

Plasma/Serum test for total carbon dioxide

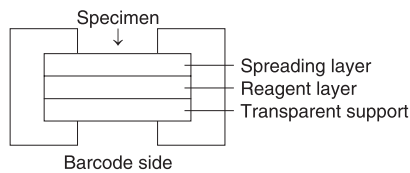
FUJI DRI-CHEM SLIDE TCO₂-P

[Warnings and precautions]

- Only the required number of slides should be taken out of the refrigerator and warmed up to room temperature before opening the individual packages.
- Do not touch either the center part of the surface or the back of the slide.
- A new slide must be used for each measurement. Do not reuse.
- Handle all patient specimens, control serum and used tips carefully as biohazardous samples. Wear proper gloves, glasses and other protective gear for your safety.
- 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.
- Because it is highly sensitive to light, as soon as the slide is removed from its package, it should be set in the cartridge and slide weight placed on it.
- For FUJI DRI-CHEM ANALYZER equipped with a 415 nm filter use only.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

- Phosphoenolpyruvic acid 0.34 mg (2.02 μmol)
- Phosphoenolpyruvate carboxylase 0.39 U
- ThioNADH 0.33 mg (0.45 μmol)
- Malate dehydrogenase 4.0 U

[Intended use]

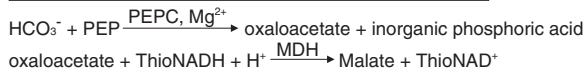
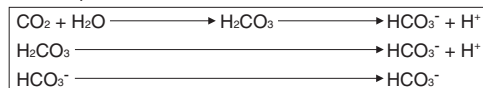
Quantitative measurement of total carbon dioxide (CO₂) concentration in plasma or serum.

For *in vitro* diagnostic use only.

[Principle of the measurement]

10 μL of plasma or serum is deposited on a FUJI DRI-CHEM SLIDE TCO₂-P. The specimen is uniformly distributed on the spreading layer. Eventually all Carbon dioxide in the specimen is converted to the bicarbonate form by the alkaline pH in the spreading layer. Phosphoenolpyruvic acid (PEP) is carboxylated by bicarbonate in the presence of phosphoenolpyruvate carboxylase (PEPC) to generate oxaloacetate and inorganic phosphoric acid in the reagent layer. The conversion of oxaloacetate into malate using thioNADH is catalyzed by malate dehydrogenase (MDH). The reaction scheme is as shown below.

Alkaline pH



The decrease of absorbance by the oxidation of thioNADH is measured for a fixed time at 415 nm by reflective spectrophotometry and the concentration of the total CO₂ is calculated according to the installed formula.

[Additional special equipment]

Analyzer: FUJI DRI-CHEM ANALYZER equipped with a 415 nm filter
 Other implements: FUJI DRI-CHEM QC CARD (attached)
 : FUJI DRI-CHEM AUTO TIPS
 : FUJI HEPARIN/PLAIN TUBE or Blood collection tube specified in the "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER

PF function cannot be applied to TCO₂ slide.

[Specimen requirements]

- After collecting the blood specimen, immediate measurement is recommended.
- If the specimens are not used immediately, blood collection tubes should be filled with specimens completely and capped as soon as possible to avoid decrease in CO₂. The specimens capped tightly can be stored at room temperature for 6 hours or at 2–8 °C for 24 hours. The gaseous dissolved CO₂ may escape from the specimens into the air, with a consequent loss of CO₂ value of up to 6 mmol/L in the course of an hour when the specimens are not capped.
- 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 monoiodoacetic acid.
- Avoid using plasma or serum with precipitate such as fibrin.
- Do not use hemolytic plasma or serum. Measured values may be more than 10% lower due to the enzyme secreted from the blood cells.
- When the measured value exceeds the upper limit of the dynamic range, dilute the sample twice 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]

- Read in the new QC-card when you switch to a new box of slides.
- Set slides on FUJI DRI-CHEM ANALYZER.
- Set a sample tube in the specified sample rack.
- Input a sequence No. and a sample ID if appropriate.
- Press the "START" key to initiate testing.
- For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[Reference interval]

Plasma or serum, venous: 22–29 mmol/L

As the reference interval depends on the population of the test, it is required that each laboratory set its own reference interval. 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** 5–40 mmol/L

2. **Accuracy**

Concentration range	Accuracy
5–20 mmol/L	Within ±4 mmol/L
20–40 mmol/L	Within ±20 %

3. **Precision**

Concentration range	Precision
5–20 mmol/L	SD ≤ 2 mmol/L
20–40 mmol/L	CV ≤ 10 %

4. **Correlation**

Correlation was evaluated between the calculation method using the Henderson-Hasselbalch equation and FUJI DRI-CHEM system. This method was run on a GEM Premier 3000 analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

	n	Slope	Intercept	Correlation coefficient
Serum	95	0.991	0.16	0.996
Plasma	52	0.988	1.04	0.997

5. Known interfering substances

(1) No significant effect was observed to the following concentration for each substance.

Ascorbic acid	0.57 mmol/L
Bilirubin	340 μmol/L
Total protein	50–90 g/L

These results are representative;

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

[Internal quality control]

- The accuracy and precision of this product can be evaluated with control materials such as pooled human serum. Commercially available control sera may give results which differ between the FUJI DRI-CHEM method and the liquid methods owing to their matrix effect.
- Concentration levels of the control materials should be adjusted in accordance with clinically significant levels or individual purpose.
- The control materials should be measured in the same way as patient samples.
- We recommend that control limits be established for assayed analytes so as to enable assessment of the control status.
- If results are found outside of the control limits, investigate the cause before submitting reports.

[Traceability of calibrators and control materials]

Bicarbonate...NIST (SRM 351a)

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

[Storage and shelf life]

- Storage: This product must be stored between 2–8 °C (35.6–46.4 °F) before use.
- Expiry date is printed on the carton.
- Use immediately after opening the individual package.

[Contents]

- : Slide 24
- : QC card 1



<http://www.fujifilm.com/products/medical/>



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