

This package insert must be read carefully prior to use.

Class II Biochemical Test Series (General)
(Classification No.: 80022002)
Phosphorus/inorganic phosphorus assay kit
(Classification No.: 30191002)

Clinimate IP-2

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

IP-2 Coloring Solution 1

IP-2 Coloring Solution 2: Ammonium molybdate

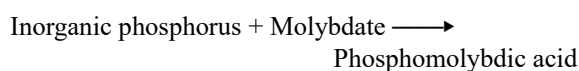
Intended Use

Measurement of inorganic phosphorus in serum, plasma or urine

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 molybdenum blue.



Reduction
Phosphomolybdic acid \rightarrow Molybdenum blue (blue color)
p-Methylaminophenol sulfate

2. Features

- 1) Reagent preparation is not required.
- *2) Chemical method, Phosphomolybdic acid reduction assay.

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^{1) 6)}

If the isolated serum or plasma sample cannot be tested on the same day, specimens should be stored as follows:

2–10°C: for tests within 1 week

≤ -20°C: for tests within 2–3 months

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 bilirubin (up to 20 mg/dL).
- 2) Hemolysis of samples may cause positive error in assay results.

3. Others

- *1) Always use Serum Multicalibrator (SEKISUI), Seronorm Multicalibrator, or Anaserum IP 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 (1):

IP-2 Coloring Solution 1 is ready to use.

Reagent (2):

IP-2 Coloring 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	+	5 μL	Reagent (1)	37°C 300 μL 3 min	→	Measurement (Absorbance I [†])	
			Reagent (2)	37°C 100 μL 4.5 min	→	Measurement (Absorbance II [†])	→
							Calculation of concentration

† Absorbance I and II :

The difference in absorbance between 600 nm and 700 nm

Calibration material:

Serum Multicalibrator (SEKISUI), Seronorm Multicalibrator, or Anaserum IP Standard Solution (Manufacturer's assigned value)

Reagent blank: Purified water or saline

Assessment of Assay Results

** 1. Reference Interval

Serum²⁾: 2.7–4.6 mg/dL (Within the JCCLS common standard)

Urine³⁾: 400–800 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 being equal to or lower than 0.03

2) Sensitivity:

The absorbance is 0.44–0.54 per 20 mg/dL of inorganic phosphorus.

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

3. Within-run Reproducibility:

Coefficient of variation $\leq 3\%$

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

4. Measurement Range⁶⁾ (On Hitachi 7170S automated analyzer): 0.2–35.0 mg/dL

5. Correlation⁶⁾:

1) Serum N = 60 $r = 0.999$ $y = 0.99x + 0.11$
Control method: Approved in vitro diagnostics (Fiske-Subbarow method)

2) Plasma N = 60 $r = 0.999$ $y = 0.99x - 0.11$
Control method: Approved in vitro diagnostics (Enzymatic method)

3) Urine N = 60 $r = 0.999$ $y = 1.01x - 0.08$
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-2 Coloring Solution 1 and IP-2 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 replenish the reagents.

**4) The product should be tightly stoppered and stored as instructed when not in use.

5) 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 121°C 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

Name		Storage temperature	Shelf life
Clinimate IP-2	IP-2 Coloring Solution 1	2–10°C	1 year from the date of manufacture
	IP-2 Coloring Solution 2	Room temperature	1 year from the date of manufacture

(The expiration date is printed on the outer package.)

Packaging

Name			Package
Clinimate IP-2	(1)	IP-2 Coloring Solution 1	2 × 100 mL
	(2)	IP-2 Coloring Solution 2	2 × 50 mL

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

References

- 1) Sasaki M. et al. Sampling of constituents of the human body. Tokyo: Kodansha; 1972. Japanese.
- * 2) Kanai M, editor. Kanai's manual of clinical laboratory medicine. 35th ed. Tokyo: Kanehara Shuppan; 2020. Japanese.
- 3) Kanai M, editor. Kanai's manual of clinical laboratory medicine. 32th ed. Tokyo: Kanehara Shuppan; 2005. Japanese.
- 4) Yamamura Y. (supervisor): Medical and Chemical Experimentations 3B, Clinical Chemistry I, Tokyo: Nakayama Shoten, 1973. Japanese.
- 5) SEKISUI MEDICAL CO., LTD. In house data. Japanese.

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