

AMR Verification Summary

Analyzer Name and Serial number: Roche Cobas 8000-1/Module C702/SN:15F8-04
Sample material used: Validate® Linearity panels

Analyte	Unit	Total Allowable Error	Mfg's AMR		Manufacturer AMR		Laboratory Measured Results			Mfr AMR verified?
					Mfr lower/upper AMR	Range	Theoretical value	Range	Measured value	
ALB	g/L	2 g/L or 10%	2 – 60 (g/L)	Lower	2	2g/L ± 2 Range: 0 - 4g/L	3.10	3.1g/L ± 2 Range: 1.1 - 5.1g/L	3.10	Yes
(g/L)				Upper	60	60g/L ± 10% Range: 54 - 66g/L	61.37	61.37g/L ± 0.1 Range: 55.233 - 67.507g/L	57.60	Yes
AST	U/L	5 U/L or 20%	5 – 700 (U/L)	Lower	5	5U/L ± 5 Range: 0 - 10U/L	7.33	7.33U/L ± 5 Range: 2.33 - 12.33U/L	7.33	Yes
(U/L)				Upper	700	700U/L ± 20% Range: 560 - 840U/L	691.33	691.33U/L ± 0.2 Range: 553.064 - 829.596U/L	689.67	Yes
ALT	U/L	5 U/L or 20%	5 – 700 (U/L)	Lower	5	5U/L ± 5 Range: 0 - 10U/L	5.00	5U/L ± 5 Range: 0 - 10U/L	5.00	Yes
(U/L)				Upper	700	700U/L ± 20% Range: 560 - 840U/L	739.67	739.67U/L ± 0.2 Range: 591.736 - 887.604U/L	737.00	Yes
Bil-D	µmol/L	6.84 µmol/L or 20%	1.4 - 236 µmol/L	Lower	1.4	1.4µmol/L ± 6.84 Range: 0 - 8.24µmol/L	1.67	1.67µmol/L ± 6.84 Range: 0 - 8.51µmol/L	1.67	Yes
(µmol/L)				Upper	236	236µmol/L ± 20% Range: 188.8 - 283.2µmol/L	290.93	290.93µmol/L ± 0.2 Range: 232.744 - 349.116µmol/L	280.87	Yes
Ca	mmol/L	0.25 mmol/L or 8%	0.20 - 5.0 mmol/L	Lower	0.2	0.2mmol/L ± 0.25 Range: 0 - 0.45mmol/L	0.32	0.32mmol/L ± 0.25 Range: 0.07 - 0.57mmol/L	0.32	Yes
(mmol/L)				Upper	5	5mmol/L ± 8% Range: 4.6 - 5.4mmol/L	4.83	4.83mmol/L ± 0.08 Range: 4.4436 - 5.2164mmol/L	4.84	Yes
Creatinine	µmol/L	26.55 µmol/L or 15%	5 - 2700 µmol/L	Lower	5	5µmol/L ± 26.55 Range: 0 - 31.55µmol/L	14.00	14µmol/L ± 26.55 Range: 0 - 40.55µmol/L	14.00	Yes
(µmol/L)				Upper	2700	2700µmol/L ± 15% Range: 2295 - 3105µmol/L	2724.67	2724.67µmol/L ± 0.15 Range: 2315.9695 - 3133.3705µmol/L	2703.67	Yes
CK	U/L	5 U/L or 30%	7 - 2000 U/L	Lower	7	7U/L ± 5 Range: 2 - 12U/L	15.00	15U/L ± 5 Range: 10 - 20U/L	15.00	No
(U/L)				Upper	2000	2000U/L ± 30% Range: 1400 - 2600U/L	2303.67	2303.67U/L ± 0.3 Range: 1612.569 - 2994.771U/L	2207.30	Yes
Glucose	mmol/L	0.33 mmol/L or 10%	0.11 - 41.6 mmol/L	Lower	0.11	0.11mmol/L ± 0.33 Range: 0 - 0.44mmol/L	0.30	0.3mmol/L ± 0.33 Range: 0 - 0.63mmol/L	0.30	Yes
(mmol/L)				Upper	41.6	41.6mmol/L ± 10% Range: 37.44 - 45.76mmol/L	37.83	37.83mmol/L ± 0.1 Range: 34.047 - 41.613mmol/L	37.97	Yes
Cholesterol	mmol/L	0.08 mmol/L or 10%	0.1 - 20.7 mmol/L	Lower	0.1	0.1mmol/L ± 0.08 Range: 0.02 - 0.18mmol/L	0.15	0.15mmol/L ± 0.08 Range: 0.07 - 0.23mmol/L	0.15	Yes
(mmol/L)				Upper	20.7	20.7mmol/L ± 10% Range: 18.63 - 22.77mmol/L	21.15	21.15mmol/L ± 0.1 Range: 19.035 - 23.265mmol/L	21.00	Yes
HDL-Cholesterol	mmol/L	0.05 mmol/L or 30%	0.08 – 3.88 mmol/L	Lower	0.08	0.08mmol/L ± 0.05 Range: 0.03 - 0.13mmol/L	0.14	0.14mmol/L ± 0.05 Range: 0.09 - 0.19mmol/L	0.14	No
(mmol/L)				Upper	3.88	3.88mmol/L ± 30% Range: 2.716 - 5.044mmol/L	3.87	3.87mmol/L ± 0.3 Range: 2.709 - 5.031mmol/L	4.42	Yes
Total Protein	g/L	2 g/L or 10%	2.0 - 120 g/L	Lower	2	2g/L ± 2 Range: 0 - 4g/L	3.97	3.97g/L ± 2 Range: 1.97 - 5.97g/L	3.97	Yes
(g/L)				Upper	120	120g/L ± 10% Range: 108 - 132g/L	123.70	123.7g/L ± 0.1 Range: 111.33 - 136.07g/L	117.27	Yes
Triglycerides	mmol/L	0.15 mmol/L or 25%	0.1 - 10.0 mmol/L	Lower	0.1	0.1mmol/L ± 0.15 Range: 0 - 0.25mmol/L	0.13	0.13mmol/L ± 0.15 Range: 0 - 0.28mmol/L	0.13	Yes
(mmol/L)				Upper	10	10mmol/L ± 25% Range: 7.5 - 12.5mmol/L	9.71	9.71mmol/L ± 0.25 Range: 7.2825 - 12.1375mmol/L	9.44	Yes
Uric Acid	µmol/L	29.75 µmol/L or 17%	11.9 - 1487 µmol/L	Lower	11.9	11.9µmol/L ± 29.75 Range: 0 - 41.65µmol/L	25.33	25.33µmol/L ± 29.75 Range: 0 - 55.08µmol/L	25.33	Yes
(µmol/L)				Upper	1487	1487µmol/L ± 17% Range: 1234.21 - 1739.79µmol/L	1426.00	1426µmol/L ± 0.17 Range: 1183.58 - 1668.42µmol/L	1407.67	Yes
Urea (BUN)	mmol/L	0.714 mmol/L or 9%	0.5 - 40 mmol/L	Lower	0.5	0.5mmol/L ± 0.714 Range: 0 - 1.214mmol/L	0.67	0.67mmol/L ± 0.714 Range: 0 - 1.384mmol/L	0.67	Yes
(mmol/L)				Upper	40	40mmol/L ± 9% Range: 36.4 - 43.6mmol/L	39.53	39.53mmol/L ± 0.09 Range: 35.9723 - 43.0877mmol/L	39.37	Yes