

Lot No.
307450

Date of Manufacturing
JUN-2025

Expiry Date
JUN-2028

List of Analytes							
Analyte	Method	Unit	Target	Min	Max	Result	Assessment
Acid Phosphatase	Colorim.	IU/L	15,0	12,0	18,0	14,9	Approved
Acid Phosphatase, prostatic	Calcul.	IU/L	8,00	6,40	9,60	9,00	Approved
Alanine Aminotransferase (ALT)	IFCC	IU/L	40,0	32,0	48,0	43,5	Approved
Albumin	Colorim.	g/L	35,0	28,0	42,0	36,0	Approved
Alkaline Phosphatase	IFCC	IU/L	90,0	72,0	108	90,2	Approved
Amylase, total	IFCC	IU/L	90,0	72,0	108	83,5	Approved
Amylase, pancreatic	IFCC	IU/L	30,0	24,0	36,0	29,2	Approved
Aspartate Aminotransferase (AST)	IFCC	IU/L	40,0	32,0	48,0	40,2	Approved
Bilirubin, total	Diazo	μmol/L	20,0	16,0	24,0	21,1	Approved
Bilirubin, direct	Diazo	μmol/L	15,0	12,0	18,0	14,2	Approved
Calcium	Colorim.	mmol/L	2,30	1,84	2,76	2,19	Approved
Chloride	ISE	mmol/L	95,0	76,0	114	100	Approved
Cholesterol, total	Colorim.	mmol/L	3,40	2,72	4,08	3,68	Approved
Cholesterol, HDL	Colorim.	mmol/L	0,91	0,81	1,16	1,01	Approved
Cholesterol, LDL	Colorim.	mmol/L	1,67	1,49	2,14	1,86	Approved
Cholinesterase	Colorim.	KIU/L	5,68	5,05	7,26	6,31	Approved
Copper	Colorim.	μmol/L	18,0	-	22,0	12,0	Approved
Creatine Kinase (CK)	UV-Test	IU/L	160	120	200	168	Approved
Creatine Kinase (CKMB)	UV-Test	IU/L	30,0	24,0	36,0	27,8	Approved
Creatinine	Enzym.	μmol/L	100	80,0	120	98,9	Approved
Glucose	HK	mmol/L	5,50	4,40	6,60	5,22	Approved
Glutamate Dehydrogenase (GLDH)	Colorim.	IU/L	20,0	16,0	24,0	21,5	Approved
γ-Glutamyltransferase (GGT)	Colorim.	IU/L	40,0	32,0	48,0	39,2	Approved
Iron	Colorim.	μmol/L	20,0	16,0	24,0	18,6	Approved
Lactate Dehydrogenase (LDH)	IFCC	IU/L	160	128	192	168	Approved
Lactic Acid	Colorim.	mmol/L	1,50	1,20	1,80	1,59	Approved
Lipase	Colorim.	IU/L	40,0	32,0	48,0	41,0	Approved
Lithium	Colorim.	mmol/L	1,00	0,80	1,20	1,00	Approved
Magnesium	Colorim.	mmol/L	0,90	0,72	1,08	0,85	Approved
Phosphate	UV-Test	mmol/L	1,30	1,04	1,56	1,22	Approved
Potassium	ISE	mmol/L	4,80	3,84	5,76	4,51	Approved
Protein, total	Colorim.	g/L	55,0	44,0	66,0	54,4	Approved
Sodium	ISE	mmol/L	135	108	162	139	Approved
Triglycerides	Colorim.	mmol/L	1,40	1,12	1,68	1,43	Approved
Urea	Colorim.	mmol/L	8,00	6,40	9,60	7,48	Approved
Uric Acid	Colorim.	μmol/L	300	240	360	313	Approved
Zinc	Colorim.	μmol/L	30,5	-	38,2	23,0	Approved



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MFG LIC NO: MFG/IVD/2025/00073



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1) Physical, Chemical & Biological Parameters				
Parameter	Method	Specification	Result	Assessment
Solubilization time	Visual inspection	≤ 30 min	Yes	Approved
Optical density	A _{546nm} undiluted	≤ 1.000	0,48	Approved
Residual moisture	Thermal balance	<1,5 %	0,51%	Approved
pH value	pH-measurement	7.00 (6.60 - 7.40)	6,90	Approved
Bioburden	Fertile Soil	≤ 100 cfu/ml	1	Approved
2) Primary Packaging Material				
Parameter	Method	Specification	Result	Assessment
Vial	Visual Inspection	GL-18	GL-18	Approved
Stopper	Visual Inspection	Lyo Stopper	Lyo Stopper	Approved
Cap Colour	Visual Inspection	Green	Green	Approved
Labeling	Visual Inspection	No	No	Approved
3) Stability				
Parameter	Storage Temperature	Specification	Result	Assessment
After first use	room temperature	8 hours (±10%)	Confirmed	Approved
After first use	+2 to +8 °C	5 days (±10%)	Confirmed	Approved
4) Homogeneity				
Parameter	Method	Specification	Result	Assessment
ALT / GPT	According to AA 14	ΔCV ≤ 1.5 %	-0,08%	Approved
Bilirubin, total	According to AA 14	ΔCV ≤ 1.5 %	-0,08%	Approved
Glucose	According to AA 14	ΔCV ≤ 1.5 %	0,61%	Approved

This lot meets our specification

This certificate is a computer printout and has therefore not been signed by hand.



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