This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Marketing Approval No. 20300AMZ00140000

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This package insert must be read carefully prior to use.

Class II General and Biochemical Test Series
(Classification No.: 80022002)
Direct bilirubin assay kit
(Classification No.: 30157002)

Clinimate D-BIL-2

General Precautions

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
4. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
5. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
6. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component: Ingredients
D-BIL-2 Buffer Solution 1: Glycine buffer
BIL・D-BIL-2 Reactant Reagent 2: Sodium nitrite
BIL・D-BIL-2 Dissolution Solution 2:
Sulfanilic acid
Hydric acid

Intended Use

Measurement of direct bilirubin in serum

The total amount of serum bilirubin varies according to the disintegration of hemoglobin and depending on the condition of metabolism in the liver. On the other hand, the direct to indirect bilirubin ratio plays an important role in the diagnosis and course evaluation of hepatobiliary and hematological diseases.

Assay Principle

1. Assay Principle

Chemical method (azobilirubin method)
Direct bilirubin (conjugated bilirubin) in samples reacts with diazo solution and formred azobilirubin. The direct bilirubin content is determined by measuring the absorbance of this red sample.

Diazo solution
Direct bilirubin in sample→Azobilirubin (red)

2. Features

1) Because self-sample blank method is used, analytical results are hardly affected by interfering substance.
2) Instruments are not damaged.

Procedural Precautions *

1. Properties of Samples and Sampling Methods

1) Samples
Serum may be used.
2) Storage of samples
If the isolated serum or plasma sample cannot be tested on the same day, specimens should be stored as follows:
2–10°C: for tests within 1 week
≤- 20°C: for tests after more than 1 week
Bring samples to room temperature (15–30°C) before use.
Bilirubin is isomerized by light (both artificial and solar), resulting is discoloration. Store under light shielding.

2. Interfering substances

Hemolyzed and chyle samples give positive errors to analytical results. Perform remeasurement by different methods, if the analytical result is extremely higher than those of other related variables.

3. Others

1) For calibration, use the FACTOR obtained with total bilirubin as the conversion factor.
2) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.
3) Do not perform the assay under direct sunlight.

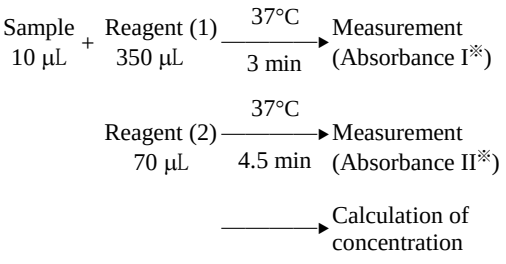
Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

Reagent (1): D-BIL-2 Buffer Solution 1 is ready to use.
Reagent (2): Dissolve BIL・D-BIL-2 Reactant Reagent 2 with BIL・D-BIL-2 Dissolution Solution 2.
Reagent (2) is stable for 7 days after preparation when stored at 2–10°C with protection from light.

2. Assay Procedure

This product is compatible with various types of automated analyzers. An example of the assay procedure is indicated below.



※Absorbance I and II: The difference in absorbance between 600 nm and 546 nm.
Calibration method: Conversion factor (FACTOR for total bilirubin)
Reagent blank: Purified water or saline

Assessment of Assay Results

1. **Reference standard range**[2)]
   0–0.6 mg/dL
2. There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement (if necessary, after dilution) or try another analytical methods.

Performance

1. **Sensitivity**
   1) Reagent blank: absorbance being equal to or lower than 0.02
   2) Sensitivity: The absorbance is 0.19–0.26 per 10 mg/dL of bilirubin.
2. **Accuracy:** 90–110% of the expected assay value
3. **Within-run Reproducibility**:
   Coefficient of variation ≤ 3%

(Test methods used for 1. –3. are in-house methods.)

4. **Measurement Range**[5)]: (On Hitachi 7170S automated analyzer)
   0.05–20.0 mg/dL
5. **Correlatio**[5)]
   Serum N=55 r=0.999 y=0.92x–0.13
   Control method: Approved in vitro diagnostics (Alkaline azobilirubin method)
6. **Standard Material**
   SRM916a（NIST）

Precautions for Use or Handling **

1. Precautions for Handling (to Ensure Safety)

All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.

2. Precautions for use

1) This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
3) Do not replenish the reagents.
4) Do not perform the assay under direct sunlight

3. Precautions for Disposal

1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121ºC for 20 minutes.
2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1%.
3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.

4. Other precautions

Do not use the containers for other purposes.

Storage and Shelf Life **

Name		Storage temperature	Shelf life
Clinimate D-BIL-2	D-BIL-2 Buffer Solution 1	2–10°C	1 year from the date of manufacture
	BIL・D-BIL-2 Reactant Reagent 2	2–10°C	2 years from the date of manufacture
	BIL・D-BIL-2 Dissolution Solution 2	Room temperature	2 years from the date of manufacture

When the above reagents are combined in use, refer to the information about storage and expiration date listed on the outer package.)

Packaging

Name			Package
Clinimate D-BIL-2	(1)	D-BIL-2 Buffer Solution 1	4 × 100 mL
	(2)	BIL・D-BIL-2 Reactant Reagent 2	4 × for 50 mL
		BIL・D-BIL-2 Dissolution Solution 2	4 × 50 mL

Constituent reagents are available in other configurations. For further details please contact SEKISUI MEDICAL CO., LTD.

References *

1) Michaelson, M.: Scand. J. Clin. & Lab. Invest, 13, Supple, 56, 1961.
2) Sasaki M. et al.: Sampling of constituents of the human body, 79, Kodansha, 1972.
3) Kitamura M. (author and editor): Practical Clinical Chemistry, 277, Ishiyaku Shuppan, 1974.
4) Kanai I and Kanai M. (author and editor): Kanai's manual of clinical laboratory medicine. 32nd ed. 577, Kanehara Shuppan, 2005.
5) In house data, SEKISUI MEDICAL CO., LTD.

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