### Intended use
Quantitative measurement of γ-glutamyltransferase activity 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 GGT-PIII. After depositing, the sample spreads uniformly on the spreading layer. In the process, γ-GTP (GGT) in the sample catalyses the amino-transfer reaction with the substrate of L-γ-glutamyl-p-nitroanilide. Increase in absorption by the generated dye is measured at 400 nm by reflective spectrophotometry and the γ-GTP (GGT) activity is calculated according to the installed formula.

L-γ-Glutamyl-p-nitroanilide + Glycylglycine → L-Glutamylglycylglycine + p-Nitroaniline

### Composition of the slide
1. Multi-layered structure

Sample

Spreading layer

Water absorbing layer

Barcode side

Transparent support

2. Ingredients per slide
- L-γ-Glutamyl-p-nitroanilide 0.078 mg (0.27 μmol)
- Glycylglycine 0.25 mg (1.9 μmol)

### Additional special equipment
- Analyzer: FUJI DRI-CHEM ANALYZER
- Other implements: FUJI DRI-CHEM QC CARD (attached)
- FUJI HEPARIN/PLAIN TUBE or Blood collection tube
- Barcode side

### 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, or prescribed in the “INSTRUCTION MANUAL” for FUJI DRI-CHEM ANALYZER.

### Sample requirements
1. After collecting blood sample immediate measurement is recommended.
2. For plasma, heparin can be used as the anticoagulant. When using heparin, less than 40 units of heparin should be used per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and monooiodoacetic 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.

### 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 ANALYZER.

### Reference intervals
16–73 U/L (IFCC Consensus Method, 37°C) (0.27–1.22 mkat/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.

### Known interfering substances
No significant effect was observed to the following concentration for each substance:
- Ascorbic acid 10 mg/dL (0.57 mmol/L)
- Bilirubin 10 mg/dL (170 μmol/L)
- Total protein 40–95 g/dL

These results are representative;
- Test condition may have some influence on your results.
- Interferences from other substances are not predictable.

### Performance characteristics
1. Dynamic range
   - 10–1200 U/L (0.17–20.04 μkat/L)
2. Accuracy
   - Concentration range: 10–50 U/L (0.17–0.84 μkat/L) Accuracy: Within ± 10 U/L
   - 50–1200 U/L (0.84–20.04 μkat/L) Accuracy: Within ± 20%
3. Precision
   - Concentration range: 10–60 U/L (0.17–1.00 μkat/L) Precision: CV < 5%
   - 60–1200 U/L (1.00–20.04 μkat/L) CV < 5%
4. Correlation
   Correlation was evaluated between JSCC Standard Method, 37 °C and FUJI DRI-CHEM system. JSCC Standard 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
γ-GTP...ReCCS (ERM)

Note: This reference material is applied to the reference method of FUJIFILM Corporation and not applicable to FUJI DRI-CHEM SLIDE directly. ReCCS: Reference Material Institute for Clinical Chemistry Standards
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