



skyla™ ER Panel

HB1

IVD

PN : 800-140

For In Vitro Diagnostic Use and For Professional Use Only

Rev : E

1. Intended Use

The skyla ER Panel used with skyla Clinical Chemistry Analyzer, is intended to be used for the quantitative determination of Alanine Aminotransferase (ALT/GPT), Amylase (AMY), Aspartate Aminotransferase (AST/GOT), Blood Urea Nitrogen (BUN), Calcium (Ca), Chloride (Cl), Creatine Phosphokinase (CPK), Creatinine (CREA), Blood Glucose (GLU), Lipase (LIPA), Phosphorus (PHOS), Potassium (K), Sodium (Na) in human whole blood, plasma, or serum. The calculated values of Estimated Glomerular Filtration Rate (eGFR) can then be obtained.

2. Principles

The skyla ER Panel contains a total of 13 types of dried reagents located in the respective detection wells of the reagent disc. The user only needs to inject the blood specimens into the sample port of the disc, and places the disc into the analyzer. The test will be done automatically within 15 minutes. Additional calculated value of eGFR is also obtained after the test. For the detail description of disc, please refer to “skyla Clinical Chemistry Analyzer Operator’s Manual”.

Clinical Significance:

Alanine Aminotransferase (ALT/GPT)

ALT is one of the indicators of liver function. Acute and chronic hepatitis, drug induced liver injury, fatty liver, cirrhosis, myocardial infarction, myocarditis and biliary diseases can lead to elevated ALT activity.

Amylase (AMY)

The AMY activity is clinically related to the diseases of the pancreas and for evaluation of salivary gland. AMY activity increased considerably in acute pancreatitis and mumps.

Aspartate Aminotransferase (AST/GOT)

AST is one of the indicators of liver function. Increased AST activity can be associated with medical conditions involving heart, liver, kidney or pancreas. Myocardial infarctions cause an increase of AST levels in the blood within 6-8 hours, gradually returning to normal levels after 48-60 hours. Hepatitis or other hepatobiliary diseases can also increase AST activity.

Blood Urea Nitrogen (BUN)

BUN is one of the important markers for diagnosis and prognosis tracking of kidney diseases and metabolic disorders. Other common possible causes of elevated BUN include dehydration and heart failure.

Calcium (Ca)

Ca plays an important role in the management of the critically ill patient. Increased serum Ca may be caused by hyperparathyroidism, hypervitaminosis, sarcoidosis, myeloma, and certain cancers of the bone. Decreased serum Ca is observed in hypoparathyroidism, rickets, nephrosis, nephritis, steatorrhea, and pancreatitis.

Chloride (Cl)

Cl is an important marker in acid-base balance. The disorder of Cl might be response to cystic fibrosis, diabetic acidosis, renal tubular disease, hydration disorders, diarrhea and vomiting.

Creatine Phosphokinase (CPK)

CPK is an enzyme found mainly in the skeletal muscle, cardiac muscle, and brain tissue. CPK can be used for the diagnosis of myocardial infarction, heart attack, dermatomyositis, polymyositis and other muscle disorders.

Creatinine (CREA)

CREA is the degradation product of creatine in human muscles. It is a commonly used marker to examine renal functions. Elevated CREA in the blood may be caused by severe muscle disease, nephritis, hyperthyroidism and malnutrition.

Glucose (GLU)

GLU can be used for the diagnosis of diabetes and diseases related to the carbohydrate metabolism. Diabetes, chronic pancreatitis and certain endocrine diseases may lead to hyperglycemia. Abnormal glucose metabolism, islet cell tumors, pancreatic tumors and severe liver diseases may lead to hypoglycemia.

Lipase (LIPA)

LIPA is a reliable marker in diagnosis of pancreatic disease. Evaluated LIPA can be found in acute pancreatitis or obstruction of the pancreatic duct.

Phosphorus (PHOS)

PHOS plays an important role in cell metabolic activities. It can be measured for the determination of disorders including parathyroid gland and kidney diseases, and vitamin D imbalance.

Potassium (K)

K is one of the important markers in electrolyte balance. The disorder of K might be response to kidney disease, medication use, renal glomerular and tubular disease, Addison's disease, diabetic ketoacidosis, sepsis, in vitro hemolysis, and dehydration.

Sodium (Na)

Na is one of the important markers in electrolyte balance. The disorder of Na might be response to diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, hyperaldosteronism, and inappropriate ADH secretion.

Estimated Glomerular Filtration Rate (eGFR)

eGFR is the kidney filtrate per minute, which is calculated from CREA. It is used to assess renal function.

Method:

ALT

ALT activity is enzymatically determined. ALT catalyses the reaction of Alanine with α -Ketoglutarate, converting them into Glutamate and Pyruvate. In the presence of NADH, Lactate Dehydrogenase converts Pyruvate into Lactate. In the course of the reaction NADH is oxidized to NAD. The decrease of NADH absorbance is measured at a wavelength of 340 nm and is proportional to ALT activity.

AMY

AMY activity is enzymatically determined. The substrate α -(2-Chloro-4-Nitrophenyl)- β -1,4-Galactopyranosylmaltoside (Gal-G2- α -CNP) reacts directly with AMY and releases 2-Chloro-4-Nitrophenol (CNP) from the substrate. The resulting absorbance is measured at a wavelength of 405 nm and is directly related to the AMY activity in the sample.

AST

AST activity is enzymatically determined. When the test sample reacts with the substrate-enzyme reagent, AST converts L-Aspartic acid and α -Ketoglutarate into Monosodium Glutamate and Amide Acetate. Amide Acetate is subsequently converted into Malate by Malate Dehydrogenase while NADH undergoes oxidation to NAD. The decrease of NADH absorbance is measured at a wavelength of 340 nm and is proportional to AST activity.

BUN

BUN is enzymatically determined. Urea undergoes a Urease catalyzed hydrolysis, thus producing Ammonia and Carbon Dioxide. In a Glutamate Dehydrogenase (GLDH) catalyzed reaction Ammonia reacts with 2-Oxoglutarate yielding L-Glutamate. In the process of this reaction, NADH is oxidized to NAD which in turn undergoes a color reaction. The rate of change of absorbance at wavelength of 340 nm is measured and proportional to the BUN concentration.

Ca

Ca is determined through the endpoint chemical reaction approach. Calcium reacts with Arsenazo III and form a purple-colored complex. The complex formation is measured at wavelength of 650 nm and is proportional to the amount of Ca in the sample.

Cl

Cl is enzymatically determined. Chloride will bind to Amylase and consequently lead to reactivation of the enzyme. Amylase will then convert a synthetic substrate α -(2-Chloro-4-Nitrophenyl)- β -1,4-Galactopyranosylmaltoside (Gal-G2- α -CNP) to 2-chloro-4-nitrophenol (CNP). Its formation and absorption at a wavelength of 405 nm is proportional to the amount of Chloride in the sample.

CPK

CPK is enzymatically determined. CPK catalyzes the Creatine Phosphate and ADP to form a Creatine and ATP. Then Hexokinase catalyzed the Glucose and ATP, produces the D-Glucose-6-Phosphate

(G-6-P). In the presence of NAD, G-6-PD converts G-6-P into 6- Phosphogluconate and NADH. The absorbance at the wavelength of 340 nm can be measured in the presence of NADH. The absorbance is proportional to the CPK concentration.

CREA

CREA is determined through the endpoint enzymatic reaction approach. Creatinine Amidohydrolase hydrolyzes CREA to Creatine. Then Creatine is converted into Sarcosine through catalysis of Creatine Amidinohydrolase. Furthermore, Sarcosine Oxidase oxidizes Sarcosine, yielding Glycine, Formalehyde and Peroxide (H_2O_2) in the process. The enzyme Peroxidase processes Hydrogen Peroxide, 2,4,6-3 Hydroxy-Benzoic acid (TBHBA) and 4-Amine Triazolam Alternate Pyrazol (4-AAP), forming a Quinoneimine dye as a product. The dye formation is measured at wavelength of 546 nm and is proportional to the amount of CREA in the sample.

GLU

GLU is determined through the endpoint enzymatic reaction approach. The Sucrose is catalyzed by Hexokinase to D-Glucose-6-Phosphate (G-6-P). In the presence of NAD, G-6-PD converts G-6-P into 6- Phosphogluconate and NADH. The absorbance at the wavelength of 340 nm can be measured in the presence of NADH. The absorbance is proportional to the GLU concentration.

LIPA

LIPA activity is enzymatically determined. The substrate 1,2-O-Dilauryl-Rac-Glycerol-3-Glutaric acid-(6'-Methylresorufin) Ester(DGGMR) reacts directly with LIPA and releases Methylresurofin from the substrate. The resulting absorbance is measured at a wavelength of 546 nm and is directly related to the LIPA activity in the sample.

PHOS

PHOS is enzymatically determined. By going through a series of enzymatic reactions with Sucrose Phosphorylase, Phosphoglucomutase, and Glucose-6-Phosphate Dehydrogenase, PHOS forms

6-Phosphogluconate and NADH. And NADH is measured at a wavelength of 340 nm and is proportional to the amount of PHOS in the sample.

K

K is enzymatically determined. Pyruvate Kinase (PK) dephosphorylates Phosphoenolpyruvate (PEP) to form Pyruvate. Then the Pyruvate convert to Lactate under catalysis of Lactate Dehydrogenase (LDH). At the same time, NADH is oxidized to NAD⁺ which in turn undergoes a color reaction. The rate of change of absorbance at wavelength of 340 nm is measured and proportional to the potassium in the sample.

Na

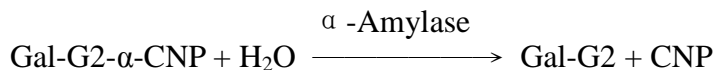
Na is enzymatically determined. By going through the activation of β -Galactosidase with Na ion, o-Nitrophenyl- β -Galactopyranoside (ONPG) is further catalyzed by activated β -Galactosidase, form o-Nitrophenol and Galactose. The absorbance caused by o-Nitrophenol is measured at a wavelength of 405 nm and is proportional to the amount of Na in the sample.

Reaction pathway :

ALT



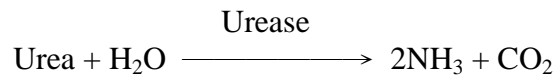
AMY



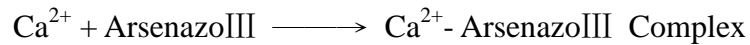
AST



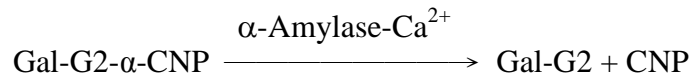
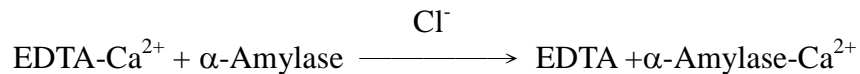
BUN



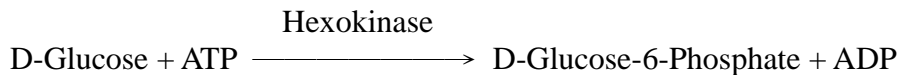
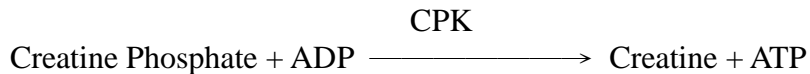
Ca



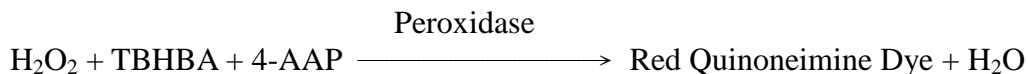
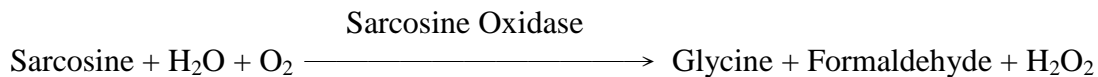
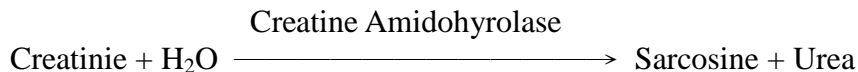
Cl



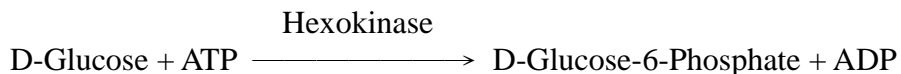
CPK



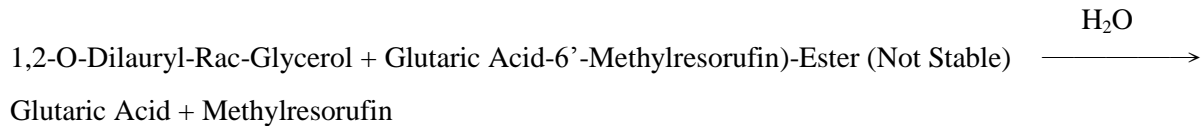
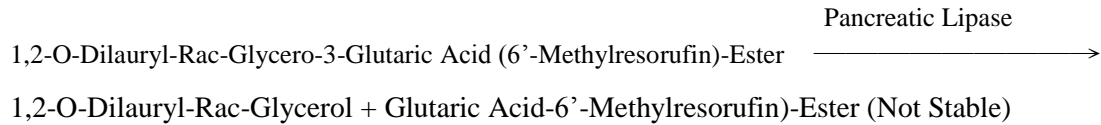
CREA



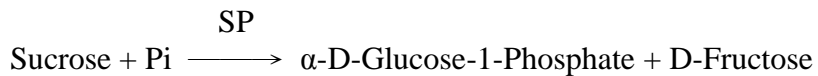
GLU



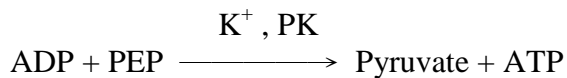
LIPA



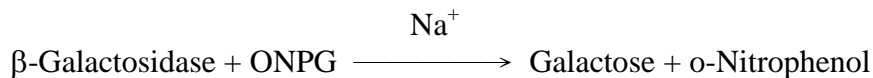
PHOS



K



Na



3. Reagents

Included:

Each panel contains dried reagent beads, dried internal QC beads and the diluent.

Reagent Composition:

Composition	Quantity/Panel
1,4-Piperazinediethanesulfonic Acid	0.08 mg
4-AAP	0.02 mg
ADP	0.05 mg
Arsenazo III	7 µg
ATP	0.04 mg
Colipase Porcine Pancreas	0.1 µg
Creatinase	2.8 U
Creatine Phosphate	0.3 mg
Creatininase	5.6 U
DGGMR	0.004 mg
D-Glucose	0.1 mg
EDTA-calcium	0.4 mg
G6PDH	0.38 U
Gal-G2- α -CNP	0.14 mg
Glutamate Dehydrogenase	0.05 U
Hexokinase	0.2 U
Lactate Dehydrogenase	0.9 U
L-Alanine	0.3 mg
L-Aspartic Acid	1 mg
Malate Dehydrogenase	0.04 U

Composition	Quantity/Panel
Monosodium Phosphoenolpyruvate	0.02 mg
NAD	0.2 mg
NADH	0.11 mg
ONPG	0.04 mg
Peroxidase	0.1 U
Phosphoglucomutase	0.05 U
Pyruvate Kinase	0.05 U
Sarcosine Oxidase	0.4 U
Sucrose	0.3 mg
Sucrose Phosphorylase	0.01 U
TBHBA	0.2 mg
Urease	0.03 U
α -Amylase	0.2 U
α -Ketoglutaric Acid	0.25 mg
β -Galactosidase	0.3 U

Reagent Storage:

- The reagent disc should be stored at 2~8°C.
- The expiry date of the reagent is printed on the outside of the sealed pouch of reagent disc. Do not use if the reagents have expired.

4. Specimen Collection and Preparation

Specimen Collection:

- Specimens suitable for skyla ER Panel include lithium heparinized whole blood, lithium heparinized plasma, serum and quality control solutions. The sample requirement is 200 μ L. ($\pm 10\mu$ L tolerance are allowable)
- Collection, preservation and handling of specimens in accordance with local legal requirements or the standard operating procedures of your organization.

Note: Do not use specimens containing other coagulants. That would cause in incorrect test results.

Specimen Preparation:

- Before applying a sample to the reagent disc, gently rotate the sample tube up and down several times, to confirm the sample is homogeneous (evenly mixed). If the sample is whole blood, do not shake the sample container vigorously to avoid occurrence of hemolysis.

Note: 1. Perform testing within 10 minutes after applying the sample to the reagent disc.

2. The use of whole blood specimens with hematocrits (Hct) higher than 60% may affect the test results.

For further information in specimen collection and preparation, please refer to “skyla Clinical Chemistry Analyzer Operator’s Manual”.

5. Test Procedures

Material Preparation:

1 piece of the reagent disc of skyla ER Panel

Required materials not included in the panel:

The skyla Clinical Chemistry Analyzer

Sample collection container

Micropipette / Tips

Control reagents available on the market.

Test Conditions:

Test should be carry out in an environment with temperatures of 10°C~32°C. Each test will take about 15 minutes. During the test, chamber in the analyzer keeps the temperature at 37°C for stable assay.

Test Steps:

1. Open the aluminum pouch and remove the reagent disc.
2. Remove the diluent container sealing.
3. Using a micropipette to inject 200µL of the sample into the reagent disc through the sample port.
4. Place the reagent disc to the analyzer drawer.
5. Press the “start” button on the screen to initiate testing.

For details on the operating steps and instrument setting, refer to “the skyla™ Clinical Chemistry Analyzer Operator’s Manual.”

- Note:
1. To operate the reagent disc or instrument, please wear lab gloves and other protective gear to avoid contamination by specimen.
 2. The used reagent disc, tips should be discarded as biomedical waste.
 3. Testing should be performed within 20 minutes after the pouch is opened.
 4. Do not place the reagent disc at the environment more than 25°C and longer than 48 hours prior to use.
 5. If the reagent disc or its package is damaged or is over the expiry date, do not use it.

6. Calibration

The barcode on every manufactured reagent disc contains all information required for calibration of the test items. The analyzer will automatically read the barcode information during testing.

7. Quality Control

External quality control materials can be used for the accuracy monitor of skyla system. The recommended frequency of QC testing is as follows. (External quality control materials are not provided by LITE-ON)

- At least every 30 days.
- Before a new batch of reagents is used for testing.
- When the analyzer is moved or the operating environment significantly changes.

8. Reference interval

The table below shows the reference interval for each test item. These ranges are provided as a reference only. It is recommended that every laboratory or test site should establish its own reference interval from its particular patient population.

Test Item		Reference Interval	Reference Interval (SI Unit)
ALT		< 40 U/L	< 40 U/L
AMY		30 – 118 U/L	30 – 118 U/L
AST		< 42 U/L	< 42 U/L
BUN		9 – 23 mg/dL	3.2 – 8.2 mmol urea/L
Ca		8.3– 10.6 mg/dL	2.1 – 2.7 mmol/L
Cl		99 – 109mmol/L	99 – 109 mmol/L
CPK	Male	< 294 U/L	< 294 U/L
	Female	< 211 U/L	< 211 U/L
CREA	Male	0.7 – 1.3 mg/dL	62 – 115 µmol/L
	Female	0.6 – 1.1 mg/dL	53 – 97.2 µmol/L
GLU		70 – 110 mg/dL	3.9 – 6.1 mmol/L
LIPA		73 – 393 U/L	73 – 393 U/L
PHOS		2.5 – 4.9 mg/dL	0.8 – 1.6 mmol/L
K		3.5 – 5.5 mmol/L	3.5 – 5.5 mmol/L
Na		132 – 146 mmol/L	132 – 146 mmol/L

9. Limitation

Interference studies:

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]
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%
GLU	600 mg/dL	62.5 mg/dL	55.5 mg/dL	0.017%
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%

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	K	17.6% Dec.
Acetylsalicylic acid	65 mg/dL	K	12.8% Inc.
Ampicillin	5 mg/dL	No significant interference	
Ascorbic acid	6 mg/dL	No significant interference	
Caffeine	6 mg/dL	No significant interference	
Cephalothin	30 mg/dL	No significant interference	
Cimetidine	2 mg/dL	No significant interference	
Ibuprofen	50 mg/dL	CREA	12.7% Inc.
Salicylic acid	60 mg/dL	CREA	12.7% Inc.
Theophylline	4 mg/dL	No significant interference	

10. Performance Characteristics

Dynamic range:

The dynamic range was determined by linearity study, as follows:

Test Item	Dynamic Range	Dynamic Range (SI Unit)
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
GLU	30 – 600 mg/dL	1.7 – 33.3 mmol/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 – 8.5 mmol/L
Na	110 – 170 mmol/L	110 – 170 mmol/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
ALT	20 U/L	CREA	0.6 mg/dL
AMY	22 U/L	GLU	30 mg/dL
AST	20 U/L	LIPA	60 U/L
BUN	2 mg/dL	PHOS	0.4 mg/dL
Ca	4 mg/dL	K	1.5 mmol/L
Cl	70 mmol/L	Na	110 mmol/L
CPK	40 U/L		

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.

Level 1					
Test Item	Mean	Within-Run		Total	
		SD	%CV	SD	%CV
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	3.8
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	134.2 U/L	2.4	1.8	2.5	1.9
CREA	3.0 mg/dL	0.09	2.9	0.11	3.6

Level 1					
Test Item	Mean	Within-Run		Total	
		SD	%CV	SD	%CV
GLU	84.7 mg/dL	1.4	1.6	1.4	1.7
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

Level 2					
Test Item	Mean	Within-Run		Total	
		SD	%CV	SD	%CV
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
GLU	274.7 mg/dL	2.4	0.9	3.2	1.1
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

Method Comparison:

The automatic clinical chemistry analyzer in clinical laboratory 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		Intercept	SEE	N	Sample range
	Coefficient (R)	Slope				
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
GLU	0.9986	1.004	0.2	6.3	56	32 – 640 mg/dL
LIPA	0.9997	0.999	0	10.2	40	56 – 1943U/L
PHOS	0.99	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

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
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

Test Item	N	Matrix type	Correlation Coefficient (R)	Slope	Intercept
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
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
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

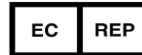
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Symbol Index			
	Catalogue number		Consult instruction for use
	Batch code		Use by
	Manufacturer		Authorized representative in the European Community
	In Vitro diagnostic medical device		CE mark
	Temperature limitation		Caution
	Do not reuse		



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