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

In Vitro Diagnostics
Marketing Approval No. 20800AMZ10019000

** Revised: January 2017 (7th edition)
* Revised: April 2008 (6th edition)

This package insert must be read carefully prior to use.

Urea nitrogen assay kit
(Classification No.: 42849002)

Pureauto S UN

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
UN Coenzyme Solution 1:
Nicotinamide adenine dinucleotide phosphate (reduced form)
α-Ketoglutaric acid
Carbonate buffer
UN Enzyme Solution 2:
Urease (sword bean origin)
Glutamate dehydrogenase (yeast origin)
N,N-bis (2-hydroxyethyl) Glycine buffer

Intended Use

Measurement of urea nitrogen in serum, plasma or urine

Urea is the final product of protein metabolism. It is released into the blood from the liver and then eliminated from the body via the kidneys.
In patients with nephropathy, the blood urea nitrogen level increases because of impaired excretion. Abnormal values are seen in patients with heart disease, liver disorder, dehydration, or hemorrhage (especially gastrointestinal hemorrhage), as well as those with nephropathy.

Assay Principle

1. Assay Principle

Urea is degraded by urease to produce ammonia. When glutamate dehydrogenase (GLDH) acts on ammonia and α-ketoglutaric acid, glutamic acid is produced. At the same time, NADPH is converted to NADP, and the absorbance at 340 nm decreases. The urea nitrogen content is determined by measuring the change of absorbance.

$$\text{Urea} \xrightarrow{\text{Urease}} 2NH_3+CO_2$$

$$NH_3 + \alpha\text{-Ketoglutaric acid} + NADPH \xrightarrow{\text{GLDH}} \text{Glutamic acid} + H_2O + NADP$$

2. Features

1) The influence of endogenous ammonia is eliminated.
2) Analytical results are hardly affected by hemolysis or bilirubin, because the rate method is used.
3) Liquid reagents, ready-to-use.
4) Applicable to various automated analyzers.

Procedural Precautions * *

1. Properties of Samples and Sampling Methods

1) Samples
Serum, plasma, or urine (1:21 dilution) may be used.
2) Storage of samples[1)]
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 after more than 1 week
Bring samples to 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 ammonia (up to 4 mg/dL).

3. Others

1) Always use Anaserum UN standard solution, Seronorm Human, 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.

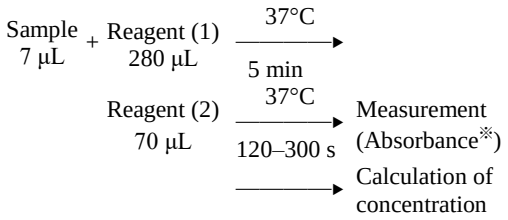
Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

Reagent (1): UN Coenzyme Solution 1 is ready to use.
Reagent (2): UN Enzyme Solution 2 is ready to use.

2. Assay Procedure

This product is compatible with various types of automated analyzer. Assay procedure is indicated below.



※Absorbance: The difference in absorbance between 405 nm and 340 nm
Calibration material: Anaserum UN standard solution, Seronorm Human, or Seronorm Multicalibrator (Manufacture's assigned value)
Reagent blank: Purified water or saline

Assessment of Assay Results **

1. Reference standard range
In blood: 8–20 mg/dL[2)]
In urine: 6.5–13.0 g/day[3)]

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 0.05
2) Sensitivity: The change of absorbance is 0.020–0.045/min per 30 mg/dL of urea nitrogen.

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 Hitachi 7070 automated analyzer)
0.5–200 mg/dL

5. Correlation[4)]
1) Serum N=100 r=0.999 y=1.00x–0.23
Control method: Approved in vitro diagnostic (urease-GLDH method)
2) Plasma N=100 r=0.999 y=1.03x –0.19
Control method: Approved in vitro diagnostic (urease-GLDH method)
3) Urine (1:21 dilution)
N=50 r=0.999 y=1.01x –9.09
Control method: Approved in vitro diagnostic (urease-GLDH method)

6. Standard Material
SRM912 (NIST)

Precautions for Use or Handling * *

1. Precautions for Handling (to Ensure Safety)
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. 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: 1year from the date of manufacture
(The expiration date is printed on the outer package.)

Packaging

Name			Package
Pureauto S UN	(1)	UN Coenzyme Solution 1	2 × 400 mL
	(2)	UN Enzyme Solution 2	4 × 100 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. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. Tokyo; Kanehara Shuppan; 2015. Japanese.
3) Kanai M. (supervising editor): Kanai's manual of clinical laboratory medicine. 34th ed. Tokyo: Kanehara Shuppan; 2015. Japanese.
4) SEKISUI MEDICAL CO., LTD. In house data. Japanese.

Contact *

SEKISUI MEDICAL CO., LTD.
international@sekisui.com

Manufacturer * *

SEKISUI MEDICAL CO., LTD.
1-3, Nihonbashi 2-chome, Chuo-ku, Tokyo, Japan