



HB1

Analytical Performance Evaluation Report

- **General Biochemistry Panel**
- **Basic Biochemistry Panel**
- **Liver Panel**
- **Metabolic Panel**
- **ER Panel**
- **Renal Panel**
- **Lipid Panel**
- **Liver Panel II**
- **Metabolic Panel II**
- **ER Panel II**



CE
ISO 13485

Albumin (ALB)
Alkaline Phosphatase (ALP)
Alanine Aminotransferase (ALT/GPT)
Amylase (AMY)
Aspartate Aminotransferase (AST/GOT)
Blood Urea Nitrogen (BUN)
Calcium (Ca)
Chloride (Cl)
Creatine Phosphokinase (CPK)
Creatinine (CREA)
Direct Bilirubin (DBIL)
γ-Gamma-Glutamyl Transpeptidase (GGT)
Glucose (GLU)
High-Density Lipoprotein (HDL)
Lactic Dehydrogenase (LDH)
Lipase (LIPA)
Potassium (K)
Sodium (Na)
Phosphorus (PHOS)
Total Bilirubin (TBIL)
Total Cholesterol (TC)
Triglyceride (TG)
Total Protein (TP)
Uric Acid (UA)

Analytical Performance Evaluation Report

Ver. 09

■ Dynamic range and Linearity

Dynamic range was determined by linearity and recovery study

Test Item	Dynamic Range	Dynamic Range (SI Unit)
ALB	1.0 – 6.0 g/dL	10 – 60 g/L
ALP	41 – 2000 U/L	41 – 2000 U/L
ALT	20 – 1100 U/L	20 – 1100 U/L
AMY	22 – 3000U/L	22 – 3000U/L
AST	20 – 1000 U/L	20 – 1000 U/L
BUN	2 – 120 mg/dL	0.7 – 42.8 mmol urea/L
Ca	4 – 15 mg/dL	1 – 3.8 mmol/L
Cl	70 – 140 mmol/L	70 – 140 mmol/L
CPK	40 – 2400 U/L	40 – 2400 U/L
CREA	0.6 – 20 mg/dL	53 – 1768 µmol/L
DBIL	0.1 – 15 mg/dL	1.7 –256.6 µmol/L
GGT	10 – 1500 U/L	10 – 1500 U/L
GLU	30 – 600 mg/dL	1.7 – 33.3 mmol/L
HDL	20 – 75 mg/dL	0.5 – 1.9 mmol/L
LDH	25 – 650 U/L	25 – 650 U/L
LIPA	60 – 1500 U/L	60 – 1500 U/L
PHOS	0.4 – 18 mg/dL	0.1 – 5.8 mmol/L
K	1.5 – 8.5 mmol/L	1.5 – 8.5mmol/L
Na	110 – 170 mmol/L	110 – 170 mmol/L
TBIL	0.4 – 30 mg/dL	6.8 –513.1 µmol/L
TC	50 – 540 mg/dL	1.3 – 14.0 mmol/L
TG	35 – 600 mg/dL	0.4 – 6.8 mmol/L
TP	1.5 – 10 g/dL	15 – 100 g/L
UA	1 – 20 mg/dL	59 – 1190 µmol/L

■ Analytical Sensitivity

The sensitivity (limits of Quantitation) was determined according to the lowest concentration of the dynamic range which had an acceptable CV (CV<20%). The sensitivity of each test item is shown in the table below.

Test Item	Limit of Detection	Test Item	Limit of Detection
ALB	1.0 g/dL	GLU	30 mg/dL
ALP	41 U/L	HDL	20 mg/dL
ALT	20 U/L	LDH	25 U/L
AMY	22 U/L	LIPA	60 U/L
AST	20 U/L	PHOS	0.4 mg/dL
BUN	2 mg/dL	K	1.5 mmol/L
Ca	4 mg/dL	Na	110 mmol/L
Cl	70 mmol/L	TBIL	0.4 mg/dL
CPK	40 U/L	TC	50 mg/dL
CREA	0.6 mg/dL	TG	35 mg/dL
DBIL	0.1 mg/dL	TP	1.5 g/dL
GGT	10 U/L	UA	1 mg/dL

■ Analytical Specificity (Interference study)

1. Effect of endogenous substances

Physiological interferents in blood include hemolysis, icterus, and lipemia. For every test item, 2 Levels human serum pool supplemented with known concentrations of the endogenous substances were used for the testing. Significant interference is defined as a >10% shift in the test result.

Test Item	substance concentration with interferences of less than 10%			
	Hemolysis [Hemoglobin]	Icterus [Bilirubin(unconjugated)]	Icterus [Bilirubin(conjugated)]	Lipemia [Intralipid]
ALB	147.6 mg/dL	62.5 mg/dL	57.5 mg/dL	0.11%
ALP	600 mg/dL	31.7 mg/dL	57.5 mg/dL	0.02%
ALT	290 mg/dL	43.5 mg/dL	22.3 mg/dL	0.02%
AMY	290.3 mg/dL	40.2 mg/dL	39.8 mg/dL	0.4%
AST	3.3 mg/dL	22.9 mg/dL	47.2 mg/dL	0.05%
BUN	522.5 mg/dL	50.5 mg/dL	34.8 mg/dL	0.1%
Ca	600 mg/dL	40.2 mg/dL	39.8 mg/dL	0.35%
Cl	300 mg/dL	47.1 mg/dL	44.9 mg/dL	0.4%
CPK	247.3 mg/dL	35.7 mg/dL	22.0 mg/dL	0.06%
CREA	170 mg/dL	5.2 mg/dL	1.2 mg/dL	0.12%
DBIL	400 mg/dL	---	---	0.03%
GGT	265.4 mg/dL	33.4 mg/dL	10.5 mg/dL	0.2%
GLU	600 mg/dL	62.5 mg/dL	55.5 mg/dL	0.017%
HDL	700 mg/dL	14.97 mg/dL	0.89 mg/dL	0.22%
LDH	14.4mg/dL	5.78mg/dL	23.3 mg/dL	0.06%
LIPA	305.1 mg/dL	49.9 mg/dL	53 mg/dL	0.4%
PHOS	190 mg/dL	32.2 mg/dL	41.6 mg/dL	0.02%
K	90 mg/dL	40.2 mg/dL	3.5 mg/dL	0.1%
Na	600 mg/dL	40.2 mg/dL	39.8 mg/dL	0.2%
TBIL	293.2 mg/dL	---	---	0.03%
TC	300 mg/dL	30.0 mg/dL	30.0mg/dL	0.2%
TG	315.2 mg/dL	14.6 mg/dL	2.6 mg/dL	---
TP	157.2 mg/dL	62.5mg/dL	57.5 mg/dL	0.07%
UA	253.1 mg/dL	9.8 mg/dL	6.26 mg/dL	0.03%

2. Effect of exogenous substances

Ten exogenous substances were selected as potential interferents for the study. For every test item, human serum pool supplemented with a known concentration of the substances was used for the testing. Significant interference is defined as a >10% shift in the test result.

Substance	Test Concentration	Affected Test Item	Effect
Acetaminophen	20 mg/dL	DBIL	11.1% Dec.
		K	17.6% Dec.
Acetylsalicylic acid	65 mg/dL	ALP	10.2% Dec.
		HDL	23.0% Dec.
		K	12.8% Inc.
Ampicillin	5 mg/dL	TG	11.9% Inc.
		HDL	12.4% Inc.
Ascorbic acid	6 mg/dL	UA	15.7% Dec.
		TG	13.4% Inc.
Caffeine	6 mg/dL	No significant interference	
Cephalothin	30 mg/dL	HDL	18.9% Dec.
Cimetidine	2 mg/dL	HDL	11.9% Dec.
Ibuprofen	50 mg/dL	CREA	12.7% Inc.
Salicylic acid	60 mg/dL	HDL	11.2% Dec.
		CREA	12.7% Inc.
Theophylline	4mg/dL	No significant interference	

■ Precision

Precision studies adopt serum pool of high and low concentrations as test samples. Tests are performed twice a day for a total of 20 days. Results for repeatability and reproducibility of each test item are shown in the table below.

Test Item	Mean	Level 1			
		Within-Run		Total	
		SD	%CV	SD	%CV
ALB	4.89 g/dL	0.09	1.8	0.09	1.8
ALP	71.9 U/L	1.7	2.3	1.7	2.3
ALT	54.0 U/L	1.6	3.0	1.7	3.1
AMY	74.5 U/L	2.4	3.3	2.5	3.4
AST	43.7 U/L	1.8	4.1	2.0	4.5
BUN	14.46 mg/dL	0.52	3.6	0.55	4.5
Ca	8.72 mg/dL	0.19	2.2	0.23	2.6
Cl	88.04 mmol/L	2.51	2.8	4.08	4.6
CPK	134.2U/L	2.4	1.8	2.5	1.9
CREA	3.0 mg/dL	0.09	2.9	0.11	3.6
DBIL	0.5 mg/dL	0.02	3.2	0.02	3.2
GGT	51.2 U/L	1.7	3.3	1.7	3.3
GLU	84.7 mg/dL	1.4	1.6	1.4	1.7
HDL	56.1 mg/dL	2.1	3.8	2.5	4.4
LDH	155.5 U/L	4.8	3.1	5.7	3.6
LIPA	168.7 U/L	2.8	1.7	2.8	1.7
PHOS	3.02 mg/dL	0.14	4.6	0.14	4.7
K	3.98 mmol/L	0.144	3.6	0.145	3.7
Na	140.5 mmol/L	1.7	1.2	1.8	1.3
TBIL	1.41 mg/dL	0.02	1.1	0.07	4.7
TC	246.6 mg/dL	3.1	1.3	3.4	1.4
TG	180.6 mg/dL	2.8	1.5	3.3	1.8
TP	6.65 g/dL	0.07	1.0	0.07	1.0
UA	3.25 mg/dL	0.14	4.4	0.14	4.4

Level 2					
Test Item	Mean	Within-Run		Total	
		SD	%CV	SD	%CV
ALB	2.56 g/dL	0.05	2.1	0.06	2.2
ALP	423.7 U/L	9.2	2.2	10.3	2.4
ALT	194.6 U/L	6.1	3.1	6.3	3.2
AMY	371.0 U/L	4.9	1.3	4.9	1.3
AST	202.3 U/L	3.1	1.5	3.8	1.9
BUN	23.29 mg/dL	0.73	3.1	0.79	3.4
Ca	12.3 mg/dL	0.34	2.8	0.38	3.1
Cl	93.52 mmol/L	2.54	2.7	4.49	4.8
CPK	410.2 U/L	7.6	1.9	8.7	2.1
CREA	7.5 mg/dL	0.32	4.3	0.32	4.3
DBIL	2.21 mg/dL	0.02	0.7	0.04	1.6
GGT	141.2 U/L	3.3	2.3	3.9	2.8
GLU	274.7 mg/dL	2.4	0.9	3.2	1.1
HDL	33.8 mg/dL	1.4	4.1	1.6	4.7
LDH	363.4 U/L	8.6	2.4	8.6	2.4
LIPA	244.3 U/L	3.0	1.2	3.3	1.3
PHOS	7.52 mg/dL	0.22	3.0	0.23	3.0
K	6.23 mmol/L	0.14	2.2	0.14	2.2
Na	120.7 mmol/L	1.7	1.4	1.8	1.5
TBIL	4.58 mg/dL	0.1	2.3	0.11	2.4
TC	109.8 mg/dL	1.4	1.3	2.3	2.1
TG	96.9 mg/dL	1.7	1.8	1.9	1.9
TP	4.16 g/dL	0.06	1.4	0.06	1.5
UA	6.52 mg/dL	0.21	3.2	0.22	3.4

■ Method Comparison (Accuracy)

The Commercial clinical chemistry analyzer was used as comparative method in the study. The tests are performed by using the same clinical serum sample for two methods. Correlation between two methods can be determined through statistical analysis.

Test Item	Correlation			SEE	N	Sample range
	Coefficient (R)	Slope	Intercept			
ALB	0.9850	1.008	-0.015	0.148	52	1.63 – 5.34 g/dL
ALP	0.9923	0.997	-0.5	22	48	45 – 888 U/L
ALT	0.9995	1.019	0.9	5.1	44	4 – 807 U/L
AMY	0.9995	0.996	2.2	7.8	46	16 – 1719 U/L
AST	0.9987	1.008	2.7	7	44	2 – 851 U/L
BUN	0.9976	0.994	0.248	1.325	53	3.9 – 106.3 mg/dL
Ca	0.9844	1.002	-0.15	0.28	40	6.6 – 17.4 mg/dL
Cl	0.9828	1.018	-3.1	2.4	41	70 – 136 mmol/L
CPK	0.9982	0.998	2.0	23.7	87	8 – 2177 U/L
CREA	0.9979	0.895	0.142	0.231	40	0.21 – 18.11 mg/dL
DBIL	0.9910	1.000	0.036	0.243	46	0.02 – 11.6 mg/dL
GGT	0.9990	0.999	0.6	5.7	54	5 – 1224 U/L
GLU	0.9986	1.004	0.2	6.3	56	32 – 640 mg/dL
HDL	0.9886	0.926	3.71	2.92	40	19.2 – 82.9 mg/dL
LDH	0.9971	0.998	0.7	9.6	50	24 – 542 U/L
LIPA	0.9997	0.999	0	10.2	40	56-1943 U/L
PHOS	0.9900	1.052	0.4	0.37	55	1.4 – 12.6 mg/dL
K	0.9905	1.026	-0.11	0.15	42	2.9 – 7.9 mmol/L
Na	0.9930	0.988	1.4	2.4	45	72 – 175 mmol/L
TBIL	0.9949	1.001	0.096	0.501	47	0.11 – 25.98 mg/dL
TC	0.9814	0.988	13.1	11	41	44 – 346 mg/dL
TG	0.9886	0.990	-0.2	14	58	39 – 474 mg/dL
TP	0.9911	0.999	-0.008	0.202	52	2.36 – 9.34 g/dL
UA	0.9967	1.012	-0.048	0.254	63	2.02 – 18.57 mg/dL

■ Matrix Comparison

The Correlation between WB, plasma and serum was determined. The clinical sample was used in the study.

Test Item	N	Matrix type	Correlation Coefficient (R)	Slope	Intercept
ALB	5	Serum vs. Plasma	0.9949	1.000	-0.04
		Plasma vs. WB	0.9999	1.005	-0.10
		WB vs. Serum	0.9961	0.996	0.14
ALP	5	Serum vs. Plasma	0.9986	0.996	-6.2
		Plasma vs. WB	0.9998	0.962	0.6
		WB vs. Serum	0.9977	1.044	5.6
ALT	11	Serum vs. Plasma	0.9991	0.984	-0.261
		Plasma vs. WB	0.9980	0.996	-1.003
		WB vs. Serum	0.9989	1.020	1.288
AMY	8	Serum vs. Plasma	0.9942	1.096	-8.9
		Plasma vs. WB	0.9908	1.032	-4.0
		WB vs. Serum	0.9996	0.941	4.4
AST	12	Serum vs. Plasma	0.9982	0.954	-0.074
		Plasma vs. WB	0.9962	1.047	-0.732
		WB vs. Serum	0.9980	1.001	0.805
BUN	11	Serum vs. Plasma	0.9971	1.011	-0.129
		Plasma vs. WB	0.9996	1.006	-0.344
		WB vs. Serum	0.9967	0.983	0.466
Ca	9	Serum vs. Plasma	0.9963	0.988	-0.2
		Plasma vs. WB	0.9954	0.956	0.4
		WB vs. Serum	0.9927	0.944	0.21
Cl	8	Serum vs. Plasma	0.9959	0.979	0.4
		Plasma vs. WB	0.9964	0.976	2.4
		WB vs. Serum	0.9946	1.046	-3.0
CPK	4	Serum vs. Plasma	0.9998	1.029	-8.0
		Plasma vs. WB	1.0000	0.977	14
		WB vs. Serum	0.9999	0.994	-4.9
CREA	11	Serum vs. Plasma	0.9991	0.999	0.035
		Plasma vs. WB	0.9995	1.006	-0.005
		WB vs. Serum	0.9999	0.994	-0.030
DBIL	10	Serum vs. Plasma	0.9987	1.033	0.013
		Plasma vs. WB	0.9990	1.047	0.018
		WB vs. Serum	0.9983	0.925	-0.029

GGT	11	Serum vs. Plasma	0.9980	0.912	-8.942
		Plasma vs. WB	0.9996	1.078	-3.013
		WB vs. Serum	0.9987	1.017	-6.726
GLU	15	Serum vs. Plasma	0.9831	1.002	2.040
		Plasma vs. WB	0.9851	1.060	-3.935
		WB vs. Serum	0.9911	0.941	1.619
HDL	9	Serum vs. Plasma	0.9960	1.034	-2.8
		Plasma vs. WB	0.9944	1.010	-1.2
		WB vs. Serum	0.9927	0.977	1.5
LDH	5	Serum vs. Plasma	0.9964	1.000	-2.9
		Plasma vs. WB	0.9931	0.971	36.3
		WB vs. Serum	0.9962	1.030	-34.7
LIPA	9	Serum vs. Plasma	0.9993	0.986	4.4
		Plasma vs. WB	0.9996	0.984	3.5
		WB vs. Serum	0.9998	0.997	-0.9
PHOS	12	Serum vs. Plasma	0.9994	1.003	-1.12
		Plasma vs. WB	0.9996	0.971	0.32
		WB vs. Serum	0.9992	0.973	-0.87
K	5	Serum vs. Plasma	0.9783	1.031	-0.34
		Plasma vs. WB	0.9817	0.879	0.7
		WB vs. Serum	0.9976	1.101	-0.44
Na	9	Serum vs. Plasma	0.9775	1.020	-2.8
		Plasma vs. WB	0.9879	0.950	5.6
		WB vs. Serum	0.9730	0.968	-3.0
TBIL	13	Serum vs. Plasma	0.9939	1.030	0.003
		Plasma vs. WB	0.9980	1.031	0.062
		WB vs. Serum	0.9948	0.941	-0.061
TC	15	Serum vs. Plasma	0.9923	1.032	-2.900
		Plasma vs. WB	0.9804	0.928	9.433
		WB vs. Serum	0.9897	1.043	-6.927
TG	13	Serum vs. Plasma	0.9923	1.019	-1.824
		Plasma vs. WB	0.9892	1.042	-2.049
		WB vs. Serum	0.9948	0.942	3.678
TP	15	Serum vs. Plasma	0.9926	0.967	0.325
		Plasma vs. WB	0.9965	1.038	-0.188
		WB vs. Serum	0.9960	0.996	-0.148
UA	13	Serum vs. Plasma	0.9958	0.988	0.239
		Plasma vs. WB	0.9979	1.050	-0.244
		WB vs. Serum	0.9971	0.964	-0.006