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

In Vitro Diagnostics
Marketing Approval No. 21600AMZ00478000

** Revised: January 2017 (6th edition)
* Revised: January 2009 (5th edition)

This package insert must be read carefully prior to use.

Phosphorus/inorganic phosphorus assay kit
(Classification No.: 30191002)

QUALIGENT IP

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
IP Coloring Solution 1:
p-Methylaminophenol sulfate
Nonionic surfactant
IP Coloring Solution 2:
Ammonium molybdate
Sulfuric acid

Intended Use

Measurement of P (inorganic phosphorus) in serum, plasma or urine

Phosphorus is largely contained in bone tissues. It is also found in blood and play an important role in various metabolic processes. It has been reported that blood phosphorus levels are closely related to blood calcium levels and are affected by thyroid function as well as bone disease.

Assay Principle

1. Assay Principle

Inorganic phosphorus binds to molybdate to form phosphomolybdic acid, which is then reduced by p-methylaminophenol to form molybdenum blue. The inorganic phosphorus content is determined by measuring the absorbance of the molybdenum blue.

Inorganic phosphorus + Molybdate ⟶ Phosphomolybdic acid

Phosphomolybdic acid —(Reduction; p-Methylaminophenol sulfate)→ Molybdenum blue (blue color)

2. Features

1) Analytical values are hardly affected by interfering substances.
2) The accuracy of measurement is high because the self-sample blank method is employed.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples

Serum, plasma (heparin plasma, EDTA 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[2]:

2–10°C: for tests within 1 week
≤ -20°C: for tests after more than 1 week

Bring samples to room temperature (15–30°C) before use.

Urine samples should be tested on the same day.

If samples cannot be measured on the same day, store in a refrigerator (4°C) or freeze (–20°C or lower). Samples have been shown to be stable for 1 week with refrigeration or frozen.

2. Interfering substances

1) Assay results are not affected by formazin turbidity (up to 3000 FTU) or ascorbic acid (up to 50 mg/dL).
2) Jaundice samples, hemolyzed samples may result positive error.

3. Others

1) Always use Anaserum IP Standard Solution or Seronorm Multicalibrator 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): IP Coloring Solution 1 is ready to use.
Reagent (2): IP Coloring Solution 2 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 2.0 μL	+ Reagent (1) 100 μL	37°C, 5 min		Measurement (Absorbance I※)
	+ Reagent (2) 33 μL	37°C, 5 min		Measurement (Absorbance II※)
			⟶	Calculate of concentration

※Absorbance I and II: The difference in absorbance between 600 nm and 700 nm
Calibration material: Anaserum IP Standard Solution or Seronorm Multicalibrator (Manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results **

1. **Reference standard range**[3)]
   2.7–4.6 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 0.03
   2) Sensitivity: The absorbance is 0.44–0.54 per 20 mg/dL inorganic phosphorus.
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**[4)]: (On a Hitachi 9000 series automated analyzer)
   0.1–40.0 mg/dL
5. **Correlation**[4)]
   1) Serum N=70 r=0.999 y=0.99x–0.10
      Control method: Approved in vitro diagnostics (Fiske-Subbarow method)
   2) Plasma N=143 r=0.999 y=0.99x –0.03
      Control method: Approved in vitro diagnostics (Fiske-Subbarow method)
   3)Urine N=60 r=0.999 y=1.01x－0.10
      Control method: Approved in vitro diagnostics (Fiske-Subbarow method)
6. **Standard Material**
   SRM200 (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) IP Coloring Solution 1 and IP Coloring Solution 2 contain sulfuric acid. If any reagent is accidentally ingested or contacted with 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: 1 year from the date of manufacture
   (The expiration date is printed on the outer package.)

Packaging **

Name	Package		
QUALIGENT IP	Set (Cassette for Hitachi 9000 series)	IP Coloring Solution 1 1×15.0 mL IP Coloring Solution 2 1×5.0 mL	× 2
	L set (Set for Hitachi LABOSPECT series)	IP Coloring Solution 1 1×46 mL IP Coloring Solution 2 1×16 mL	× 2

References **

1) Kanai M. (editor): Kanai's manual of clinical laboratory medicin e. 32nd ed. 577, Kanehara Shuppan, 2005.
2) Sasaki M. et al.: Sampling of constituents of the human body, 141, Kodansha, 1972.
3) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. 545, Kanehara Shuppan, 2015.
4) In house data, SEKISUI MEDICAL CO., LTD.

Contac

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Manufacturer **

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