**Intended use**
Quantitative measurement of total bilirubin concentration in plasma or serum. For in vitro diagnostic use only.

**Principle of the measurement**
10 μL of plasma is deposited on a FUJI DRI-CHEM SLIDE TBIL-PIII. After depositing, the sample spreads uniformly on the spreading and reagent layer and indirect bilirubin is dissociated with dyphylline and undergoes diazo reaction together with direct bilirubin by 2,4-dichlorobenzenediazonium salt to form diazo dye. The slide is incubated at 37 °C for a fixed time in the FUJI DRI-CHEM ANALYZER and the optical reflection density is measured at 540 nm. The optical reflection density is then converted into the total bilirubin concentration using a calibration curve preinstalled in the analyzer.

**Composition of the slide**
1. Multi-layered structure
2. Ingredients per slide
   - 2,4-Dichlorobenzenediazonium salt: 0.14 mg (0.36 μmol)
   - Dyphylline: 3.1 mg (12 μmol)

**Additional special equipment**
Analyzer: FUJI DRI-CHEM ANALYZER
Other implements: FUJI DRI-CHEM QC CARD (attached)
   - FUJI DRI-CHEM CLEAN TIPS or FUJI DRI-CHEM AUTO TIPS
   - FUJI HEPARIN/PLAIN TUBE or Blood collection tube

**Storage and shelf life**
1. Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before warmed up to room temperature before opening the individual packages.
2. Expiry date is printed on the carton.
3. A new slide must be used for each measurement. Do not reuse.
4. Handle all patient samples, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
5. Used slides are categorized as infectious waste. Make sure to dispose them in accordance with the Waste Disposal Law and other related regulations, which prescribe the proper method of disposal, such as incineration, melting, sterilization or disinfection.
6. Keep QC card away from magnetic material.
7. Do not use the slide if the individual package is damaged.

**Sample requirements**
1. After collecting blood sample immediate measurement is recommended.
2. For plasma, heparin and EDTA·2Na can be used as the anticoagulant. When using heparin, less than 100 units of heparin should be used per 1 mL of whole blood. When using EDTA·2Na, less than 10 mg should be used per 1 mL of whole blood. Do not use EDTA·2K, sodium fluoride, citric acid, oxalic acid and monooiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. Do not use hemolyzed plasma or serum.
5. When the measured value exceeds the upper limit of the dynamic range, dilute the sample with distilled water or saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation.

**Procedure**
1. Read in the new QC-card when you switch to a new box of slides.
2. Set slides on FUJI DRI-CHEM ANALYZER.
3. Set a sample tube in the specified sample rack.
4. Input a sequence No. and a sample ID if appropriate.
5. Press the “START” key to initiate testing.

**Internal quality control**
The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL QP-L and/or QP-H.
1. Select control level in accordance with your purpose.
2. Measure FUJI DRI-CHEM CONTROL QP-L and/or QP-H in the same way as patient samples.
3. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L or QP-H, investigate the cause.
For additional information, consult “Instructions for Use” for FUJI DRI-CHEM CONTROL QP-L or QP-H.

**Reference intervals**
0.1–1.2 mg/dL (2–21 μmol/L)
As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals.

**Limitation of the examination procedure**
The clinical diagnosis must be made by the doctor in charge based on the measured results in the light of clinical symptoms and other test results.

1. Known interfering substances
   - Ascorbic acid: 10 mg/dL (0.57 mmol/L)
   - Hemoglobin: 500 mg/L
   - Total protein: 50–90 g/L
2. Other limitations
   - Bilirubin is decomposed by light. Do not put the sample under strong light, especially sunlight.
3. Performance characteristics
   - 1. Dynamic range
      - 0.2–30.0 mg/dL (3–513 μmol/L)
2. Accuracy
   - Concentration range
     - 0.2–3.0 mg/dL (3–51 μmol/L)
     - Within ± 0.4 mg/dL (Within ± 7 μmol/L)
     - Within ± 0.2 mg/dL (Within ± 3 μmol/L)
   - SD ± 0.15 mg/dL (SD ± 3 μmol/L)
     - 3.0–30.0 mg/dL (51–513 μmol/L)
4. Correction
   Correlation was evaluated between alkaline azobilirubin method and FUJI DRI-CHEM system. Alkaline azobilirubin method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

**Traceability of calibrators and control materials**
Total bilirubin...NIST (SRM916)
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
NIST: National Institute of Standards & Technology
[Symbols]

- Do not touch the center part of the slide.
- Warmed up to room temperature before opening the individual packages.
- Do not reuse
- Lot number
- Use by
- Contains sufficient for <n> tests
- Temperature limitation
- Consult instructions for use
- In vitro diagnostic medical devices
- Manufacturer
- Authorized representative in the European Community