

# HBDH2

HBDH Gen.2

## Order information

**cobas**<sup>®</sup>  
Enzymes

REF	CONTENT	Analyzer(s) on which <b>cobas c</b> pack(s) can be used
06750036 190	HBDH Gen.2	System-ID 07 6790 5 COBAS INTEGRA 400 plus COBAS INTEGRA 800
10759350 190	Calibrator f.a.s. (12 × 3 mL)	System-ID 07 3718 6
10171743 122	Precinorm U (20 × 5 mL)	System-ID 07 7997 0
10171735 122	Precinorm U (4 × 5 mL)	System-ID 07 7997 0
10171778 122	Precipath U (20 × 5 mL)	System-ID 07 7998 9
10171760 122	Precipath U (4 × 5 mL)	System-ID 07 7998 9
12149435 122	Precinorm U plus (10 × 3 mL)	System-ID 07 7999 7
12149443 122	Precipath U plus (10 × 3 mL)	System-ID 07 8000 6
05117003 190	PreciControl ClinChem Multi 1 (20 × 5 mL)	System-ID 07 7469 3
05947626 190	PreciControl ClinChem Multi 1 (4 × 5 mL)	System-ID 07 7469 3
05117216 190	PreciControl ClinChem Multi 2 (20 × 5 mL)	System-ID 07 7470 7
05947774 190	PreciControl ClinChem Multi 2 (4 × 5 mL)	System-ID 07 7470 7

## English

### System information

Test HBDH2, test ID 0-190

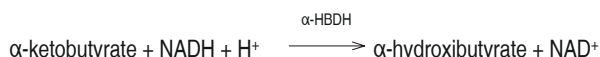
### Intended use

In vitro test for the quantitative determination of the catalytic activity of HBDH (EC 2.2.4.3-lactate dehydrogenase-1-isoenzyme) in human serum and plasma on COBAS INTEGRA systems.

### Summary

Lactate dehydrogenase in serum is composed of 5 isoenzymes. These enzymes are present in a tetrameric structure. There are two types of subunits, namely the M-subunit predominantly found in skeletal muscle, and the H-subunit, found predominantly in the myocardium. Due to their electrophoretic migration characteristics to the anode, the isoenzymes are termed LDH1, LDH2, LDH3, LDH4 and LDH5. LDH1 migrates most rapidly to the anode. The subunits are composed accordingly: H4, H3M, H2M2, HM3 and M4. By using various substrates (e.g. α-ketobutyrate is used for α-HBDH), lactate dehydrogenases from the liver and the heart can be differentiated from each other. Each organ is associated with a characteristic enzyme pattern which can contribute to the identification of organ damage.<sup>1</sup> Recent studies have shown that changes in the proportion of heart-specific LDH isoenzyme activities to the total LDH activity yield a reliable indication of the severity and progress of a recent myocardial infarction.<sup>2,3</sup> Rudolph et al.<sup>4</sup> report that the combination of CK-MB- and heart-specific LDH isoenzyme determinations can predict with 99 % certainty the classification of a myocardial infarction as being acute or non-acute. Rotenberg et al.<sup>5,6</sup> report also that the measurement of heart-specific LDH isoenzymes 24 to 48 hours after heart surgery is a meaningful test for the diagnosis of perioperative myocardial infarction. This method is in accordance with the optimized standard method as recommended by the German Society for Clinical Chemistry in 1972.<sup>7</sup>

### Test principle

UV test according to a standardized method<sup>7</sup>

α-Hydroxybutyrate dehydrogenase catalyzes the conversion of α-ketobutyrate to α-hydroxybutyrate in a reaction where NADH is oxidized to NAD. The rate of the NADH decrease is directly proportional to the α-HBDH activity and is measured photometrically.

### Reagents - working solutions

**R1** Phosphate buffer: 68 mmol/L, pH 7.5 (25 °C); α-ketobutyrate: 3.7 mmol/L; preservative

**SR** NADH: ≥ 1.1 mmol/L; preservative

R1 is in position A and SR is in position C.

### Precautions and warnings

Pay attention to all precautions and warnings listed in Section 1 / Introduction of this Method Manual.

### Reagent handling

Ready for use

### Storage and stability

Shelf life at 2-8 °C	See expiration date on <b>cobas c</b> pack label
COBAS INTEGRA 400 plus systems	
On-board in use at 10-15 °C	12 weeks
COBAS INTEGRA 800 system	
On-board in use at 8 °C	12 weeks

### Specimen collection and preparation

For specimen collection and preparation only use suitable tubes or collection containers.

Only the specimens listed below were tested and found acceptable.

Serum: Collect serum using standard sampling tubes.

Plasma: Heparin (Li-, Na-, NH<sub>4</sub><sup>+</sup>-) or EDTA (K<sub>2</sub>-, K<sub>3</sub>-) plasma.

\* K3 EDTA plasma values are about 10 % lower than serum values.

The sample types listed were tested with a selection of sample collection tubes that were commercially available at the time of testing, i.e. not all available tubes of all manufacturers were tested. Sample collection systems from various manufacturers may contain differing materials which could affect the test results in some cases. When processing samples in primary tubes (sample collection systems), follow the instructions of the tube manufacturer.

Centrifuge samples containing precipitates before performing the assay.

Stability: <sup>8</sup>	3 days at 15-25 °C
	7 days at 2-8 °C (activity decrease 5 %)

### Materials provided

See "Reagents – working solutions" section for reagents.

### Assay

For optimum performance of the assay follow the directions given in this document for the analyzer concerned. Refer to the appropriate operator's manual for analyzer-specific assay instructions.

**Application for serum/plasma****COBAS INTEGRA 400 plus test definition**

Measuring mode	Absorbance
Abs. calculation mode	Kinetic
Reaction mode	R1-S-SR
Reaction direction	Decrease
Wavelength A/B	340/409 nm
Calc. first/last	45/62
Unit	U/L

**Pipetting parameters**

		Diluent (H <sub>2</sub> O)
R1	105 µL	
Sample	3 µL	10 µL
SR	21 µL	5 µL
Total volume	144 µL	

**COBAS INTEGRA 800 test definition**

Measuring mode	Absorbance
Abs. calculation mode	Kinetic
Reaction mode	R1-S-SR
Reaction direction	Decrease
Wavelength A/B	340/409 nm
Calc. first/last	65/95
Unit	U/L

**Pipetting parameters**

		Diluent (H <sub>2</sub> O)
R1	105 µL	
Sample	3 µL	10 µL
SR	21 µL	5 µL
Total volume	144 µL	

**Calibration**

Calibrator	Calibrator f.a.s. Use deionized water as zero calibrator.
Calibration mode	Linear regression
Calibration replicate	Duplicate recommended
Calibration interval	Each lot and as required following quality control procedures.

Traceability: This method has been standardized against Roche reagent (manual measurement).

**Quality control**

Reference range	Precinorm U, Precinorm U plus or PreciControl ClinChem Multi 1
Pathological range	Precipath U, Precipath U plus or PreciControl ClinChem Multi 2
Control interval	24 hours recommended

Control sequence

User defined

Control after calibration

Recommended

For quality control, use control materials as listed in the "Order information" section. In addition, other suitable control material can be used.

The control intervals and limits should be adapted to each laboratory's individual requirements. Values obtained should fall within the defined limits. Each laboratory should establish corrective measures to be taken if values fall outside the defined limits.

Follow the applicable government regulations and local guidelines for quality control.

**Calculation**

COBAS INTEGRA analyzers automatically calculate the analyte activity of each sample. For more details, please refer to Data Analysis in the Online Help (COBAS INTEGRA 400 plus/800 analyzers).

Conversion factor: U/L × 0.0167 = µkat/L

**Limitations - interference**

Criterion: Recovery within ± 10 % of initial value.

Icterus:<sup>9</sup> No significant interference up to an I index of 60 for conjugated and unconjugated bilirubin (approximate conjugated and unconjugated bilirubin concentration: 1026 µmol/L or 60 mg/dL).

Hemolysis:<sup>9</sup> No significant interference up to an H index of 25 (approximate hemoglobin concentration: 16 µmol/L or 25 mg/dL).

Lipemia (Intralipid):<sup>9</sup> No significant interference up to an L index of 600.

There is poor correlation between the L index (corresponds to turbidity) and triglycerides concentration.

Drugs: No interference was found at therapeutic concentrations using common drug panels.<sup>10, 11</sup>

In very rare cases, gammopathy, in particular type IgM (Waldenström's macroglobulinemia), may cause unreliable results.<sup>12</sup>

For diagnostic purposes, the results should always be assessed in conjunction with the patient's medical history, clinical examination and other findings.

**ACTION REQUIRED**

*Special wash programming:* The use of special wash steps is mandatory when certain test combinations are run together on COBAS INTEGRA analyzers. Refer to the Method Manual, Introduction, Extra Wash Cycles for further instructions.

**Where required, special wash/carry-over evasion programming must be implemented prior to reporting results with this test.**

**Limits and ranges****Measuring range**

6-700 U/L (0.10-11.7 µkat/L)

Determine samples having higher concentrations via the rerun function. Dilution of samples via the rerun function is a 1:5 dilution. Results from samples diluted using the rerun function are automatically multiplied by a factor of 5.

**Lower limits of measurement**

Lower detection limit of the test:

6 U/L (0.10 µkat/L)

The lower detection limit represents the lowest measurable analyte level that can be distinguished from zero. It is calculated as the value lying 3 standard deviations above that of a zero sample (zero sample + 3 SD, repeatability, n = 21).

**Expected values**

72-182 U/L\* (1.20-3.03 µkat/L)<sup>13</sup>

\*Calculated with a temperature conversion factor of 1.30 (25 → 37 °C).<sup>14</sup>

Each laboratory should investigate the transferability of the expected values to its own patient population and if necessary determine its own reference ranges.

**Specific performance data**

Representative performance data on the analyzers are given below.  
Results obtained in individual laboratories may differ.

**Precision**

Precision was determined using human samples and controls in an internal protocol with repeatability (n = 21) and intermediate precision (1 aliquot per run, 1 run per day, 21 days). The following results were obtained:

<i>Repeatability</i>	<i>Mean</i> U/L (μkat/L)	<i>SD</i> U/L (μkat/L)	<i>CV</i> %
Precinorm U	156 (2.60)	2 (0.03)	1.5
Precipath U	238 (3.97)	2 (0.03)	1.1

<i>Intermediate precision</i>	<i>Mean</i> U/L (μkat/L)	<i>SD</i> U/L (μkat/L)	<i>CV</i> %
Precinorm U	156 (2.60)	2 (0.03)	1.4
Precipath U	237 (3.95)	3 (0.05)	1.3

**Method comparison**

HBDH values for human serum and plasma samples obtained on a COBAS INTEGRA 700 analyzer (y) were compared with those determined using the same reagent on a Roche/Hitachi 917 analyzer (x).

Roche/Hitachi 917 analyzer	Sample size (n) = 89
Passing/Bablok <sup>15</sup>	Linear regression
$y = 0.992x - 3.60 \text{ U/L}$	$y = 0.993x - 3.26 \text{ U/L}$
$r = 0.973$	$r = 1.00$

The sample activities were between 50.3 and 637 U/L (0.840 and 10.6 μkat/L).

**References**

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A point (period/stop) is always used in this Method Sheet as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

**Symbols**

Roche Diagnostics uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard.

**CONTENT**

Contents of kit

Volume after reconstitution or mixing

COBAS INTEGRA, COBAS, COBAS C, PRECINORM, PRECIPATH and PRECICONTROL are trademarks of Roche.

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Significant additions or changes are indicated by a change bar in the margin.

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