

5 November 2022

To whom it may concern,

The performance of Mindray reagents on a BS-600M system was evaluated at Uniwersyteckie Centrum Kliniczne - Gdański Uniwersytet Medyczny, Poland, in October 2022.

Results were compared with those generated in routine operation in our laboratory, on the Abbott Alinity C system.

I agree that the attached evaluation document is a true representation of the procedure followed, and the results obtained, in the evaluation.

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BS-600M Chemistry Analyzer

Evaluation Report



The aim of this study was to evaluate the possibility of applying Mindray BS-600M system in clinical chemistry practice at our laboratory. Method comparison was performed with our routine testing system Abbott Alinity c.

**BS-600M Evaluation at Uniwersyteckie Centrum Kliniczne –
Gdański Uniwersytet Medyczny**

Evaluation Summary

BS-600M

Mindray, the leading medical instrument manufacturer in China, proposed a new flagship stand-alone chemistry analyzer of Mindray, BS-600M. BS-600M achieves a perfect balance between size and throughput with uniform reagent package and software:

- **Sample throughput:** Constant 600 photometric tests/hour, up to 800 tests/hour with ISE
- **Large loading capacity:** 80 reagent positions, 120 samples by 12 racks
- **HbA1c:** supports whole blood sample & HbA1c onboard hemolysis
- **Advanced software platform:** auto QC, auto reflex, substrate depletion & enzyme linearity extension, etc.
- **Low reagent consumption:** minimal 70 μ l reaction volume
- **Dimensions:** 1380mm (length) \times 860mm (width) \times 1200mm (high)

Analytes

No.	Parameter	Mindray Analytical Method	Comparison Analytical Method
1	ALT	IFCC without P5P	NADH (without P-5'-P)
2	AST	IFCC without P5P	NADH (without P-5'-P)
3	CREA	Enzymatic	Enzymatic
4	CRP	Turbidimetry Method	Immunoturbidimetric
5	Glu	Glucose oxidase-POD	Hexokinase/G-6-PDH
6	HDL-C	Direct method	Homogeneous method
7	T-Bil	Diazotized sulfanilic acid	Diazonium salt
8	TC	CHOD-POD	Enzymatic
9	TG	GPO-POD	Glycerol phosphate oxidase

Reagents, Calibrators, QC Materials

Category	Test Materials
Reagent	Alanine Aminotransferase, Aspartate Aminotransferase, Bilirubin Total (DSA), CRP, Creatinine, Glucose, HDL-Cholesterol, Total Cholesterol, Triglycerides
Calibrator	Multi Sera Calibrator

	Lipids Calibrator
Control material	ClinChem Multi Control (level 1) ClinChem Multi Control (level 2)
Others	CD80 Detergent Probe Cleanser Aqua for injection Sterile water for injection

Evaluation Results

QC Recording

ALT		
No.	QC 1	QC 2
1	57.80	142.60
2	57.50	139.60
3	56.30	140.60
4	57.80	140.40
5	58.50	143.20
6	56.80	140.50
7	57.70	139.60
8	58.10	141.10
9	57.00	139.80
Mean	57.50	140.82
SD	0.69	1.29
CV	1.19%	0.91%

AST		
No.	QC 1	QC 2
1	53.80	155.90
2	50.50	158.50
3	48.80	150.50
4	48.40	149.60
5	48.90	152.50
6	48.00	149.30
7	48.70	150.90
8	49.00	150.30
9	49.00	150.20
Mean	49.46	151.97
SD	1.77	3.17
CV	3.57%	2.09%

CREA		
No.	QC 1	QC 2
1	1.10	4.40
2	1.10	4.40
3	1.00	4.30
4	1.00	4.30
5	1.00	4.30
6	1.00	4.40
7	1.10	4.30
8	1.10	4.40
Mean	1.05	4.35

CRP		
No.	QC 1	QC 2
1	8.19	51.56
2	7.59	49.66
3	7.68	49.54
4		50.14
5	9.94	52.26
6	8.05	49.79
7	8.53	49.67
8	8.53	50.68
Mean	8.36	50.41

SD	0.05	0.05
CV	5.09%	1.23%

SD	0.79	1.01
CV	9.44%	2.00%

GLU		
No.	QC 1	QC 2
1	97.41	237.87
2	97.32	232.98
3	97.64	233.73
4	94.35	233.44
5	95.40	237.03
6	94.51	237.27
7	95.42	235.02
8	96.45	232.28
9	95.14	235.38
Mean	95.96	235.00
SD	1.27	2.04
CV	1.33%	0.87%

HDL-C		
No.	QC 1	QC 2
1	33.79	58.87
2	34.30	58.56
3	34.04	59.33
4	33.60	58.62
5	34.13	59.43
6	34.05	58.92
7	33.72	58.32
8	33.82	58.94
Mean	33.93	58.87
SD	0.24	0.38
CV	0.69%	0.64%

T-Bil		
No.	QC 1	QC 2
1	1.12	4.09
2	1.11	4.11
3	1.17	4.29
4	1.16	4.30
5	1.17	4.28
6	1.17	4.29
7	1.17	4.24
8	1.13	4.20
9	1.17	4.33

TC		
No.	QC 1	QC 2
1	107.21	180.17
2	104.27	174.57
3	105.15	174.73
4	103.51	174.61
5	106.18	178.52
6	105.01	176.30
7	104.31	173.46
8	104.40	173.19
9	105.21	175.54

Mean	1.15	4.24
SD	0.02	0.09
CV	2.16%	2.03%

Mean	105.03	175.68
SD	1.11	2.32
CV	1.06%	1.32%

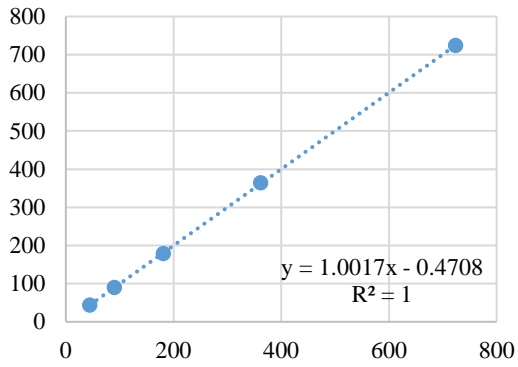
TG		
No.	QC 1	QC 2
1	118.60	222.84
2	115.29	217.09
3	113.28	216.34
4	114.35	216.26
5	116.24	219.65
6	115.29	217.67
7	115.81	218.06
8	116.03	215.05
9	114.72	217.11
Mean	115.51	217.79
SD	1.48	2.29
CV	1.28%	1.05%

Linearity

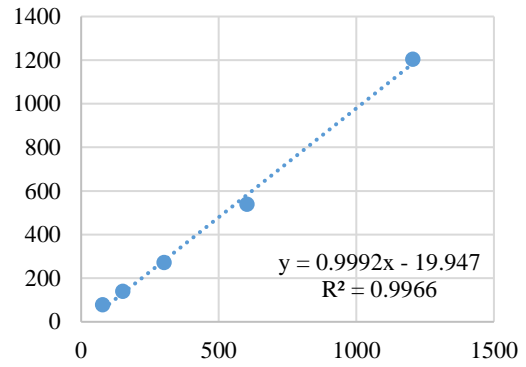
Analyte	Linearity	Validated
ALT	4 - 1000 U/L	42 - 724 U/L
AST	4 - 800 U/L	77 - 1204 U/L
CREA	0.11-79.3 mg/dL	0.7 - 11 mg/dL
CRP	2 - 250 mg/L	13 - 224 mg/dL
Glu	5.4 - 450 mg/dL	20 - 318 mg/dL
HDL-C	1.93 - 232 mmol/L	9.96 - 140 mg/dL
T-Bil	0.099 - 35.09 mg/dL	1 - 14.51 mg/dL

Analyte	Linearity	Validated
TC	3.85-769.23 mg/dL	27.7 - 323 mg/dL
TG	8.85 - 1106.19 mg/dL	21.2 - 915 mg/dL

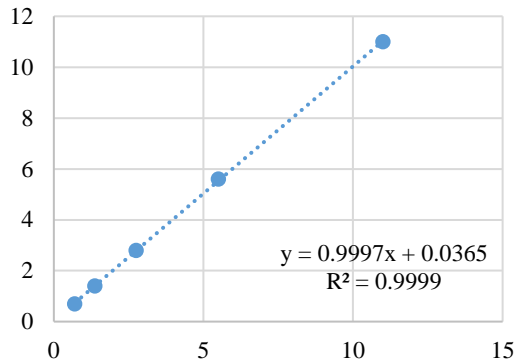
ALT Linearity



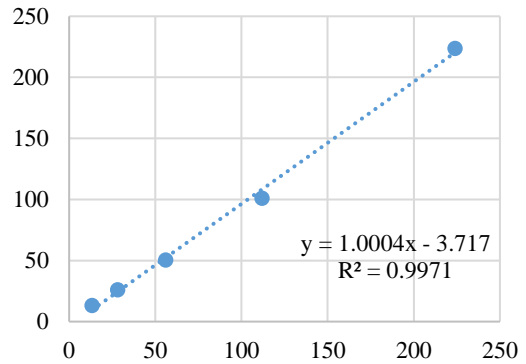
AST Linearity



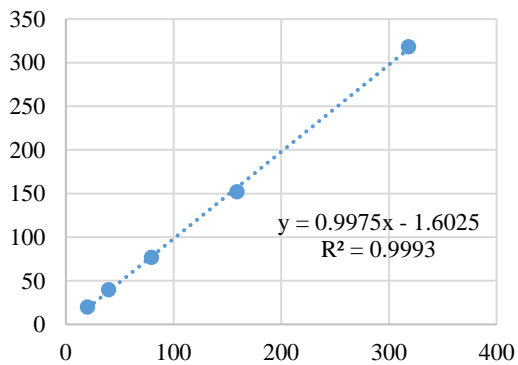
CREA Linearity



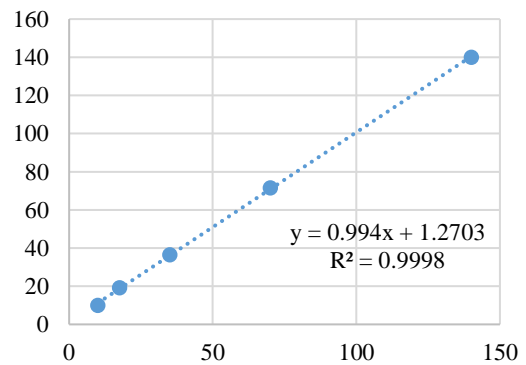
CRP Linearity



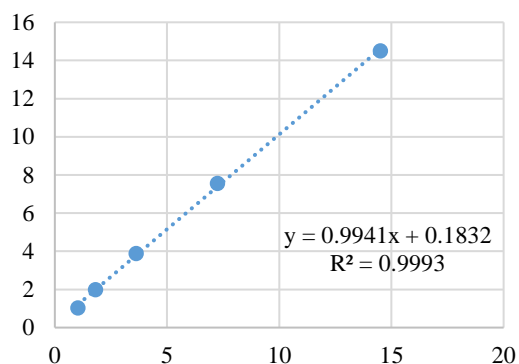
Glu Linearity



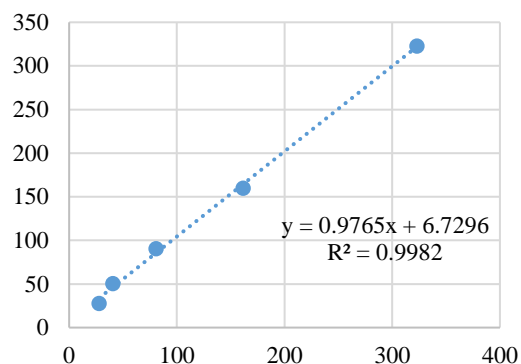
HDL-C Linearity



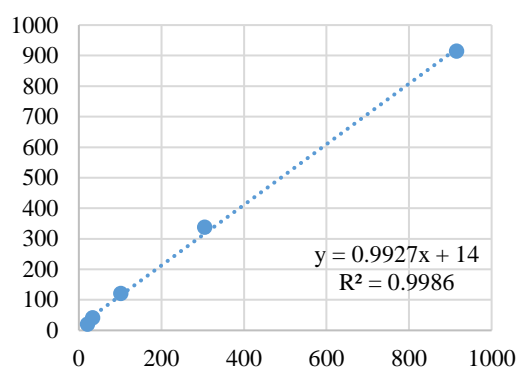
T-Bil Linearity



TC Linearity



TG Linearity

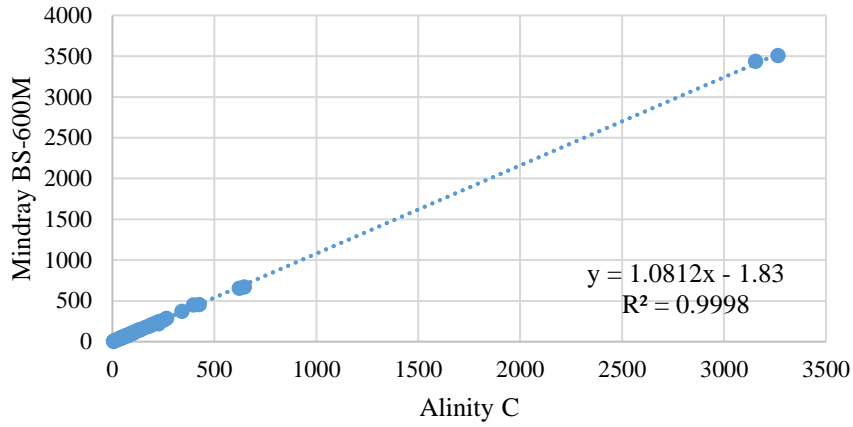


Method Comparison

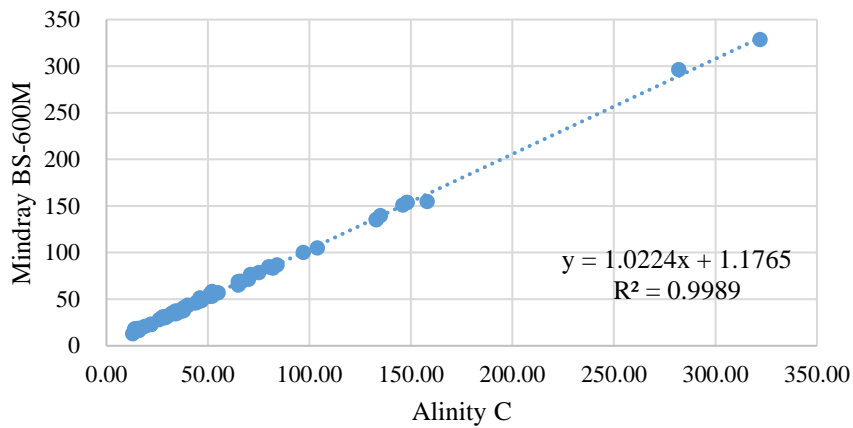
Analyte	Slope	Intercept	Correlation coefficient
ALT	1.0812	-1.8300	0.9998
AST	1.0224	1.1765	0.9989
CREA	1.0610	-0.0233	0.9966
CRP	0.8420	3.6418	0.9950
Glu	0.9800	3.4381	0.9978
HDL-C	1.0752	3.7613	0.9924
T-Bil	0.9663	-0.0128	0.9970
TC	1.0413	0.8432	0.9950
TG	1.1358	-4.2708	0.9933

Method Comparison Charts

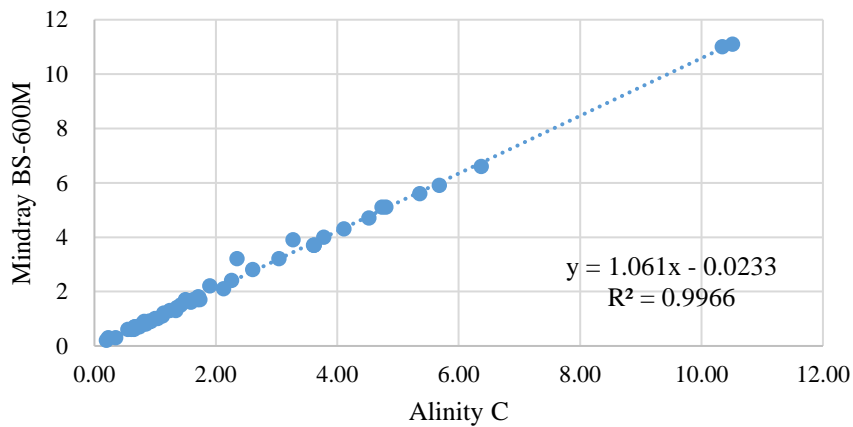
Method Comparison · ALT



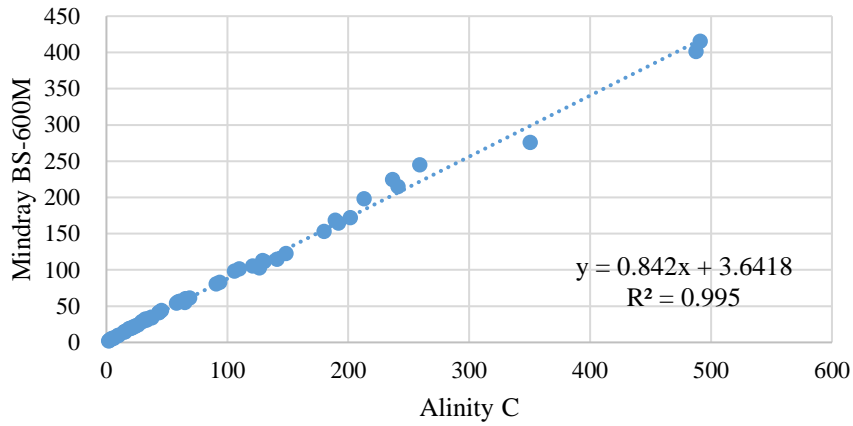
Method Comparison · AST



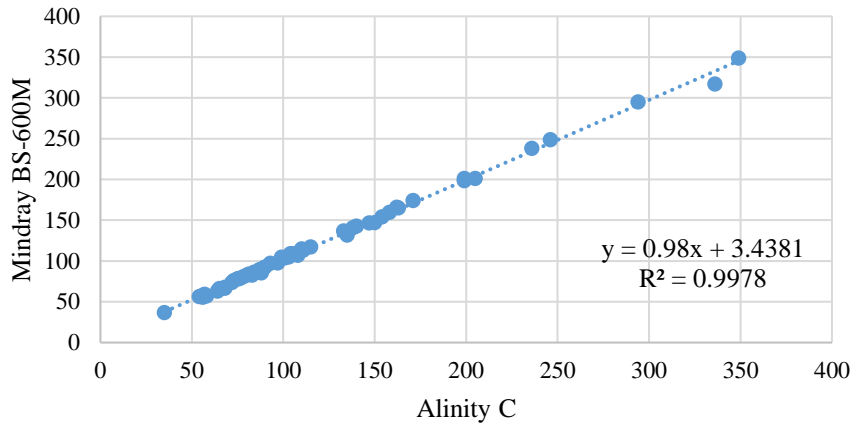
Method Comparison · CREA



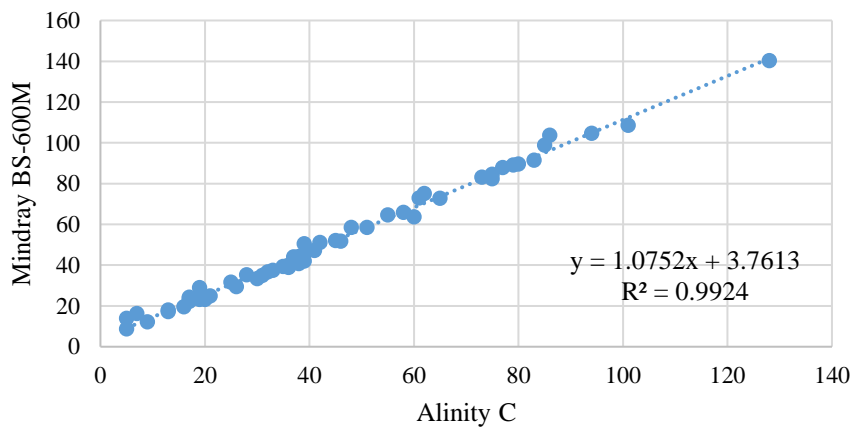
Method Comparison · CRP



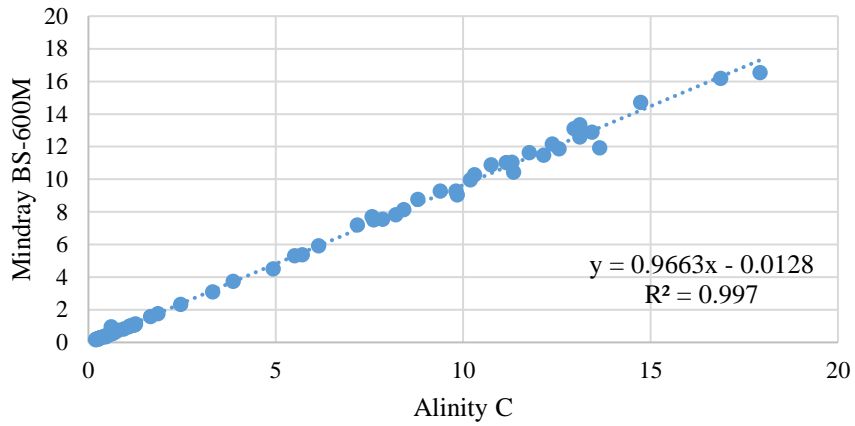
Method Comparison · Glu



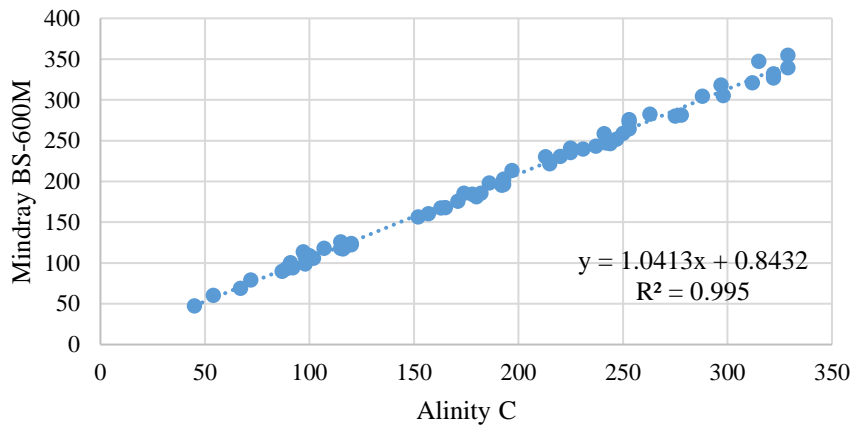
Method Comparison · HDL-C



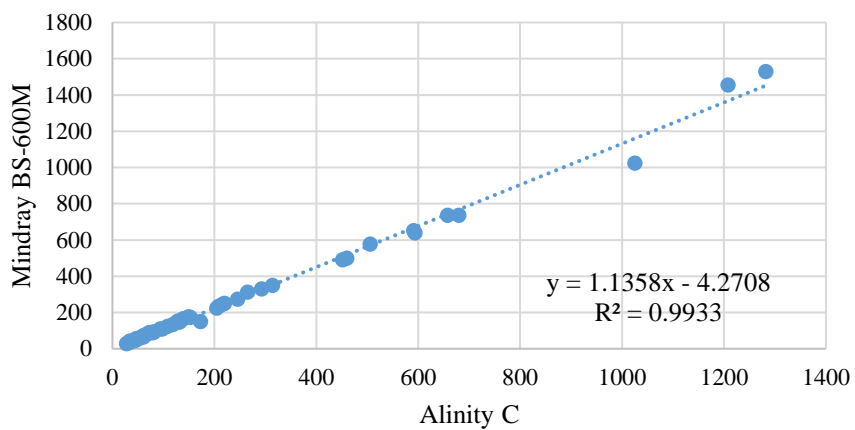
Method Comparison · T-Bil



Method Comparison · TC



Method Comparison · TG



Conclusion

Mindray BS-600M chemistry analyzer demonstrated good performance in this evaluation. The method comparison revealed good methodological alliance to our routine operating biochemistry systems.