

CERTIFICATE OF ANALYSIS

Cat No: BXC0312E
Lot No: HSN026
Expiry: 2019/04
Product: Human Assayed Control Normal

PARAMETER	QUALITY ASSURANCE
Appearance Lyophilised	White fluffy lyophilised plug
Appearance after reconstitution	Slightly turbid solution
Appearance after 6 hours of manufacturing @ 25°C – open tube	Maintains conformity
Moisture Content	<1.0%
Bio-burden	<5 CFU/ml

HOMOGENEITY	QUALITY ASSURANCE
Alkaline Phosphatase across 30 bottles	0.96 % CV
ALT across 30 bottles	0.42 % CV
AST across 30 bottles	0.69 % CV

COMPONENTS	PROJECTED VALUE	RANGE	UNITS	PASS/FAIL
Alkaline Phosphatase	85.79	72.92-98.66	U/l	PASS
ALT	33.34	28.34-38.34	U/l	PASS
AST	42.18	35.85-48.51	U/l	PASS
Gamma GT	53.86	45.78-61.94	U/l	PASS
Albumin	37.26	31.67-42.85	g/l	PASS
Calcium	2.35	2.00-2.70	mmol/l	PASS
Total Cholesterol	6.56	5.58-7.54	mmol/l	PASS
Creatinine	217.97	185.27-250.67	µmol/L	PASS
Total protein	62.77	53.35-72.19	g/l	PASS
Urea	5.8	4.93-6.67	mmol/l	PASS

QC PASS/FAIL: PASS

Signed: *Cherith Morris* (QC Manager) **Date:** 2017-06