text{Abs. sample / min}}{\text{Abs. standard / min}} \times \text{Standard Conc. (µmol/L)} = \text{TBA Conc. (µmol/L)}$$

Please refer to instrument application if testing under different conditions.

## *EXPECTED VALUES*

≦12 µmol/L

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

## *QUALITY CONTROL*

Using included Bioway 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. The test result from the Kit should not be used as the only basis for definite diagnosis.
3. Samples with TBA exceeding the maximum measurement range should be diluted with saline and retested.

## *PERFORMANCE CHARACTERISTICS*

**Linearity**: 0 – 90 μmol/L (R≥0.990)

**Accuracy**: Bias proportion 90%~110%

**Precision**: Within Run: CV≤3%;
Run-to-Run: CV≤5%

**Interference:** no interference detected for: ascorbic acid (≤40mg/dl), chylomicrons (≤2200NTU), bilirubin (≤20mg/dl), unconjugated bilirubin (≤20mg/dl) and hemoglobin (≤450mg/dl).

**Reagent Blank Absorbance:** at 405nm wavelength and 10 mm optical diameter, O.D. ≤ 0.5

## *REFERENCES*

1. Kirti Rani Sharma, Int J Pharm Biomed Sci 3(2):28-34 (2012)
2. Shima T. *et al*., J Gastroenterol Hepatol. 15(3):294-9 (2000)
3. Brandon Bartling *et al*., *Analyst* 134:973-979 (2009)

Not Intended for Sale in the United States.

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