Veterinary Chemistry Analyser

Correlation Study – Kidney Panel

Contents

Approved By: _____   **Date:** 10/9/2021
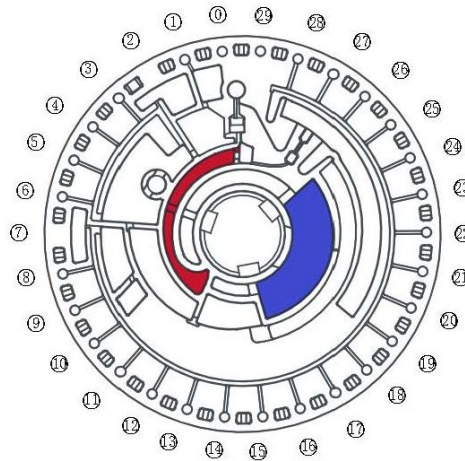
1. Clinical Evaluation Purposes

This clinical evaluation trial is a set of comparison tests to examine the equivalence of the InSight V-CHEM Kidney Panel and the control product for the same set of specimens.

2. Product Introduction

Each independently packaged reagent disc is formed by injection moulding a transparent material. A freeze-dried spherical biochemical detection reagent is arranged in the outer periphery of the rotor which is equivalent to a colorimetric device of a conventional biochemical analyser when the optical detection is performed. All blood separation, the mixing of the sample with the diluent and the biochemical reaction were performed on the reagent disc.

There is an injection port on the reagent disc where the sample is introduced. Diluent is released by pulling the aluminium strip on the rotor.

There is a device on the disc to separate the whole blood so the sample can use serum, plasma or anticoagulant whole blood. The disc can accurately quantify the samples and diluents, and the quantitative samples and diluents can be mixed in the mixing tank. Under the action of centrifugal force and capillary force, the sample will be filled with the outer pores of the disk, and the pores will be detected optically after the reaction is completed.

The InSight V-CHEM Kidney Panel is used to quantitative test the concentration of the seven biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:

a) Albumin (ALB)
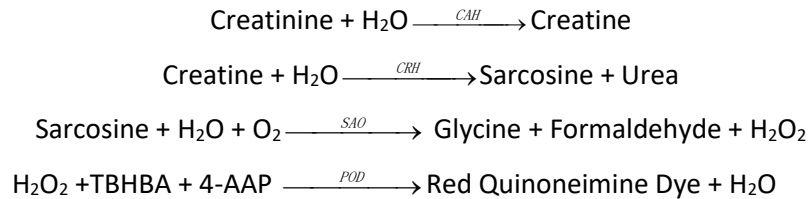
Bromocresol green (BCG), when bound with albumin, changes from a yellow to green colour. The absorbance maximum changes with the colour shift.

$$BCG + Albumin \xrightarrow{\text{Acid } pH} Albumin\ Complex$$
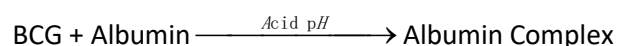
Bound albumin is proportional to the concentration of albumin in the sample. This is an endpoint reaction that is measured as the difference in absorbance between 600 nm and 700 nm.
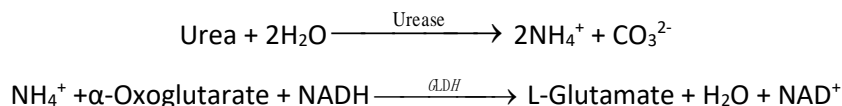
b) Creatinine (CRE)

In the coupled enzyme reactions, creatinine amidohydrolase (CAH) hydrolyses creatinine to creatine. A second enzyme, creatine amidinohydrolase (CRH), catalyses the formation of sarcosine from creatine. Sarcosine oxidase (SAO) causes the oxidation of sarcosine to glycine, formaldehyde and hydrogen peroxide (H_2O_2). In a Trinder finish, peroxidase (POD) catalyses the reaction among the hydrogen peroxide, 2, 4, 6-tribromo-3-hydroxybenzoic acid (TBHBA) and 4-aminoantipyrine (4-AAP) into a red quinoneimine dye. Potassium ferrocyanide and ascorbate oxidase are added to the reaction mixture to minimise the potential interference of bilirubin and ascorbic acid respectively.

$$\text{Creatinine} + H_2O \xrightarrow{\quad CAH \quad} \text{Creatine}$$

$$\text{Creatine} + H_2O \xrightarrow{\quad CRH \quad} \text{Sarcosine} + \text{Urea}$$

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

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

Two cuvettes are used to determine the concentration of creatinine in the sample. Endogenous creatine is measured in the blank cuvette, which is subtracted from the combined endogenous creatine and the creatine formed from the enzyme reactions in the test cuvette. Once the endogenous creatine is eliminated from the calculations, the concentration of creatinine is proportional to the intensity of the red colour produced. The endpoint reaction is measured as the difference in absorbance at 546 nm and 700 nm.

c) Urea Nitrogen (BUN)

In the coupled-enzyme reaction, urease hydrolyses urea into ammonia and carbon dioxide. Upon combining ammonia with α-oxoglutarate and reduced nicotinamide adenine dinucleotide (NADH), the enzyme glutamate dehydrogenase (GLDH) oxidises NADH to NAD^+.

$$\text{Urea} + 2H_2O \xrightarrow{\quad \text{Urease} \quad} 2NH_4^+ + CO_3^{2-}$$

$$NH_4^+ + \alpha\text{-Oxoglutarate} + \text{NADH} \xrightarrow{\quad GLDH \quad} \text{L-Glutamate} + H_2O + NAD^+$$

The rate of change of the absorbance difference between 340 nm and 405 nm is caused by the conversion of NADH to NAD^+ and is directly proportional to the amount of urea present in the sample.

d) Potassium (K^+)

In the coupled enzyme reaction, pyruvate kinase (PK) dephosphorylates phosphoenolpyruvate (PEP) to form pyruvate. Lactate dehydrogenase (LDH) catalyses conversion of pyruvate to lactate. Concomitantly, NADH is oxidised to NAD^+. The rate of change in absorbance due to the conversion of NADH to NAD^+ is directly proportional to the amount of potassium in the sample.

Interferences from other ions are minimised with the addition of some special ingredients.

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

$$\text{Pyruvate} + \text{NADH} + H^+ \xrightarrow{\quad LDH \quad} \text{Lactate} + NAD^+$$
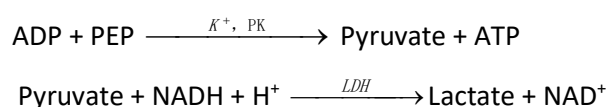
e) Calcium (Ca^{2+})

Calcium in the patient sample binds with arsenazo III to form a calcium-dye complex.

$$Ca^{2+} + \text{Arsenazo III} \longrightarrow Ca^{2+}\text{-Arsenazo III Complex}$$
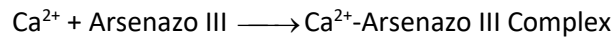
It is an endpoint reaction. The amount of total calcium in the sample is proportional to the absorbance.

f) Phosphorus (P)

The enzymatic method for the InSight V-CHEM uses maltose phosphorylase (MP) coupled through β-phosphoglucomutase (β-PGM) and glucose-6-phosphate dehydrogenase (G6PDH). The amount of NADH formed can be measured as an endpoint at 340/405 nm.

$$\text{Maltose + Pi} \xrightarrow{\quad MP \quad} \text{Glucose-1-Phosphate (G-1-P) + Glucose}$$

$$\text{Glucose-1-Phosphate (G-1-P)} \xrightarrow{\quad \beta-PGM \quad} \text{Glucose-6-Phosphate (G-6-P)}$$

$$\text{Glucose-6-Phosphate (G-6-P) + NAD}^+ \xrightarrow{\quad G6PDH \quad} \text{NADH+ 6-Phosphogluconate+H}^+$$

g) Carbon Dioxide (CO$_2$)

In the enzymatic method, the specimen is first made alkaline to convert all forms of carbon dioxide (CO_2) to bicarbonate (HCO_3^-). Phosphoenolpyruvate (PEP) and HCO_3^- then react to form oxaloacetate and phosphate in the presence of phosphoenolpyruvate carboxylase (PEPC). Malate dehydrogenase (MDH) catalyses the reaction of oxaloacetate and reduced nicotinamide adenine dinucleotide (NADH) to NAD$^+$ and malate. The rate of change in absorbance due to the conversion of NADH to NAD$^+$ is directly proportional to the amount of CO_2 in the sample.

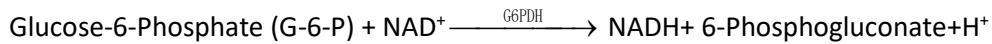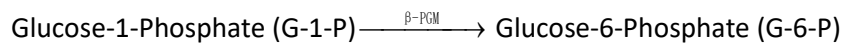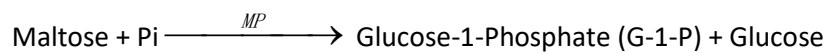$$\text{PEP + HCO}_3^- \xrightarrow{\quad PEPC \quad} \text{Oxaloacetate + Phosphate}$$

$$\text{Oxaloacetate + NADH + H}^+ \xrightarrow{\quad MDH \quad} \text{NAD}^+\text{+Malate}$$
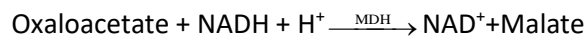
2.1. Normal Reference Ranges

These ranges are provided as a guideline only. It is recommended that your office or institution establish normal ranges for your particular patient population.

Analyte	SI Units	Common Units
ALB	Dog: 25 ~ 44g/L	Dog: 2.5 ~ 4.4 g/dL
	Cat: 27 ~ 45g/L	Cat: 2.7 ~ 4.5 g/dL
CRE	Dog: 27 ~ 118μmol/L	Dog: 0.3 ~ 1.3mg/dL
	Cat: 27 ~ 141μmol/L	Cat: 0.3 ~ 1.6mg/dL
BUN	Dog: 2.5 ~ 8.9mmol/L	Dog: 7 ~ 25mg/dL
	Cat: 3.6 ~ 10.7mmol/L	Cat: 10 ~ 30mg/dL
K^+	Dog: 3.7 ~ 5.8mmol/L	Dog: 3.7 ~ 5.8mmol/L
	Cat: 3.7 ~ 5.8mmol/L	Cat: 3.7 ~ 5.8mmol/L
Ca^{2+}	Dog: 2.15 ~ 2.95mmol/L	Dog: 8.6 ~ 11.8mg/dL
	Cat: 2 ~ 2.95mmol/L	Cat: 8.0 ~ 11.8mg/dL
P	Dog: 0.94 ~ 2.13mmol/L	Dog: 2.9 ~ 6.6mg/dL
	Cat: 1.1 ~ 2.74mmol/L	Cat: 3.4 ~ 8.5mg/dL
CO_2	Dog: 12 ~ 27mmol/L	Dog: 12 ~ 27mmol/L
	Cat: 15 ~ 24mmol/L	Cat: 15 ~ 24mmol/L

3. Evaluation Method

In this clinical evaluation study, the test system is provided by Woodley Equipment Company Ltd which is composed of an InSight V-CHEM Veterinary Chemistry Analyser and its associated Kidney Panel containing 7 biochemical detection items. The control system is a detection system consisting of Abaxis VS2 biochemical analyser and profiles.

The evaluation plan is designed with reference to the relevant regulations and authoritative professional guidelines for human medical clinical evaluation. The actual number of samples tested in each project is in line with statistical requirements.

Table 1-1 Number of Completed Projects in this Clinical Evaluation

	Comparative test of the same group of serum samples for control and test products
ALB	100
CRE	100
BUN	100
K^+	100
Ca^{2+}	100
P	100
CO_2	100

4. Experimental Procedure

4.1. Sample Selection Basis, Inclusion Criteria, Exclusion of Specimens, Rejection Criteria

The samples used in this clinical evaluation were the daily blood samples of the laboratory for the biochemistry analyser. Specimens that are detectable for the intended use of the test and control products.

According to the daily test results of the hospital and the requirements of the test plan for data distribution, samples that met the requirements were selected. When a range of samples was difficult to collect, two (but no more than two) samples of different concentrations were mixed to obtain a specific range of samples. When it was still difficult to collect a suitable sample using the above mixing method, dilution (salt dilution) was added (increasing the sample reagent ratio) to obtain a specific range of samples.

Selected samples were excluded according to the following a~b criteria:
a) The remaining sample size is less than 0.5mL, which is not enough to complete the test.
b) The number of samples has exceeded the number of planned tests for the day.

4.2. Quality Control Method

During the clinical evaluation process, the control system and the test system were measured before the measurement of the same batch of quality control products to ensure that the test results were under control. Control products and test products are tested daily for quality control before testing samples to ensure that the test results are under control.

4.3. Test Operation

Standard samples that met the criteria were selected and divided into two equal parts and tests were performed according to the operating system and test system operating instructions, and test results were recorded.

4.4. Data and Statistical Management

All test results were automatically recorded by the instrument. After the test, they were exported to the pre-designed record form, the original test record of this clinical trial, using Excel software for statistics.

5. Test Results

5.1. Evaluation Test Results (Default Unit mmol/L):

V-CHEM reagent value ALB g/L	VS2 reagent value ALB g/L	V-CHEM reagent value BUN	VS2 reagent value BUN	V-CHEM reagent value CRE umol/L	VS2 reagent value CRE umol/L	V-CHEM reagent value K+	VS2 reagent value K+	V-CHEM reagent value Ca2+	VS2 reagent value Ca2+	V-CHEM reagent value P	VS2 reagent value P	V-CHEM reagent value CO2	VS2 reagent value CO2
23.1	23	5.86	6.06	45	47	3.68	3.65	2.68	2.67	2.15	2.18	22	10
36.1	36.6	7	7.2	216	218	2.81	2.78	2.24	2.22	1.51	1.54	10	10
25.8	25.6	5.83	5.93	92	93	3.21	3.19	2.07	2.05	6.82	6.83	13	11
18.7	18.5	2.83	2.93	31	32	3.05	3.03	2.2	2.22	2	2.03	8	8
30.6	30.5	21.2	21.1	168	167	4.25	4.29	2.79	2.77	1.12	1.11	24	15
30.8	30.7	5.44	5.14	63	60	3.39	3.37	2.56	2.61	1.79	1.76	17	17
24.8	25	4.22	4.52	45	48	2.81	2.86	2.43	2.48	1.87	1.90	20	10
33.3	33.5	4.25	4.75	72	77	4.14	4.18	2.61	2.62	2.46	2.48	20	9
32.4	32.5	20.5	21	172	177	3.74	3.71	2.12	2.13	1.76	1.73	20	10
32.2	32.3	7.88	8.38	119	124	3.61	3.60	2.36	2.39	1.02	1.00	19	20
26.5	26.4	4.82	5.22	117	121	3.15	3.13	2.38	2.41	1.53	1.58	19	19
28.1	27.8	11.5	11.4	74	73	3.4	3.38	2.48	2.45	0.9	0.95	26	17
29.3	29.6	3.98	3.88	85	84	4.41	4.43	2.19	2.18	2.03	2.08	14	13
27.3	27.4	6.9	7.1	85	87	5.57	5.55	1.79	1.84	3.84	3.88	14	14
27.6	27.3	8.11	8.31	115	117	2.1	2.15	1.96	1.93	1.03	1.00	21	12
30.1	29.9	2.55	2.35	65	63	2.63	2.68	2.17	2.14	2.92	2.91	13	12
23.1	23.6	4.42	4.92	44	49	4.2	4.21	1.04	1.03	0.45	0.48	18	19
28.4	28.9	6.1	6.6	80	85	3.54	3.55	3.06	3.04	2.71	2.74	18	17
31.3	31.8	24.6	25.1	366	371	4.28	4.31	2.58	2.61	3.22	3.25	21	10
23.4	23.8	14	14.4	160	164	5.27	5.30	2.49	2.52	4.28	4.29	13	12
24.2	24.1	29.9	29.8	235	234	3.46	3.43	2.11	2.12	2.24	2.22	15	14
33	32.9	18.9	18.8	187	186	3.97	3.96	2.67	2.70	1.61	1.65	15	14
26.2	26.4	4.09	3.89	67	65	3.64	3.69	3.06	3.05	3.74	3.78	19	19
26	26.2	7.37	7.57	78	80	4.14	4.11	1.27	1.24	0.3	0.28	16	15
32	32.1	14	13.9	131	130	3.84	3.81	3.56	3.59	3.79	3.81	11	12

27.2	27.3	4.48	4.68	89	91	4.02	4.01	2.64	2.66	1.13	1.10	19	19
27.5	27.3	8.36	8.76	153	157	4.41	4.39	2.54	2.51	1.21	1.23	31	22
29.4	29.8	6.62	7.02	188	192	3.91	3.94	2.47	2.45	1.6	1.64	13	13
23.8	24.2	29.5	29.2	328	325	3.8	3.83	2.45	2.50	0.73	0.77	11	10
24.6	24.4	2.14	2.24	43	44	4.69	4.70	2.16	2.21	1.89	1.86	22	11
36.9	37.1	4.46	4.76	99	102	3.25	3.28	2.99	3.04	1.42	1.43	13	13
24.8	24.7	6.29	6.39	68	69	3.62	3.61	2.62	2.66	0.69	0.72	15	16
33.7	33.9	6.34	6.44	145	146	3.39	3.36	1.31	1.28	1.79	1.77	10	10
30.6	31	4.4	4.5	131	132	4.83	4.86	1.82	1.81	5.69	5.73	9	8
34.6	35	7.11	7.21	160	161	9.95	9.97	2.67	2.70	1.73	1.78	23	12
28.2	27.9	15.9	15.7	167	165	4.62	4.59	1.38	1.41	0.31	0.29	16	16
29.1	29.2	6.12	6.32	138	140	8.04	8.02	2.3	2.33	3.22	3.24	15	16
33.6	33.9	4	3.8	64	62	6.39	6.44	2.31	2.32	10.86	10.85	1	2
32.1	32	6.5	6.3	45	43	3.53	3.58	2.04	2.02	1.62	1.59	18	17
25.4	25.8	5	5.1	73	74	6.05	6.10	2.26	2.30	6.52	6.53	3	1
31.2	31.7	7.64	8.14	152	157	3.27	3.31	2.08	2.12	1.63	1.65	10	11
38.1	38	13.2	13.1	90	89	2.89	2.86	3.12	3.10	1.16	1.18	21	12
32.6	32.7	7.66	7.76	64	65	3.87	3.86	2.51	2.53	1.53	1.54	19	20
29.3	29.2	2.69	2.59	68	67	2.97	3.00	1.78	1.75	0.4	0.38	15	15
31.9	31.8	3.29	3.19	57	56	3.43	3.46	1.76	1.78	4.29	4.32	23	11
32.9	33	7.33	7.43	111	112	2.72	2.75	2.85	2.89	1.49	1.47	15	15
30.9	31	11.9	12	203	204	5.15	5.16	0.8	0.84	0.63	0.61	23	13
29.8	29.9	8.72	8.82	218	219	4.08	4.06	2.87	2.84	1.14	1.15	22	10
29.1	29.2	6.86	6.96	132	133	3.85	3.89	2.54	2.55	1.74	1.73	11	12
27.8	27.6	1.01	0.81	40	38	3.26	3.30	2.52	2.55	1.39	1.40	16	15
28.9	29.1	9.04	9.24	138	140	4.37	4.35	2.87	2.85	2.79	2.82	18	18
23.3	23.1	6.3	6.1	39	37	4.03	4.05	2.27	2.31	1.88	1.87	18	19
31	30.8	4.16	4.06	98	97	3.5	3.47	2.48	2.53	0.67	0.70	19	20
26.9	27	29.4	29.5	327	328	4.33	4.35	2.23	2.21	1.68	1.65	13	11
28.9	28.8	5.03	5.13	116	117	4.44	4.48	2.71	2.73	1.68	1.65	12	12
31.4	31.5	6.63	6.73	134	135	6.94	6.98	1.57	1.56	9.85	9.84	10	11
28.9	29.2	9.29	9.39	154	155	3.5	3.47	2.47	2.44	1.51	1.56	17	16
36.8	36.7	7.76	7.66	234	233	2.66	2.67	2.67	2.68	1.64	1.67	17	17
27.3	27.5	4.91	5.11	81	83	3.92	3.95	2.27	2.29	1.02	1.06	17	18
28.6	28.5	15.3	15.2	313	312	1.99	1.97	2.06	2.08	1.69	1.74	28	17
35.1	34.9	3.88	3.68	31	29	2.89	2.93	2.15	2.16	2.28	2.33	21	12
29.7	29.6	3.15	3.05	102	101	4.38	4.43	2.37	2.35	0.87	0.89	16	16
30.3	30.8	7.07	7.57	112	117	4.15	4.13	2.33	2.36	1.77	1.82	20	9
30.9	31.1	9.47	9.67	118	120	7.68	7.70	1.65	1.63	9.89	9.92	11	12

31.1	31.5	7.35	7.85	146	151	3.82	3.81	2.7	2.68	2.53	2.51	15	15
35	35.5	8.39	8.29	228	227	2.66	2.63	2.29	2.30	1.88	1.93	24	15
24.6	25.1	3.2	3.4	101	103	3.85	3.86	2.61	2.60	1.13	1.15	28	19
33.2	33.3	12.2	11.9	95	92	4.94	4.96	3.28	3.29	3.87	3.86	13	12
24.7	25.2	5.04	5.44	97	101	3.8	3.82	2.62	2.65	0.78	0.76	17	18
30	30.1	34.2	34.3	288	289	2.61	2.62	2.07	2.06	1.79	1.76	14	13
32.2	32	4.32	4.52	73	75	2.29	2.27	1.99	2.02	1.01	1.04	13	11
26.3	26.8	9.02	9.12	239	240	3.58	3.61	2.55	2.52	0.9	0.92	16	17
26.2	26.4	32.2	32.4	314	316	2.72	2.70	2.37	2.34	0	-0.03	6	5
31.8	31.7	5.6	5.7	67	68	5.26	5.24	2.52	2.51	0.52	0.55	14	15
28.5	28.3	17.8	17.9	347	348	3.92	3.93	2.65	2.70	1.62	1.60	17	18
29.4	29.3	7.16	7.06	122	121	3.42	3.41	2.43	2.46	1.21	1.26	25	14
33.9	34.2	6.61	6.91	59	62	3.76	3.77	2.64	2.68	1.55	1.60	22	11
28.2	28.3	8.58	8.68	84	85	3.5	3.53	2.86	2.91	1.97	2.01	18	17
24.7	24.5	19.2	19	267	265	3.22	3.21	3.08	3.13	1.21	1.24	18	17
28.3	28.6	28.2	28.5	393	396	3.15	3.18	2.23	2.25	1.66	1.71	14	13
30.2	30.1	8.79	8.69	180	179	3.69	3.66	2.51	2.56	1.28	1.25	21	11
30.9	31.4	9.27	9.77	145	150	3.77	3.74	2.21	2.24	1.21	1.22	21	12
30.8	31.3	5.99	6.49	76	81	4.1	4.09	3.03	3.01	2.68	2.70	20	10
32.2	32.6	34.9	35.3	231	235	3.51	3.56	2.41	2.46	1.86	1.91	19	19
34.2	34.4	9.16	9.36	44	46	2.47	2.50	1.47	1.49	2.01	1.99	23	11
27.5	28	8.84	9.34	114	119	4.06	4.10	2.43	2.42	2.34	2.36	17	18
29.8	29.6	15.3	15.1	184	182	2.73	2.78	1.82	1.80	2.92	2.89	21	11
31.2	31.3	8.02	8.12	50	51	3.97	4.02	2.67	2.64	1.05	1.09	14	15
34.6	34.7	7.14	7.24	101	102	5.34	5.36	2.49	2.52	5.06	5.09	5	5
35.2	35.7	7.25	7.75	105	110	2.82	2.87	2.85	2.87	0.89	0.91	20	11
29.9	29.8	17.4	17.3	280	279	3.86	3.89	2.96	2.93	2.07	2.10	18	18
20.9	21.1	28.1	28.3	86	88	2.86	2.84	2.48	2.51	1.46	1.48	19	18
27.1	26.8	9.37	9.07	84	81	3.16	3.21	2.58	2.56	4.5	4.51	10	10
24.7	25.1	4.76	4.66	65	64	3.31	3.33	2.51	2.56	1.53	1.54	21	10
32.4	32.5	10.2	10.7	79	84	4.01	4.00	0.97	1.02	0.79	0.77	19	19
30.9	31.1	10.5	11	149	154	4.18	4.16	2.97	3.01	1.65	1.69	13	13
29.8	29.9	1.95	2.35	37	41	3.56	3.53	2.58	2.61	2.05	2.03	17	16
29.5	29.7	29.3	29.5	253	255	4.04	4.07	1.73	1.78	2.49	2.54	13	12
33.2	33.3	6.38	6.88	76	81	3.83	3.85	2.3	2.27	1.26	1.25	20	9
30.2	30.3	4.05	3.85	92	90	4.14	4.11	2.59	2.60	1.18	1.15	12	12

5.2. Results Statistics and Analysis (ALB)

Data Mapping: Plot the difference between the measured value of the test system and the control system, and the measured value of the control system (the centre horizontal line is zero) and the measured system scatter plot (linear regression graph) of the test system and the control system. The results are shown below.
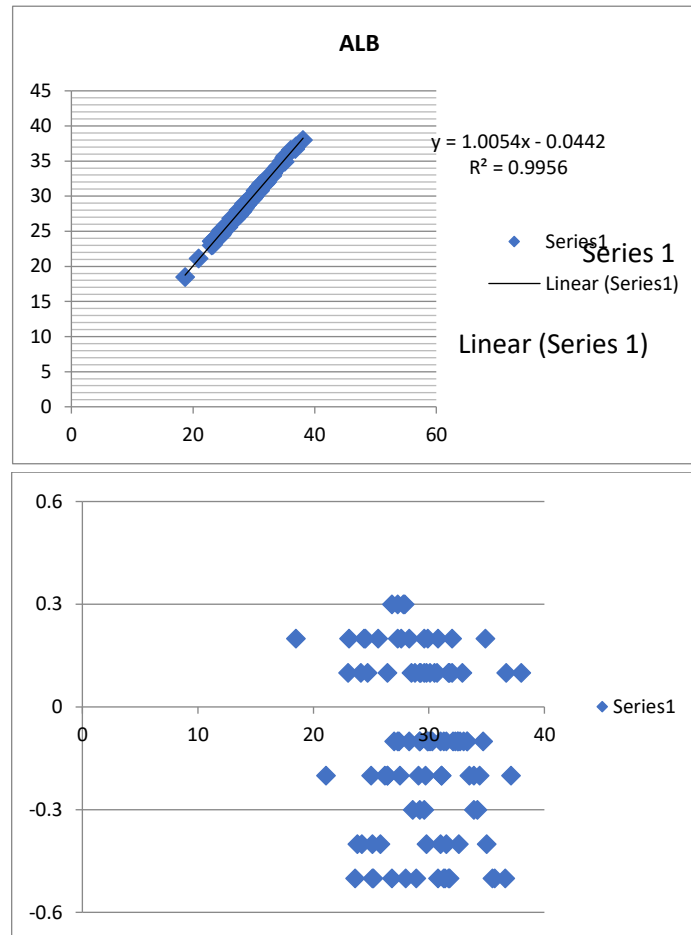
5.2.1. Visually Measure Linearity and Calculate Correlation Coefficient

The visual test system and the control system showed no outliers.

The correlation coefficient between the test system and the control system is r=0.9977, which is greater than 0.975. The range of values is appropriate and the correlation and consistency are good.
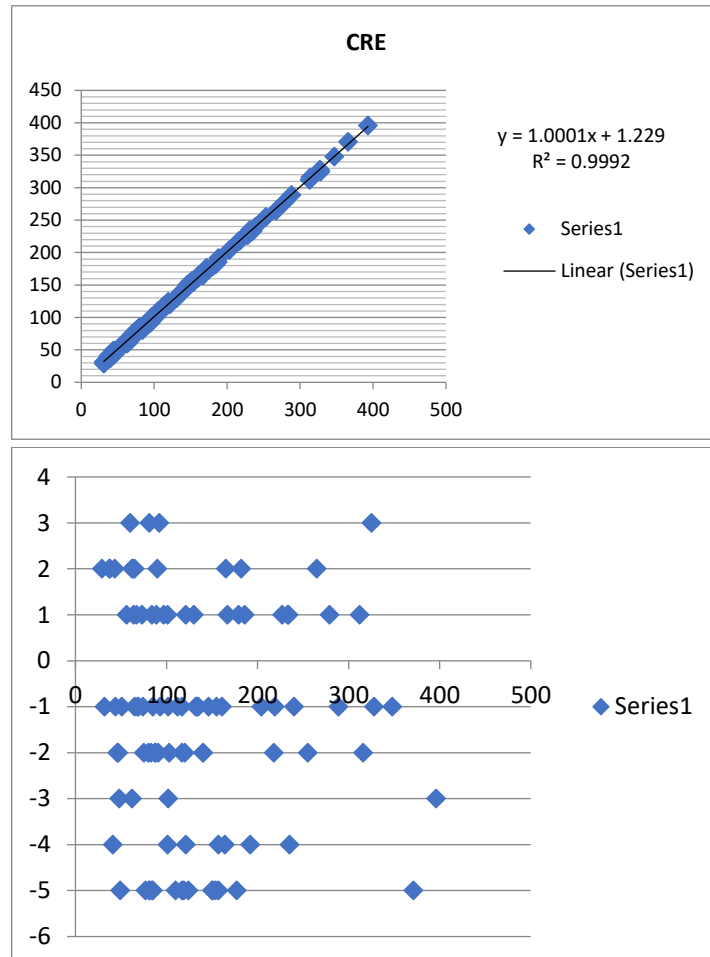
5.2.2. Linear Regression Analysis

Calculated regression equation y = 1.0054x - 0.0442

5.2.3. Statistical Analysis

The t-test was performed on the linear regression equations of the test system and the control system, and the t value was > t0.05, P < 0.05. There was a good linear relationship between the two groups of data, no significant difference.

5.3. Results Statistics and Analysis (BUN)

Data Mapping: Plot the difference between the measured value of the test system and the control system, and the measured value of the control system (the centre horizontal line is zero) and the measured system scatter plot (linear regression graph) of the test system and the control system. The results are shown below.

BUN

$y = 0.9996x + 0.1277$
$R^2 = 0.9991$

♦ Series1
—— Linear (Series1)

♦ Series1
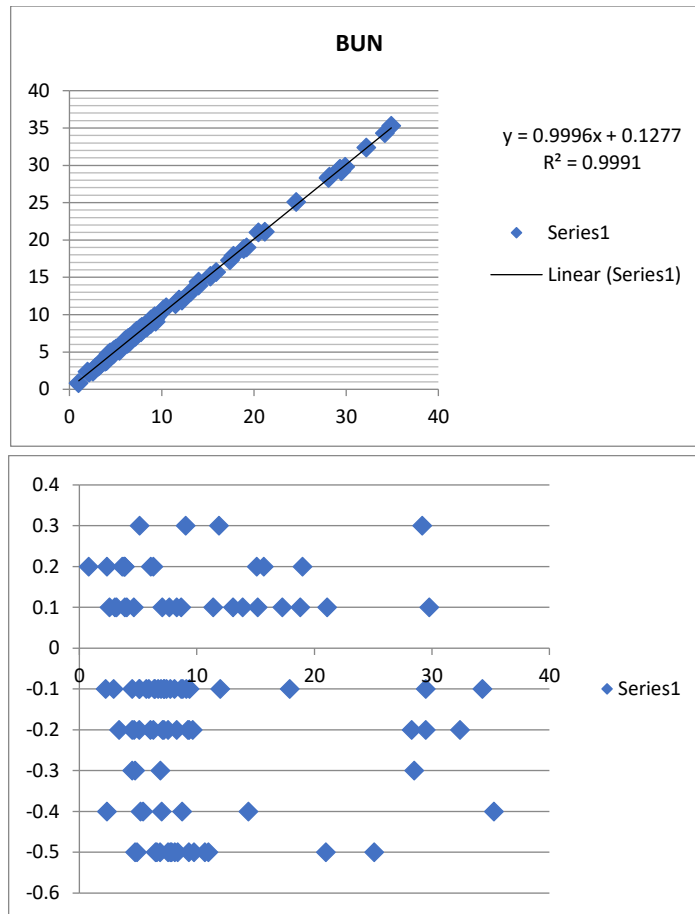
5.3.1. Visually Measure Linearity and Calculate Correlation Coefficient

The visual test system and the control system showed no outliers.

The correlation coefficient between the test system and the control system is r=0.9995, which is greater than 0.975. The range of values is suitable and the correlation and consistency are good.
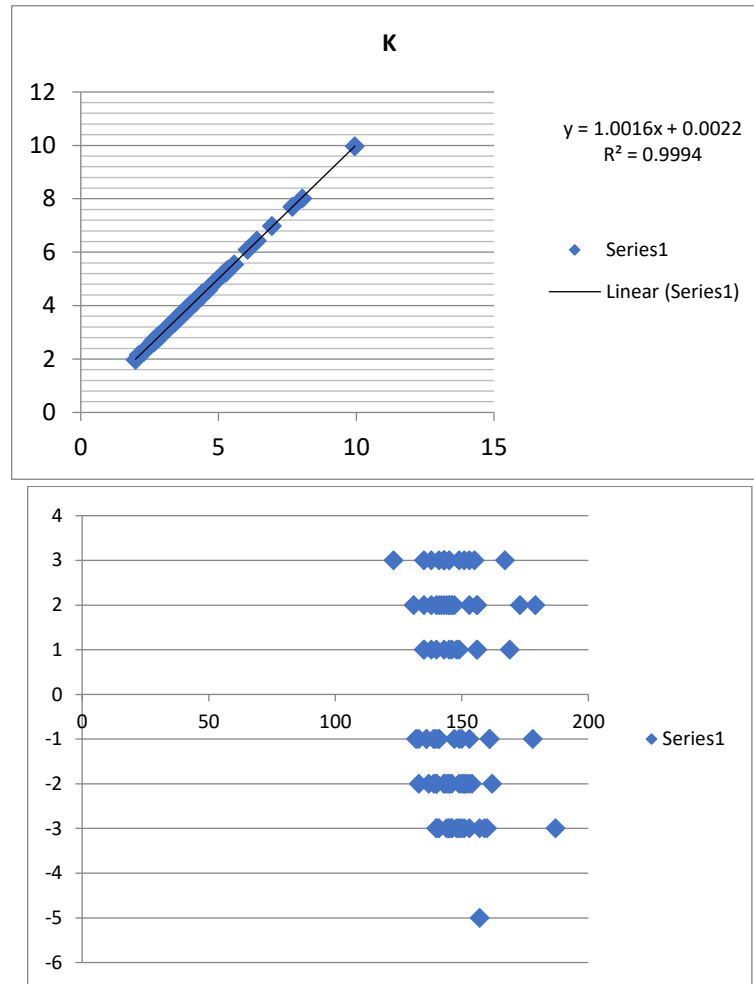
5.3.2. Linear Regression Analysis

Calculated regression equation $y = 0.9996x + 0.1277$

5.3.3. Statistical Analysis

The t-test was performed on the linear regression equations of the test system and the control system, and the t value was > t0.05, P < 0.05. There was a good linear relationship between the two groups of data, no significant difference.

5.4. Results Statistics and Analysis (CRE)

Data Mapping: Plot the difference between the measured value of the test system and the control system, and the measured value of the control system (the centre horizontal line is zero) and the measured system scatter plot (linear regression graph) of the test system and the control system. The results are shown below.

5.4.1. Visually Measure Linearity and Calculate Correlation Coefficient

The visual test system and the control system showed no outliers.

The correlation coefficient between the test system and the control system is calculated to be r=0.9996, which is greater than 0.975. The range of values is appropriate and the correlation and consistency are good.
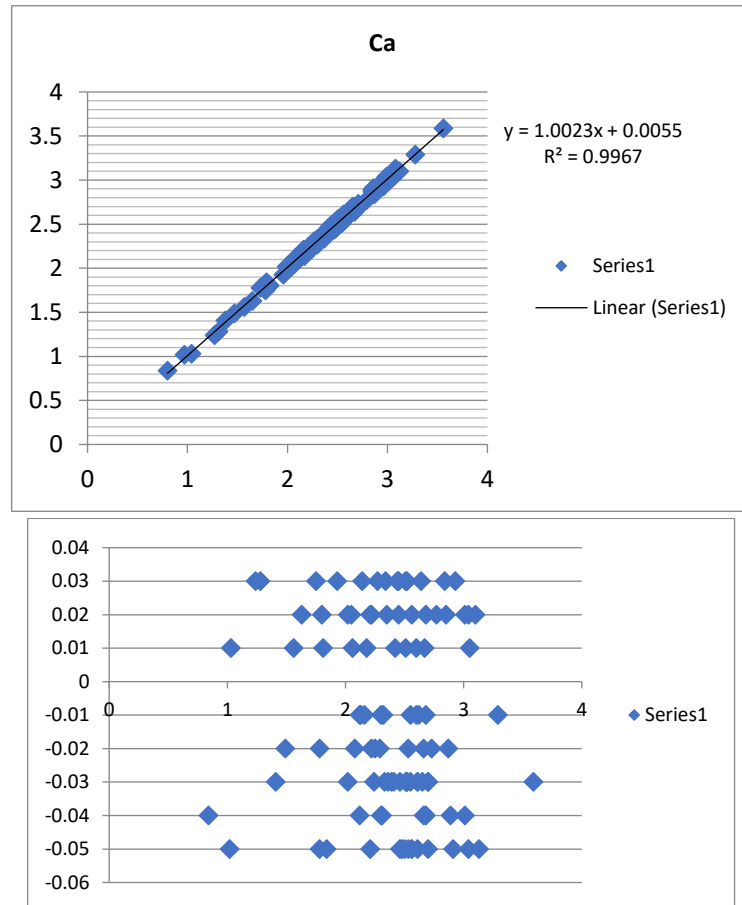
5.4.2. Linear Regression Analysis

Calculated regression equation y = 1.0001x + 1.229

5.4.3. Statistical Analysis

The t-test was performed on the linear regression equations of the test system and the control system, and the t value was > t0.05, P < 0.05. There was a good linear relationship between the two groups of data, no significant difference.

5.5. Results Statistics and Analysis (K)

Data Mapping: Plot the difference between the measured value of the test system and the control system, and the measured value of the control system (the centre horizontal line is zero) and the measured system scatter plot (linear regression graph) of the test system and the control system. The results are shown below.

5.5.1. Visually Measure Linearity and Calculate Correlation Coefficient

The visual test system and the control system showed no outliers.

The correlation coefficient between the test system and the control system is r=0.9997, which is greater than 0.975. The range of values is suitable and the correlation and consistency are good.

5.5.2. Linear Regression Analysis

Calculated regression equation y = 1.0016x + 0.0022

5.5.3. Statistical Analysis

The t-test was performed on the linear regression equations of the test system and the control system, and the t value was > t0.05, P < 0.05. There was a good linear relationship between the two groups of data, no significant difference.

5.6. Results Statistics and Analysis (Ca)

Data Mapping: Plot the difference between the measured value of the test system and the control system, and the measured value of the control system (the centre horizontal line is zero) and the measured system scatter plot (linear regression graph) of the test system and the control system. The results are shown below.

5.6.1. Visually Measure Linearity and Calculate Correlation Coefficient

The visual test system and the control system showed no outliers.

The correlation coefficient between the test system and the control system is r=0.9983, which is greater than 0.975. The range of values is suitable and the correlation and consistency are good.
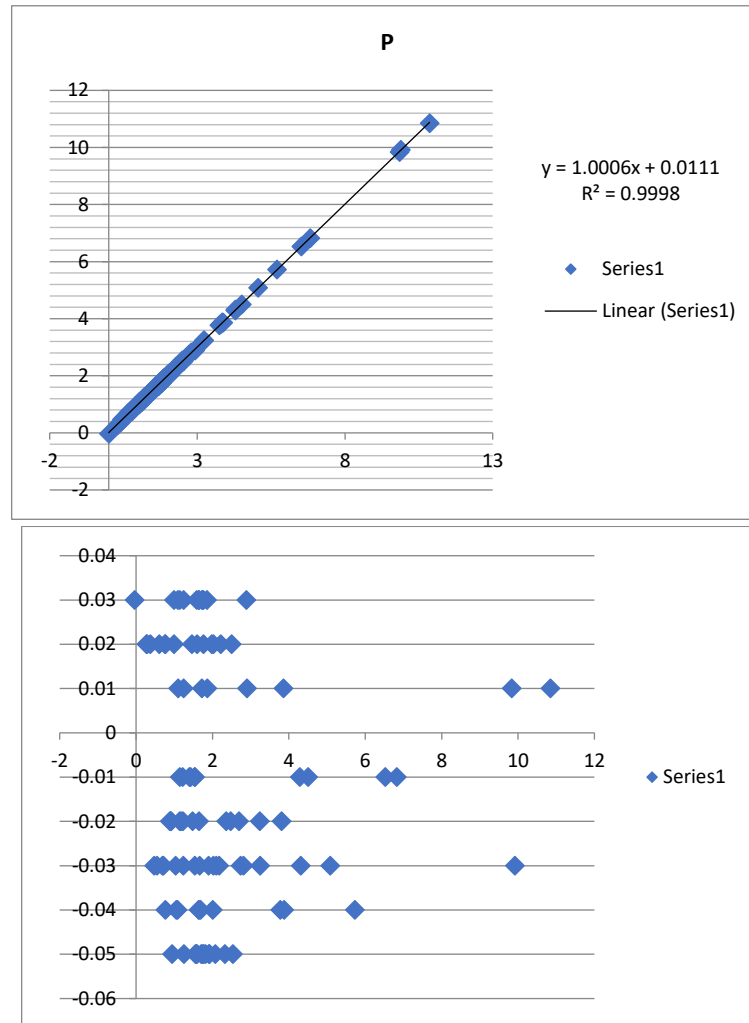
5.6.2. Linear Regression Analysis

Calculated regression equation y = 1.0023x + 0.0055

5.6.3. Statistical Analysis

The t-test was performed on the linear regression equations of the test system and the control system, and the t value was > t0.05, P < 0.05. There was a good linear relationship between the two groups of data, no significant difference.

5.7. Results Statistics and Analysis (P)

Data Mapping: Plot the difference between the measured value of the test system and the control system, and the measured value of the control system (the centre horizontal line is zero) and the measured system scatter plot (linear regression graph) of the test system and the control system. The results are shown below.

5.7.1. Visually Measure Linearity and Calculate Correlation Coefficient

The visual test system and the control system showed no outliers.

The correlation coefficient between the test system and the control system is r=0.9991, which is greater than 0.975. The range of values is suitable and the correlation and consistency are good.
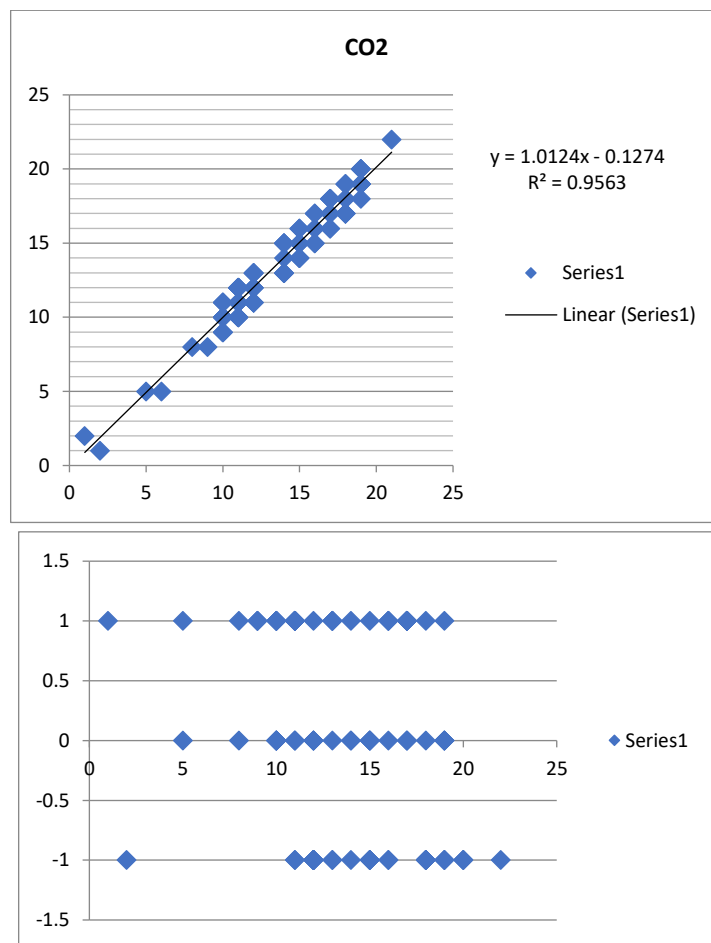
5.7.2. Linear Regression Analysis

Calculated regression equation y = 1.0006x + 0.0111

5.7.3. Statistical Analysis

The t-test was performed on the linear regression equations of the test system and the control system, and the t value was > t0.05, $P < 0.05$. There was a good linear relationship between the two groups of data, no significant difference.

5.8. Results Statistics and Analysis (CO2)

Data Mapping: Plot the difference between the measured value of the test system and the control system, and the measured value of the control system (the centre horizontal line is zero) and the measured system scatter plot (linear regression graph) of the test system and the control system. The results are shown below.

5.8.1. Visually Measure Linearity and Calculate Correlation Coefficient

The visual test system and the control system showed no outliers.
The correlation coefficient of the test system and the control system is calculated to be r=0.9780, which is greater than 0.975. The range of values is appropriate and the correlation and consistency are good.

5.8.2. Linear Regression Analysis

Calculated regression equation y = 1.0124x - 0.1274

5.8.3. Statistical Analysis

The t-test was performed on the linear regression equations of the test system and the control system, and the t value was > t0.05, P < 0.05. There was a good linear relationship between the two groups of data, no significant difference.

6. Clinical Evaluation Conclusion

The test results show that the test system is equivalent to the control system and the correlation is good. There is no significant difference between the two test results and there is no significant deviation in clinical test.

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