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

**Principle of the measurement**
10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE DBIL-PII. After depositing, the sample spreads uniformly on the special spreading layer, direct bilirubin react with diazonium salt of benzensulfonic acid 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 577 nm. The optical reflection density is then converted into the DBIL concentration using a calibration curve preinstalled in the analyzer.

**Composition of the slide**

1. **Multi-layered structure**
   - Sample
   - Spreading and reagent layer
   - Water absorbing layer
   - Transparent support
   - Barcode side

2. **Ingredients per slide**
   - Sulfanilic acid: 0.27 mg (1.5 μmol)
   - Sodium nitrite: 0.012 mg (0.18 μmol)

**Additional special equipment**
- **Analyzer:** FUJI DRI-CHEM ANALYZER
- **Other implements:** FUJI DRI-CHEM CLEAN TIPS or FUJI DRI-CHEM AUTO TIPS

**Storage and shelf life**
1. **Storage:** This product must be stored between 2–8 °C (35.6–46.4 °F) before use.
2. **Expiry date:** is printed on the carton.

**Warnings and precautions**
1. Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
2. Do not touch the membrane in the center of the slide.
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 50 units of heparin should be used per 1 mL of whole blood. When using EDTA·2Na, less than 5 mg should be used per 1 mL of whole blood. Do not use EDTA-2K, sodium fluoride, citric acid, oxalic acid and monoiodoacetic acid.
3. Avoid using plasma or serum with precipitate such as fibrin.
4. Do not use hemolytic 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. **CAUTION:** Use immediately after opening the individual package.
6. For further details of operation procedure, consult “INSTRUCTION MANUAL” for FUJI DRI-CHEM ANALYZER.

**Internal quality control**
The accuracy and precision of this product can be evaluated with FUJI DRI-CHEM CONTROL QP-L.
1. Measure FUJI DRI-CHEM CONTROL QP-L in the same way as patient samples.
2. When the results obtained are outside the expected range shown in the sheet attached to FUJI DRI-CHEM CONTROL QP-L, investigate the cause.

**Reference intervals**
0.1–0.4 mg/dL (2–7 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**
   - No significant effect was observed to the following concentration for each substance.
     - Ascorbic acid: 10 mg/dL (0.57 mmol/L)
     - Indirect bilirubin: 15 mg/dL (255 μmol/L)
     - Total protein: 50–90 g/L*

   (2) The sample from renal failure patient shows incorrect measured value due to the effect of endogenous substances.

2. **Other limitations**
   - Bilirubin is decomposed by light. Do not put the sample under strong light, especially sunlight.
   - These results are representative; Test condition may have some influence on your results.
   - Interferences from other substances are not predictable.

   *At the normal range of DBIL concentration.

**Performance characteristics**

1. **Dynamic range**
   - 0.1–16.0 mg/dL (2–274 μmol/L)

2. **Accuracy**
   - Concentration range: 0.1–1.5 mg/dL (2–26 μmol/L)
   - Accuracy: Within ± 0.2 mg/dL (Within ± 4 μmol/L)
   - Concentration range: 1.5–16.0 mg/dL (26–274 μmol/L)
   - Accuracy: Within ± 15 %

3. **Precision**
   - Concentration range: 0.1–1.5 mg/dL (2–26 μmol/L)
   - Precision: SD ≤ 0.1 mg/dL (SD ≤ 1.3 μmol/L)
   - Concentration range: 1.5–16.0 mg/dL (26–274 μmol/L)
   - Precision: CV ≤ 5 %

4. **Correlation**
   - Correlation was evaluated between bilirubin oxidase method and FUJI DRI-CHEM system. Bilirubin oxidase method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.
   - | n | Slope | Intercept | Correlation coefficient |
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<tr>
<td>Serum</td>
<td>67</td>
<td>1.032</td>
<td>0.01</td>
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**Traceability of calibrators and control materials**
The calibration of this product has already been accomplished in our factory before shipping using internal calibrators which are not commercially available. Calibration data are supplied by a QC card enclosed in this package. Assigned values of the internal calibrators for DBIL are traceable to a bilirubin oxidase method.
Do not touch the center part of the slide.

Warmed up to room temperature before opening the individual packages.

SLIDE CODE

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