

RANBUT

D-3-Hydroxybutyrate

	RB 1007	RB 1008
COBAS 4000/6000/8000	10 x 92 tests	10 x 462 tests
COBAS C303/C503/C703	10 x 92 tests	10 x 462 tests
COBAS C111	10 x 82 tests	10 x 413 tests

FOR FULL PRODUCT DETAILS, PLEASE REFER TO THE KIT INSERT.

INTENDED USE.

For the quantitative *in vitro* determination of D-3-Hydroxybutyrate in serum and plasma. This product is suitable for use on the Cobas 4000 (c311 module), Cobas 6000 (c501 module), Cobas Pure (c303), Cobas Pro (c503), Cobas 8000 (c502, c701 and c702 modules), Cobas c703 and Cobas c111 analysers.

Cat. No.

RB 1007	R1a. Buffer	1 x 105 ml
	R1b. Enzyme/Coenzyme	10 x 10 ml
	CAL Standard	1 x 5.5 ml
RB 1008	R1a. Buffer	10 x 50 ml
	R1b. Enzyme/Coenzyme	10 x 50 ml
	CAL Standard	1 x 5.5 ml

SAMPLE

Serum, heparinised plasma or EDTA plasma.

STABILITY AND PREPARATION OF REAGENTS

R1a. Buffer

Contents stable as supplied up to the expiry date if stored at +2 to +8°C.

R1b. Enzyme/Coenzyme

Cat. No. RB 1007 10 x 10 ml

Reconstitute the contents of one vial R1b with 10 ml of Buffer R1a. Stable for 24 hours at +15 to +25°C or 7 days at +2 to +8°C.

Cat. No. RB 1008 10 x 50 ml

Reconstitute the contents of one vial R1b with a portion of Buffer R1a and then transfer the entire contents to bottle R1a, rinsing vial R1b several times. Stable for 24 hours at +15 to +25°C or 7 days at +2 to +8°C.

CAL Standard

Contents ready for use. Stable up to the expiry date if stored at +2 to +8°C.

R1 = Enzyme/Coenzyme

R2 = None

MATERIALS PROVIDED

Buffer
Enzyme/Coenzyme
Standard

MATERIALS REQUIRED BUT NOT PROVIDED

Randox Assayed Multisera Level 2 (Cat. No. HN 1530) and Level 3 (Cat. No. HE 1532)

Randox Calibration Serum Level 3 (Cat. No. CAL 2351)

INSTRUMENT SETTINGS FOR COBAS 4000 (c311)

ANALYZE

CH/Test/Type	*-RANBUT-SER-PL
Assay/Time/Point	2 POINT RATE-5-4-13-0-0
Wave (2 nd /Primary)	415-340
Sample Volume	
Normal	2.5-0-0
Decrease	0-0-0
Increase	0-0-0
Diluent	WATER-0
Reagent Volume R1	108-0
Reagent Volume R2	0-0
Reagent Volume R3	0-0
Linearity Limit	0-0-0-0
Prozone Limit	0-0-0-0-0-0
ABS Limit	32000-INCREASE
Cell Detergent	DETERGENT 1
Stirring Level	8

CALIBRATION

Calibration Type	LINEAR
Point/Span/Weight	2-2-0
Auto Calibration	
Timeout	Lot CANCEL
	Cassette CANCEL
Changeover	Lot CANCEL
	Cassette CANCEL
SD Limit	0.1
Duplicate Limit	99%-100 Abs
Sensitivity Lim.	-99999-99999
SI ABS Limit	-32000-32000

RANGE

Test	Ranbut
Unit	mmol/l (mg/dl)
Decimal Places	2
Report Name	RANBUT
Data Mode	Active
Technical Limit	0.1 - 3.2 (1.04 - 33.28)
Repeat Limit	*_*
Control Interval Time	0
AutoQC On Board Stability	0
Expected value	
(Male)	*_*
(Female)	*_*

CALIBRATORS

	(1)	(2)	(3)	(4)	(5)	(6)
Calibration Code	*	*				
Concentration	0.0	*				
Rack No. - Pos.	*	*				
Sample Volume	2.5	2.5				
Diluted S. Volume	0	0				
Diluent Volume	0	0				
K-FACTOR						

* Data entered by operator

INSTRUMENT SETTINGS FOR COBAS 6000 (c501) AND COBAS 8000 (c502)

ANALYZE

CH/Test/Type	*.RANBUT-SER-PL
Assay/Time/Point	2 POINT RATE-5-8-21-0-0
Wave (2 nd /Primary)	415-340
Sample Volume	
Normal	2.5-0-0
Decrease	0-0-0
Increase	0-0-0
Diluent	WATER-0
Reagent Volume R1	108-0
Reagent Volume R2	0-0
Reagent Volume R3	0-0
Linearity Limit	0-0-0-0
Prozone Limit	0-0-0-0-0-0
ABS Limit	32000-INCREASE
Cell Detergent	DETERGENT I
Stirring Level	8

CALIBRATION

Calibration Type	LINEAR
Point/Span/Weight	2-2-0
Auto Calibration	
Timeout	Lot CANCEL
	Cassette CANCEL
Changeover	Lot CANCEL
	Cassette CANCEL
SD Limit	0.1
Duplicate Limit	99%-100 Abs
Sensitivity Lim.	-99999-99999
SI ABS Limit	-32000-32000

RANGE

Test	Ranbut
Unit	mmol/l (mg/dl)
Decimal Places	2
Report Name	RANBUT
Data Mode	Active
Technical Limit	0.1 - 3.2 (1.04 - 33.28)
Repeat Limit	.*
Control Interval Time	0
AutoQC On Board Stability	0
Expected value	
(Male)	.*
(Female)	.*

CALIBRATORS

	(1)	(2)	(3)	(4)	(5)	(6)
Calibration Code	*	*				
Concentration	0.0	*				
Rack No. - Pos.	*	*				
Sample Volume	2.5	2.5				
Diluted S. Volume	0	0				
Diluent Volume	0	0				
K-FACTOR						

* Data entered by operator

INSTRUMENT SETTINGS FOR COBAS 8000 (c701, c702)

ANALYZE

CH/Test/Type	*.RANBUT-SER-PL
Assay/Time/Point	2 POINT RATE-5-5-12-0-0
Wave (2 nd /Primary)	415-340
Sample Volume	
Normal	2.5-0-0
Decrease	0-0-0
Increase	0-0-0
Diluent	WATER-0
Reagent Volume R1	108-0
Reagent Volume R2	0-0
Reagent Volume R3	0-0
Linearity Limit	0-0-0-0
Prozone Limit	0-0-0-0-0-0
ABS Limit	32000-INCREASE
Cell Detergent	DETERGENT I
Stirring Level	8

CALIBRATION

Calibration Type	LINEAR
Point/Span/Weight	2-2-0
Auto Calibration	
Timeout	Lot CANCEL
	Cassette CANCEL
Changeover	Lot CANCEL
	Cassette CANCEL
SD Limit	0.1
Duplicate Limit	99%-100 Abs
Sensitivity Lim.	-99999-99999
SI ABS Limit	-32000-32000

RANGE

Test	Ranbut
Unit	mmol/l (mg/dl)
Decimal Places	2
Report Name	RANBUT
Data Mode	Active
Technical Limit	0.1 - 3.2 (1.04 - 33.28)
Repeat Limit	.*
Control Interval Time	0
AutoQC On Board Stability	0
Expected value	
(Male)	.*
(Female)	.*

CALIBRATORS

	(1)	(2)	(3)	(4)	(5)	(6)
Calibration Code	*	*				
Concentration	0.0	*				
Rack No. - Pos.	*	*				
Sample Volume	2.5	2.5				
Diluted S. Volume	0	0				
Diluent Volume	0	0				
K-FACTOR						

* Data entered by operator

INSTRUMENT SETTINGS FOR COBAS c111

TEMPLATES

Template I (Abs-R1-S)

GENERAL

Application Code *
Short Name RB
Long Name RANBUT
Version 1
Created *
Last modified *
Modified by *

DILUENT

Pre Diluent ID 0
Pre Diluent dilution (%) 0

CALIBRATION

Calibration ID *
Number of Standards 2
Calibration Sequence No Interval
Calibration Interval 0
Standard Series 0
Dilution of Standard Series -
Calibration Replicates 2

PIPETTING

SAMPLE AND CONTROL DEFINITIONS

Pre dilution used 0
Pre dilution -
Post dilution factor -

PIPETTING VOLUMES

Specimen 2.8
Water 0
Special Diluent 0
R1 Reagent 121
R1 Water 0
SR reagent 0
SR water 0
SR pipetting cycle -

CALCULATION

GENERAL

Abs Calculation Model 0
Wavelength 1 (nm) 340
Wavelength 2 used 1
Wavelength 2 (nm) 409
Reaction Direction 0 (INCREASE)
First Calculation Point 11
Last Calculation Point 16
Last Used Cycle 16

UNITS

Standard Unit` mmol/L
Lab unit mg/dL
Lab Unit Factor -
Displayed Unit 1
Max. Decimal Positions 2

CALIBRATION

Low Reagent Range Used 0
Low reagent range (Abs) -
High Reagent range Used 0
High Reagent range (Abs) -
Curve Direction Check ON
Curve Direction 0 (INCREASING)
Calculation model 2
Linear Regression Factor Used 0
Linear Regression Factor 0
Linear Regression Offset Used 0
Linear Regression Offset 0

REAGENT DATA

Expiry Date *
On Board Stability *
Warning Level 5
Version 1
Number of Tests *
Daily Evaporation R1 10
Fill Volume R1 *

* Data entered by operator

INSTRUMENT SETTINGS COBAS PURE (c303)

ANALYZE

ACN *
 Test RANBUT
 Subtype Standard Application
 Unit mmol/l
 Decimal Places 2
 Application Type Normal Application
 Assay/Time/Point 2 Point Rate / 5 / 5 / 14 / 0 / 0
 Wavelength (2nd/ Pri) 415 / 340

Sample Volume

	Sample	Diluted	Diluent	Mixing
Normal	2.5	0	0	4
Decreased	0	0	0	
Increased	0	0	0	

Reagent Volume

	Reagent	Diluent	Type	Mixing
R1	108	0	INACTIVE	13
R2	0	0		
R3	0	0		

Diluent

Type	WATER
Special Reagent	NOT USED
Pair Application	NONE
Linearity Limit	0 / 0 / 0 / 0
Prozone Limit	Factor Offset
Enable	Off
Assay Point 1	1
Assay Point 2	1
Technical Limit	0.0
Repeat Limit	0.1-3.2
Automatic Re-Run	Below OFF
	Above OFF

CALIB.

Autocalibration	Lot	Cancel
Timeout	Cassette	Cancel
Changeover	Lot	
	Cassette	
SD Limit	0.1	
Duplicate Limit	99% -3.3 Abs	
Sensitivity Lim.	-99999 - 99999	
SI ABS Limit	-3.3000 - 3.3000	
Calibration Type	LinReg	
Point/ Span/ Weight	2/2/0	

CALIBRATORS

	(1)	(2)	(3)	(4)	(5)	(6)
Calibration Code	*	*				
Concentration	0.0	*				
Rack No. - Pos.	*	*				
Sample Volume	2.5	2.5				
Diluted S. Volume	0	0				
Diluent Volume	0	0				

* Data entered by operator

INSTRUMENT SETTINGS COBAS PRO (c503)

ANALYZE

ACN *
 Test RANBUT
 Subtype Standard Application
 Unit mmol/l
 Decimal Places 2
 Application Type Normal Application
 Assay/Time/Point 2 Point Rate / 5 / 4 / 11 / 0 / 0
 Wavelength (2nd/ Pri) 415 / 340

Sample Volume

	Sample	Diluted	Diluent	Mixing
Normal	2.5	0	0	7
Decreased	0	0	0	
Increased	0	0	0	

Reagent Volume

	Reagent	Diluent	Type	Mixing
R1	108	0	INACTIVE	7
R2	0	0		
R3	0	0		

Diluent

Type	WATER
Special Reagent	NOT USED
Pair Application	NONE
Linearity Limit	0 / 0 / 0 / 0
Prozone Limit	Factor Offset
Enable	Off
Assay Point 1	1
Assay Point 2	1
Technical Limit	0.0
Repeat Limit	0.1-3.2
Automatic Re-Run	Below OFF
	Above OFF

CALIB.

Autocalibration	Lot	Cancel
Timeout	Cassette	Cancel
Changeover	Lot	
	Cassette	
SD Limit	0.1	
Duplicate Limit	99% -3.3 Abs	
Sensitivity Lim.	-99999 - 99999	
SI ABS Limit	-3.3000 - 3.3000	
Calibration Type	LinReg	
Point/ Span/ Weight	2/2/0	

CALIBRATORS

	(1)	(2)	(3)	(4)	(5)	(6)
Calibration Code	*	*				
Concentration	0.0	*				
Rack No. - Pos.	*	*				
Sample Volume	2.5	2.5				
Diluted S. Volume	0	0				
Diluent Volume	0	0				

* Data entered by operator

INSTRUMENT SETTINGS COBAS c703

ANALYZE

ACN				*
Test			RANBUT	
Subtype			Standard Application	
Unit			mmol/l	
Decimal Places			2	
Application Type			Normal Application	
Assay/Time/Point			2 Point Rate / 5 / 5 / 12 / 0 / 0	
Wavelength (2 nd / Pri)			415 / 340	

Sample Volume

	Sample	Diluted	Diluent	Mixing
Normal	2.5	0	0	7
Decreased	0	0	0	
Increased	0	0	0	

Reagent Volume

	Reagent	Diluent	Type	Mixing
R1	108	0	INACTIVE	7
R2	0	0		
R3	0	0		

Diluent

Type				WATER
Special Reagent				NOT USED
Pair Application				NONE
Linearity Limit				0 / 0 / 0 / 0
Prozone Limit	Enable	Assay Point 1	Assay Point 2	Factor Offset
	Off	1	1	0.0 0.0
Technical Limit				0.1-3.2
Repeat Limit				-
Automatic Re-Run		Below		OFF
		Above		OFF

CALIB.

Autocalibration				
Timeout	Lot			Cancel
	Cassette			Cancel
Changeover	Lot			
	Cassette			
SD Limit				0.1
Duplicate Limit				99% -3.3 Abs
Sensitivity Lim.				-99999 - 99999
SI ABS Limit				-3.3000 - 3.3000
Calibration Type				LinReg
Point/ Span/ Weight				2/2/0

CALIBRATORS

	(1)	(2)	(3)	(4)	(5)	(6)
Calibration Code	*	*				
Concentration	0.0	*				
Rack No. - Pos.	*	*				
Sample Volume	2.5	2.5				
Diluted S. Volume	0	0				
Diluent Volume	0	0				

* Data entered by operator

CALIBRATION

We recommend that this assay should be calibrated using Randox Calibration Serum Level 3.

QUALITY CONTROL

Randox Assayed Multisera, Level 2 and Level 3 are recommended for daily quality control. Two levels of controls should be assayed at least once a day. Values obtained should fall within a specified range.

If these values fall outside the range and repetition excludes error the following steps should be taken:

1. Check instrument settings and light source.
2. Check cleanliness of all equipment in use.
3. Check water. Contaminants, i.e. bacterial growth, may contribute to inaccurate results.
4. Check reaction temperature.
5. Check expiry date of kit and contents.
6. Contact Randox Laboratories Technical Services, Northern Ireland +44 (0) 28 9445 1070.

LINEARITY

This assay is linear to approximately 3.2 mmol/l (33.28 mg/dl). This value is for reference only.

The presence of a vertical bar in the margin indicates a technical update from the previous revision.

Preliminary Application awaiting further validation data.

Revised 07 Jul 25 pl