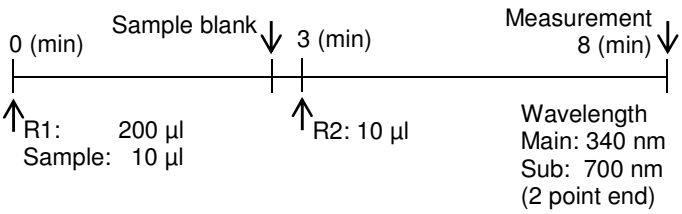
β-HBA - AUTOMATIC

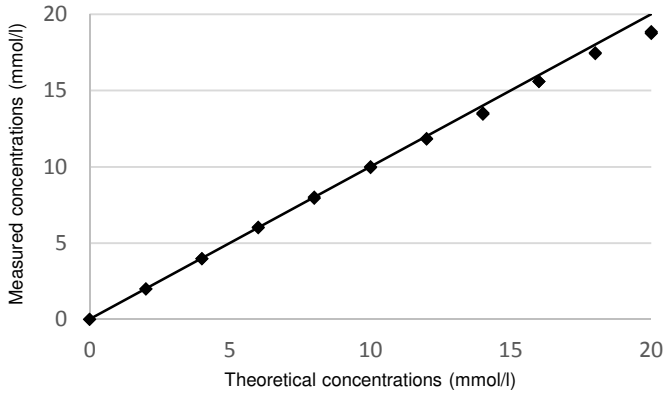
DETERMINATION OF D-3-HYDROXYBUTYRATE (β-HBA) IN EDTA BLOOD

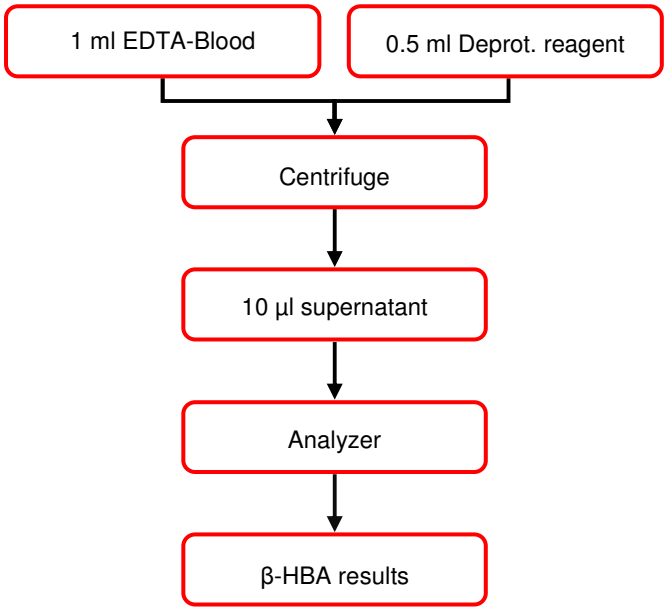
Enzymatic method
Suitable for all analyzers – 150 tests
Product insert with instructions for automated and manual procedures
Stability reagents > 5 years after production
β-HBA/Lactate/Pyruvate controls available

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

Settings for automatic analyzers







Linearity: 18 mmol/l **Mean CV's: 1.74 %** **Mean recovery: 101.6 %**

Product name	Product no.	Quantity
β-HBA AUT Reagent Set	3076	30 -150 tests
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

β-HBA AUTOMATED – ENZYMATIC METHOD

DETERMINATION OF D-3-HYDROXYBUTYRATE (β-HBA) 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*

Products	Product no.	Quantity
β-HBA - AUT Reagent Set	3076	30 -150 tests
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

SUMMARY

PRINCIPLE

The procedure utilizes the enzyme, D-3-hydroxybutyrate dehydrogenase, which catalyses the following reaction:

$$\text{D-3-Hydroxybutyrate} + NAD^+ \xrightarrow{\text{D-3-hydroxybutyrate dehydrogenase}} \text{Acetoacetate} + NADH + H^+$$

In the presence of excess NAD^+, substantially all β-hydroxybutyrate (β-HBA) is converted to acetoacetate. The increase in absorbance at 340 nm, due to the reduction of NAD^+ to NADH, is directly proportional to the β-HBA concentration in the sample.

SAMPLE MATERIAL

Deproteinized EDTA blood. Plasma and serum cannot be used.

LINEARITY

Up to 18 mmol/l

EXPECTED VALUES

Fasting venous EDTA blood:

Adults:	0 – 0.43	mmol/l
Children:	0.02 – 0.30	mmol/l

QUALITY CONTROL

Products	Product no.	Quantity
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

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.

β-HBA

CONCENTRATION MEASUREMENTS

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

β-HBA measurements

	Normal	*High*	*Extra High*
Δ Absorbance	0.0585	0.2456	0.4386
Concentration (mmol/l)	0.50	2.10	3.75

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

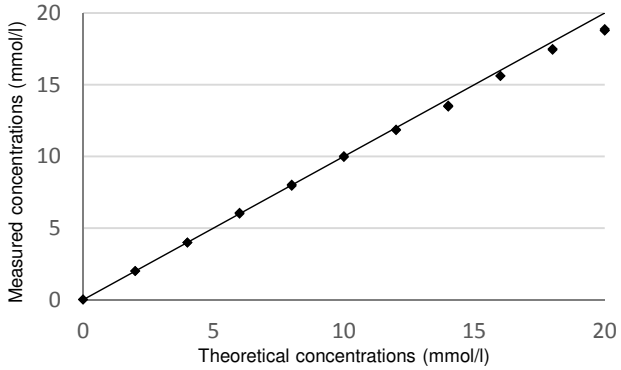
The sensitivity (limit of detection) was determined by measuring deproteinized human control material (β-HBA concentration = 0 mmol/l) 20 times.

Sensitivity = 3 x standard deviation = 0.01 mmol/l

LINEARITY

The β-HBA AUT assay is linear up to 18 mmol/l.

Linearity measurements with an automatic analyzer



RECOVERY

The recovery is determined by measuring the β-HBA concentration in spiked deproteinized Bovine Serum Albumin 10 times using an automatic analyzer.

Recovery:

Added β-HBA (mmol/l)	Measured (mmol/l)	Recovery (%)
0.57	0.57	100.0
3.40	3.59	105.6
11.33	11.24	99.2

PRECISION

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

Repeatability:

	Sample (mmol/l)	Control (mmol/l)
Mean	0.31	0.47
Standard deviation	0.005	0.006
Variation coefficient (%)	1.61	1.28

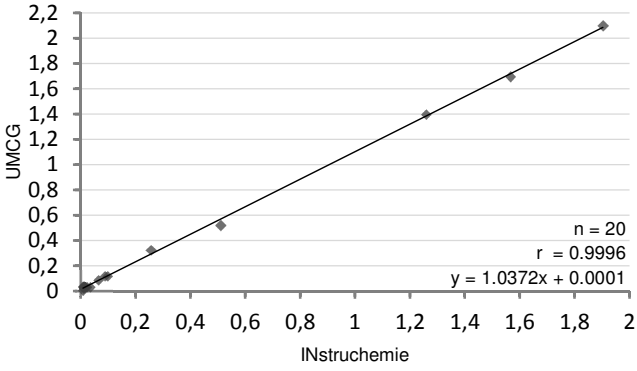
Reproducibility:

	Sample (mmol/l)	Control (mmol/l)
Mean	0.31	0.47
Standard deviation	0.006	0.010
Variation coefficient (%)	1.93	2.13

CORRELATION

Pearsons' correlation is determined by measuring the β-HBA concentration in multiple deproteinized human blood samples with INstruchemie β-HBA AUT (3076) and reagent from another manufacturer

Correlation measured with an automatic analyzer (mmol/l)



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