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

In Vitro Diagnostics
Certification No. 229ADEZX00007000

**Revised: November 2019(6th edition)
*Revised: July 2019(5th edition)

This package insert must be read carefully prior to use.

Kit for IL-1a/IL-1b/IL-1RA/IL-2r/IL-6r
(Classification No. 30619000)

Nanopia IL-2R

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 section 2.3 "Cross-reactivity", under "Procedural Precautions" carefully, as well as section 2 "Precautions for Assessment" under "Assessment of Assay 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
IL-2R Buffer Solution 1	
IL-2R Latex Reagent 2:	Mouse monoclonal anti-human IL-2R antibody-coated latex Rat monoclonal anti-human IL-2R antibody coated latex

Intended Use

Measurement of soluble interleukin-2 receptor (sIL-2R) concentration in serum or plasma

The interleukin-2 receptor (IL-2R) is a protein expressed on the surface of T cells and B cells activated by antigenic stimulation. Measuring that part of IL-2R released into blood (the α chain) is useful in the diagnosis of non-Hodgkin's lymphoma, adult T cell leukemia (ATL), and monitoring-patients after definitive diagnosis of non-Hodgkin's lymphoma or ATL .[1),2),3),4)]

Assay Principle

1. Assay Principle

sIL-2R in the specimen reacts with mouse monoclonal anti-human IL-2R antibody conjugated to latex beads and rat monoclonal anti-human IL-2R antibody conjugated to latex beads, forming latex agglutinates. The degree of agglutination is detected as absorbance change to determine the sIL-2R level.

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 and EDTA plasma) may be used.
2) Storage of samples
(1) After separation of serum (plasma), samples may be stored refrigerated (2–10°C) for up to 7 days. If samples cannot be analyzed within 7 days after separation, store at −20°C or lower and analyze within 2 months. Stored samples should be brought to room temperature (15–30°C) before use.
(2) Frozen samples should be thawed at room temperature or in a water bath. Mix thoroughly before analyzing.
(3) Samples may be frozen and thawed up to 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), hemoglobin (up to 500 mg/dL), formazin turbidity (up to 1500 FTU), or rheumatoid factors (up to 500 IU/mL).
2) Specimens from antibody drug-treated patients may not show accurate sIL-2R values.
3) Cross-reactivity
Assay results are not affected by each of the following substances (up to 1 μg/mL).

Substance
IL-1α, IL-1β, IL-2, IL-4, IL-6, IL-8, IFN-γ, TNFα, and IL-2Rβ

3. Other

1) Calibration Material
Use Nanopia IL-2R Calibrator N (manufactured by SEKISUI MEDICAL CO., LTD.) for calibration and perform a multi-point calibration.
2) Precautions for assay range
If the concentration of sample exceeds assay range, dilute the sample with saline and repeat the measurement.

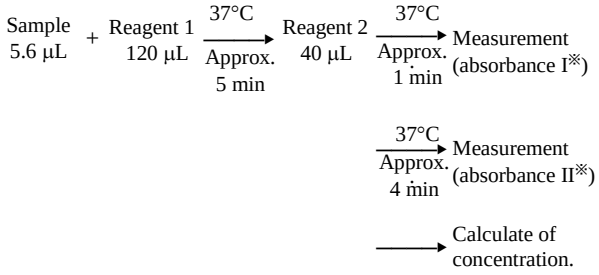
Dosage/Administration (Assay Procedure)

1. Preparation of reagents

Reagent (1): IL-2R Buffer Solution 1 is ready to use.
Reagent (2): IL-2R Latex Reagent 2 is ready to use.
Mix Reagent 2 by gentle inversion prior to use, being careful to avoid the formation of bubbles.

2. Assay Procedure

This product is compatible with various types of automated analyzers. 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 : IL-2R Calibrator N for Nanopia (Manufacturer's assigned value)
Reagent blank : Purified water or saline

Assessment of Assay Results

1. Reference Range

Each institution should determine its own reference range. However, for informational purpose only, the following external[3] and in-house[5] ranges are provided.

1) 122－496U/mL[3]
2) 204－587U/mL[5]

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

The Absorbance difference between saline and Calibrator 3 used as a specimen is 46.4－103.0 mAbs per 2,000 U/mL of IL-2R.

2. Accuracy

85－115% of the expected assay value.

3. Within-run Reproducibility

Coefficient of variation ≤ 15%
(Test methods used for items 1 to 3 above are in-house methods.)

4. Measurement Range[5] (On Hitachi 7180 automated analyzer)

50－10,000 U/mL

5. Correlation[5]

1) Serum
N = 254 r = 0.978 y = 1.05x + 23.9
Control method 1: Approved in vitro diagnostic (enzyme immunoassay)
N = 259 r = 0.986 y = 0.90x + 55.2
Control method 2: Approved in vitro diagnostic (chemiluminescent enzyme immunoassay)

2) Plasma
Heparin plasma:
N = 244 r = 0.998 y = 1.00x + 5.5
EDTA plasma:
N = 57 r = 0.999 y = 0.97x + 4.2
Control method: Comparison with the values for serum specimens obtained simultaneously with plasma specimens.

6. Standard Material

In-house standard material (purified recombinant human IL-2R solution)

Precautions for Use or Handling

1. Precautions for Handling (to Ensure Safety)

1) All specimens 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 to the IL-2R Buffer Solution 1 and IL-2R 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 in a tightly-stopped container. Avoid freezing. Do not use this product if it has been frozen because freezing can cause deterioration of the reagents, leading to inaccurate results.
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 reagents 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 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: 1 year from the date of manufacture

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

Packaging

Name		Package
Nanopia IL-2R	IL-2R Buffer Solution 1	2 × 18 mL
	IL-2R Latex Reagent 2	2 × 7 mL

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

References

1) Yamamoto J, Harikae H: Diagnosis and Treatment 97 (9) 244 (2009).
2) Kato H, Ogura M: Japanese Journal of Cancer and Chemotherapy 32 (6) 883 (2005).
3) Medical Practice Editing Committee: Guide for

Laboratory Tests, 2015 revision 1014 (2015).
4) Japanese Society of Laboratory Medicine Guideline Preparation Committee: Guidelines for Laboratory Tests JSLM2015, 414 (2015).
5) In house data, SEKISUI MEDICAL CO., LTD.

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