

CAT.NO. CAL2351

CALIBRATION SERUM LEVEL 3 (CAL 3)

EXPIRY: 2023-10-28

LOT.NO. 1196UE

SIZE: 20 x 5ml

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. CAL2351 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 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 Acid Phosphatase is 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 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.

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.

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.

CALIBRATION SERUM LEVEL 3 (CAL3)

MEAN OF ALL INSTRUMENTS Lot. No. 1196UE Cat. No. CAL2351

Size 20 x 5ml Expiry 2023-10-28

Analyte	Unit	Target	Methods
Albumin	g/dl	3.03	Bromocresol Green
Alkaline Phosphatase	U/l	448	Diethanolamine buffer DEA 37°C(DGKC)
ALT(GPT)	U/l	150	Tris buffer without P5P 37°C
Amylase Total	U/l	298	pNP Maltotrioxide substrates 37°C (CNP3)
	U/l	315	Liquid Ethylidene pNPG7 37°C (EPSG7)
AST(GOT)	U/l	147	Tris buffer without P5P 37°C
Bilirubin Direct	mg/dl	2.11	Dichlorophenyl Diazonium (DPD)
	mg/dl	2.21	Diazo with Sulphanilic Acid
	mg/dl	2.18	Diazo with Dichloroaniline (DCA)
Bilirubin Total	mg/dl	5.57	Diazo with Dichloroaniline (DCA)
	mg/dl	5.49	Diazo with Sulphanilic Acid
	mg/dl	5.25	Dichlorophenyl Diazonium (DPD)
Calcium	mg/dl	12.5	Cresolphthalein complexone (CPC)
	mg/dl	12.5	Arsenazo III
Chloride	mmol/l	112	Colorimetric
	mmol/l	114	ISE indirect
	mmol/l	115	ISE direct
Cholesterol	mg/dl	288	Cholesterol Oxidase
CK Total	U/l	548	CK-NAC (IFCC) 37°C
Copper	µg/dl	165	Colorimetric
Creatinine	mg/dl	4.22	Enzymatic UV method
	mg/dl	3.93	Jaffe rate blanked
D-3-Hydroxybutyrate	mmol/l	1.16	Tris buffer 100mmol pH 8.5
gamma-GT	U/l	179	Gamma glutamyl-3-carboxy-4-nitroanilide 37°C (SZASZ)
Glucose	mg/dl	281	Glucose oxidase
Iron	µg/dl	214	Colorimetric without ppt.
Lactate	mg/dl	47.9	Colorimetric Lactate Oxidase
	mg/dl	48.8	UV LDH
LD (LDH)	U/l	710	P->L German methods 37°C (DGKC)
Lipase	U/l	66	Other Colorimetric 37°C
	U/l	82	Randox Colorimetric 37°C
Lithium	mmol/l	1.95	Ion selective electrode
Magnesium	mg/dl	4.13	Calmagite
	mg/dl	4.3	Xylidyl Blue
Phosphorus	mg/dl	6.98	Phosphomolybdate UV
Potassium	mmol/l	6.01	ISE method - direct
	mmol/l	6.11	ISE method - indirect
Protein Total	g/dl	4.61	Biuret reaction end point
Sodium	mmol/l	157	ISE method - direct
	mmol/l	160	ISE method - indirect
TIBC	µg/dl	255	Randox Direct
Triglycerides	mg/dl	250	Lipase/GPO-PAP no correction
Urea	mg/dl	129	Urease kinetic
	mg/dl	60.3	BUN
Uric Acid (Urate)	mg/dl	9.42	Uricase peroxidase no ascorbate oxidase (TOOS)
	mg/dl	9.36	Uricase Peroxidase with ascorbate oxidase@546nm(TBHBA)
Zinc	µmol/l	36.2	Colorimetric
	µg/dl	236	