Pyruvate Assay Kit (PYR)

Method: Enzymatic

Cat .No.	Size	Instrument
GB4126T	R1:1×60 ml R2:1×15 ml	For Hitachi 717 & ShimadzuCL7200/8000
GS4127T	R1:1×60 ml R2:1×15 ml	For Hitachi 917 & OlympusAU640/400/600
GD4127T	R1: 24×3.8ml R2: 6×3.8ml	Dupont

INTENDED USE

For the *in vitro* quantitative determination of PYR in serum.

CLINICAL SIGNIFICANCE

PYR Mainly used in clinical diagnosis of diabetic ketoacidosis.

Pyruvate is the major intermediates for glucose catabolism and anabolism, pyruvate is the product of glycolysis, to oxidize to CO2 and H2O by citric acid cycle, keep the blood of L / P ratio at about 9. When the body is under hypoxic metabolism, pyruvate is reduced to lactate, L / P increased. More severe hypoxia, more obvious of the L / P increasing. According to L / P ratio, the severity of circulatory failure can be speculated. Vitamin B1 deficiency, chronic alcoholism, chronic pulmonary heart disease, diabetes and ketoacidosis can cause pyruvate level elevate in blood.

ASSAY PRINCIPLE

$$PYR + NADH + H^+ \xrightarrow{LDH} LAC + NAD^+ + H_2O$$

Measuring the change in absorbance of NADH at 340nm wavelength, it is proportional to decrease in the content of the absorbance of the sample pyruvate.

REAGENT COMPOSITION

Contents	Element
R1	
NADH	**0.35mmol/L**
Tris Buffer	
Preservatives	1%
R2	
LDH	**300U/L**
Preservatives	

STABILITY AND PREPARATION OF REAGENTS

1.Reagents stabilize for one year under 2 - 8 ℃ Sealed storage.
2.The reagent has been turned attention to avoid contamination.

SAMPLE REQUIREMENT

Serum. Day of fasting serum without hemolysis, because long-term placement of whole blood would reduce the concentration of pyruvate, so the separation of blood plasma were measured promptly.

Test Method

1.Reagent preparation: liquid reagent that is ready to use.
2.Measurement Conditions：

Main Wave	340nm	Sample	20μl
Sub Wave	600nm	R1	200μl
Temperature	37℃	R2	50μl
Cuvette Path	1cm	Reaction Type	End Point 2

3. Operation Procedures

Add water into cuvette：	
Sample	20μl
R1	200μl
Mix sample with R1 and incubate at 37℃ for 300 seconds, read the absorbance A1.	
R2	50μl
Mix sample, R1 with R2 and incubate at 37℃ for 300 seconds, read the absorbance A1, calculate $\Delta A=A_2-A_1$.	

Note: To know the specific setting parameter, please contact with BSBE or visit www.bsbe.com.cn.

3.Calibration

Recommend that this assay should be calibrated using PYR Calibration Serum.

4.Quality control

Please select the quality control to match the PYR calibrators.The measured value of control should be within the range of values indicated. If the results deviate from the range, please follow the steps below to find reasons:
A. Check instrument settings and light source.
B. Check reaction temperature.
C. Check expiration date of kit and contents.
D. Check the cleanness of cuvette and suction sample needles.
E. Check whether the water was polluted, bacterial growth can lead to incorrect results.

5.Result Calibration：

$$\text{Concentration} = \frac{\text{Sample}\Delta A}{\text{Calibration}\Delta A} \times \text{Calibrator Concentration}$$

Normal Value:

Serum：20-100umol/L
It is recommended that each laboratory establish its own reference range to reflect the age, sex, diet and geographical location of the population.

Analysis of the test results, influenced by age, sex, diet, geographic influence, it will considerate normal if the result within the reference range, if the test results exceed the linear range, please do diluted with 0.9% saline, multiply the result by the dilution factor. If you

detect or confirm the test results ,which are still out of range again, the cause should be analyzed and find out.

Limitations and immunity of test methods
When VC ≤ 50mg/dl, LDH ≤ 1000U / L, the determination of pyruvate will not be interfered.

Products Performance

1. Accuracy
Using the calibrated automatic biochemical analyzer to measure the calibration, the accuracy deviation shall not exceed ± 10%.

2.Precision

a) Repeatability
Using the same serum sample to repeat the measurement for 10 times, the coefficient of variation (CV%) of the measured value should be ≤ 10%.

b) The intra assay precision
The kit batch difference among the random three batches sample should be ≤ 10%.

3 Linearity
In the 1000 μmol / L range, linearity error measurement should be ≤ 10% (37 ℃). In the dose range specified linear correlation coefficient r2> 0.99.

4 Sensitivity
The rate of change in absorbance per minute is between 0.0120-0.0180, when sample concentration is 200umol / L.

SAFETY PRECAUTIONS AND WARNINGS
1. The reagent contains Sodium Azide. Avoid ingestion or contact with skin or mucous membranes. In case of skin contact, flush affected area with copious amounts of water. In case of contact with eyes or if ingested, seek immediate medical attention.
2. Sodium Azide reacts with lead and copper plumbing, to form potentially explosive azides. When disposing of such reagents, flush with large volumes of water to prevent azide build up. Exposed metal surfaces should be cleaned with 10% sodium hydroxide.
3. During the measurement, please don't mix or change using different batch reagents.
4. The uncap reagents should be sealed storage as per requirement, it is prohibited when expired.
5. Please dispose detecting specimen tubes and other equipment in accordance with the provisions of the relevant medical waste treatment.

References
1.Zhang Xiuming,, Study of clinical and biochemical examination,Beijing:The Military Press,2010.
2.Han Zhijun, Used Items of Clinical Chemistry Automatic Analysis Method,Liaoning Science and Technology Press,2005.

INDEX OF SYMBOLS

	Manufacture
REF	Catalogue Number
LOT	Lot number
	Date of manufacture
	Use by(Expiration date)
IVD	For In-Vitro Diagnostic use only
2℃ 8℃	Stored at 2-8℃
	Attention:See instruction for use
EC REP	Authorized Representative in the European Company

Manufacture：Beijing Strong Biotechnology, Inc.
Address： No. 15, Yanqi North Second Street, Yanqi Economic Development Area, Huairou District, Beijing 101400, P. R. China
Tel：+86 10 61667168

EC REP :Lotus NL B.V.
Address： Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.
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