PRODUCT INFORMATION

CAL2351

1448UE

Please note: AST in reconstituted serum is stable for 3 days at +2°C to +8°C if kept capped in original container and free from contamination.

Should you require any further information, please contact Technical.Services@Randox.com.

CCS INC 2157

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PRODUCT INFORMATION

Catalogue Number: CAL2351

Lot number 1448UE

Please note Total & Prostatic Acid Phosphatase is not present in this control material. For any queries, please contact Technical Services at technical.services@randox.com.

CCS INC1548

FORM NO. 8373-GP
REVISION (2)
2 Aug 2019

CALIBRATION SERUM LEVEL 3 (CAL 3)

CAT. NO. CAL 2351 **LOT NO.** 1448UE
SIZE: 20 x 5ml **EXPIRY:** 2028-02-28
GTIN: 05055273200966

INTENDED USE
For use as a Calibrator in clinical chemistry assays. RANDOX Calibration Sera are based on lyophilised human serum. The concentrations and activities are suitable for calibration of clinical chemistry assays on a wide range of automatic analysers. Constituent concentrations are available at 2 levels.

SAFETY PRECAUTIONS AND WARNINGS
Human source material, from which this product has been derived, has been tested at donor level for the Human Immunodeficiency Virus (HIV 1, HIV 2) antibody, Hepatitis B Surface Antigen (HbsAg), and Hepatitis C Virus (HCV) antibody and found to be NON-REACTIVE. FDA approved methods have been used to conduct these tests.

However, since no method can offer complete assurance as to the absence of infectious agents, this material and all patient samples should be handled as though capable of transmitting infectious diseases and disposed of accordingly. For *in vitro* diagnostic use only.

STORAGE AND STABILITY
Unreconstituted serum is stable up to the expiry date shown on the side of each individual bottle. Once reconstituted, the components of the Calibration Sera are stable for 8 hours at +15°C to +25°C, 7 days at +2°C to +8°C, and 28 days at –20°C when frozen once (see limitations).

PREPARATION FOR USE
Serum must only be reconstituted using the following procedure:
1. Open the vial carefully, avoiding any loss of material.
2. Reconstitute by pipetting exactly 5 ml of distilled water at +15°C to +25°C, into the vial.
3. Replace the rubber stopper and leave to stand for 30 minutes out of bright light before use.
4. Swirl gently several times during the reconstitution period to ensure that the contents are completely dissolved.
5. Prior to use, mix the contents by inverting the vial. Do not shake the vial as the formation of foam should be avoided. Ensure that no lyophilised material remains unreconstituted.
6. The serum is then ready for use with either a manual test or with an automated instrument.

MATERIALS PROVIDED
Calibration Serum - Level 3
Cat No. CAL 2351 20 x 5ml

MATERIALS REQUIRED BUT NOT PROVIDED
Calibrated pipette, double deionised water.

LIMITATIONS
After reconstitution, Bicarbonate is stable for 8 hours in the closed bottle and 1 hour in the open bottle.
Alkaline Phosphatase is stable for 3 days at +2 °C to +8°C and levels in the reconstituted serum will rise over the stability period. It is recommended that the reconstituted serum be allowed to stand for 1 hour at +15°C to +25°C before measurement.

Bilirubin in the serum is light sensitive and it is recommended that the serum is stored in the dark. Stored in the dark, it is stable for1 day at +2°C to +8°C. Do not store at +15°C to +25°C. Do not freeze.
GLDH is stable for 1 day at +2°C to +8°C
AST in reconstituted serum is stable for 3 days at +2°C to +8°C

Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components. Different lot numbers of this calibrator should not be interchanged, as the values assigned to the calibrators vary from lot to lot.

Due to the zinc content in some batches of rubber stoppers, the QC material should be aliquoted into suitable containers without rubber stoppers and stored at +2°C to +8°C to ensure stable zinc levels throughout the stability period.

VALUE ASSIGNMENT

Each batch of serum is distributed to approximately 3000 laboratories worldwide and values are assigned by a consensus of results obtained by these laboratories. The Calibration values for each instrument have been determined in at least 10 independent laboratories. Values are verified against a master lot of calibrator, which is traceable to reference methods or reference materials. In some cases values may be assigned at Randox Laboratories in comparison to a master lot of calibrator, which is traceable to reference methods or reference materials.

If an instrument specific value is not available, refer to the Method section. If necessary, contact Randox Laboratories - Technical Services, Northern Ireland, tel: +44 (0) 28 9445 1070 or email Technical.Services@randox.com.

NOTES

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(1) Values established by reference laboratories officially recognised by the Federal Chamber of Physicians in Germany.
(2) DGKC: German Society for Clinical Chemistry.
(3) IFCC: International Federation of Clinical Chemistry.
(4) SCE: Scandinavian Committee on Enzymes.

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Rev. 25 Nov '25 me

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Table of Content

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All enzyme values are quoted to a temperature of 37°C, unless otherwise stated

RANDOX

Method

Calibration Serum Level 3 (CAL 3)

Lot. No: 1448UE Cat. No: CAL2351 Expiry: 2028/02/28

Size: 20 x 5 ml

Analyte	Unit	Target	Method
Albumin	g/dl	3.28	Bromocresol Green
	g/l	32.8	
Alkaline Phosphatase	U/l	345	AMP optimised to IFCC
ALT (GPT)	U/l	152	Tris Buffer Without P5P
Amylase Total	U/l	281	Randox Liquid Ethylidene pNPG7
AST (GOT)	U/l	145	Tris Buffer Without P5P
Bile Acids	µmol/l	44.8	5th Generation Colorimetric
Bilirubin Direct	mg/dl	2.05	Modified Jendrassik
	µmol/l	35.0	
	mg/dl	2.04	Diazo With Sulphanilic Acid
	µmol/l	34.9	
	mg/dl	1.97	Oxidation to Biliverdin/Vanadate
	µmol/l	33.7	
Bilirubin Total	mg/dl	5.83	Modified Jendrassik
	µmol/l	99.7	
	mg/dl	5.57	Diazo With Sulphanilic Acid
	µmol/l	95.2	
	mg/dl	5.76	Oxidation to Biliverdin/Vanadate
	µmol/l	98.5	
Calcium	mg/dl	12.4	Arsenazo III
	mmol/l	3.09	
Cholesterol	mg/dl	298	Cholesterol Oxidase - Abell Kendall
	mmol/l	7.73	
Cholinesterase	U/l	5835	Colorimetric - Butyrylthiocholine
CK Total	U/l	559	CK-NAC (IFCC)
	U/l	560	CK-NAC substrate start (DGKC)
Creatinine	mg/dl	3.57	Alkaline picrate no deproteinisation
	µmol/l	316	
gamma-GT	U/l	213	Gamma glut.-3-carb.-4-nitro.
GLDH	U/l	28	Triethanolamine buffer
Glucose	mg/dl	286	Glucose Oxidase
	mmol/l	15.9	
	mg/dl	276	Hexokinase
	mmol/l	15.3	
Iron	µg/dl	226	Colorimetric without ppt.
	µmol/l	40.4	
Lactate	mg/dl	49.6	Colorimetric - Lactate oxidase
	mmol/l	5.51	

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Method

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Lot. No: 1448UE Cat. No: CAL2351 Expiry: 2028/02/28

Size: 20 x 5 ml

Analyte	Unit	Target	Method
LD (LDH)	U/l	672	P to L, German methods
Lipase	U/l	78	Colorimetric Randox
Magnesium	mg/dl	4.20	Xylidyl Blue
	mmol/l	1.73	
Phosphate Inorganic	mg/dl	7.16	Phosphomolybdate UV
	mmol/l	2.31	
Protein Total	g/dl	4.94	Biuret reaction, end point
	g/l	49.4	
TIBC	µg/dl	275	Direct Colorimetric
	µmol/l	49.2	
Triglycerides	mg/dl	247	Lipase/GPO-PAP No Correction
	mmol/l	2.79	
Urea	mg/dl	116	Urease, kinetic
	mg/dl (BUN)	54.0	
	mmol/l	19.3	
Uric Acid (Urate)	mg/dl	9.16	Uricase Perox. with ascorb. ox @ 546nm
	mmol/l	0.545	
	µmol/l	545	

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