

Pyruvate Estimation Kit

High-Q Pyruvate-UV

(Quantitative / Enzymatic Method)

Intended Use:

Kit for the quantitative determination of Pyruvate in human Serum.

Summary:

Pyruvate levels are very important, because they give an information about circulatory disease. The increase of pyruvate levels are mentioned in several disease such as diabetes mellitus, liver diseases, neoplastic disorders, muscular dystrophy and congestive heart failure

Method:

The Lactate Dehydrogenase (LDH) catalyzes the reduction of pyruvate to lactate with simultaneous oxidation of NADH to NAD. The decrease of absorbance of NADH is directly proportional to the pyruvate concentration in the sample.

Reagents:

Components of the kit: 50 ml 100 ml
Reagent (R1) (liquid) 2 x 20 ml 2 x 40 ml
Reagent (R2) (liquid) 2 x 5 ml 2 x 10 ml
Serum Pyruvate Calibrator (Lyophilized) 1 x 3 ml

Reagent Composition

Good Buffer >500 mmol/L
 LDH >250 KU/L
 NADH >0,1 mmol/L
 Activators, Stabilizers

Storage Instructions and Reagent Stability:

The reagents are stable up to the end of the indicated expiry date if stored at 2 – 8 °C and when the contamination is avoided. Do not freeze the reagents!

Reagent Preparation:

The reagents are ready to use. Do not shake.

Calibrator: Pyruvate Calibrator is available as Lyophilized vial. Carefully open the vial without losing the materials.

Add 3 ml distilled water and keep at 30 Minutes at room temperature. Reconstituted Calibrator is stable for 15 Days at 2-8°C and 30 days when frozen as aliquots at -20 °C. Look for the Calibrator Concentration on the vial for the calibration.

Specimen:

Fasting Serum is the only specimen

Specimen Stability : 7 days at 20 -25 °C
 7 days at 4 -8 °C
 1 Month at -20 °C

Discard contaminated specimens.

System Parameters

Reaction Type (Mode) : Fixed Time
 Reaction Direction : Decreasing
 Wave Length : 340 nm
 Flow Cell Temp. : 37°C
 Zero Setting with : Distilled Water
 Delay Time : 60 Seconds
 Measuring Time : 240 Seconds
 Reagent Volume : 0.8 ml (R1) + 200 µl (R2)
 Calibrator / Sample Volume : 100 µl
 Calibrator Concentration : 1.35 mg/dl
 Linearity : 5.0 mg/dl
 High Normal : 0.7 mg/dl

Procedure :

Reagent	Calibrator	Serum
Reagent 1	800 µL	800 µL
Calibrator (Conc: 1.33 mg/dl)	100 µL	—
Serum	-----	100 µL
Reagent 2	200 µL	200 µL

Mix well and start the stopwatch. Record the first absorbance (A1) at 60 seconds after adding the Calibrator /Sample. Exactly 240 Seconds after the first reading record the absorbance (A2) at 37 °C.

Calculate the change in absorbance for the Calibrator and Samples.

Calculations with calibrator:

A1-A2 Sample
 Pyruvate (mg/dl) ----->x 1.35 (Conc. Calibrator mg/dl)
 A1-A2 Calibrator

Performance Characteristics:

These performance characteristics were determined using a spectrophotometer or analyzer typically found in clinical laboratories, under the stated assay conditions.

Linearity:

High-Q Pyruvate-UV Kit is linear up to 5 mg/dl

For concentrations ≥ 5 mg/dl, dilute the sample 1:2 with saline solution and repeat the determination and multiply the result x 2.

Sensitivity: The minimum detectable is 0.01 mg/dl

Within-run Precision:

Sample	Mean (mg/dL)	± 2s CV %
Sample	0,4 ± 0,05	4,7
Sample	2,6 ± 2,3	1,7

Run-to-run (Day-to-day) Precision:

Sample	Mean (mg/dL)	± 2s CV %
Sample	0,4 ± 0,06	4,9
Sample	2.5 ± 2,51,	9

Method Comparison:

Correlation: A group of 20 samples from 0,3 to 2,8 mg/dL was assayed by this procedure and using a similar commercially available Pyruvate Reagent. Comparison of the data gave the following results:

Linear regression equation $y = 1,0098 x - 0,12$
 Correlation coefficient $r = 0,9877$

Interference:

The following concentrations were not found to affect the assay:

Conjugated Bilirubin 40 mg/dl, Free Bilirubin 70 mg/dl, Haemoglobin 1000 mg/dl, Intralipid 800 mg/dl, Triglycerides 1000 mg/dl

Reference Values:

Pyruvic Acid 0.0 - 0.7 mg/dl (In fasting Serum)

Every laboratory should determine its reference values.

References:

1. Textbook of Clinical Chemistry, Ed. by N.W. Tietz, W.B. Saunders Co., Philadelphia (1999).
2. Young D.S. et al., Clin. Chem. 21, 302D (1975)



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







Ordering information

Ref./Cat. No.	Pack Size	Presentation
P-PYR-50	50 ml	(2 x 20 ml R1 + 2 x 5 ml R2) and Calibrator

Product Features

- Intended to be used only for determining serum pyruvate.
- Two Liquid Reagents (4 parts R1+ 1 part R2) with Calibrator.
- Linearity : 5 mg/dl.
- Measuring wavelength 340 nm.
- Two Point Kinetic (Fixed Time) Assay : 60 Sec Delay+ 240 Sec Measuring.

Symbols used with IVD devices

	Date of manufacture		Manufactured by
	In vitro diagnostic device		Keep away from sunlight
	Do not freeze		This way up
	Use by (yyyy-mm-dd or mm/yyyy)		Reagent
	Calibrator Material		Batch code
	Temperature limitation (store at)		Control
	Consult instructions for use		Keep dry Keep away from rain
	Catalog Number		

eIFU Indicator



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