WOODLEY
EQUIPMENT COMPANY LTD.

InSight V-CHEM®

Veterinary Chemistry Analyser

Correlation Study – Avian & Reptile Panel

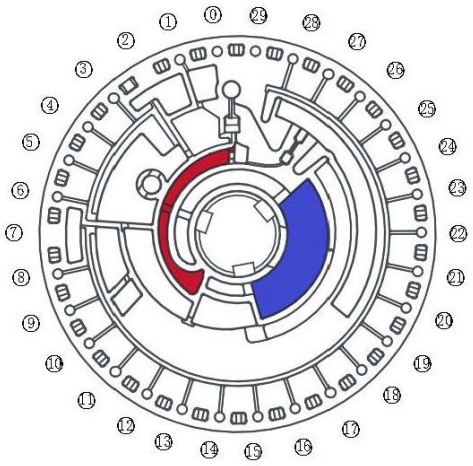
Contents

Approved By: _____ **Date:** 10/9/2021

1. Clinical Evaluation Purposes

This clinical evaluation trial is a set of comparison experiments to investigate the equivalence of the InSight V-CHEM Avian & Reptile Panel and control products on 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 underside of 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 disc and the pores will be detected optically after the reaction is completed.

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

a) Total Protein (TP)

The total protein method is a Biuret reaction, the protein solution is treated with cupric [Cu(II)] ions in a strong alkaline medium. The Cu(II) ions react with peptide bonds between the carbonyl oxygen and amide nitrogen atoms to form a coloured Cu-protein complex.

The amount of total protein present in the sample is directly proportional to the absorbance of the Cu-protein complex. The total protein test is an endpoint reaction and the absorbance is measured as the difference in absorbance between 546 nm and 800 nm.

$$\text{Total Protein} + \text{Cu(II)} \xrightarrow{OH^-} \text{Cu-Protein Complex}$$

b) Albumin (ALB)

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

$$\text{BCG + Albumin} \xrightarrow{\textit{Acid pH}} \text{Albumin Complex}$$

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.

c) Aspartate Aminotransferase (AST)

AST catalyses the reaction of L-aspartate and α-ketoglutarate into oxaloacetate and L-glutamate. Oxaloacetate is converted to malate and NADH is oxidised to NAD^+ by the catalyst MDH.

$$\text{L-aspartate + α-ketoglutarate} \xrightarrow{\text{AST}} \text{Oxaloacetate + L-glutamate}$$

$$\text{Oxaloacetate + NADH+H}^+ \xrightarrow{\text{MDH}} \text{Malate + NAD}^+$$

The rate of absorbance change at 340 /405 nm caused by the conversion of NADH to NAD^+ is directly proportional to the amount of AST present in the sample.

d) Creatine Kinase (CK)

Creatine kinase catalyses the formation of creatine and adenosine triphosphate (ATP) from creatine phosphate and adenosine diphosphate (ADP). With hexokinase (HK) as a catalyst, ATP reacts with D-glucose to form ADP and D-glucose-6-phosphate (G-6-P), which is reacted with nicotinamide adenine dinucleotide phosphate ($NADP^+$) in the presence of glucose-6-phosphate dehydrogenase (G-6-PDH) to produce 6-Phosphogluconate (6-PG) and NADPH.

The formation of NADPH is measured as a change in absorbance at 340 nm relative to 405 nm. This absorbance change is directly proportional to creatine kinase activity in the sample.

$$\text{Creatine phosphate + ADP} \xrightarrow{\text{CK}} \text{Creatine + ATP}$$

$$\text{ATP + D-glucose} \xrightarrow{\text{HK}} \text{ADP + G-6-P}$$

$$\text{G-6-P + NADP}^+ \xrightarrow{\text{G-6-PDH}} \text{6-Phosphogluconate + NADPH + H}^+$$

e) Glucose (GLU)

The reaction of glucose with adenosine triphosphate (ATP) catalysed by hexokinase (HK), produces glucose-6-phosphate (G-6-P) and adenosine diphosphate (ADP). Glucose-6-phosphate dehydrogenase (G-6-PDH) catalyses the reaction of G-6-P into 6-phosphogluconate and the reduction of nicotinamide adenine dinucleotide phosphate (NADP) to NADPH.

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

$$\text{G-6-P + NADP} \xrightarrow{\text{G-6-PDH}} \text{6-Phosphogluconate + NADPH+H}^+$$

The absorbance is measured bichromatically at 340 nm and 405 nm. The production of NADPH is directly proportional to the amount of glucose present in the sample.

f) Uric Acid (UA)

The uricase method is coupled through a Trinder peroxidase finish. In this method, uricase catalyses the oxidation (UAO) of uric acid to allantoin and hydrogen peroxide. Peroxidase (POD) catalyses the reaction among the hydrogen peroxide (H_2O_2), 4-aminoantipyrine (4-AAP) and 3,5-dichloro-2-hydroxybenzenesulfonic acid (DHBSA)into a red quinoneimine dye. Sodium ferrocyanide and ascorbate oxidase are added to the reaction mixture to minimise the potential interference of bilirubin and ascorbic acid.

$$\text{Uric acid} + O_2 + H_2O \xrightarrow{\text{UAO}} \text{Allantoin} + CO_2 + H_2O_2$$

$$H_2O_2 + \text{4-AAP} + \text{DHBSA} \xrightarrow{\text{POD}} \text{Quinoneimine dye} + H_2O$$

g) 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.

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

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

h) 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.

i) 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.

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

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

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

j) Sodium (Na^+)

In the enzymatic reaction, β-D-galactosidase is activated by the sodium in the sample. The activated enzyme catalyses the reaction of o-nitrophenyl-β-D-galactopyranoside (ONPG) to o-nitrophenol and galactose.

$$\text{ONPG} \xrightarrow{Na^+,\ \beta\text{-D-galactosidase}} \text{o-Nitrophenol + Galactose}$$

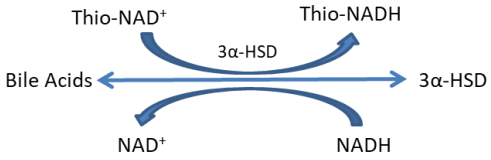
k) Chloride (Cl^-)

The method is based on the determination of chloride-dependent activation of α-amylase activity. Deactivated α-amylase is reactivated by addition of the chloride ion. The reactivation of α-amylase activity is proportional to the concentration of chloride ion in the sample. The reactivated α-amylase converts the substrate, 2-chloro-4-nitrophenyl-β-1,4-galactopyranosylmaltoside (CNP-G2) to 2-chloro-4-nitrophenol (CNP) producing colour and 1,4-galactopyranosylmaltoside. The reaction is measured bichromatically and the increase in absorbance is directly proportional to the reactivated α-amylase activity and the concentration of chloride ion in the sample.

$$\text{CNP-G2} \xrightarrow{Cl^-,\ \alpha\text{-amylase}} \text{CNP + G2}$$

l) Total Bile Acids (TBA)

In the presence of the thio-derivative of nicotinamide adenine dinucleotide (Thio-NAD+) the enzyme 3-α-Hydroxysteroid Dehydrogenase (3-α-HSD) reversibly oxidises bile acids to oxidised bile acids (3-α-keto forms) with the concomitant conversion of Thio-NAD+ to its reduced from Thio-NADH. In a cycling reaction, the oxidised bile acids are returned to their reduced state when excess NADH is present. The NADH is converted to NAD+. The rate of increase in absorbance at 405nm (Thio-NADH) is measured and is proportional to the concentration of bile acids in the sample. The rate is measured bichromatically at 405 and 500nm.



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
TP	Dog: 54 ~ 82g/L Cat: 54 ~ 82g/L	Dog: 5.4 ~ 8.2g/dL Cat: 5.4 ~ 8.2g/dL
ALB	Dog: 25 ~ 44g/L Cat: 27 ~ 45g/L	Dog: 2.5 ~ 4.4 g/dL Cat: 2.7 ~ 4.5 g/dL
UA	Dog: 0 ~ 60umol/L Cat: 0 ~ 60umol/L	Dog: 0 ~ 60umol/L Cat: 0 ~ 60umol/L
AST	Dog: 8.9 ~ 48.5U/L Cat: 9.2 ~ 39.5U/L	Dog: 8.9 ~ 48.5U/L Cat: 9.2 ~ 39.5U/L
GLU	Dog: 3.89 ~ 7.95mmol/L Cat: 4.11 ~ 8.84mmol/L	Dog: 70 ~ 143mg/dL Cat: 74 ~ 159mg/dL
K	Dog: 3.7 ~ 5.8mmol/L Cat: 3.7 ~ 5.8mmol/L	Dog: 3.7 ~ 5.8mmol/L Cat: 3.7 ~ 5.8mmol/L
TBA	Dog: 0 ~ 15µmol/L Cat: 0 ~ 15µmol/L	Dog: 0 ~ 15µmol/L Cat: 0 ~ 15µmol/L
CK	Dog: 20 ~ 200U/L Cat: 50 ~ 450U/L	Dog: 20 ~ 200U/L Cat: 50 ~ 450U/L
NA	Dog: 138 ~ 160mmol/L Cat: 142 ~ 164mmol/L	Dog: 138 ~ 160mmol/L Cat: 142 ~ 164mmol/L
Ca^{2+}	Dog: 2.15 ~ 2.95mmol/L Cat: 2 ~ 2.95mmol/L	Dog: 8.6 ~ 11.8mg/dL Cat: 8.0 ~ 11.8mg/dL
P	Dog: 0.94 ~ 2.13mmol/L Cat: 1.1 ~ 2.74mmol/L	Dog: 2.9 ~ 6.6mg/dL Cat: 3.4 ~ 8.5mg/dL
CL	Dog: 106 ~ 120mmol/L Cat: 112 ~ 126mmol/L	Dog: 106 ~ 120mmol/L Cat: 112 ~ 126mmol/L

3. Evaluation Method

In this clinical evaluation study, the test system is provided by Woodley Equipment Company which is composed of an InSight V-CHEM Veterinary Chemistry Analyser and its associated Avian & Reptile Panel containing 12 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 veterinary 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
TP	100
ALB	100
AST	100
UA	100
K	100
CK	100
NA	100
Ca	100
P	100
CL	100
GLU	100
TBA	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 TP g/L	VS2 reagent value TP g/L	V-CHEM reagent value AST U/L	VS2 reagent value AST U/L	V-CHEM reagent value UA U/L	VS2 reagent value UA U/L	V-CHEM reagent value K U/L	VS2 reagent value K U/L	V-CHEM reagent value NA	VS2 reagent value NA	V-CHEM reagent value GLU	VS2 reagent value GLU
23.7	23.9	61	61.5	41	43	29	28	3.68	3.65	158	156	5.73	5.56
19.4	19.6	92.8	93.3	50	52	137	139	2.81	2.78	131	132	5.61	5.29
30.4	30.5	62.2	62.7	32	33	74	75	3.21	3.19	148	146	5.4	5.19
21.1	21.2	58.5	58.9	33	34	32	35	3.05	3.03	141	143	14.59	14.51
29.4	29.3	64.1	64	21	20	64	68	4.25	4.29	177	178	14.62	14.02
25.2	24.9	48.6	48.5	222	221	272	270	3.39	3.37	148	146	14.66	14.89
38.6	38.9	83.7	83.8	61	62	28	27	2.81	2.86	141	140	11.06	11.31
33.4	33.9	73.4	73.5	42	44	68	72	4.14	4.18	144	142	5.94	6.27
23.7	24.2	60.7	60.6	104	106	26	30	3.74	3.71	137	135	6.17	6.6
27	27.5	68.4	68.9	22	24	110	108	3.61	3.60	151	153	13.25	13.17
25.7	26.1	67.9	68.3	41	45	54	62	3.15	3.13	149	147	6.52	5.86
25.3	25.2	69.9	69.8	87	86	80	82	3.4	3.38	138	140	5.26	5.81
21.1	21	84.6	84.5	16	15	58	52	4.41	4.43	144	143	6.15	5.56
37.7	37.9	64.5	64.6	17	19	57	54	5.57	5.55	131	132	6.32	5.73
32.1	32.3	79.4	79.5	27	29	59	61	2.1	2.15	135	136	3.91	3.79
31.2	31	81.6	81.5	48	46	32	35	2.63	2.68	137	140	11.93	12.38
31.5	32	68.1	68.6	27	29	342	343	4.2	4.21	141	144	7.32	7.84
30.3	30.8	57.7	58.2	23	25	20	18	3.54	3.55	146	143	2.82	2.51
27.1	27.6	62.3	62.8	14	16	55	56	4.28	4.31	157	156	12.19	12.8
28.9	29.3	64.3	64.7	72	76	152	146	5.27	5.30	150	152	6.85	7.36
32.7	32.6	67.9	68	41	40	68	68	3.46	3.43	141	138	16.23	16.58
34.6	34.5	68.6	68.7	72	71	575	569	3.97	3.96	154	151	7.68	7.63
36.5	36.3	68.8	68.7	38	36	132	130	3.64	3.69	146	145	7.48	6.94
23.1	23.3	75.8	76.3	16	18	87	88	4.14	4.11	175	173	5.65	5.53
30.9	30.8	60.7	61.2	21	20	76	75	3.84	3.81	150	153	5.84	6.03
33.4	33.6	71.8	71.9	80	82	25	24	4.02	4.01	143	146	6.47	6.97
30	30.4	69.9	70.3	36	40	29	28	4.41	4.39	140	141	6.43	6.99
32.6	33	66.8	67.2	12	16	137	139	3.91	3.94	137	140	4.75	5.05
20.1	19.8	51.1	50.8	61	58	74	75	3.8	3.83	136	135	4.79	4.57
29.5	29.6	72.3	72.4	27	28	32	35	4.69	4.70	146	143	5	5.35

29.8	30.1	68.1	68.4	23	26	64	68	3.25	3.28	157	160	6.47	6.15
27	27.1	58.5	58.6	32	33	575	569	3.62	3.61	143	145	5.3	5.58
31.1	31.2	70.6	70.7	27	28	132	130	3.39	3.36	146	143	8.1	7.57
30.3	30.8	64.2	64.7	21	22	87	88	4.83	4.86	155	153	22.51	21.9
28.5	29	82.5	83	51	52	76	75	9.95	9.97	152	157	4.96	4.33
21.9	22.3	71.7	72.1	24	22	25	24	4.62	4.59	138	140	6.25	6.17
28.4	28.3	67.8	67.9	40	42	225	226	8.04	8.02	143	146	3.12	3.41
33	32.9	63.2	63.3	48	46	69	69	6.39	6.44	149	151	4.42	4.92
27	26.8	64	63.9	25	23	38	39	3.53	3.58	136	135	5.39	5.97
26.1	26.2	66.5	67	32	33	80	81	6.05	6.10	139	138	6.2	5.64
33	33.5	62.6	63.1	42	44	44	46	3.27	3.31	156	159	8.16	8.35
33.4	33.3	61.2	61.1	25	24	57	58	2.89	2.86	148	151	6.19	6.53
25.1	25.2	64.3	64.4	18	19	49	51	3.87	3.86	132	133	6.49	6
28.7	29.2	62.5	63	25	24	67	66	2.97	3.00	135	136	5.82	6.1
36.1	36.6	64.7	65.2	15	14	25	24	3.43	3.46	181	179	5.76	5.43
29.5	29.9	53.8	54.2	75	76	90	88	2.72	2.75	149	151	4.54	4.64
20.6	20.5	49.9	49.8	105	106	55	57	5.15	5.16	152	153	5.85	5.5
20.8	20.7	44.2	44.3	344	345	86	84	4.08	4.06	147	145	6.9	7.03
30.9	31	72.9	73	18	19	32	31	3.85	3.89	143	145	5.96	5.66
32.9	32.7	76.9	76.8	20	18	66	65	3.26	3.30	170	167	5.67	6.17
28.3	28.5	65.6	66.1	39	41	473	468	4.37	4.35	147	149	5.12	5.06
35.3	35.1	81.2	81.7	29	27	71	70	4.03	4.05	141	143	5.93	5.39
35.4	35.3	73.1	73	28	27	113	109	3.5	3.47	138	139	5.35	4.89
39.3	39.4	81.8	81.9	32	33	85	82	4.33	4.35	156	153	3.73	3.83
16.2	16.3	53.6	53.7	69	70	224	222	4.44	4.48	160	161	5.56	5.05
33.5	33.6	59.7	59.8	37	38	82	81	6.94	6.98	146	149	7.31	6.74
32.3	32.8	63	63.5	61	62	84	79	3.5	3.47	158	156	5.35	5.63
36.1	36.6	79.4	79.9	50	49	26	25	2.66	2.67	160	162	7.78	7.72
33.3	33.7	77.6	78	31	33	90	91	3.92	3.95	148	150	7	6.87
27.3	27.2	71.8	71.7	50	49	69	72	1.99	1.97	143	141	10.86	11.44
29.3	29.2	69.7	69.8	24	22	168	170	2.89	2.93	137	139	6.58	6.81
28	27.9	84	84.1	20	19	60	59	4.38	4.43	170	169	8.5	9.05
30.9	31.4	68.6	68.5	29	31	23	25	4.15	4.13	152	149	5.16	4.67
27.6	27.8	83.4	83.9	386	388	272	275	7.68	7.70	160	161	15.74	16.05
32.8	33.3	79.2	79.7	37	39	67	65	3.82	3.81	144	146	6.63	6.71
35.3	35.2	59.4	59.3	20	19	190	191	2.66	2.63	135	137	6.1	5.5

34.9	35.1	75	75.1	23	25	71	70	3.85	3.86	148	149	4.26	3.73
37	36.7	62.5	62.2	28	27	59	55	4.94	4.96	145	143	6.26	6.71
35.4	35.8	56.3	56.7	21	25	346	349	3.8	3.82	142	145	4.91	5.28
25.1	25.2	71.6	71.7	78	79	81	83	2.61	2.62	146	144	6.25	6.42
24	24.2	57.7	57.8	38	40	157	160	2.29	2.27	133	131	4.96	4.98
28.8	28.9	66.8	66.9	89	90	611	608	3.58	3.61	138	139	5.21	5.2
28.5	28.7	62.5	62.6	23	25	45	43	2.72	2.70	147	146	5.67	5.75
26.6	27.1	65.8	66.3	103	104	79	78	5.26	5.24	140	141	5.36	5.18
21.6	22.1	48.1	48.6	166	167	63	65	3.92	3.93	154	157	4.84	5.25
25.7	26.1	66	66.4	78	77	90	89	3.42	3.41	157	156	5.38	5.98
29.8	29.7	70.7	70.8	35	38	60	66	3.76	3.77	145	148	5.51	5.18
31.5	31.4	64.5	64.6	23	24	16	20	3.5	3.53	148	145	4.85	4.77
20.7	20.5	36.6	36.5	678	676	202	199	3.22	3.21	158	155	11.47	11.64
26.5	26.8	41.8	42.3	717	720	132	134	3.15	3.18	149	148	6.12	6.32
35.7	35.6	62.6	63.1	23	22	83	85	3.69	3.66	149	150	5.51	5.4
33.2	33.7	75.6	76.1	35	37	262	263	3.77	3.74	142	145	6.14	6.68
36.9	37.4	79.8	80.3	47	49	70	72	4.1	4.09	149	151	6.45	6.08
30.1	30.5	69.2	69.6	50	54	58	56	3.51	3.56	139	140	5.85	6.37
27.4	27.6	56.5	56.6	87	89	115	117	2.47	2.50	144	141	4.71	5.28
29.4	29.9	67.8	68.3	23	25	55	60	4.06	4.10	152	154	7.84	7.56
31.4	31.2	67	66.9	29	27	74	73	2.73	2.78	131	133	4.55	4.43
21.7	21.8	51.9	52	92	93	68	70	3.97	4.02	138	141	7.54	7.88
19.3	19.4	65.2	65.3	23	24	156	157	5.34	5.36	142	140	5.57	5.39
25.2	25.7	44	43.9	671	673	219	220	2.82	2.87	146	147	16.66	16.51
21.3	21.2	40.8	41.3	566	565	91	93	3.86	3.89	138	140	3.22	2.97
33.4	33.6	61.8	62.3	38	40	55	54	2.86	2.84	150	149	9.23	8.67
28	27.7	68.8	68.5	46	45	75	77	3.16	3.21	147	145	5.47	5.81
25.9	25.8	54.8	54.7	22	21	218	222	3.31	3.33	138	135	6.45	6.27
21.9	22.4	63.8	64.3	50	52	75	78	4.01	4.00	146	149	9.59	10.21
27.3	27.8	73	73.5	17	19	183	181	4.18	4.16	142	144	5.94	5.33
34.6	35	71.7	72.1	40	44	190	192	3.56	3.53	126	123	8.95	8.8
35.7	35.9	72.2	72.3	123	125	162	163	4.04	4.07	184	187	5.82	6.06
33.7	34.2	64.9	65.4	32	34	41	40	3.83	3.85	140	138	14.57	14.96
23	22.8	62.9	62.8	46	44	266	267	4.14	4.11	147	150	4.37	4.26

V-CHEM reagent value Ca2+	VS2 reagent value Ca2+	V-CHEM reagent value P	VS2 reagent value P	V-CHEM reagent value CK U/L	VS2 reagent value CK U/L	V-CHEM reagent value CL U/L	VS2 reagent value CL U/L	V-CHEM reagent value TBA U/L	VS2 reagent value TBA U/L
2.68	2.67	2.15	2.18	197	202	119	117	24.8	25.1
2.24	2.22	1.51	1.54	196	192	118	119	24.7	25.3
2.07	2.05	6.82	6.83	183	181	145	144	25.3	24.7
2.2	2.22	2	2.03	570	571	110	111	25.6	24.8
2.79	2.77	1.12	1.11	546	551	117	120	24.3	24.9
2.56	2.61	1.79	1.76	569	572	118	117	24.9	25.3
2.43	2.48	1.87	1.90	285	281	156	159	25.3	25.2
2.61	2.62	2.46	2.48	206	213	118	116	25.1	24.8
2.12	2.13	1.76	1.73	96	92	120	118	24.8	25.4
2.36	2.39	1.02	1.00	59	66	115	116	24.6	24.6
2.38	2.41	1.53	1.58	96	93	116	115	25.5	24.9
2.48	2.45	0.9	0.95	143	149	92	93	25.9	25.9
2.19	2.18	2.03	2.08	156	156	130	129	25.8	25.7
1.79	1.84	3.84	3.88	34	34	92	93	24.2	25.5
1.96	1.93	1.03	1.00	95	96	115	116	24.7	24.3
2.17	2.14	2.92	2.91	523	522	121	122	24.6	24.7
1.04	1.03	0.45	0.48	96	92	125	124	25.5	25.1
3.06	3.04	2.71	2.74	164	161	117	118	24.8	25.3
2.58	2.61	3.22	3.25	399	395	118	117	25.6	24.4
2.49	2.52	4.28	4.29	341	343	113	115	24.5	24.2
2.11	2.12	2.24	2.22	259	264	124	121	25.3	26.1
2.67	2.70	1.61	1.65	213	220	111	108	24.7	25.8
3.06	3.05	3.74	3.78	240	245	118	117	24.9	24.5
1.27	1.24	0.3	0.28	180	175	120	118	25.4	25.4
3.56	3.59	3.79	3.81	200	199	129	132	25.8	25.8
2.64	2.66	1.13	1.10	75	77	122	125	25.4	24.5
2.54	2.51	1.21	1.23	200	207	103	104	25.2	24.8

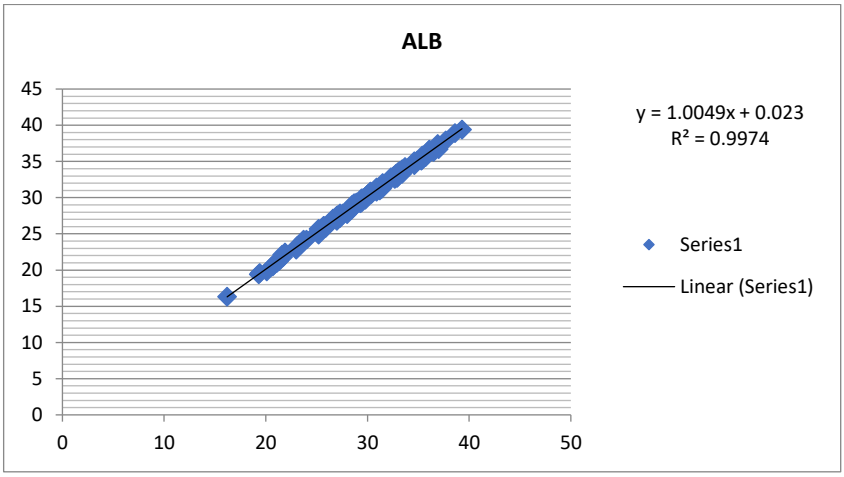
2.47	2.45	1.6	1.64	185	186	124	127	24.8	25.1
2.45	2.50	0.73	0.77	239	238	123	122	25.5	24.3
2.16	2.21	1.89	1.86	68	70	118	115	25.1	25.3
2.99	3.04	1.42	1.43	166	163	127	130	24.7	25.6
2.62	2.66	0.69	0.72	428	428	137	135	25.2	25.9
1.31	1.28	1.79	1.77	147	146	126	127	26.1	24.7
1.82	1.81	5.69	5.73	579	582	125	124	25.2	24.6
2.67	2.70	1.73	1.78	102	103	121	122	24.9	24.8
1.38	1.41	0.31	0.29	277	284	113	116	25.8	25.4
2.3	2.33	3.22	3.24	48	52	114	113	24.3	25.9
2.31	2.32	10.86	10.85	99	105	150	153	24.7	24.6
2.04	2.02	1.62	1.59	94	97	116	115	25.6	25.8
2.26	2.30	6.52	6.53	184	181	112	111	25.9	24.4
2.08	2.12	1.63	1.65	538	544	130	133	24.6	24.1
3.12	3.10	1.16	1.18	83	88	115	118	24.8	25.6
2.51	2.53	1.53	1.54	225	221	102	103	25.3	26.2
1.78	1.75	0.4	0.38	113	117	111	112	25.6	25.7
1.76	1.78	4.29	4.32	90	85	245	243	24.1	24.9
2.85	2.89	1.49	1.47	202	202	106	108	24.4	24.9
0.8	0.84	0.63	0.61	104	102	114	115	24.6	25.4
2.87	2.84	1.14	1.15	388	390	124	122	25.7	25.3
2.54	2.55	1.74	1.73	142	149	126	124	43.6	43.3
2.52	2.55	1.39	1.40	154	161	117	118	44.5	44.2
2.87	2.85	2.79	2.82	114	116	106	105	42.3	42.6
2.27	2.31	1.88	1.87	164	166	116	117	42.9	42.8
2.48	2.53	0.67	0.70	642	649	126	129	43.7	44.2
2.23	2.21	1.68	1.65	93	97	119	118	44.2	43.4
2.71	2.73	1.68	1.65	136	143	114	117	42.2	42.9
1.57	1.56	9.85	9.84	230	237	100	103	42.8	42.1
2.47	2.44	1.51	1.56	71	70	125	123	43.3	43.5

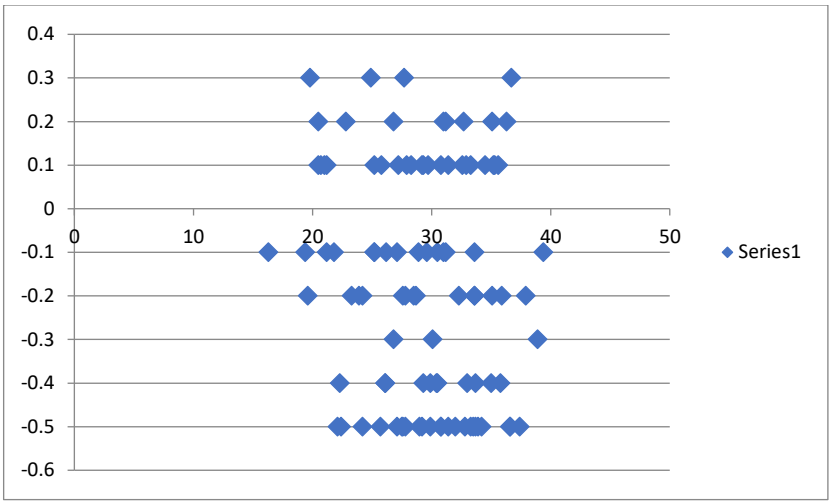
2.67	2.68	1.64	1.67	230	234	131	133	43.8	44.1
2.27	2.29	1.02	1.06	116	118	113	115	42.5	42.7
2.06	2.08	1.69	1.74	184	187	121	119	42.4	41.9
2.15	2.16	2.28	2.33	83	79	119	120	42.7	42.9
2.37	2.35	0.87	0.89	119	122	120	119	43.8	43.4
2.33	2.36	1.77	1.82	191	188	110	111	43.9	43.5
1.65	1.63	9.89	9.92	57	53	105	106	41.9	42.5
2.7	2.68	2.53	2.51	118	116	103	105	42.7	42.9
2.29	2.30	1.88	1.93	45	40	117	119	43.7	43.4
2.61	2.60	1.13	1.15	64	63	109	110	44.2	43.8
3.28	3.29	3.87	3.86	116	123	105	103	43.8	43.4
2.62	2.65	0.78	0.76	142	143	113	116	43.6	42.5
2.07	2.06	1.79	1.76	32	28	128	126	42.5	43.6
1.99	2.02	1.01	1.04	154	155	110	108	42.9	43.4
2.55	2.52	0.9	0.92	109	114	120	121	43.3	42.6
2.37	2.34	0	-0.03	218	220	135	134	43.7	42.1
2.52	2.51	0.52	0.55	209	216	93	94	42.8	43.8
2.65	2.70	1.62	1.60	87	90	118	121	42.9	43.5
2.43	2.46	1.21	1.26	32	32	124	123	43.6	42.6
2.64	2.68	1.55	1.60	300	298	125	128	43.8	43.5
2.86	2.91	1.97	2.01	187	192	114	111	42.2	42.9
3.08	3.13	1.21	1.24	740	740	115	112	42.9	43.3
2.23	2.25	1.66	1.71	177	177	123	122	43.8	44.2
2.51	2.56	1.28	1.25	304	309	122	123	43.4	42.4
2.21	2.24	1.21	1.22	156	159	114	117	42.6	42.9
3.03	3.01	2.68	2.70	36	33	122	124	41.5	43.6
2.41	2.46	1.86	1.91	367	367	112	113	41.9	43.9
1.47	1.49	2.01	1.99	153	148	114	111	43.5	42.6
2.43	2.42	2.34	2.36	282	283	122	124	43.8	43.2
1.82	1.80	2.92	2.89	105	109	112	114	42.6	43.8

2.67	2.64	1.05	1.09	298	298	116	119	43.6	43.1
2.49	2.52	5.06	5.09	176	182	115	113	41.9	42.2
2.85	2.87	0.89	0.91	429	430	102	103	43.9	42.6
2.96	2.93	2.07	2.10	370	372	110	112	42.5	43.7
2.48	2.51	1.46	1.48	137	135	119	118	43.2	44.1
2.58	2.56	4.5	4.51	189	193	128	126	43.5	43.5
2.51	2.56	1.53	1.54	690	691	108	106	42.7	42.3
0.97	1.02	0.79	0.77	429	424	118	119	42.9	42.6
2.97	3.01	1.65	1.69	61	60	132	131	43.4	43.8
2.58	2.61	2.05	2.03	704	701	121	122	43.6	43.3
1.73	1.78	2.49	2.54	70	74	132	135	44.5	44.2
2.3	2.27	1.26	1.25	394	401	116	115	42.3	42.6
2.59	2.60	1.18	1.15	143	139	150	153	42.9	42.8

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=0.9986 which is greater than 0.975. The range of values is suitable and the correlation and consistency are good.

5.2.2. Linear Regression Analysis

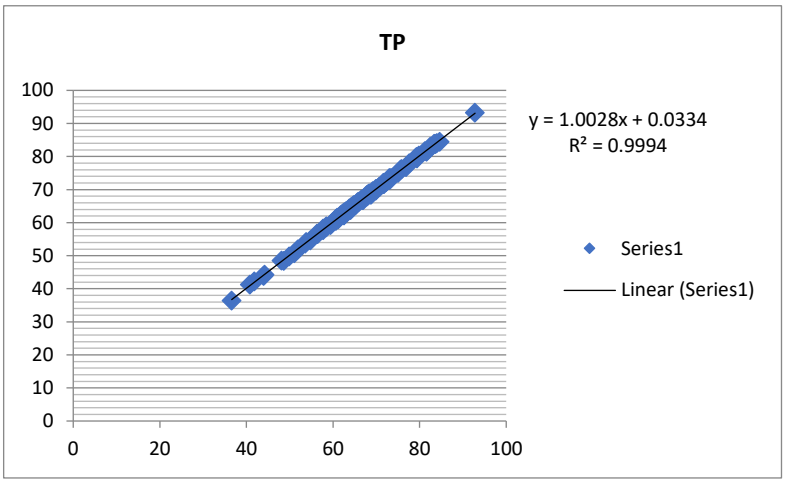
Calculated regression equation y = 1.0049x + 0.023

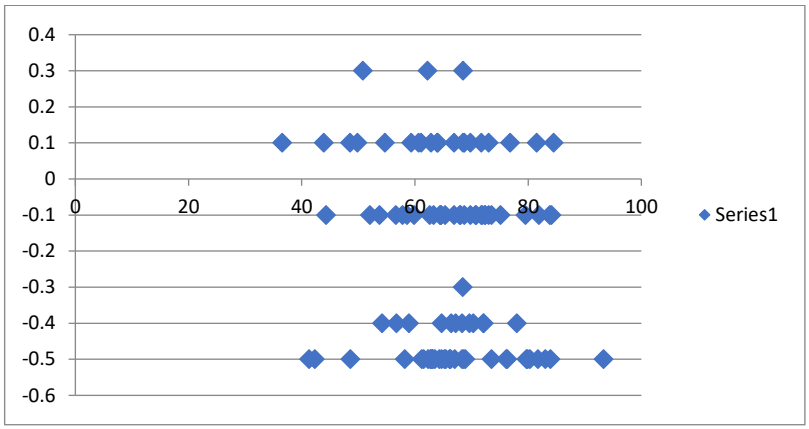
5.2.3. Statistical Analysis

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 (TP)

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.





5.3.1. 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 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.

5.3.2. Linear Regression Analysis

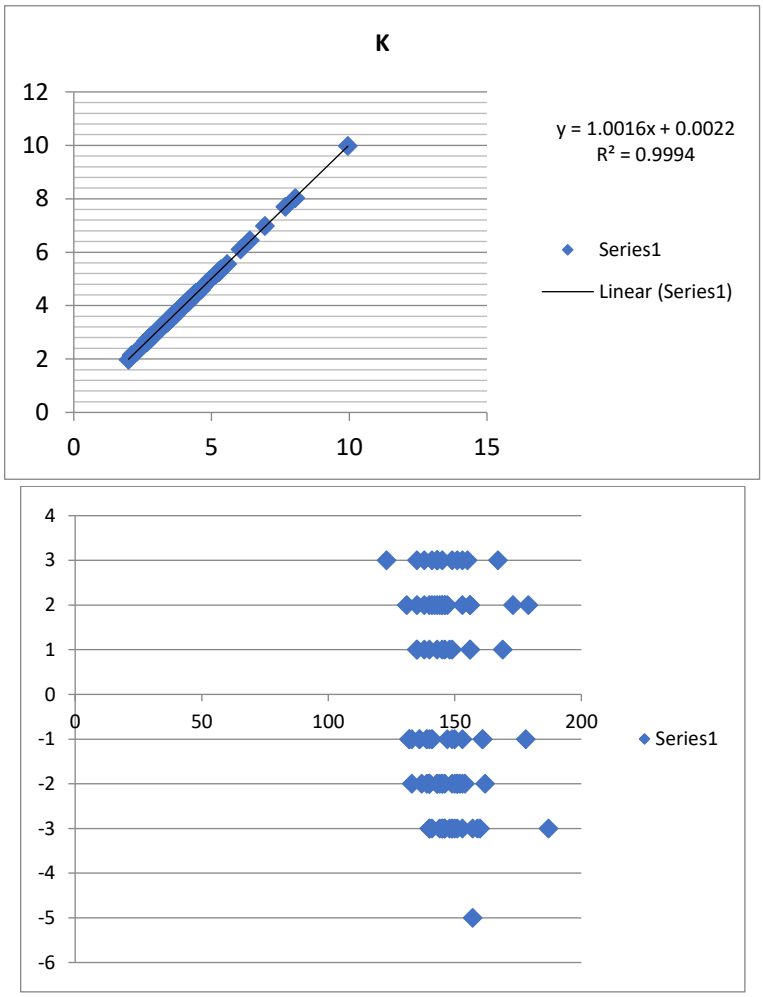
Calculated regression equation y = 1.0028x + 0.0334

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 (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.



5.4.1. 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 r=0.9997, which is greater than 0.975. The range of values is suitable and the correlation and consistency are good.

5.4.2. Linear Regression Analysis

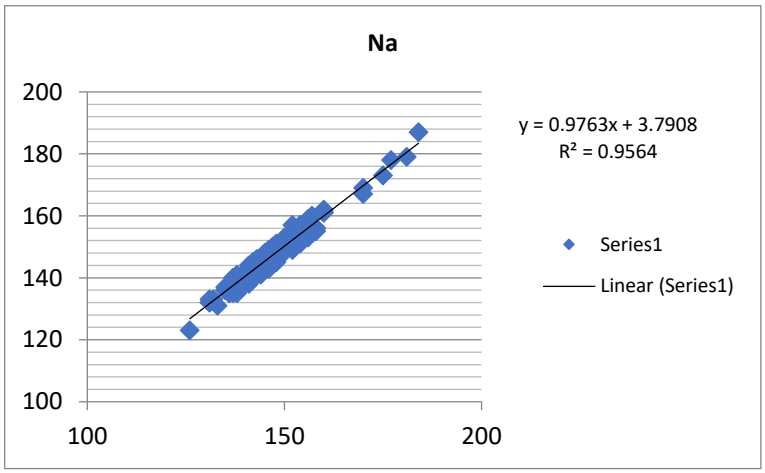
Calculated regression equation y = 1.0016x + 0.0022

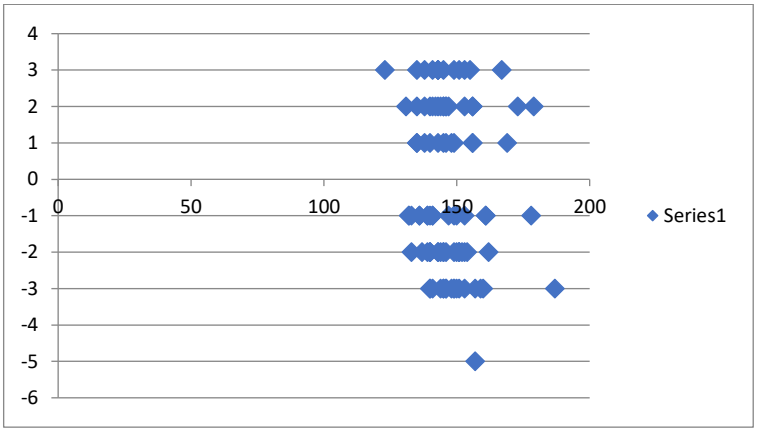
5.4.3. Statistical Analysis

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 (Na)

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 calculated to be r=0.9779, which is greater than 0.975. The range of values is appropriate and the correlation and consistency are good.

5.5.2. Linear Regression Analysis

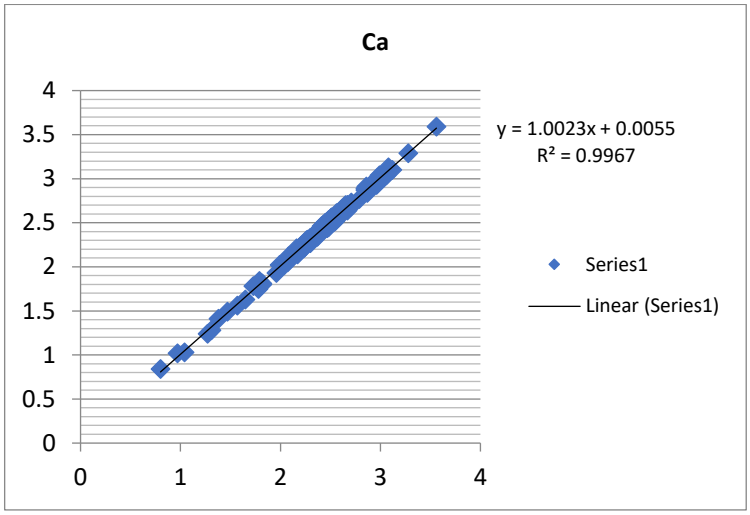
Calculated regression equation y = 0.9763x + 3.7908

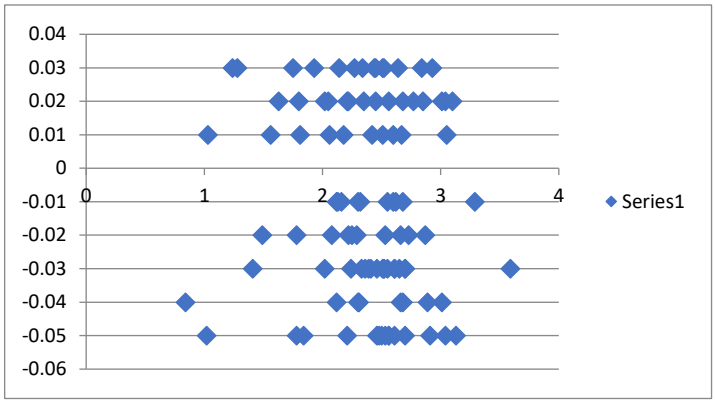
5.5.3. Statistical Analysis

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

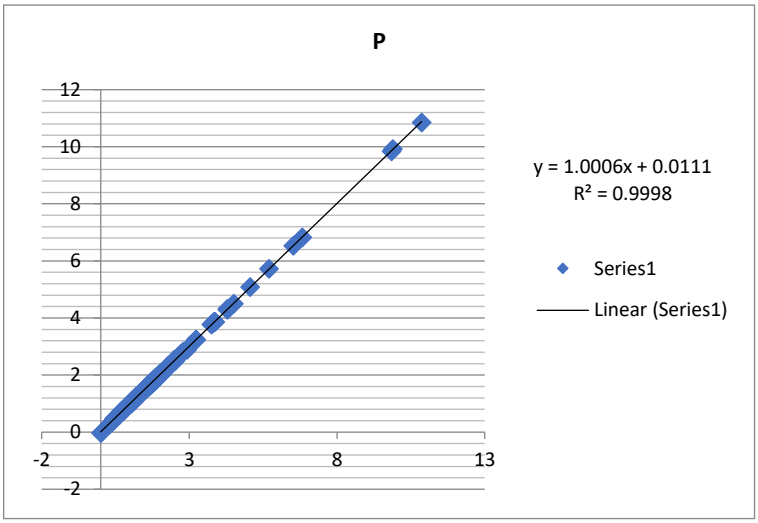
Calculated regression equation y = 1.0023x + 0.0055

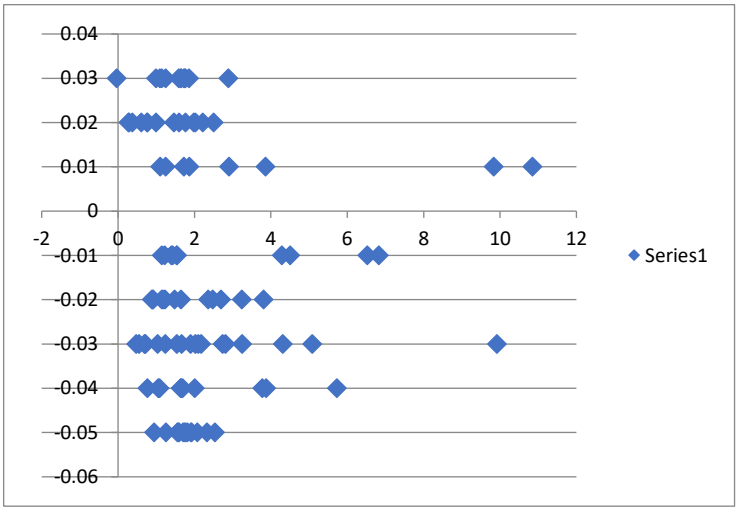
5.6.3. Statistical Analysis

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

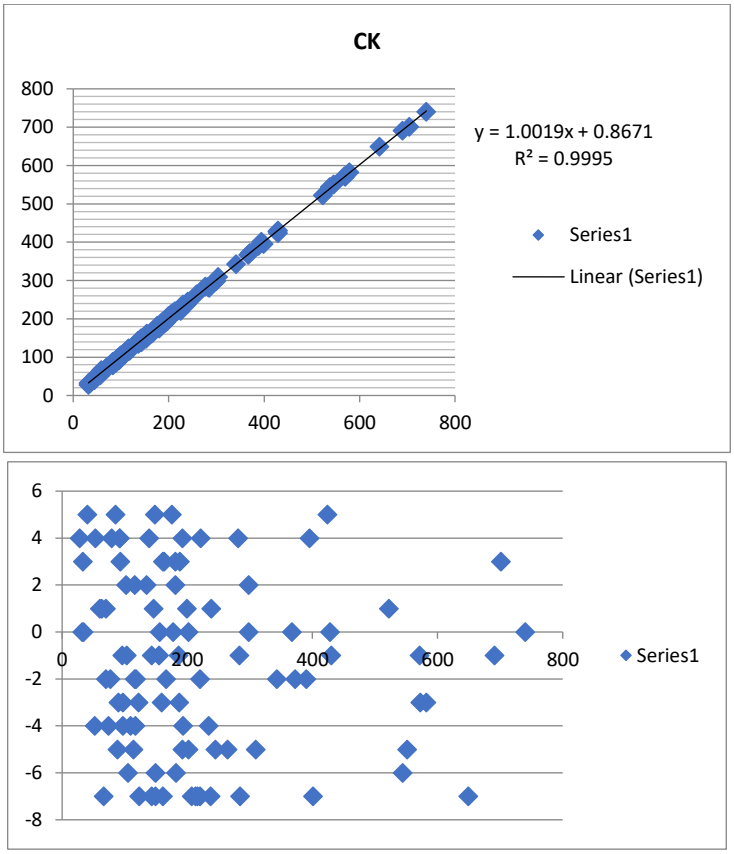
Calculated regression equation y = 1.0006x + 0.0111

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 (CK)

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 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.

5.8.2. Linear Regression Analysis

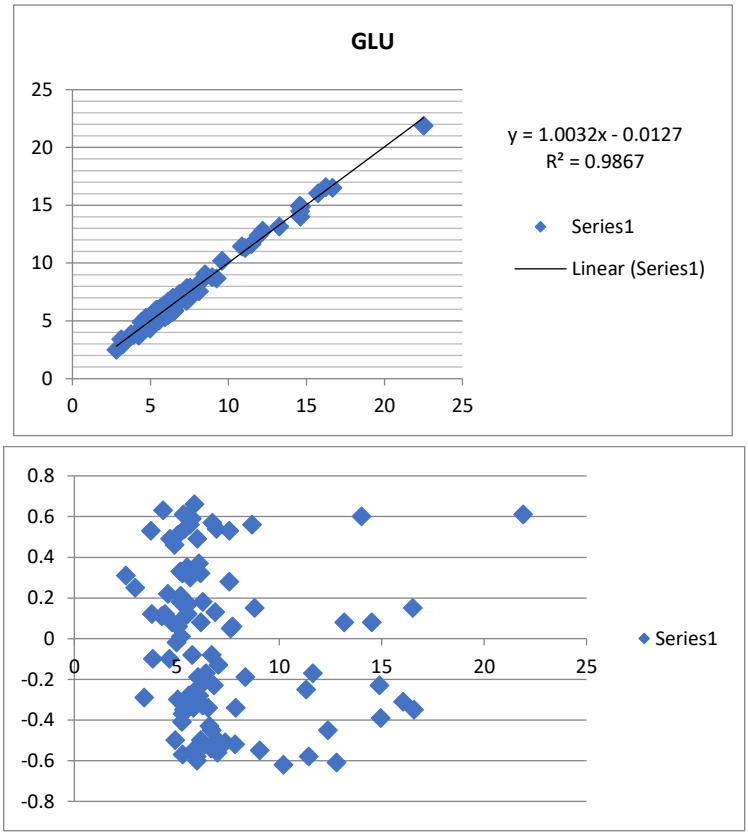
Calculated regression equation y = 1.0019x + 0.8671

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.

5.9 Results Statistics and Analysis (GLU)

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.



5.9.1. 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=0.9932, which is greater than 0.975. The range of values is suitable and the correlation and consistency are good.

5.9.2. Linear Regression Analysis

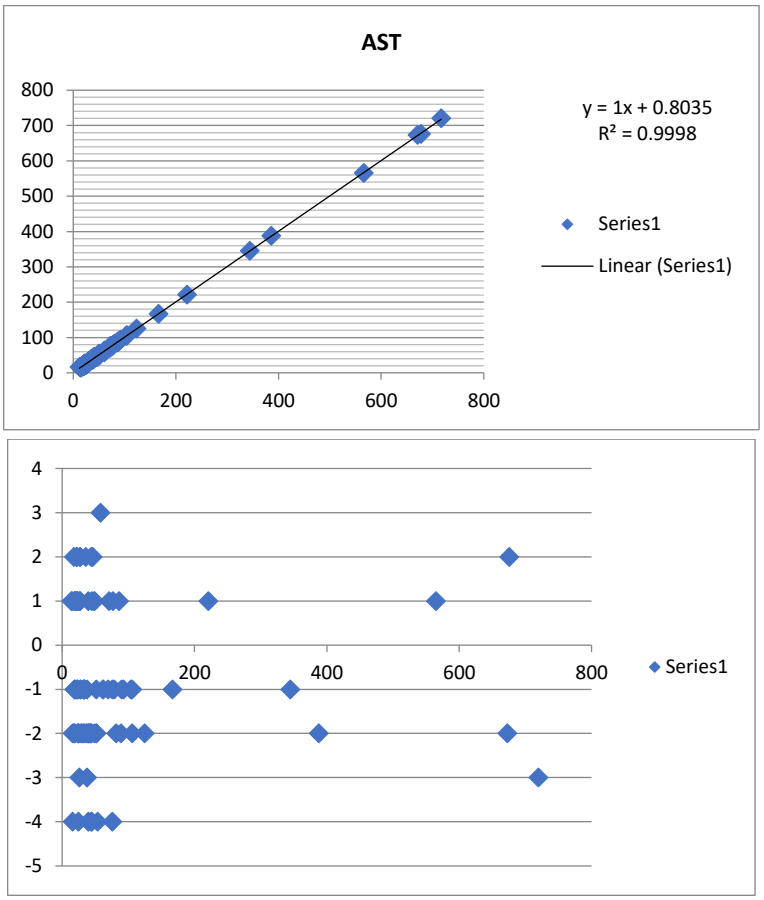
Calculated regression equation y = 1.0032x - 0.0127

5.9.3. 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 and there was no significant difference.

5.10 Results Statistics and Analysis (AST)

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.



5.10.1. 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=0.9999, which is greater than 0.975. The range of values is appropriate and the correlation and consistency are good.

5.10.2. Linear Regression Analysis

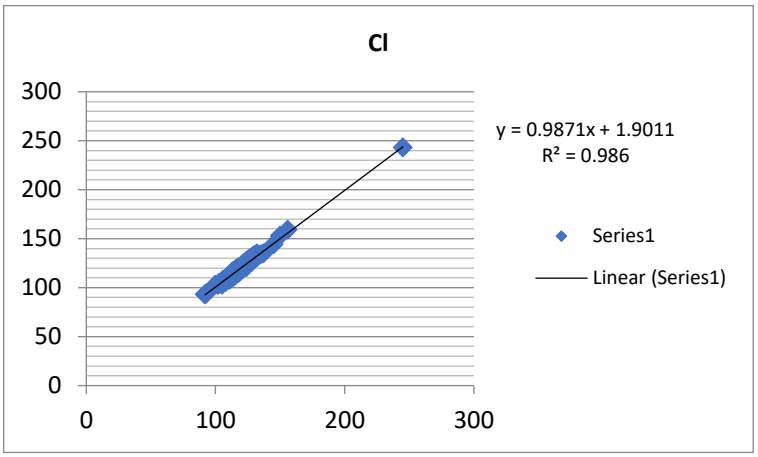
Calculated regression equation y = 1x + 0.8035

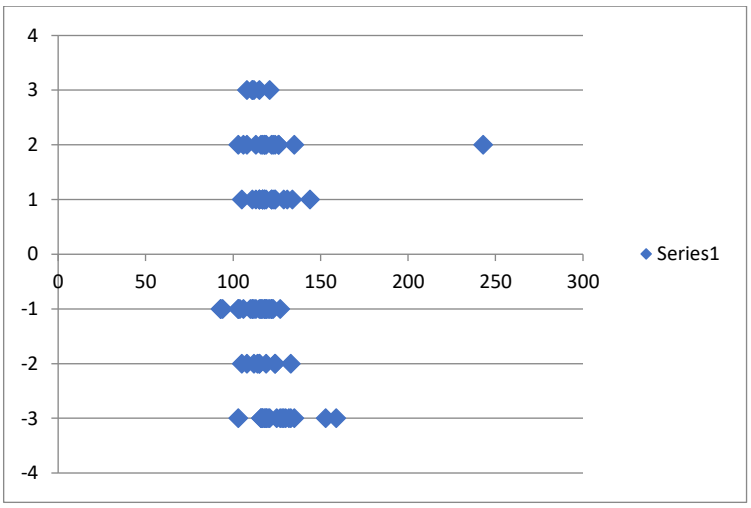
5.10.3. Statistical Analysis

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 and there was no significant difference.

5.11 Results Statistics and Analysis (Cl)

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.





5.11.1. 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=0.9929, which is greater than 0.975. The range of values is appropriate and the correlation and consistency are good.

5.11.2. Linear Regression Analysis

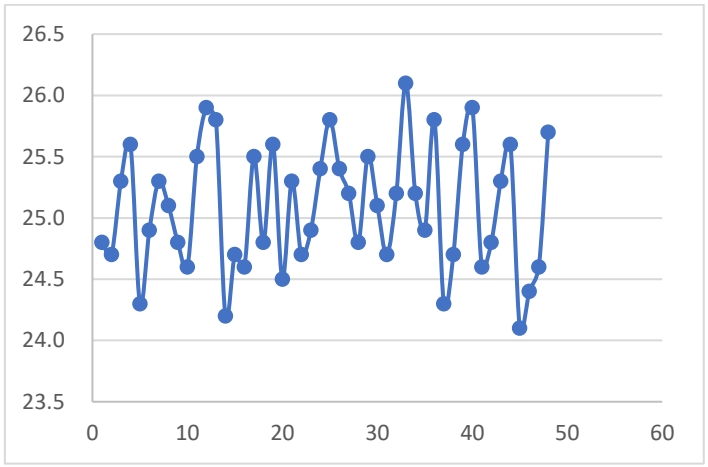
Calculated regression equation y = 0.9871x + 1.9011

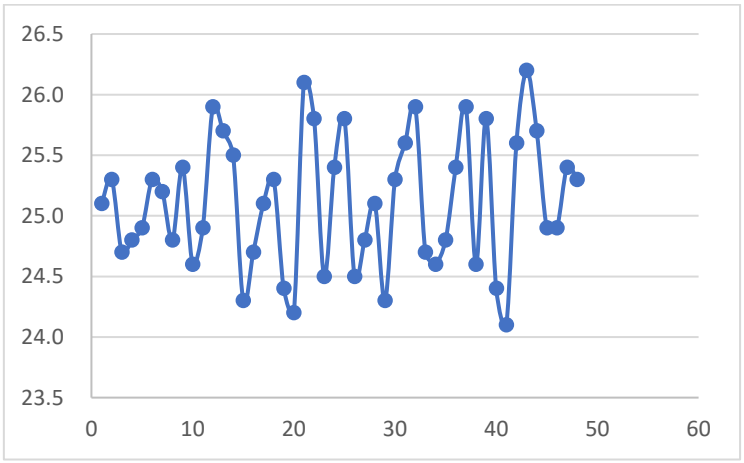
5.11.3. Statistical Analysis

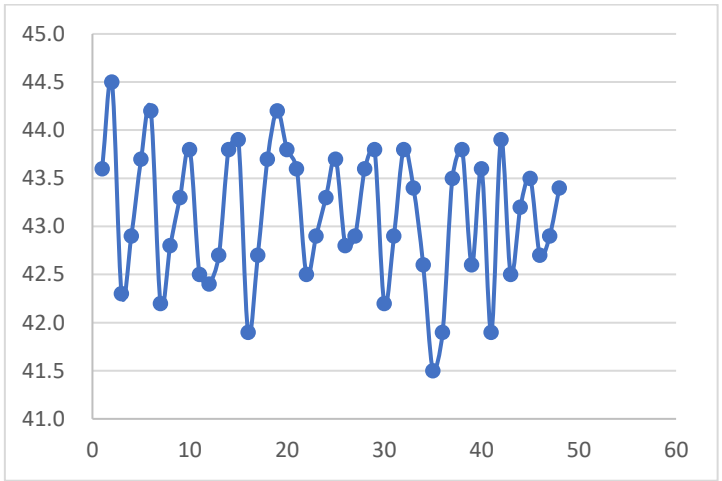
The t-test was performed on the linear regression equations of the test system and the control system, and the t value was > t0.05, P < 0.05. There was a good linear relationship between the two groups of data and there was no significant difference.

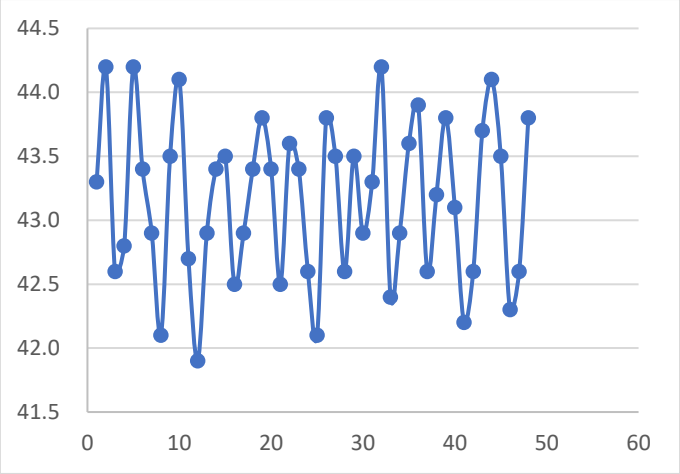
5.12 Results Statistics and Analysis (TBA)

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.









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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