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

In Vitro Diagnostics
Marketing Notification No. 13A2X00197218031

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This package insert must be read carefully prior to use.

Immunoglobulin M assay kit for blood tests
(Classification No.: 30234001)

Pureauto S IgM

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. 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.
4. 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.
5. 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.
6. Perform a quality control test prior to assay to ensure accuracy.

Description (Kit Components) **

Component: Ingredients
IgM Buffer Solution 1:
2-Amino-2-hydroxymethyl-1,3-propanediol Buffer Solution
IgM Antibody Solution 2:
Anti-human immunoglobulin M goat antiserum

Intended Use

Measurement of immunoglobulin M in serum or plasma

Immunoglobulins are produced by B cells including plasma cells as a host defense against viruses, bacteria, etc. or in response to stimulation by drugs, tissue antigens, etc., and play a very important role in humoral immunity.
Because serum/plasma immunoglobulin levels show changes in patients with viral/bacterial infections, reticuloendothelial abnormalities, impaired hepatic function, etc., measurement of IgM is important for the diagnosis and follow-up of infections, immune diseases, and liver disorders.

Assay Principle

1. Assay Principle
Immunoglobulin M (IgM) in samples undergoes an antigen-antibody reaction with anti-human immunoglobulin M goat antiserum (IgM antiserum), resulting in turbidity. The IgM content of the sample is determined by measuring the turbidity.

IgM in sample + IgM antiserum ⟶ Antigen-antibody precipitate

2. Features
1) Ready-to-use reagents do not require sample dilution.
2) There is no prozone phenomenon within the usual measurement range.
3) Applicable to various automated analyzers.

Procedural Precautions **

1. Properties of Samples and Sampling Methods
1) Samples
Serum or plasma may be used.
2) Storage of samples[1)]
The isolated serum or plasma should be tested on the same day.
Store samples at -20°C or lower.
Bring samples to room temperature (15–30°C) before use.

2. Interfering substances
Assay results are not affected by free bilirubin (up to 40 mg/dL), conjugated bilirubin (up to 40 mg/dL), or hemoglobin (up to 1000 mg/dL).

3. Others
1) Always use GAM complement calibrator 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 (1): IgM Buffer Solution 1 is ready to use.
Reagent (2): IgM Antibody Solution 2 is ready to use.

2. Assay Procedure
This product is compatible with various types of automated analyzer. An example of the assay procedure is indicated below.

Sample 3 µL + Reagent (1) 200 µL —37°C, 5 min→ Measurement (Absorbance I※)
Reagent (2) 80 µL —37°C, 5 min→ Measurement (Absorbance II※)
→ Calculation of concentration

※Absorbance I and II: The difference in absorbance between 800 nm and 340 nm.
Calibration material: GAM complement calibrator (manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results

1. Reference standard range[2)]
Male: 33–190 mg/dL
Female: 46–260 mg/dL

2. 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 being equal to or lower than 0.25
   2) Sensitivity: The absorbance is 0.16–0.60 per 100 mg/dL of IgM.
2. **Accuracy**: 90–110 % of the expected assay value
3. **Within-run Reproducibility**:
   Coefficient of variation ≤ 5 %
   (Test methods used for 1.–3. are in-house methods.)
4. **Measurement Range**[3]: (On Hitachi 7170 automated analyzer)
   1–500 mg /dL
5. **Correlation**[3]
   1) Serum N=50 r=0.999 y=0.96x+4.8
   Control method: Approved in vitro diagnostic (turbidimetric immunoassay)
   2) Plasma N=50 r=0.996 y=0.998x–7.2
   Control method: Approved in vitro diagnostic (turbidimetric immunoassay)
6. **Standard Material**
   CRM470（IRMM）

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) Proclin 300, which possesses skin-irritative potential, is added as an antiseptic agent in the IgM Buffer Solution 1 and IgM Antibody Solution 2. Therefore, if the reagent comes in contact with skin or clothes, rinse immediately with ample water, and consult the doctor if skin irritation develops.

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 replenish the reagents.
4) 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

Do not use the containers for other purposes.

Storage and Shelf Life **

1. Storage temperature: 2–10 °C
2. Shelf life: 1 year from the date of manufacture
   (The expiration date is printed on the outer package.)

Packaging

Name			Package
Pureauto S IgM	(1)	IgM Buffer Solution 1	2 × 40 mL
	(2)	IgM Antibody Solution 2	2 × 8 mL

Constituent reagents are available in other configurations. For further details please contact SEKISUI MEDICAL CO., LTD.

References *

1) Medical Practice Editorial Board: Laboratory test guide revised in 2015, Bunkodo, 683, 2015.
2) Saito K., Kawai T., Ichihara K.: Jpn J Clin Pathol (extra edition), 101, 118, 1996.
3) In house data, SEKISUI MEDICAL CO., LTD.

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Manufacturer **

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