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

In Vitro Diagnostics
Marketing Notification No. 13A2X00197225001

**Revised: January 2017 (5th edition)
*Revised: July 2015 (4th edition)

This package insert must be read carefully prior to use.

Insulin assay kit
(Classification No.: 30338000)

NORUDIA Insulin

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.
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
Insulin Buffer Solution 1
Insulin Latex Reagent 2:
Anti-human insulin mouse monoclonal antibody-coated latex

Intended Use

Measurement of insulin in serum or plasma

Insulin is a hormone that is synthesized by β cells in the islets of Langerhans in the pancreas and secreted into the blood. It reduces the blood glucose level. The blood level of insulin (immunoreactive insulin, IRI) reflects pancreatic secretion of insulin and the insulin sensitivity of target tissues. It is commonly measured to diagnose diseases associated with abnormal glucose metabolism (diabetes and hypoglycemia) and to assess the status of these diseases.[1),2)]

Assay Principle

1. Assay Principle

In samples, an antigen-antibody reaction occurs between insulin and anti-human insulin mouse monoclonal antibody-coated latex beads, resulting in aggregation of the beads. The insulin concentration in the sample is determined by measuring the aggregation as the change of absorbance.

2. Features

1) Liquid reagents, ready-to-use.
2) Applicable to various automated analyzers.

Procedural Precautions **

1. Properties of Samples and Sampling Methods

1) Samples
Serum and plasma (heparin plasma, EDTA plasma and NaF-EDTA plasma) may be used.
2) Storage of samples[1)]
Centrifuge the sample immediately after collection, and perform measurement promptly. If the sample cannot be measured promptly, it may be stored for up to 24 hours under refrigeration (2–10°C) or for approximately 2 weeks in a freezer (-30°C or lower).
Assay results are not affected if freezing/thawing is performed once or twice.

2. Interfering substances

1) Assay results are not affected by free bilirubin (up to 20 mg/dL), conjugated bilirubin (up to 20 mg/dL), formazin turbidity (up to 2000 FTU), or rheumatoid factors (up to 500 IU/mL).
2) Do not use hemolyzed samples, or low assay results may be obtained due to the insulin-degrading enzyme in erythrocytes.[3]
3) Assay results are not affected by gastrin (up to 10 μg/mL), glucagon (up to 10 μg/mL), proinsulin (up to 12.2 ng/mL), secretin (up to 10 μg/mL), or C-peptide (up to 3.9 μg/mL).

3. Others

1) Always use Insulin 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.
The sample may be diluted up to 3:1 with physiological saline.

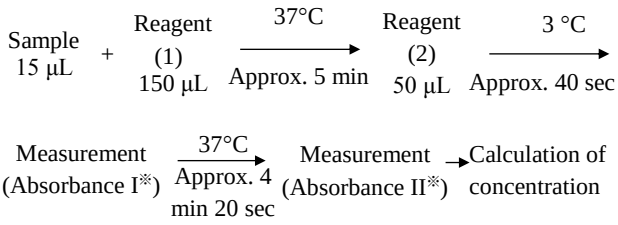
Dosage/Administration (Assay Procedure) **

1. Preparation of reagents

Reagent (1): Insulin Buffer Solution 1 is ready to use.
Reagent (2): Insulin Latex Solution 2 is ready to use.
Before using this product, gently invert the Insulin Latex Solution 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.



※Absorbance I and II: The difference in absorbance between 570 nm and 800 nm
Calibration material: Insulin Calibrator (manufacture's assigned value)
Reagent blank: Insulin Calibrator 1

Assessment of Assay Results

1. Reference standard range[4)]
Preprandial: 5 – 10 µU/mL

2. Precautions for Assessment

1) If there is anti-insulin antibody in the sample, assay results may not reflect the actual blood insulin level. In this case, comprehensive clinical evaluation should be based on both the assay results and consideration of other laboratory data.
2) If the reagent reacts with non-target substances in the sample, assay results may be affected. If assay results appear unreliable, repeat the measurement (if necessary, after dilution) or try another analytical method.

Performance

1. Sensitivity

1) Reagent blank: absorbance being equal to or lower than 0.048
2) Sensitivity: The difference of absorbance between insulin (10 µU/mL) and the reagent blank is 0.014–0.050.

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[5)]: (On Hitachi 7180 automated analyzer)
1–150 µU/mL

5. Correlation[5)]

1) Serum N=85 r=0.989 y=0.93x+0.81
Control method: Reported in vitro diagnostic (latex immuno-turbidimetric assay)
2) Plasma N=101 r=0.989 y=0.93x+0.63
Control method: Comparison with the values for whole blood samples obtained simultaneously with the serum samples.

6. Standard Material
1st WHO reference standard 66/304 (NIBSC)

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 Insulin Buffer Solution 1 and Insulin Latex Reagent 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 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: 2 years from the date of manufacture
(The expiration date is printed on the outer package.)

Packaging

Name		Package
NORUDIA Insulin	Insulin Buffer Solution 1	2 × 15 mL
	Insulin Latex Reagent 2	2 × 5 mL

References

1) Karasawa M. et al.: J Clin Lab Inst Reag, 29(5), 479, 2006.
2) Wada K. et al. (author and editor): Laboratory test guide 2013–2014, 470–471, Bunkodo, 2013.
3) Dohi K. et al.: J Clin Lab Inst Reag, 12(4), 843, 1989.
4) Kanai M. (author and editor): Kanai's manual of clinical laboratory medicine. 34th ed. 737, Kanehara Shuppan, 2015.
5) In house data, SEKISUI MEDICAL CO., LTD.

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