LACTATE
Hitachi ®
Liquid Reagent

KIT SPECIFICATIONS:

Cat. No.	*Quantity*	*Reagent*	*Storage*
917-181	2 x 40 ml	LACTATE	2-8°C

INTENDED USE:

For the quantitative determination of lactate in plasma on Hitachi® 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_2O_2, which reacts in the presence of peroxidase (POD) with 4- aminoantipyrine and phenole to a red chinonimin dye. The increase in absorbance due to the dye formation is proportional to the lactate concentration in the sample.

L-Lactate + O_2 $\xrightarrow{LOX}$ Pyruvate + H_2O_2

2 H_2O_2, + Phenol + 4-Aminoantipyrine $\xrightarrow{POD}$ Chromogen + 4 H_2O

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: 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:

This assay is designed to run on Hitachi® clinical chemistry analysers. Refer to relevant user's manual or Laboratory internal practice for routine maintenance procedures. See Overleaf for Instrument settings.

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	0.4mmol/l

REAGENT PREPARATION AND STABILITY:

Reagent 1 is ready for use.
Before use, mix reagent by gently inverting each bottle.

The reagents are stable up to the expiry date on the label when stored at +2°C to +8°C.
Onboard stability: The reagent will be stable for up to 28 days

Coloration of the reagent (reagent blank at 505 nm - 546 nm, 1 cm > 0.2) indicates contamination or damage by storage at higher temperatures.

TYPE OF SPECIMEN:

Use heparin or fluorid 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
1. Draw blood with a minimum of statis from fasting, resting patients into tubes containing fluoride/oxalate as anticoagulant.
2 Mix well by gentle inversion at least 6 times. Cool blood in an ice bath.
3. Within 30 minutes separate the plasma from blood by centrifugation at 400 x g for 10 minutes.
4. 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	*Catalog. No.*	*Description*	*Catalogue. No.*
General Chemistry Calibrator	AD983	Hitachi® Analyser	N/A
General Chemistry Control Level 1	AD922	Hitachi® Consumables	N/A
General Chemistry Control Level 2	AD932	General Laboratory Equipment	N/A

Assay procedure:
Refer to relevant user's manual for instructions on instrument start-up, loading components and samples, calibration, sample testing procedures, calculating and reporting results.

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 Programme.
Controls should be assayed:
- Prior to reporting patient results.
- Following any maintenance procedure.
- At intervals established by the Laboratory's QC Programme.

CALCULATION:

The analyser automatically calculates the lactate concentration in the sample.
Conversion factor: mg/dl = Qty in mmol/l x 9.015.

EXPECTED VALUES:

	mg/dl	*mmol/l*	
Plasma	4.5 - 19.8	0.5 - 2.2	Venous

Each laboratory should establish its own reference range. Lactate results should always be reviewed 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 400mg/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

BIBLIOGRAPHY:

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SYMBOLS: The following symbols are used in the labelling of Audit Diagnostics systems:

IVD In Vitro Diagnostics
LOT Batch Code
REAG Reagent
REF Catalogue No
CONT Content
Ab Antibody
BUF / CAL Buffer / Calibrator
SUBS Substrate
CE Mark - Device complies with the Directives 98/79/EC
Storage temperature
Expiry Date (Last day of the month)
Biological risk
Reconstitute with
Manufactured By
Consult Instruction for Use

Manufactured By: AUDIT DIAGNOSTICS, Business & Technology Park, Carrigtwohill, Co. Cork (Ireland)
Tel: 00353 - (0) 21 – 4533 652 *Fax:* 00353 - (0) 21 – 4533 653
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