This package insert follows the Pharmaceuticals, Medical devices and Other Therapeutic Products Act of Japan.

In Vitro Diagnostics
Marketing Approval No. 21600AMZ00458000

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This package insert must be read carefully prior to use.

Magnesium assay kit
(Classification No.: 30190002)

QUALIGENT MG

General Precautions **

1. This product is for in vitro diagnostic use, and must not be used for any other purposes.
2. Clinicians should make a comprehensive clinical decision based on assay results in conjunction with clinical symptoms and other examination results.
3. For the effects of an administered drug on the measured value, carefully read the Precautions for Use in the package insert of the drug, especially the section about the effects on laboratory test results. Please also read carefully the "2. Interfering Substances," in the "Procedural Precautions" section, as well as "2. Precautions for Assessment" in the "Assessment of Assay Results" section, of this package insert.
4. This product should be used only as directed in this package insert. Reliability of results cannot be guaranteed if there are any deviations from the instructions in this package insert.
5. If the reagent accidentally comes in contact with eyes and/or mouth, rinse immediately with ample water as first aid, and consult the doctor if required.
6. Carefully read the operating instructions for each type of automated analyzers prior to using this product. Parameters for each type of analyzers are available, and can be requested from SEKISUI MEDICAL CO., LTD. if required.
7. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component: Ingredients
MG Coloring Solution: Xylylazo violet I

Intended Use **

Measurement of Mg (magnesium) in serum, plasma or urine

As an electrolyte, magnesium is widely distributed in the body fluids, and is involved in various important physiological function such as glycolysis and activation of urea cycle enzymes.
The magnesium concentration in body fluids such as serum and urine is maintained within a relatively narrow range. Therefore, measurement of magnesium is useful for the diagnosis of various diseases.

Assay Principle

1. Assay Principle

Magnesium in samples binds to xylylazo violet I (xylidyl blue) to form a complex with a red color. The magnesium content is determined by measuring the absorbance of this complex.

Mg^{2+} + Xylidyl blue ⟶ Complex (red color)

2. Features

This product specifically reacts with magnesium by the single liquid method.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples
Serum, plasma (heparin plasma and citrated plasma) and urine may be used.

2) Storage of samples
If the isolated serum or plasma sample cannot be tested on the same day, specimens should be stored as follows[3]:
2–10°C: for tests within 2 weeks
≤ -20°C: for tests after more than 2 weeks
Bring samples to equibrate with room temperature (15–30°C) before use.
Urine samples should be tested on the same day.

2. Interfering substances

Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), hemoglobin (up to 500 mg/dL), ascorbic acid (up to 50 mg/dL), or formazin turbidity (up to 3000 FTU).

3. Others

1) Always use Serum Malticalibrator (SEKISUI), Seronorm Multicalibrator or Anaserum MG standard solution for calibration.
2) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

Reagent: MG Coloring Solution is ready to use.

2. Assay Procedure

This product is compatible with Hitachi 9000 series and LABOSPECT series automated analyzers. Assay procedure is indicated below.

Sample 1.5 µL + Reagent 180 µL —(37°C, 10 min)→ Measurement (Absorbance※)
Measurement (Absorbance※) ⟶ Calculation of concentration

※Absorbance: The difference in absorbance between 700 nm and 660 nm
Calibration material: Serum Malticalibrator (SEKISUI), Seronorm Multicalibrator or Anaserum MG standard solution (Manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results **

1. Reference Criteria[4]

In blood: 1.8–2.4 mg/dL

In urine: 20.6–164.9 mg/day

2. Precautions for Assessment

There may be reactions or interfering reactions with non-target substances. If assay results appear to be unreliable, repeat the measurement (if necessary, after dilution) or try another analytical methods.

Performance *

1. Sensitivity

1) Reagent blank: absorbance 1.20–1.70
2) Sensitivity: The absorbance is 0.62–0.75 per 5.0 mg/dL of magnesium.

2. Accuracy: 90–110% of the expected assay value

3. Within-run Reproducibility:

Coefficient of variation ≤ 3%

(Test methods used for 1.–3. are in-house methods.)

4. Measurement Range[5]: (On a Hitachi 9000 series automated analyzer)

0.2–7.0mg/dL

5. Correlation[5]

1) Serum N=77 r=0.987 y=1.03x–0.21
Control method: Approved in vitro puroduct (xylidyl blue method)
2) Plasma N=71 r=0.995 y=0.98x+0.08
Control method: Approved in vitro product (xylidyl blue method)
3) Urine N= 60 r=0.999 y=0.97x+0.18
Control method: Approved in vitro product (xylidyl blue method)

6. Standard Material

SRM929 (NIST)

Precautions for Use or Handling *

1. Precautions for Handling (to Ensure Safety)

1) All samples used in the test should be handled as a material possibly infected with HIV, HBV, HCV, or other viruses. To prevent infection, use disposable gloves and avoid mouth pipetting during the test.
2) This product is alkaline. If it is accidentally ingested or comes into contact with the eyes or skin, immediately wash the area with water and seek medical treatment, if necessary.

2. Precautions for use

1) This product should be stored as directed, without freezing. Freezing can deteriorate the reagents, which can produce inaccurate results. Therefore, avoid using the reagents which have been previously frozen.
2) Do not use expired reagents. Use of such reagents cannot guarantee the reliability of measurement values.
3) Do not perform the assay under direct sunlight

3. Precautions for Disposal

1) Before disposal, used samples and their containers must be immersed in sodium hypochlorite solution at a concentration of greater than 0.1% for longer than 1 hour or autoclaved at 121ºC for 20 minutes.
2) To prevent infections from spilled samples or solutions containing samples, wipe the spilled area thoroughly with disinfectants such as sodium hypochlorite solution at a concentration of greater than 0.1%.
3) The reagents and treated samples should be discarded as medical waste or industrial waste according to the waste disposal regulations.
4) The reagents should be disposed of in accordance with the Water Pollution Control act or related regulations.

4. Other precautions

1) Do not use the containers for other purposes.
2) Do not take apart the reagent cartridge before.

Storage and Shelf Life *

1. Storage temperature: 2–10°C

2. Shelf life: 18 months from the date of manufacture (The expiration date is printed on the outer package.)

Packaging *

Name	Package contents		
QUALIGENT MG	Set (Cassette for Hitachi 9000 series)	MG Coloring Solution 1× 27.0 mL	× 2
	L set (Set for Hitachi LABOSPECT series)	MG Coloring Solution 1× 48.0 mL	× 2

References **

1) Monacelli, R. et al.: Clin. Chim. Acta 1, 577, 1956.
2) Kitamura M. et al. (editors): Clinical Chemical Analysis V.Tokyo: Tokyo Kagaku Dojin; 1967. Japanese.
3) Sasaki M. et al.: Sampling of constituents of the human body. Tokyo: Kodansha; 1972. Japanese.
4) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 35th ed. Tokyo: Kanehara Shuppan; 2020. Japanese.
5) SEKISUI MEDICAL CO., LTD. In house data. Japanese.

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