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

In Vitro Diagnostics
Certification No. 220ADAMX00103000

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This package insert must be read carefully prior to use.

Albumin assay kit
(Classification No.: 30155002)

NORUDIA U-ALB

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. U-ALB Latex Reagent 2 contains human-derived components that have been shown to be negative for HBs antigens, HIV antibodies, and HCV antibodies. However, this reagent (as well as the samples) should be considered potentially infectious and therefore handled with great care.
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
U-ALB Antibody Solution 1:
Anti-human albumin mouse monoclonal antibody
U-ALB Latex Reagent 2:
Human albumin-coated latex

Intended Use

Measurement of trace levels of albumin in urine

Urinary albumin excretion increases in the early stage of diabetic nephropathy, which is a complication of diabetes. Therefore, it is a useful index for early detection of this complication.[1]

Assay Principle

1. Assay Principle

This product is a reagent for measuring human albumin based on latex immunonephelometry (competitive method).

A certain amount of the anti-human albumin mouse monoclonal antibody (subsequently referred to as anti-human albumin antibody) is added to the sample and is consumed by reacting with albumin in the sample. Next, human albumin-coated latex beads are added to the sample, and residual anti-human albumin antibody reacts with the beads to form aggregates. Since the extent of aggregation depends on the albumin concentration in the sample, the albumin concentration can be determined by measuring aggregation as the change of absorbance.

Sample (albumin) + Anti-human albumin antibody
⟶ Antigen-antibody reaction

Unreacted anti-human albumin antibody + albumin-coated latex
⟶ Aggregation by antigen-antibody reaction

2. Features

1) Because the competitive method is used for measurement, there is no hook effect.
2) Liquid reagents, ready-to-use.
3) Applicable to various automated analyzers.

Procedural Precautions *

1. Properties of Samples and Sampling Methods

Samples

Use spot urine or 24-hour urine as the sample.

After collection, measure the urine sample as soon as possible.

If suspended matter is seen in the sample, centrifuge the sample and use the supernatant.

If the sample cannot be measured on the same day, store it with refrigeration and measure within 7 days of collection.

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

2. Interfering substances

1) Assay results are not affected by free bilirubin (up to 10 mg/dL), conjugated bilirubin (up to 10 mg/dL), hemoglobin (up to 500 mg/dL), formazin turbidity (up to 2000 FTU), rheumatoid factors (up to 500 IU/mL), ascorbic acid (up to 500 mg/dL),or glucose (up to 4000 mg/dL).
2) Assay results are not affected by chloroform (up to 1%) or formalin (up to 1%) as preservatives for urine samples.

3. Others

1) Always use U−ALB 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): U-ALB Antibody Solution 1 is ready to use.

Reagent (2): U-ALB Latex Reagent 2 is ready to use.

Before using this product, gently invert the U-ALB Latex Reagent 2 bottle to mix it

thoroughly, and check that there are no bubbles.

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) 120 µL → (5 min, 37°C) → Reagent (2) 120 µL

Measurement (Absorbance I※) → (5 min, 37°C) → Measurement (Absorbance II※) → Calculation of concentration

※ Absorbance I and II : The difference in absorbance between 570 nm and 800 nm.

Calibration material: U-ALB Calibrator (Manufacture's assigned value)

Assessment of Assay Results

1. Reference standard range[1)]

Diagnostic criteria for microalbuminuria in urene

	24-hour pooled urine (mg/24 hr)	Spot urine (mg/gCr)
Normal	< 30	< 30
Microalbuminuria	30–299	30–299
Macroalbuminuria	≥ 300	≥ 300

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

a) Reagent blank: change in absorbance being 0.06 to 0.56

b) The change of absorbance is 0.003–0.124 per 500 µg/mL of human albumin

2. Accuracy: 85–115 % of the expected assay value

3. Within-run Reproducibility:

Coefficient of variation ≤ 10 %

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

4. Measurement Range[2)]: (On Hitachi 7170 automated analyzer)

5–500 µg /mL

5. Correlation[2)]

Urine N=50 r=0.998 y=-0.98x–1.06

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) U-ALB Antibody Solution 1 and U-ALB Latex Reagent 2 contain ProClin 300 as a preservative, which may irritate the skin. If these solutions are accidentally ingested or come into contact with the eyes, skin, or clothing, immediately rinse the affected area with water. 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) Do not mix materials from different kit lot numbers.

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 ºC 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 months from the date of manufacture

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

Packaging *

Name		Package
NORUDIA U-ALB	U−ALB Antibody Solution 1	1 × 10 mL
	U−ALB Latex Reagent 2	1 × 10 mL

References

1) Japan Diabetes Society: Evidence-based practice guidelines for the treatment of diabetes in Japan (2nd edition), 77−92, 2007.

2) In house data, SEKISUI MEDICAL CO., LTD.

Contact

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Manufacturer *

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