CE

skyla™ Renal Panel

HB1

IVD

PN：800-150

For In Vitro Diagnostic Use and For Professional Use Only

Rev：D

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1. Intended Use

The skyla Renal Panel used with skyla Clinical Chemistry Analyzer, is intended to be used for the quantitative determination of Albumin (ALB), Blood Urea Nitrogen (BUN), Calcium (Ca), Chloride (Cl), Creatine Phosphokinase (CPK), Creatinine (CREA), Blood Glucose (GLU), 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 Renal Panel contains a total of 10 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:

Albumin (ALB)

ALB is the major protein component of normal human serum, accounting for more than 50% of the total protein. It plays an important role in the regulation of the osmotic blood pressure. Abnormal ALB values may be caused by dehydration, malnutrition, nephrotic syndrome or liver dysfunction.

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.

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:

ALB

ALB is determined through the endpoint color reaction method. When binding to Bromocresol Green (BCG), it forms a yellow-green complex. The absorbance at a wavelength of 600 nm can be measured. The amount of ALB in the sample is proportional to the bound ALB.

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 enzymtically 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.

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 converts 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 :

ALB

$$\text{Albumin} + \text{BCG} \longrightarrow \text{Albumin-BCG Complex}$$

BUN

$$\text{Urea} + H_2O \xrightarrow{\text{Urease}} 2NH_3 + CO_2$$

$$NH_3 + \text{2-Oxoglutarate} + \text{NADH} \xrightarrow{\text{GLDH}} \text{L-Glutamate} + H_2O + NAD^+$$

Ca

$$Ca^{2+} + \text{ArsenazoIII} \longrightarrow Ca^{2+}\text{- ArsenazoIII Complex}$$

Cl

$$EDTA\text{-}Ca^{2+} + \alpha\text{-Amylase} \xrightarrow{Cl^-} EDTA + \alpha\text{-Amylase-}Ca^{2+}$$

$$Gal\text{-}G2\text{-}\alpha\text{-}CNP \xrightarrow{\alpha\text{-Amylase-}Ca^{2+}} Gal\text{-}G2 + CNP$$

CPK

$$\text{Creatine Phosphate} + ADP \xrightarrow{CPK} \text{Creatine} + ATP$$

$$\text{D-Glucose} + ATP \xrightarrow{\text{Hexokinase}} \text{D-Glucose-6-Phosphate} + ADP$$

$$\text{D-Glucose-6-Phosphate} + NAD \xrightarrow{\text{G-6-PDH}} \text{6- Phosphogluconate} + NADH + H^+$$

CREA

$$\text{Creatinine} + H_2O \xrightarrow{\text{Creatinine Amidohyrolase}} \text{Creatine}$$

$$\text{Creatinie} + H_2O \xrightarrow{\text{Creatine Amidohyrolase}} \text{Sarcosine} + \text{Urea}$$

$$\text{Sarcosine} + H_2O + O_2 \xrightarrow{\text{Sarcosine Oxidase}} \text{Glycine} + \text{Formaldehyde} + H_2O_2$$

$$H_2O_2 + \text{TBHBA} + \text{4-AAP} \xrightarrow{\text{Peroxidase}} \text{Red Quinoneimine Dye} + H_2O$$

GLU

$$\text{D-Glucose + ATP} \xrightarrow{\text{Hexokinase}} \text{D-Glucose-6-Phosphate + ADP}$$

$$\text{D-Glucose-6-Phosphate + } NAD^{+} \xrightarrow{\text{G-6-PDH}} \text{6- Phosphogluconate + NADH + } H^{+}$$

PHOS

$$\text{Sucrose + Pi} \xrightarrow{\text{SP}} \alpha\text{-D-Glucose-1-Phosphate + D-Fructose}$$

$$\alpha\text{ -D-Glucose-1-Phosphate} \xrightarrow{\text{PGM}} \alpha\text{ -D-Glucose-6-Phosphate}$$

$$\alpha\text{ -D-Glucose-6-Phosphate + } NAD^{+} \xrightarrow{\text{G6PDH}} \text{6-Phospho-D-Gluconate + NADH + } H^{+}$$

K

$$\text{ADP + PEP} \xrightarrow{K^{+}\text{, PK}} \text{Pyruvate + ATP}$$

$$\text{Pyruvate + NADH + } H^{+} \xrightarrow{\text{LDH}} \text{Lactate + } NAD^{+}$$

Na

$$\beta\text{-Galactosidase + ONPG} \xrightarrow{Na^{+}} \text{Galactose + o-Nitrophenol}$$

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
Bromocresol Green	5.4 µg
Creatinase	2.8 U
Creatine Phosphate	0.3 mg
Creatininase	5.6 U
D-Glucose	0.1 mg
EDTA-calcium	0.4 mg
G6PDH	0.38 U
Gal-G2-α-CNP	0.1 mg
Glutamate Dehydrogenase	0.05 U
Hexokinase	0.2 U
Lactate Dehydrogenase	0.6 U
Monosodium Phosphoenolpyruvate	0.02 mg
NAD	0.2 mg
NADH	0.06 mg
ONPG	0.04 mg

Composition	Quantity/Panel
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	0.05 mg
β-Galactosidase	0.3 U

Reagent Storage:

- The reagent disc should be stored at 2～8℃.
- 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 Renal Panel include lithium heparinized whole blood, lithium heparinized plasma, serum and quality control solutions. The sample requirement is 200 μL. (±10μL 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 Renal 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℃~32℃. Each test will take about 15 minutes. During the test, chamber in the analyzer keeps the temperature at 37℃ 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℃ 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)
ALB		3.5 – 5.3 g/dL	35 – 53 g/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

Test Item		Reference Interval	Reference Interval (SI Unit)
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
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]
ALB	147.6 mg/dL	62.5 mg/dL	57.5 mg/dL	0.11%
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%

Test Item	substance concentration with interferences of less than 10%			
	Hemolysis [Hemoglobin]	Icterus [Bilirubin (unconjugated)]	Icterus [Bilirubin (conjugated)]	Lipemia [Intralipid]
GLU	600 mg/dL	62.5 mg/dL	55.5 mg/dL	0.017%
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	
Caffenine	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)
ALB	1.0 – 6.0 g/dL	10 – 60 g/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
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
ALB	1.0 g/dL	CREA	0.6 mg/dL
BUN	2 mg/dL	GLU	30 mg/dL
Ca	4 mg/dL	PHOS	0.4 mg/dL

Test Item	Limit of Detection	Test Item	Limit of Detection
Cl	70 mmol/L	K	1.5 mmol/L
CPK	40 U/L	Na	110 mmol/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
ALB	4.89 g/dL	0.09	**1.8**	0.09	**1.8**
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**
GLU	84.7 mg/dL	1.4	**1.6**	1.4	**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
ALB	2.56 g/dL	0.05	**2.1**	0.06	**2.2**
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**
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 Coefficient (R)	Slope	Intercept	SEE	N	Sample range
ALB	0.9850	1.008	-0.015	0.148	52	1.63 – 5.34 g/dL
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

Test Item	Correlation Coefficient (R)	Slope	Intercept	SEE	N	Sample range
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
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
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
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

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

11. Reference

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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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