INSTRUCTION OF TOTAL BILIRUBIN (TBIL)

ASSAY KIT BY OXIDIZING METHOD

[PRODUCT NAME]

Total Bilirubin (TBil) Assay Kit by Oxidizing Method

[Packing specifications]

Basing on the bottle type, product model can be classified into 7170, 7060, 7020, Beckman, Toshiba, Mindray, Innova, Siemens, KHB, Abbott, General type, etc.

R1：60ml×3	R2：45ml×1	R1：32ml×1	R2：8ml×1
R1：90ml×2	R2：45ml×1	R1：50ml×4	R2：50ml×1
R1：80ml×1	R2：20ml×1	R1：60ml×2	R2：30ml×1
R1：40ml×2	R2：20ml×1	R1：32ml×4	R2：8ml×4
R1：60ml×1	R2：15ml×1	R1：60ml×6	R2：45ml×2
R1：60ml×9	R2：45ml×3	R1：1×460T	R2：1×460T
R1：3×460T	R2：3×460T	R1：6×460T	R2：6×460T
R1：9×460T	R2：9×460T		

[INTENDED USE]

This reagent is used to determine the TBil concentration in human serum.

[PRINCIPLE]

Total bilirubin in the sample is oxidized into biliverdin under an oxidizing agent and a surfactant effect around pH3.0. At the same time, the yellow of bilirubin disappeared. The total bilirubin concentration in the sample is calculated by measuring the absorbance difference before and after the reaction.Bilirubin $\xrightarrow{\text{oxidizing agent}}$ Biliverdin

[REAGENT COMPOSITION]

R1：

Good's buffer	100mmol/L
Reaction promoter	0.4g/L

R2：

Nonspecific reaction inhibitor	10mmol/L
Oxidizing agent	6mmol/L
Calibrator & Control	Optional

[Storage And Stability]

Stored for up to 12 months at 2-8°C, protect from light. After opening, the reagent remains stable for 30 days at 2-8°C, protect from light.

[Applicable Instrument]

This assay kit is suitable for automatic or semi-automatic biochemical analyzer with 450nm and 546nm wavelength.

[Sample Requirements]

The sample should be fasting serum. Samples testing should be completed at the same day after collected. Otherwise, the samples should be cryopreserved and avoid repeated freeze-thaw cycles. TBil in the samples remains stable for 7 days at 2-8°C and for 3 months at cryopreservation condition.

[Test Method]

1. Basic parameters:

Method：Endpoint assay　　Temperature：37°C

Primary wavelength: 450nm　　Secondary wavelength: 546nm

Sample volume：10μl　　R1：280μl

R2：70μl　　Response direction: Negative

Calibration method: two points calibration

2. Assay Procedure

	Blank(B)	Sample(U)	Calibrator (Ci)
ddH_2O(μl)	10	—	—
Sample (μl)	—	10	—
Ci (μl)	—	—	10
R1 (μl)	280	280	280
Mix well, incubate at 37°C for 5 min. Take blank well as zero. Measure the absorbance A1 at 450nm.			
R2 （μl）	70	70	70
Mix well, incubate at 37°C for 5 min. Take blank well as zero. Measure the absorbance A2.			

ASSAY PROCEDURE SUMMARY:

Set blank well:　←Detection→

Time：10 min

Temperature：37°C

Primary wavelength 450nm

↑ ↑ Secondary wavelength 546nm

R1：280μl　R2：70μl

Sample：10μl

3. CALCULATIONS

Sample $_{TBil}$（μmol/L）$=\frac{\Delta Au}{\Delta Ac}\times Cc$

ΔAu—Sample absorbance variation.

ΔAc—Calibration solution absorbance variation.

Cc—Calibration solution concentration.

[Reference Range]

2.0μmol/L-20.4μmol/L；

Recommendations: Each laboratory should establish its own reference range.

[Interpretation of Test Results]

1. The test results reflect only the status at the sampling time. Clinicians need to be combined with clinical data and other relevant test results to make judgment.

2. There is no significant effect on the test result when the sample contains Ascorbic acid ≤0.5g/L; Hemoglobin ≤2.0g/L; Triglycerides ≤10g/L.

［Test Method Limitations］

Dilute with physiological saline and multiply the result by the dilution factor when the concentration of TBil is over 1000.0μmol/L.

[Product Performance]

1. Detection range：0.7μmol/L-1000.0μmol/L ，r≥0.990.
2. Precision: Intra-assay CV≤3.4%, Inter-assay CV≤7.0%
3. Accuracy：Inaccuracy≤10％
4. Blank absorbance: The absorbance values≤0.050 when at 450nm wavelength and optical path 10mm.

[Precautions]

1. For in vitro diagnostic use only.
2. The reagent becomes cloudy or blank absorbance value >0.050, should be discarded.
3. The reagent and sample amount can be changed with same ratio according to needs.
4. The test equipment must be clean to avoid contamination.
5. Reagents and components of different batches are not interchangeable.
6. The waste solution generated by the test and decomposition difficultly packaging materials should be collected and sent to local waste treatment station.
7. Reagent in this kit contain chemical composition, should avoid to eat or contact with skin and mucous membrane. If accidentally splashed on the skin or eyes, rinse, immediately wash with plenty of water and timely seek medical treatment if there is any discomfort.

[References]

Akiyama K. and Makino I. Rinshoi, 19(suppl.), 242-244 (1993).

[MANUFACTURER]

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[Product standards]

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