

### KIT SPECIFICATIONS / ORDERING INFORMATION:

Cat. No.	Quantity	Name	Storage
GL922	20 x 5 ml	General Chemistry – Control Level 1	2 - 8°C

### INTENDED USE:

General Chemistry control is used to verify reagent and instrument performance in the quantitative determination of various chemistries on automated and semi-automated analyser, using appropriate Glenbio Ltd. Reagents. Control Level 1 has concentrations/activities in the normal range or at normal/pathological threshold.

### 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 performance.

#### Safety Precautions:

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

This product has been prepared from the blood of donors tested individually and found by FDA approved methods to be free from HbsAg and antibodies to HIV and HCV. However, as no testing method can rule out 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.
- 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.
- Tightly capped close and dark after each use.
- Take the necessary precautions required for handling all laboratory reagents.
- Do not use past the expiry date stated on the Bottles.
- Do not use for any purpose other than described in the "Intended Use" section.
- 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 coloration has no effect on the recovery of the values.*

Any significant changes from the above could indicate that material is contaminated. Refer to Laboratory's QC program for actions to be taken. In case of serious damaged to the vial and/or cap, resulting in product loss and/or contamination: do not use and contact your distributor.

### COMPOSITION:

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

### 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, all 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:
  - 12 hours at 15-25°C.
  - 5 days at 2-8° C
  - 1 month at -20° C (when frozen once)
- Exceptions of stability in the reconstituted control are as follow:
  - Inorganic phosphorous: 5 hours at 15-25° C
  - 1 day at 2-8° C
  - 1 month at -20° C (when frozen once)

Bilirubin in the serum is light sensitive and it is recommended that the serum be stored in the dark.

Stored in the dark it is stable for 4 days at +2°C to +8°C.

Do not store at +15°C to +25°C.







Do not freeze: 4 days at 2-8°C.

### 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 comply 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.  
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Lot No	Expiry Date
3742	2021-03



Analyte	Method	Target	Range		1SD	2SD	Unit
			Low	High			
<b>ACP – NPP</b> Acid phosphatase Non – prostatic Nicht - Prostata – Phosphatase Phosphatase non prostatique Fosfatasa no prostática Fosfatasi no prostática Fosfatase ácida não prostática	1- Naphthyl Phosphate, Kinetic with Pentane diol Activation 37°C	3.96	2.65	5.27	0.66	1.31	U/l
		0.07	0.04	0.09	0.01	0.02	µkat/l
<b>ACP – P</b> Acid phosphatase Prostatic Prostata – Phosphatase Phosphatase prostatique Fosfatasa prostática Fosfatasi prostática Fosfatase acide prostática	1- Naphthyl Phosphate, Kinetic with Pentane diol Activation 37°C	15.0	10.1	19.9	2.45	4.90	U/l
		0.25	0.17	0.33	0.04	0.08	µkat/l
<b>ACP</b> Acid phosphatase Total Gesamt Saure Phosphat Phosphatase acide totale Fosfatasa acida total Fosfatase ácida total	1- Naphthyl Phosphate, Kinetic with Pentane diol Activation 37°C	19.0	12.7	25.3	3.15	6.30	U/l
		0.32	0.21	0.42	0.05	0.11	µkat/l
<b>ALB</b> Albumin Albumin Albumine Albumina Albumina	Bromcresol green Bromcresolgrün Vert de bromocrésol Verde de bromocresol	42.3	36.0	48.6	3.15	6.30	g/l
		4.23	3.60	4.86	0.32	0.63	g/dl
	Bromcresol purple Bromcresol purpur Pourpre de bromocrésol Purpura de bromocresol	43.7	37.2	50.2	3.25	6.50	g/l
		4.37	3.72	5.02	0.33	0.65	g/dl
<b>ALB PLUS</b> Albumin	Albumin Plus	42.3	36.0	48.6	3.15	6.30	g/l
		4.23	3.60	4.86	0.32	0.63	g/dl
<b>ALP</b> Alkaline phosphatase Alkalische Phosphatase Phosphatase alcaline Fosfatasa alcalina Fosfatase alcalina	Diethanolamine buffer DEA 37°C(DGKC)	274	233	315	20.50	41.00	U/l
		4.57	3.88	5.25	0.34	0.68	µkat/l
	AMP optimised to IFCC 37°C	150	123	177	13.50	27.00	U/l
		2.50	2.05	2.95	0.23	0.45	µkat/l
<b>ALT</b> (ALAT / GPT) Alanine Aminotransferase Alanin – Aminotransferase Alanine- aminotransferase Alanina – aminotransferasa Alania – aminotransferase	Tris buffer with P5P IFCC/SFBC 37°C	39	31	47	4.00	8.00	U/l
		0.65	0.52	0.78	0.07	0.13	µkat/l
	Tris buffer no P5P IFCC/SFBC 37°C	33	27	39	3.00	6.00	U/l
		0.55	0.45	0.65	0.05	0.10	µkat/l



Analyte	Method	Target	Range		1SD	2SD	Unit
			Low	High			
<b>AMYL-P</b> Pancreatic $\alpha$ -amylase Pancreas- $\alpha$ -Amylase $\alpha$ -Amylase pancréatique $\alpha$ -Amilasa pancreática $\alpha$ -Amilase pancreática	Liquid at 37°C	67	57	77	5.00	10.00	U/l
		1.12	0.95	1.28	0.08	0.17	$\mu$ kat/l
<b>AMYL</b> Amylase Total $\alpha$ -Amylase $\alpha$ -Amilasa $\alpha$ -Amilase	EPS	79	67	91	6.00	12.00	U/l
		1.32	1.12	1.52	0.10	0.20	$\mu$ kat/l
	CNP3	81	69	93	6.00	12.00	U/l
		1.35	1.15	1.55	0.10	0.20	$\mu$ kat/l
<b>AST</b> (ASAT/GOT) Aspartate Aminotransferase Aspartat-Aminotransferase Aspartate-aminotransférase Aspartatoaminotransferasi Aspartato-aminotransferasa Asperato-aminotransferase	Tris buffer with P5P IFCC/SFBC	51	41	61	5.00	10.00	U/l
		0.85	0.68	1.02	0.08	0.17	$\mu$ kat/l
	Tris buffer no P5P IFCC/SFBC 37°C	38	30	46	4.00	8.00	U/l
		0.63	0.50	0.77	0.07	0.13	$\mu$ kat/l
<b>Bile Acids</b>	5 <sup>th</sup> Generation Colorimetric	26.1	20.9	31.3	2.60	5.20	$\mu$ mol/l
<b>BIL-D</b> Direct bilirubin Direktes bilirubin Bilirubine directe Bilirubina directa Bilirubina diretta	Dichlorophenyl Diazonium (DPD)	9.6	7.9	11.3	0.85	1.70	$\mu$ mol/l
		0.56	0.46	0.66	0.05	0.10	mg/dl
	Diazo with Sulphanilic Acid	19.9	15.7	24.1	2.10	4.20	$\mu$ mol/l
		1.16	0.918	1.40	0.12	0.24	mg/dl
	Vanadate	16.7	13.2	20.2	1.75	3.50	$\mu$ mol/l
		0.977	0.772	1.18	0.10	0.21	mg/dl
<b>BIL-T</b> Bilirubin Bilirubine Bilirubina Bilirubin Total	Dichlorophenyl Diazonium (DPD)	28.3	22.4	34.2	2.95	5.90	$\mu$ mol/l
		1.66	1.31	2.01	0.18	0.35	mg/dl
	Diazo with Sulphanilic Acid	28.1	22.2	34.0	2.95	5.90	$\mu$ mol/l
		1.64	1.30	1.98	0.17	0.34	mg/dl
	Vanadate	28.9	22.9	34.9	3.00	6.00	$\mu$ mol/l
		1.69	1.34	2.04	0.18	0.35	mg/dl
	O Leary	28.9	22.9	34.9	3.00	6.00	$\mu$ mol/l
		1.69	1.34	2.04	0.18	0.35	mg/dl



Analyte	Method	Target	Range		1SD	2SD	Unit
			Low	High			
<b>CA</b> Calcium Calcio Cálcio	Arsenazo III	2.21	1.99	2.43	0.11	0.22	mmol/l
		8.86	7.98	9.74	0.44	0.88	mg/dl
	Cresolphthalein complexone	2.19	1.97	2.41	0.11	0.22	mmol/l
		8.78	7.90	9.66	0.44	0.88	mg/dl
<b>CHOL</b> Cholesterol total Gesamt-Cholesterin Cholestérol total Colesterol total	Cholesterol Oxidase	4.15	3.61	4.69	0.27	0.54	mmol/l
		160	139	181	10.50	21.00	mg/dl
<b>CHE</b> Cholinesterase Cholinestérase Colinesterasa Colinesterase	Colorimetric Butyrylthiocholine 37°C	5795	4636	6954	579.50	1159.00	U/l
		96.6	77.3	115.9	9.66	19.32	µkat/l
<b>CK</b> Creatine Kinase Creatinkinase Créatine kinase Creatincinasa Creatina-quinase	CK-NAC (IFCC) 37°C	182	149	215	16.50	33.00	U/l
		3.03	2.48	3.58	0.28	0.55	µkat/l
<b>CI</b> Chloride Chlorid / Chlorures Cloruro / Cloruri / Cloreto	ISE indirect	94.9	87.3	103	3.80	7.60	mmol/l
	ISE direct	97.2	89.4	105	3.90	7.80	mmol/l
<b>CU</b> Copper	Colorimetric	17.6	14.1	21.1	1.75	3.50	µmol/l
		112	89.7	134	11.15	22.30	µg/dl
<b>CREA</b> Creatinine Creatinin Créatinine Creatinina Creatinine	Enzymatic	126	101	151	12.50	25.00	µmol/l
		1.42	1.14	1.70	0.14	0.28	mg/dl
	Jaffe rate blanked comp. (-26 µmol/l)	127	101	153	13.00	26.00	µmol/l
		1.44	1.14	1.74	0.15	0.30	mg/dl
	O Leary	127	101	153	13.00	26.00	µmol/l
		1.44	1.14	1.74	0.15	0.30	mg/dl
<b>D-3-HYDROXYBUTYRATE</b>	Tris buffer 100mmol pH 8.5	0.29	0.24	0.33	0.02	0.04	mmol/l
<b>FE</b> Iron/Eisen/Fer Hierro/Ferro	Colorimetric with ppt.	19.5	16.0	23.0	1.75	3.50	µmol/l
		109	89.4	129	9.80	19.60	µg/dl
	Colorimetric without ppt.	19.5	16.0	23.0	1.75	3.50	µmol/l
		109	89.4	129	9.80	19.60	µg/dl



Analyte	Method	Target	Range		1SD	2SD	Unit
			Low	High			
<b>GGT</b> γ-Glutamyltransferase γ-Glutamyltransférase γ-Glutamyltransferasi γ-glutamyltransferase	Gamma glutamyl -3-carboxy-4-nitroanilide 37°	46	39	53	3.50	7.00	U/l
		0.77	0.65	0.88	0.06	0.12	μkat/l
<b>GLDH</b> Glutamate Dehydrogenase Glutamat-Dehydrogenase Glutamate dehydrogénase Glutamato diedrogenasi Glutamato desidrogenasa Glutamato desidrogenasa	Triethanolamine buffer 50 mmol 37°C	15	12	18	1.50	3.00	U/l
		0.25	0.2	0.3	0.025	0.05	μkat/l
<b>GLUC</b> Glucose Glucosa	Hexokinase	6.22	5.29	7.15	0.47	0.93	mmol/l
		112	95.3	129	8.35	16.70	mg/dl
	Glucose Oxidase	6.29	5.34	7.24	0.48	0.95	mmol/l
		113	96.2	130	8.40	16.80	mg/dl
<b>HBDH</b> α-Hydroxybutyrate Dehydrogenase α-Hydroxybutyrat Dehydrogenase α-Hydroxybutrate déhydrogénase α-Idrossibutirato deidrogenasi α-Hidroxybutirato deshidrogenasa α-Hidroxybutirato desidrogenase	Oxobutyrate	215	170	260	22.50	45.00	U/l
		3.58	2.83	4.33	0.38	0.75	μkat/l
<b>K</b> Potassium	ISE Direct	4.06	3.73	4.39	0.17	0.33	mmol/l
	ISE Indirect	4.10	3.77	4.43	0.17	0.33	mmol/l
<b>LACTATE</b>	Enzymatic Colorimetric	1.65	1.35	1.95	0.15	0.30	mmol/l
		14.9	12.2	17.6	1.35	2.70	mg/dl
<b>LDH</b> Lacate Dehydrogenase Lacat-Dehydrogenase Lacate deshydrogénase Lacato-deshidrogenasa Lacato desidrogenase	DGKC	394	335	453	29.50	59.00	U/l
		6.57	5.58	7.55	0.49	0.98	μkat/l
	SCE	434	369	499	32.50	65.00	U/l
		7.23	6.15	8.32	0.54	1.08	μkat/l
	L-P	183	156	210	13.50	27.00	U/l
		3.05	2.60	3.50	0.23	0.45	μkat/l



Analyte	Method	Target	Range		1SD	2SD	Unit
			Low	High			
<b>LIPASE</b> Lipase LIPASA / LIPASI	Colorimetric	39	31	47	4.00	8.00	U/l
		0.65	0.52	0.78	0.07	0.13	µkat/l
<b>MG</b> Magnesium Magnesio Magnésio	Calmagite	0.91	0.80	1.02	0.06	0.11	mmol/l
		2.22	1.95	2.49	0.14	0.27	mg/dl
	Xylidyl Blue	0.92	0.81	1.02	0.05	0.11	mmol/l
		2.22	1.96	2.48	0.13	0.26	mg/dl
<b>NA</b> Sodium Natrium Sodio Sodio	ISE Direct	141	134	148	3.50	7.00	mmol/l
	ISE Indirect	142	135	149	3.50	7.00	mmol/l
<b>NEFA</b>	Colorimetric	1.91	1.62	2.20	0.15	0.29	mmol/l
<b>PHOS</b> Inorganic phosphorus Anorg.Phosphor Phosphore inorganique Fósforo inorgánico Fósforo inorgânico	Phosphomolybdate UV	1.35	1.15	1.55	0.10	0.20	mmol/l
		4.19	3.57	4.81	0.31	0.62	mg/dl
<b>TIBC</b> Total Iron Binding Capacity	Fe&UIBC (Saturation with Iron)	45.0	35.6	54.4	4.70	9.40	µmol/l
		252	199	305	26.50	53.00	µg/dl
<b>TG</b> Triglycerides Triglyceride Triglycerides Trigliceridos Trigliceridos	GPO-PAP	1.10	0.92	1.28	0.09	0.18	mmol/l
		97.4	81.8	113	7.80	15.60	mg/dl
<b>TP</b> Protein total Gesamt-Eiweiß Proteines totales Proteínas totales Proteínas totais	Biuret	59.6	47.7	71.5	5.95	11.90	g/l
		5.96	4.77	7.15	0.60	1.19	g/dl
<b>UA</b> Uric Acid Harnsäure Acide urique Acido úrico Acido urico	Uricase peroxidase with Ascorbate oxidase	0.35	0.30	0.39	0.02	0.05	mmol/l
		5.80	5.04	6.56	0.38	0.76	mg/dl
	Uricase peroxidase with no Ascorbate oxidase	0.34	0.30	0.39	0.02	0.04	mmol/l
		5.73	4.99	6.47	0.37	0.74	mg/dl
<b>UA PLUS</b> Uric Acid plus	Uricase peroxidase	0.35	0.30	0.39	0.02	0.05	µmol/l
		5.80	5.04	6.56	0.38	0.76	mg/dl
<b>UREA</b> Urea Harnstoff Uree Ureia	Urease Kinetic	7.33	6.23	8.43	0.55	1.10	mmol/l
		44.1	37.4	50.8	3.35	6.70	mg/dl
<b>ZN</b> Zinc	Colorimetric	21.7	17.4	26.0	2.15	4.30	µmol/l
		142	114	170	14.00	28.00	µg/dl