

Plasma/Serum test for magnesium

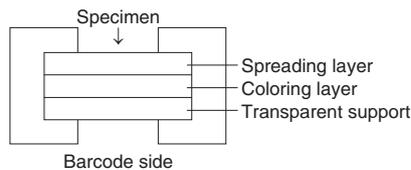
FUJI DRI-CHEM SLIDE Mg-P111

[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.

[Composition of the slide]

1. Multi-layered structure



2. Ingredients per slide

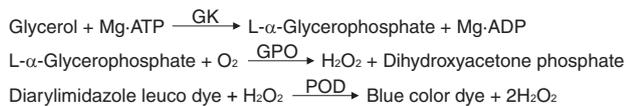
• Glycerol kinase	0.19 U
• Glycerol	0.025 mg (0.27 μmol)
• Diarylimidazole leuco dye	0.045 mg (0.090 μmol)
• ATP	0.22 mg (0.40 μmol)
• Glycerophosphate oxidase	1.5 U
• Peroxidase	2.4 U

[Intended use]

Quantitative measurement of magnesium 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 Mg-P111. The deposited specimen spreads uniformly on the spreading layer and Mg²⁺ in the sample forms the complex (Mg-ATP) with adenosine triphosphosphate 2Na (ATP) contained in the spreading layer. With the initiation of the reaction, formed Mg-ATP diffuses to the under layer and acts on glycerolkinase (GK) which phosphorylates substrate glycerol to form L-α-glycerophosphate. Formed L-α-glycerophosphate produces hydrogen peroxide by the action of L-α-glycerophosphate oxidase (GPO). This hydrogen peroxide oxidizes diarylimidazole leuco dye via peroxidase (POD) to produce imidazole blue color dye. The increase of absorbance by the generated dye is measured from 2 min to 4.5 min at 650 nm by reflective spectrophotometry and the Mg concentration is calculated according to the installed formula.



[Additional special equipment]

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

[Specimen requirements]

- For plasma, heparin can be used as the anticoagulant. When using heparin, less than 50 units of heparin should be used per 1mL 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.
- 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]

- 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.

4. Input a sequence No. and a sample ID if appropriate.

5. Press the "START" key to initiate testing.

For further details of operation procedure, consult "INSTRUCTION MANUAL" for FUJI DRI-CHEM ANALYZER.

[Reference interval]

0.74–0.99 mmol/L (1.8–2.4 mg/dL)

As the reference intervals depend on the population of the test, it is required that each laboratory set its own reference intervals. 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** 0.08–2.88 mmol/L (0.2–7.0 mg/dL)

2. **Accuracy**

Concentration range	Accuracy
0.08–0.62 mmol/L	Within ± 0.12 mmol/L
0.62–2.88 mmol/L	Within ± 20 %

3. **Precision**

Concentration range	Precision
0.08–0.62 mmol/L	SD ≤ 0.03 mmol/L
0.62–2.88 mmol/L	CV ≤ 5 %

4. **Correlation**

Correlation was evaluated between glucokinase method and FUJI DRI-CHEM system. Glucokinase method was run on a HITACHI automated analyzer. This examination was carried out at the laboratory of FUJIFILM Corporation.

	n	Slope	Intercept	Correlation coefficient
Serum	81	0.997	0.004	0.998

5. **Known interfering substances**

- (1) Dobutamine hydrochloride (cardiotonic reagent) gives minus bias.
- (2) The effects on the measured value were examined by adding substances as shown below to a serum sample obtained from a healthy volunteer or a control serum. No significant effect was observed to the following concentration for each substance.

Ascorbic acid	0.57 mmol/L
Bilirubin	170 μmol/L
Total protein	50–90 g/L
Ca	1.0–2.99 mmol/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 FUJI DRI-CHEM CONTROL QP-L.

1. Measure FUJI DRI-CHEM CONTROL QP-L in the same way as patient specimens.
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.
For additional information, consult "Instructions for Use" for FUJI DRI-CHEM CONTROL QP-L.

[Traceability of calibrators and control materials]

Magnesium...NIST(SRM909)

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]

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.
3. Use immediately after opening the individual package.

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: QC card	1

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

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