

### KIT SPECIFICATIONS / ORDERING INFORMATION:

Cat. No.	Quantity	Name	Storage
GL932	20 x 5 ml	General Chemistry – Control Level 2	2 - 8°C

### INTENDED USE:

General Chemistry control is used to verify reagent and instrument performance in the quantitative determination of various chemistries on (semi-) automated analyser, using appropriate Glenbio Reagents. Control Level 2 has concentrations/activities in the pathological range.

### WARNINGS AND PRECAUTIONS:

*For In Vitro Diagnostics Use Only - For Professional Use Only*

Carefully read instructions for use. Deviations from the described procedure may alter the performance.

#### Safety Precautions:

The product is not hazardous under EU specification. The Material Safety Data Sheet is available upon request.

This product has been prepared from the blood of donors tested which is individually and found by FDA approved methods to be free from HbsAg and antibodies to HIV and HCV. However, as no testing method can eliminate the risk of potential infection with absolute certainty, this product should be handled as a potentially infectious material. In the event of exposure follow the directives of the responsible health authorities.

#### Handling precautions:

- Store in the original container.
- Close caps tightly and store in the dark after use.
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use beyond the expiry date stated on the Bottles.
- Do not use for any purpose other than described in the "Intended Use" section of the assay IFU.
- Do not interchange caps as contamination may occur and compromise results.
- Refer to local legal requirements for safe waste disposal.

#### Component Colour and Appearance:

White lyophilised pellet.

- The possible appearance of slight green colouration has no effect on the recovery of the values.
- Any significant changes from the above could indicate that material is contaminated.
- Refer to the Laboratory's QC program for actions to be taken. In the case of serious damage to the vial and/or cap, which may result in product loss and/or contamination, do not use the product and contact your distributor.

### COMPOSITION AND TRACEABILITY:

Human serum with chemical additives and tissue extracts of human and animal origin. Concentrations are lot-specific. Traceability information is given in the enclosed value sheet.

*Please ensure that the lot number and expiry date on the vial, on this Instruction for Use and on the enclosed value sheet are identical.*

Values are verified against a master lot of calibrator which is traceable to reference methods or reference materials.

### PREPARATION, STORAGE AND STABILITY:

1. Remove carefully cap/rubber stopper, ensuring that no lyophilised material is lost in the process.
2. Using a calibrated pipette, add 5ml of distilled water to a vial.
3. Carefully close the vial and fully dissolve the content within 30 minutes by occasional gentle swirling.  
Do not shake vial – Avoid Foaming.
4. **Important:** with the exception of Alkaline Phosphatase, all enzymes can be measured immediately. To reactivate ALP, allow reconstituted controls serum to stand for 1 hour at +25°C.
5. Before each use, mix by gently inverting the vial.

#### If stored and handled properly:

- Unopened material is stable until expiry date stated on the label.
- Once reconstituted, stable for:
  - 8 hours at 15-25°C
  - 7 days at 2-8°C
  - 1 month at -20°C (when frozen once)

Exceptions of stability in the reconstituted control are as follow:

- **Total & Prostatic Acid Phosphatase** the material should be stabilised by adding 1 drop (25-30µl of 0.7M Acetic Acid solution to 1ml of the serum exactly 30 minutes after reconstitution. After stabilisation Total and Prostatic Acid Phosphatase is stable for at least:
  - 2 hours 15-25°C
  - 2 days at 2-8°C
  - 1 month when frozen once at -20°C
- **Bilirubin** in the serum is light sensitive it is recommended that the serum be stored in the dark. Stored in the dark it is stable for 4 days at 2- 8°C. Do not store at 15-25°C.














Do not freeze. Bacterial contamination of the reconstituted serum will cause reductions in the stability of many components. Different lot numbers of this control should not be interchanged as the values assigned to the controls vary from lot to lot. The control should not be used as a calibration material.

### ASSAY PROCEDURE:

Refer to relevant product instruction for use.

### SYMBOLS:

The following symbols are used in the labelling of Glenbio Ltd. QC materials:

	In Vitro Diagnostics		Catalogue No
	Batch Code		Content
	Assigned Value		Calibrator
	CE Mark - Device complies with the Directives 98/79/EC		
	Storage temperature		Reconstitute with
	Expiry Date (Last day of the month)		Manufactured By
	Biological risk		Consult Instruction for Use

Manufactured By: GLENBIO LTD.  
10 Kibbegs Road, Antrim, Co. Antrim, BT41 4NN, UK

Tel/Fax: +44(0) 28796 59842  
Email: info@glenbio.com  
Website: www.glenbio.com



Lot No	Expiry Date
3743	2022-02

Analyte	Method	Target	Range		1SD	2SD	Unit
			Low	High			
<b>ACP</b> Acid phosphatase Total Gesamt Saure Phosphat Phosphatase acide totale Fosfatasa acida total Fosfatase ácida total	1- Naphthyl Phosphate, substrate Kinetic 37°C	25.3	17.0	33.6	4.15	8.30	U/l
		0.42	0.28	0.56	0.07	0.14	µkat/l
<b>ALB</b> Albumin Albumin Albumine Albumina Albumina	Bromcresol green Bromcresolgrün Vert de bromocrésol Verde de bromocresol	30.2	25.7	34.7	2.25	4.50	g/l
		3.02	2.57	3.47	0.23	0.45	g/dl
	Bromcresol purple Bromcresol purpur Pourpre de bromocrésol Purpura de bromocresol	27.3	23.2	31.4	2.05	4.10	g/l
		2.73	2.32	3.14	0.21	0.41	g/dl
<b>ALB PLUS</b> Albumin	Albumin Plus	30.2	25.7	34.7	2.25	4.50	g/l
		3.02	2.57	3.47	0.23	0.45	g/dl
<b>ALP</b> Alkaline phosphatase Alkalische Phosphatase Phosphatase alcaline Fosfatasa alcalina Fosfatase alcalina	Diethanolamine buffer DEA 37°C (DGKC)	515	438	592	38.50	77.00	U/l
		8.58	7.30	9.87	0.64	1.28	µkat/l
	AMP optimised to IFCC 37°C	263	223	303	20.00	40.00	U/l
		4.38	3.72	5.05	0.33	0.66	µkat/l
<b>ALT</b> (ALAT / GPT) Alanine Aminotransferase Alanin – Aminotransferase Alanine- aminotransférase Alanina – aminotransferasa Alanina – aminotransferase	Tris buffer with P5P IFCC/SFBC 37°C	179	143	215	18.00	36.00	U/l
		2.98	2.38	3.58	0.30	0.60	µkat/l
	Tris buffer no P5P IFCC/SFBC 37°C	150	120	180	15.00	30.00	U/l
		2.50	2.00	3.00	0.25	0.50	µkat/l
<b>AMYL-P</b> Pancreatic α-amylase Pancreas-α-Amylase α-Amylase pancréatique α-Amilasa pancreática α-Amilase pancreática	Liquid at 37°C	323	275	371	24.00	48.00	U/l
		5.38	4.58	6.18	0.40	0.80	µkat/l
<b>AMYL</b> Amylase Total α-Amylase α-Amilasa α-Amilase	EPS	277	230	324	23.50	47.00	U/l
		4.62	3.83	5.40	0.39	0.78	µkat/l
	CNPG3	294	242	346	26.00	52.00	U/l
		4.90	4.03	5.77	0.43	0.87	µkat/l

Analyte	Method	Target	Range		1SD	2SD	Unit
			Low	High			
<b>AST</b> (ASAT/GOT) Aspartate Aminotransferase Aspartat-Aminotransferase Aspartate-aminotransférase AspartatoAminotransferasi Aspartato-aminotransferasa Asperato-aminotransferase	Tris buffer with P5P IFCC/SFBC	238	190	286	24.00	48.00	U/l
		3.97	3.17	4.77	0.40	0.80	µkat/l
	Tris buffer no P5P IFCC/SFBC 37°C	159	127	191	16.00	32.00	U/l
		2.65	2.12	3.18	0.27	0.53	µkat/l
<b>Bile Acids</b>	5 <sup>th</sup> Generation Colorimetric	49.4	39.5	59.3	4.95	9.90	µmol/l
<b>BIL-D</b> Direct bilirubin Direktes bilirubin Bilirubine directe Bilirubina directa Bilirubina diretta	Dichlorophenyl Diazonium (DPD)	25.40	20.83	29.97	2.29	4.57	µmol/l
		1.49	1.22	1.75	0.13	0.27	mg/dl
	Diazo with Sulphanilic Acid	33.0	26.0	39.9	3.49	6.97	µmol/l
		1.93	1.52	2.34	0.21	0.41	mg/dl
	Vanadate	33.4	26.4	40.4	3.50	7.00	µmol/l
		1.95	1.54	2.36	0.21	0.41	mg/dl
<b>BIL-T</b> Bilirubin Bilirubine Bilirubina Bilirubin Total	Dichlorophenyl Diazonium (DPD)	103	81.1	124	10.75	21.50	µmol/l
		6.00	4.74	7.26	0.63	1.26	mg/dl
	Diazo with Sulphanilic Acid	96.0	75.8	116	10.10	20.20	µmol/l
		5.62	4.43	6.81	0.60	1.19	mg/dl
	Vanadate	100	79.0	121	10.50	21.00	µmol/l
		5.85	4.62	7.08	0.62	1.23	mg/dl
	O Leary	100	79.0	121	10.50	21.00	µmol/l
		5.85	4.62	7.08	0.62	1.23	mg/dl
<b>CA</b> Calcium Calcio Cálcio	Arsenazo III	3.03	2.73	3.33	0.15	0.30	mmol/l
		12.1	10.9	13.3	0.60	1.20	mg/dl
	Cresolphthalein complexone	3.10	2.60	3.60	0.25	0.50	mmol/l
		12.4	10.4	14.4	1.00	2.00	mg/dl
<b>CHOL</b> Cholesterol total Gesamt-Cholesterin Cholestérol total Colesterol total	Cholesterol Oxidase	7.44	6.47	8.41	0.49	0.97	mmol/l
		287	250	324	18.50	37.00	mg/dl



Analyte	Method	Target	Range				Unit
			Low	High	1SD	2SD	
<b>CHE</b> Cholinesterase Cholinestérase Colinesterasa Colinesterase	Colorimetric Butyrylthiocholine 37°C	5555	4444	6666	555.50	1111.00	U/l
		92.58	74.07	111.10	9.26	18.52	µkat/l
<b>CK</b> Creatine Kinase Creatinkinase Créatine kinase Creatincinasa Creatina-quinase	CK-NAC (IFCC) 37°C	568	466	670	51.00	102.00	U/l
		9.47	7.77	11.17	0.85	1.70	µkat/l
<b>Cl</b> Chloride Chlorid / Chlorures Cloruro / Cloruri / Cloreto	ISE indirect	119	109	129	5.00	10.00	mmol/l
	ISE direct	113	104	122	4.50	9.00	mmol/l
<b>CU</b> Copper	Colorimetric	30.6	24.5	36.7	3.05	6.10	µmol/l
		195	156	234	19.50	39.00	µg/dl
<b>CREA</b> Creatinine Creatinin Créatinine Creatinina Creatinine	Enzymatic	401	321	481	40.00	80.00	µmol/l
		4.53	3.63	5.43	0.45	0.90	mg/dl
	Jaffe rate blanked comp. (-26 µmol/l)	384	315	453	34.50	69.00	µmol/l
		4.34	3.56	5.12	0.39	0.78	mg/dl
<b>D-3-HYDROXYBUTYRATE</b>	Tris buffer 100mmol pH 8.5	1.16	0.99	1.33	0.09	0.17	mmol/l
<b>FE</b> Iron/Eisen/Fer Hierro/Ferro	Colorimetric with ppt.	38.1	31.2	45.0	3.45	6.90	µmol/l
		213	174	252	19.50	39.00	µg/dl
	Colorimetric without ppt.	38.1	31.2	45.0	3.45	6.90	µmol/l
		213	174	252	19.50	39.00	µg/dl
<b>GGT</b> γ-Glutamyltransferase γ-Glutamyltransférase γ-Glutamiltransferasi γ-glutamilttransferase	Gamma glutamyl.-3- carboxy-4-nitroanilide 37°	187	159	215	14.00	28.00	U/l
		3.12	2.65	3.58	0.23	0.47	µkat/l
<b>GLDH</b> Glutamate Dehydrogenase Glutamat-Deydrogenase Glutamate dehydrogénase Glutamato diedrogenasi Glutamato desidrogenasa Glutamato desidrogenesa	Triethanolamine buffer 50 mmol 37°C	31	24	38	3.50	7.00	U/l
		0.52	0.40	0.63	0.06	0.12	µkat/l

Analyte	Method	Target	Range		1SD	2SD	Unit
			Low	High			
<b>GLUC</b> Glucose Glucosa	Hexokinase	16.1	13.7	18.5	1.20	2.40	mmol/l
		290	247	333	21.50	43.00	mg/dl
	Glucose Oxidase	16.6	14.1	19.1	1.25	2.50	mmol/l
		299	254	344	22.50	45.00	mg/dl
<b>HBDH</b> α-Hydroxybutyrate Dehydrogenase α-Hydroxybutyrat Dehydrogenase α-Hydroxybutrate déhydrogénase α-Idrossibutirrato deidrogenasi α-Hidroxybutirato deshidrogenasa α-Hidroxybutirrato desidrogenase	Oxobutyrate	438	358	518	40.00	80.00	U/l
		7.30	5.97	8.63	0.66	1.33	µkat/l
<b>K</b> Potassium	ISE Direct	6.30	5.80	6.80	0.25	0.50	mmol/l
	ISE Indirect	6.43	5.92	6.94	0.26	0.51	mmol/l
<b>LACTATE</b>	Enzymatic Colorimetric	5.62	4.61	6.63	0.51	1.01	mmol/l
		50.6	41.5	59.7	4.55	9.10	mg/dl
<b>LDH</b> Lacate Dehydrogenase Lacat-Dehydrogenase Lacate deshydrogénase Lacato-deshidrogenasa Lacato desidrogenase	DGKC	760	646	874	57.00	114.00	U/l
		12.67	10.77	14.57	0.95	1.90	µkat/l
	SCE	828	688	968	70.00	140.00	U/l
		13.80	11.47	16.13	1.16	2.33	µkat/l
	L-P	371	315	427	28.00	56.00	U/l
		6.18	5.25	7.12	0.47	0.93	µkat/l
<b>LIPASE</b> Lipase LIPASA / LIPASI	Colorimetric	89	71	107	9.00	18.00	U/l
		1.48	1.18	1.78	0.15	0.30	µkat/l
<b>MG</b> Magnesium Magnesio Magnésio	Calmagite	1.70	1.40	2.00	0.15	0.30	mmol/l
		4.14	3.41	4.87	0.36	0.73	mg/dl
	Xylidyl Blue	1.76	1.55	1.97	0.11	0.21	mmol/l
		4.28	3.77	4.79	0.26	0.51	mg/dl



Analyte	Method	Target	Range		1SD	2SD	Unit
			Low	High			
<b>NA</b> Sodium Natrium Sodio Sodio	ISE Direct	160	152	168	4.00	8.00	mmol/l
	ISE Indirect	163	155	171	4.00	8.00	mmol/l
<b>NEFA</b>	Colorimetric	0.38	0.32	0.43	0.03	0.06	mmol/l
<b>PHOS</b> Inorganic phosphorus Anorg.Phosphor Phosphore inorganique Fósforo inorgánico Fósforo inorgánico	Phosphomolybdate UV	2.30	1.96	2.64	0.17	0.34	mmol/l
		7.13	6.08	8.18	0.53	1.05	mg/dl
<b>TIBC</b> Total Iron Binding Capacity	Fe&UIBC (Saturation with Iron)	50.8	41.8	59.8	4.50	9.00	µmol/l
		283.8	233.5	334.1	25.1	50.3	µg/dl
<b>TG</b> Triglycerides Triglyceride Triglycerides Triglyceridos Trigliceridos	GPO-PAP	2.93	2.46	3.40	0.24	0.47	mmol/l
		259	218	300	20.50	41.00	mg/dl
<b>TP</b> Protein total Gesamt-Eiweiß Proteines totales Proteinas totales Proteinas totais	Biuret	46.3	37.0	55.6	4.65	9.30	g/l
		4.63	3.70	5.56	0.47	0.93	g/dl
<b>UA</b> Uric Acid Harnsäure Acide urique Acido úrico Ácido urico	Uricase peroxidase with Ascorbate oxidase	0.58	0.50	0.65	0.04	0.08	mmol/l
		9.68	8.42	10.9	0.63	1.26	mg/dl
	Uricase peroxidase with no Ascorbate oxidase	0.58	0.50	0.65	0.04	0.08	mmol/l
		9.71	8.45	11.0	0.63	1.26	mg/dl
<b>UA PLUS</b> Uric Acid plus	Uricase peroxidase	0.58	0.50	0.65	0.04	0.08	mmol/l
		9.68	8.42	10.9	0.63	1.26	mg/dl
<b>UREA</b> Urea Harnstoff Uree Ureia	Urease Kinetic	19.7	16.7	22.7	1.50	3.00	mmol/l
		118	100	136	9.00	18.00	mg/dl
<b>ZN</b> Zinc	Colorimetric	36.7	29.4	44.0	3.65	7.30	µmol/l
		240	192	288	24.00	48.00	µg/dl