**Intended use**
Quantitative measurement of amylase activity in plasma or serum.
*In vitro* diagnostic use only.

**Principle of the measurement**
10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE AMYL-PIII. The sample is distributed uniformly by the spreading layer and reacts with the substrate (4,6-ethylidene-4-nitrophenyl-α-D-maltoheptaoside : Et-G-7-PNP). The product generated by amylase is further decomposed by α-glucosidase to release p-nitrophenol. The increase of absorbance by the generated dye is measured at 400 nm by reflective spectrophotometry and the amylase activity is calculated according to the installed formula.

Et-G-7-PNP, Amylase → Et-Gm + Gn-PNP (m+n=7, n=2,3,4)
Gn-PNP, α-Glucosidase → Gn + PNP

**Composition of the slide**
- Sample
- Spreading layer
- Water absorbing layer
- Transparent support
- Barcode slide

**Ingredients per slide**
- 4,6-ethylidene-4-nitrophenyl-α-D-maltoheptaoside: 0.42 mg (0.32 μmol)
- α-Glucosidase: 0.8 U

**Additional special equipment**
Analyzer: FUJI DRI-CHEM ANALYZER
Other implements: FUJI DRI-CHEM CLEAN TIPS or FUJI DRI-CHEM AUTO TIPS
Other: FUJI DRI-CHEM QC CARD (attached)
Analyzer: FUJI DRI-CHEM ANALYZER

**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. Do not use hemolytic plasma or serum.
5. Keep QC card away from magnetic material.
6. 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.
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 is recommended to use as an anticoagulant.
When using heparin, less than 50 units of heparin should be used per 1 mL of whole blood. Do not use EDTA salt, sodium fluoride, citric acid, oxalic acid and monocloacetic 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 saline. Since the data obtained by dilution may deviate more widely than usual, the data should be treated as estimation. Do not use distilled water for dilution.

**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.

**Reference intervals**
37–125U/L (IFCC Consensus Method, 37 °C) (0.62–2.09 μkat/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.

**Performance characteristics**
1. Dynamic range
2. Accuracy

**Correlation**
Correlation was evaluated between IFCC Consensus Method and FUJI DRI-CHEM system. IFCC Consensus Method was run on a HITACHI automated analyzer. This examination was carried out by the laboratory of FUJIFILM Corporation.

**Traceability of calibrators and control materials**
AMY...ReCCS (ERM)
Note: This reference material is applied to the reference method of FUJIFILM Corporation and is not directly applicable to FUJI DRI-CHEM SLIDE.
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.

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