

# LACTATE

## Multi Purpose (MPR)

### Liquid Reagent

#### KIT SPECIFICATIONS:

Cat. No.	Quantity	Reagent	Storage
GL1008LT	10 x 18ml	LACTATE	2-8°C
GL1018LT	4 x 250ml	LACTATE	2-8°C
GL1028LT	6 x 60ml	LACTATE	2-8°C

#### INTENDED USE:

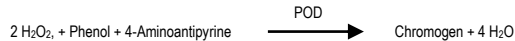
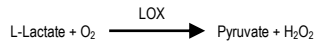
In Vitro Diagnostic reagent pack for the quantitative determination of lactate in serum and CSF samples on automated and semi-automated analysers.

#### SUMMARY AND EXPLANATION:

Anaerobic glycolysis markedly increases blood lactate and causes some increase in pyruvate levels, especially with prolonged exercise. The common cause for increased blood lactate and pyruvate is anoxia resulting from such conditions as shock, pneumonia and congestive heart failure. Lactic acidosis may also occur in renal failure and leukaemia. Thiamine deficiency and diabetic ketoacidosis are associated with increased levels of lactate and pyruvate. Lactate measurements that evaluate the acid-base status are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity in the blood).

#### PRINCIPLE OF THE TEST:

Lactate- oxidase (LOX) cleaves lactate into pyruvate and H<sub>2</sub>O<sub>2</sub>, which reacts in the presence of peroxidase (POD) with 4- aminoantipyrine and phenol to a red quinoneimine dye. The increase in absorbance due to the formation of the dye is directly proportional to the lactate concentration in the sample.



#### WARNINGS AND PRECAUTIONS:

For In Vitro Diagnostics Use Only - For Professional Use Only

Carefully read instructions for use. Deviations from this procedure may alter performance of the assay.

#### Colour and Appearance:

A clear, slightly pink liquid.

Any significant changes from the above could indicate that the assay might be compromised. Refer to Laboratory's QC program for actions to be taken. In case of serious damage to the bottle and/or cap, resulting in product leakage and/or contamination, do not use the reagent pack and contact your distributor.

#### Safety precautions:

**Caution:** Take all necessary precautions required when handling laboratory reagents. Material Safety Data Sheet is available upon request.

#### Handling precautions:

- Do not use components past the expiry date stated on the Bottles.
- Do not Freeze Reagents.
- Do not use components for any purpose other than described in the "Intended Use" section.
- Do not interchange caps among components as contamination may occur and compromise test results.
- Refer to local legal requirements for safe waste disposal.

#### INSTRUMENTS:

Instrument application procedures are available upon request.

#### COMPONENT COMPOSITION:

Component	Ingredients	Concentration in Tests
Reagent 1	MONOREAGENT	
	TRIS-Buffer pH 7.5	50.0 mmol/l
	LOX	0.2 KU/l
	POD	3 KU/l
	4-aminoantipyrin	0.4 mmol/l

#### REAGENT PREPARATION AND STABILITY:

**Reagent 1** ready-to-use

Before use, mix reagent by gently inverting each bottle.  
Unopened component is stable until expiry date stated on the label when stored at 2 – 8 °C

#### TYPE OF SPECIMEN:

Use **Plasma** as Specimen

#### Specimen Collection

It is recommended that specimen collection be carried out in accordance with NCCLS document M29-T2. No known test method can offer complete assurance that human blood samples will not transmit infection. Therefore, all blood derivatives should be considered potentially infectious.

Large and Variable change in lactate concentration may occur after sample collection. These changes may be minimised by using fluoride-oxalate as anti-coagulant, keeping samples on ice and separating plasma from blood without delay.

While lactate levels are stable in whole blood, the separated plasma may be stored at 2-8°C for 48 hours prior to use. Plasma lactate is stable up to at least 1 month stored frozen at -20°C

#### Sample preparation

- Draw blood with a minimum of stasis from fasting, resting patients into tubes containing fluoride/oxalate as anticoagulant.
- Mix well by gentle inversion at least 6 times. Cool blood in an ice bath.
- Within 30 minutes separate the plasma from blood by centrifugation at 400 x g for 10 minutes.
- Avoid excessive forces which contribute haemolysis. Note: If separation of plasma from blood (kept on ice) is delayed, lactate values may variably increase by about 10% after 1 hour, and up to 15% after 2 hours.

#### TEST PROCEDURE:

Materials required but not supplied:

Description	Catalogue No.	Description	Catalogue No.
General Chemistry Calibrator	GL983	Photometer	N/A
General Chemistry Control Level 1	GL922	General Laboratory Equipment	N/A
General Chemistry Control Level 2	GL932	Saline solution 9 g/l NaCl	N/A

#### Assay procedure:

Wavelength: 546 nm

Temperature: +25/ +30/ +37°C

Cuvette: 1 cm light path

Zero adjustment: against reagent blank

	Blank	Calibrator (Cal)	Sample
Reagent 1	1000 µl	1000 µl	1000 µl
Sample	----	----	10 µl
Calibrator (Cal)	----	10 µl	----

Mix well and measure the OD after 10 minutes against the reagent blank.

#### Calibration:

Using recommended Calibrator, calibrate the assay:

- When using a new reagent kit or changing lot number.
- Following preventive maintenance or replacement of a critical part.
- When Quality Controls are out of range.

#### Quality Control:

All clinical laboratories should establish an Internal Quality Control program. Verify instrument and reagent performance with recommended controls or similar. The values obtained for QC should fall within manufacturer's acceptable ranges or should be established according to the Laboratory's QC program.

Controls should be assayed:

- Prior to reporting patient results.
- Following any maintenance procedure.
- At intervals established by the Laboratory QC Programme

#### CALCULATIONS:

Concentration of Lactate =  $\frac{\Delta A \text{ Sample}}{\Delta A \text{ Standard}} \times \text{Conc. of Calibrator}$

(Conversion factor: Qty in mg/dl = Qty in mmol/l x 9.015)

#### EXPECTED VALUES:

Serum	mg/dl	mmol/l
	4.5 - 19.8	0.5 - 2.2

Each laboratory should establish its own reference range. Lactate results should always be reviews with the patient's medical examination and history.

#### PERFORMANCE CHARACTERISTICS:

Performance results can vary with the instrument used. Data obtained in each individual laboratory may differ from these values.

#### Linearity:

Linear up to 140mg/dL

For samples with a higher concentration, dilute 1:1 with 0.9% NaCl (9g/l) and re-assay. Multiply result by 2.

**Interfering substances:** Results of study are as follows:

Bilirubin: < 10% interference up to 600mg/L Bilirubin  
Haemolysis: < 10% interference up to 20g/L Haemoglobin.  
Lipemia: <10% interference up to 10g/L Intralipid.

#### Sensitivity:

The Lowest Detectable Level was estimated at 2.0 mg/dl (0.2 mmol/l).

#### Precision:

Within Run	Mean mg/dl	SD mg/dl	% CV	Between Run	Mean mg/dl	SD mg/dl	% CV
Level 1	13.6	0.25	1.80	Level 1	14.3	0.40	2.79
Level 2	45.7	0.46	1.01	Level 2	46.8	0.38	0.82

#### Method Comparison:

A method comparison between this Lactate test (y) and another commercially available test (x), gave the following results:

$y = 1.0976x - 1.4738$	$R = 0.9992$	Sample range: 8.3-55 mg/dl
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





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#### SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. systems:

<b>IVD</b>	In Vitro Diagnostics	<b>REF</b>	Catalogue No
<b>LOT</b>	Batch Code	<b>CONT</b>	Content
<b>REAG</b>	Reagent	<b>Ab</b>	Antibody
<b>CAL</b>	Calibrator	<b>SUBS</b>	Substrate
<b>BUF</b>	Buffer	<b>STD</b>	Aqueous Standard

<b>CE</b>	CE Mark - Device complies with the Directives 98/79/EC		Reconstitute with
	Storage temperature		Manufactured By
	Expiry Date (Last day of the month)		Consult Instruction for Use
	Biological risk		

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