

CALIBRATION SERUM LEVEL 3 (CAL 3)

CAT. NO. CAL2351 **GTIN:** 05055273200966
LOT NO. 1249UE **SIZE:** 20 x 5ml
EXPIRY: 2024-07-28

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.

For Total and Prostatic Acid Phosphatase, the material should be stabilised by adding 1 drop (25 µl - 30 µl) of 0.7M Acetic acid solution to 1 ml of the serum exactly 30 minutes after reconstitution. After stabilisation, Total & Prostatic

Acid Phosphatase are stable for 2 hours at +15°C to +25°C, 2 days at +2°C to +8°C, and 28 days when frozen once at -20°C.

Alkaline Phosphatase is stable for 3 days at 2 - 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 for 1 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 - 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

* All trademarks recognised.

(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.

METHOD CALIBRATION SERUM LEVEL 3 (CAL 3)

Lot. No.	1249UE	EXPIRY:	2024-07-28	Cat. No.	CAL2351
Analyte	unit	Target	methods		
Albumin	g/dl	3.15	Bromocresol Green		
Alkaline Phosphatase	U/L	503	Diethanolamine buffer DEA 37°C		
ALT (GPT)	U/L	139	Tris buffer without P5P 37°C		
AST (GOT)	U/L	137	Tris buffer without P5P 37°C		
Amylase Total	U/L	293	pNP Maltotrioxide substrates 37°C		
Bile Acids	μmol/l	44.7	4th Generation Colorimetric		
	μmol/l	44.3	5th Generation Colorimetric		
Bilirubin Direct	mg/dl	1.94	Modified Jendrassik		
	mg/dl	1.8	Diazo with Dichloroaniline (DCA)		
Bilirubin Total	mg/dl	4.5	Dichlorophenyl Diazonium (DPD)		
	mg/dl	5.03	Diazo with Dichloroaniline (DCA)		
Calcium	mg/dl	12.5	Arsenazo III		
	mg/dl	12.6	Cresolphthalein complexone (CPC)		
Cholesterol	mg/dl	308	Cholesterol Oxidase		
Chloride	mmol/l	113	ISE direct		
CK Total	U/L	512	CK-NAC (IFCC) 37°C		
Copper	μg/dl	162	Colorimetric		
Creatinine	mg/dl	4.26	Jaffe rate blanked		
	mg/dl	4.46	Enzymatic UV method		
gamma-GT	U/L	158	Gamma Glutamyl-3-Carboxy-4-nitroanilide (IFCC) 37°C		
Glucose	mg/dl	279	Glucose oxidase		
Iron	μg/dl	219	Colorimetric without ppt.		
Lactate	mg/dl	51.5	Colorimetric Lactate Oxidase		
LD (LDH)	U/L	684	P->L German methods 37°C		
Lipase	U/L	60	Other Colorimetric 37°C		
Lithium	mmol/l	2	Ion selective electrode		
	mg/dl	1.39			
Magnesium	mg/dl	4.33	Xylidyl Blue		
Phosphorus	mg/dl	6.91	Phosphomolybdate UV		
Potassium	mmol/l	6.02	ISE method - direct		
	mmol/l	6.11	ISE method - indirect		
Sodium	mmol/l	158	ISE method - direct		
	mmol/l	160	ISE method - indirect		
Protein Total	g/dl	4.73	Biuret reaction end point		
TIBC	μg/dl	241	Direct Colorimetric		
Triglycerides	mg/dl	254	Lipase/GPO-PAP		
Uric Acid (Urate)	mg/dl	9.12	Uricase Peroxidase with ascorbate oxidase @ 546nm		
Urea	mg/dl	117	Urease kinetic		
	mg/dl	54.7	BUN		
Zinc	μg/dl	226	Colorimetric		