INSTRUCTION OF 5'-NUCLEOTIDASE

ASSAY KIT BY ENZYMATIC COLORIMETRIC METHOD

Szybio
LIFE ORIGIN BIOTECH

[Product Name]

5'-Nucleotidase Assay Kit by Enzymatic Colorimetric Method

[Packing specifications]

Basing on the bottle type, product model can be classified into 7170, 7060, 7020, Beckman, Toshiba, Mindray, Dupont, Innova, Siemens, KHB, Abbott, General types, etc.

R1：60ml×2　R2：60ml×1	R1：20ml×1　R2：10ml×1
R1：80ml×2　R2：80ml×1	R1：40ml×1　R2：20ml×1
R1：40ml×2　R2：20ml×2	R1：50ml×2　R2：50ml×1
R1：60ml×1　R2：30ml×1	R1：60ml×4　R2：60ml×2
R1：60ml×2　R2：30ml×2	R1：60ml×4　R2：30ml×4
R1：60ml×8　R2：60ml×4	R1：60ml×8　R2：30ml×8
R1：6×76T　R2：6×76T	R1：12×76T　R2：12×76T
R1：1×700T　R2：1×700T	R1：2×700T　R2：2×700T
R1：4×700T　R2：4×700T	R1：8×700T　R2：8×700T

[Intended Use]

This product is used to determine 5'-Nucleotidase activity in human serum.

[Principle]

The kit is based on continuous monitoring assay use the 5'-Nucleotidase coupling purine nucleoside phosphorylase (PNP), xanthine oxidase (XOD) and peroxidase (POD).

5'-nucleotidase hydrolyze inosine acid to generate inosine, then coupled by the action of PNP to generate hypoxanthine. Uric Acid and hydrogen peroxide formed from hypoxanthine under Oxidation of XOD. Finally, Fuchsia colored quinone was produced under POD effect by the Trinder reaction.

The 5'-nucleotidase activity can be calculated by measuring the increase rate of colored quinone absorbance at 550nm wavelength.

[Composition]

R1：Detection Reagent 1

Glycine Buffer	6g/L
Purine nucleoside phosphorylase	> 0.5KU/L
Xanthine oxidase	> 0.8KU/L
Peroxidase	> 0.6KU/L
TOPS	0.5g/L

R2：Detection Reagent 2

5'-hypoxanthine nucleotide	3.482g /L
4-Aminoantipyrene	0.406g /L

Calibrator& Control　Optional

Calibrator：0.5ml×1；Control：0.5ml×1

[Storage and Stability]

Stored for up to 12 months at 2-8°C, protect from light. After opening, the reagent remains stable for 28 days at 2-8°C, protect from light.

] Applicable Instrument]

This assay kit is suitable for automatic or semi-automatic biochemical analyzer with 546nm and 800nm wavelength.

[Sample Requirements]

Serum without hemolysis used as sample. Samples testing should be completed at the same day after collected. Otherwise, the samples should be cryopreserved and avoid repeated freeze-thaw cycles. 5'-Nucleotidase in the samples remains stable for 7days at 2-8°C and for 3 months at cryopreservation condition.

[Test Method]

1. Basic parameters:

Method: Rate assay　Temperature: 37℃

Primary wavelength: 546nm　Secondary wavelength: 800nm

Sample volume: 5μl　R1: 180μl

R2: 90μl　Response direction: Positive

Calibration mode: Two points calibration

2. Assay Procedure

	Blank（B）	Sample（U）	Calibrator（Ci）
ddH_2O(μl)	5	-	-
Sample(μl)	-	5	-
Ci(μl)	-	-	5
Reagent R1(μl)	180	180	180
	Mix, incubate for 5 min at 37°C.		
Reagent R2（μl）	90	90	90

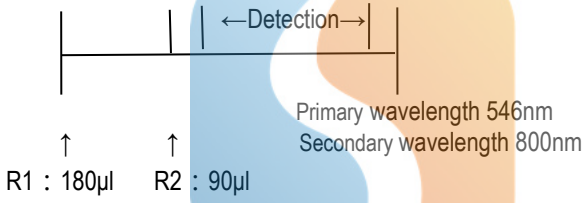
Mix and incubate for 120 seconds at 37°C, measure the initial absorbance. Then accurately measure the absorbance change rate per minute ΔA / min within 120 seconds.

ASSAY PROCEDURE SUMMARY:

Set blank well

Time: 10 min

Temperature: 37°C



Sample：5μl

3. CALCULATIONS

Based on two point calibrator concentration and the corresponding absorbance change rate ΔA/min, the two point linear calibration model is used to define the working curve. The concentration of 5'-Nucleotidase in the samples is determined by comparing the ΔA/min of the sample to the standard curve.

[Reference Range]

2.0U/L-11.4U/L

Recommendations: Each laboratory should establish its own reference range.

[Interpretation of Test Results]

1. The test results reflect only the status at the sampling time. Clinicians need to be combined with clinical data and other relevant test results to make judgment.

2. There is no significant effect on the test result when the sample contains Ascorbic acid ≤0.5g/L, Hemoglobin ≤5.0g/L, Triglycerides ≤2g/L.

[Test Method Limitations]

Dilute with physiological saline and multiply the result by the dilution factor when the concentration of 5'-Nucleotidase activity is over 100U/L.

[Product Performance]

1. Detection Range：5U/L-100U/L，r≥0.990.
2. Precision: Intra-assay CV≤6.0%, Inter-assay CV≤10.0%.
3. Accuracy: inaccuracy ≤10%.
4. Blank absorbance: The absorbance value ≤0.200 at 340nm wavelength and optical path 10mm.

[PRECAUTIONS]

1. For in vitro diagnostic use only.
2. Reagents become cloudy or blank absorbance value >0.200, should be discarded.
3. The reagent and sample amount can be changed with same ratio according to needs.
4. The test equipment must be clean to avoid contamination.
5. Reagents and components of different batches are not interchangeable.
6. The waste solution generated by the test and decomposition difficultly packaging materials should be collected and sent to local waste treatment station.

[Reference]

YW Ye et al. National Guide to Clinical Laboratory Procedures (Third Edition). Southeast University Press, 2006:436-438.

[MANUFACTURER]

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[Product standards]

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[Specification approval date]

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