



LACTATE - AUTOMATIC

DETERMINATION OF LACTATE IN EDTA BLOOD

Enzymatic method

Suitable for all analyzers – 150 tests

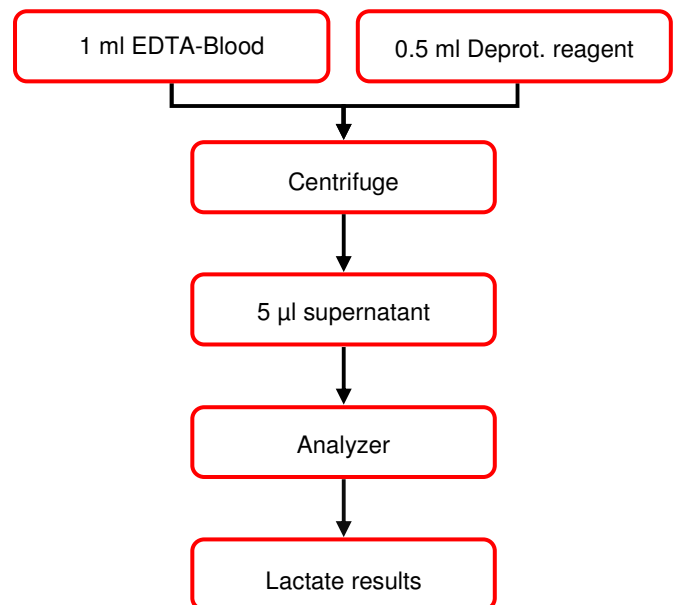
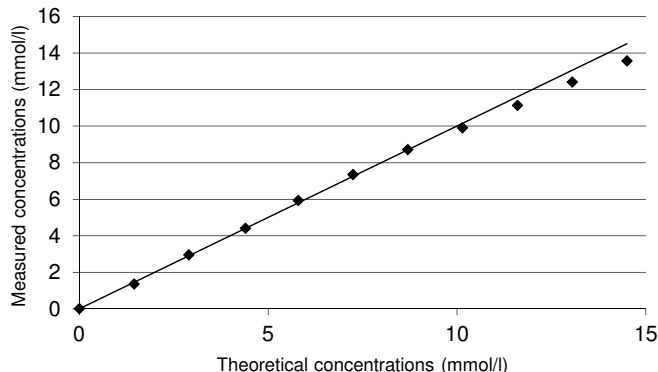
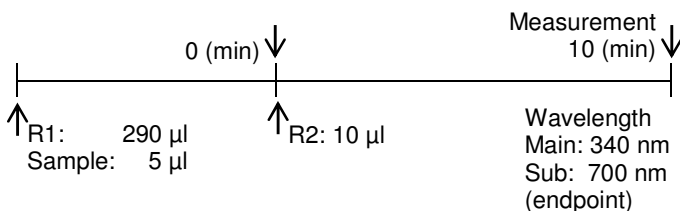
Product insert with instructions for automated and manual procedures

Stability reagents > 4 years after production

β -HBA/Lactate/Pyruvate controls available

Acetoacetate, β -HBA,
Lactate and Pyruvate
from 1 sample

Settings for automatic analyzers



Linearity: 10 mmol/l

Mean CV's: 1.10 %

Mean recovery: 98.9 %

Product name	Product no.	Quantity
Lactate - AUT Reagent Set	3100	30 -150 tests
Lactate / Pyruvate Control - AUT, Low- Normal Level	3047	10 x 1 ml
Lactate / Pyruvate Control - AUT, High Level	3048	10 x 1 ml
Lactate / Pyruvate Control - AUT, Extra High Level	3049	10 x 1 ml
β -HBA / Lactate / Pyruvate Control - AUT, Low-Normal Level	3112	10 x 1 ml
β -HBA / Lactate / Pyruvate Control - AUT, High Level	3113	10 x 1 ml
β -HBA / Lactate / Pyruvate Control - AUT, Extra High Level	3114	10 x 1 ml





LACTATE AUTOMATED – ENZYMATIC METHOD

DETERMINATION OF LACTATE IN EDTA BLOOD

- Enzymatic method
- Suitable for all analyzers – 150 tests
- Product insert with instructions for automated and manual procedures
- Stability reagents > 5 years after production
- β -HBA/Lactate/Pyruvate controls available
- Wavelength 340 nm

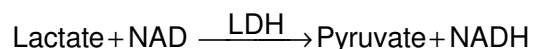


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β-HBA/Lactate/Pyruvate Control - AUT, High Level	3113	10 x 1 ml
β-HBA/Lactate/Pyruvate Control - AUT, Extra High Level	3114	10 x 1 ml

SUMMARY

PRINCIPLE

Lactate and pyruvate levels provide an index of the severity of circulatory failure. Increased blood lactate levels are reported in a number of disorders including: liver disease, congestive heart failure, diabetes mellitus, muscular dystrophy, thiamine deficiency and neoplastic disorders. The procedure utilizes the enzyme, lactate dehydrogenase, which catalyses the following reaction:



In the presence of excess NAD and Hydrazine, substantially all lactate is converted to pyruvate. The increase of absorbance at 340 nm due to reduction of NAD to NADH becomes a measure of the amount of lactate originally present.

SAMPLE MATERIAL

Deproteinized EDTA blood. Plasma and serum cannot be used.

LINEARITY

Up to 10 mmol/l

EXPECTED VALUES

Fasting venous EDTA blood:

Fasting Venous Blood: 0 – 0.43 mmol/l
Cerebrospinal Fluid, children up to age 16: 0.02 – 0.30 mmol/l

QUALITY CONTROL

Products	Product no.	Quantity
Lactate / Pyruvate Control - AUT, Low-Normal Level	3047	10 x 1 ml
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β-HBA/Lactate/Pyruvate Control - AUT, Extra High Level	3114	10 x 1 ml

QUANTITY OF DETERMINATIONS

Procedure

- Automated : 150 tests
- Manual : 30 tests

NOTES

1. For in vitro diagnostic use only.
2. For professional use only.
3. Contact INstruChemie for the complete validation report and the latest edition product insert.



CONCENTRATION MEASUREMENTS

The concentrations of a normal, high and extra high sample were measured with an automatic analyzer in order to verify acceptable absorbances.

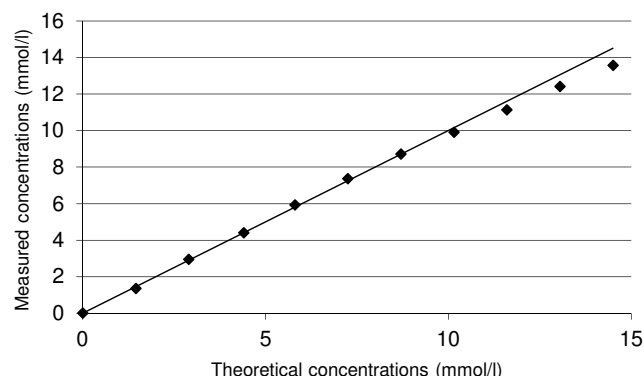
Lactate measurements

	Normal	High	Extra High
Absorbance	0.0280	0.0848	0.2344
Concentration (mmol/l)	0.22	1.19	3.16

LINEARITY

The Lactate AUT assay is linear up to 10 mmol/l.

Linearity measurements with an automatic analyzer



PRECISION

The precision is determined by measuring deproteinized human blood sample and Lactate Control AUT Extra High Level 10 times a day (repeatability) for 5 consecutive days (reproducibility), using an automatic analyzer.

Repeatability:

	Sample (mmol/l)	Control (mmol/l)
Mean	1.29	3.33
Standard deviation	0.02	0.01
Variation coefficient (%)	1.55	0.43

Reproducibility:

	Sample (mmol/l)	Control (mmol/l)
Mean	1.29	3.34
Standard deviation	0.02	0.03
Variation coefficient (%)	1.55	0.89

TEST CONDITIONS

All tests were performed under the following conditions:

Temperature	: 37 °C
Wavelength	: 340 nm
Light path	: 0.7 cm
Blank	: Distilled or deionized water
Sample	: Deproteinized EDTA blood

SENSITIVITY

The sensitivity (limit of detection) was determined by measuring deproteinized human control material (Lactate concentration = 0 mmol/l) 20 times.

Sensitivity = 3 x standard deviation = 0.12 mmol/l

RECOVERY

The recovery is determined by measuring the Lactate concentration in spiked deproteinized human blood 10 times using an automatic analyzer.

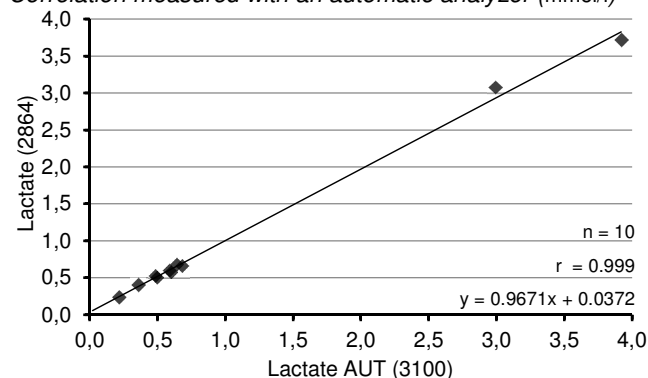
Recovery:

Added Lactate (mmol/l)	Measured (mmol/l)	Recovery (%)
2.67	2.67	100.0
4.73	4.66	98.5
6.78	6.66	98.2

CORRELATION

Pearsons' correlation is determined by measuring the Lactate concentration in multiple deproteinized human blood samples with INstruChemie Lactate AUT (3100) and INstruChemie Lactate (2864)

Correlation measured with an automatic analyzer (mmol/l)



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