WOODLEY
EQUIPMENT COMPANY LTD.

InSight V-CHEM®

Veterinary Chemistry Analyser

Correlation Study – General Health Panel

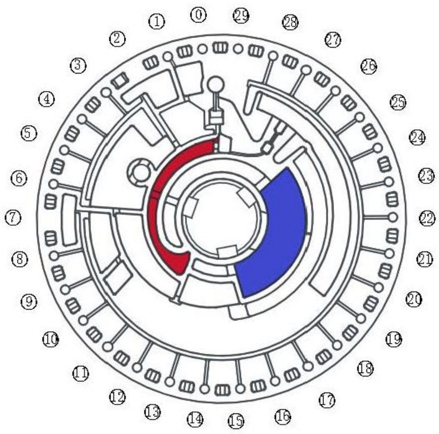
Contents

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 General Health 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 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 General Health Panel is used to quantitative test the concentration of the thirteen 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.

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

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) Alanine Aminotransferase (ALT)

ALT catalyses the transfer of an amino group from L-alanine to α-ketoglutarate to form L-glutamate and pyruvate. Lactate dehydrogenase catalyses the conversion of pyruvate to lactate. Concomitantly, NADH is oxidised to NAD^+, as illustrated in the following reaction scheme.

$$\text{L-Alanine + α-Ketoglutarate} \xrightarrow{\text{ALT}} \text{L-Glutamate + Pyruvate}$$

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

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

d) Alkaline Phosphatase (ALP)

Under the catalysis of ALP, the Phosphoric acid on nitrobenzene (4-NNP) was turned into Para nitro phenol (4-NP). 4-NP shows a yellow colour in alkaline solution. At the wavelength of 405/505nm, the ALP activity can be calculated by monitoring the absorbance change rate.

$$\text{4-NNP} \xrightarrow{\text{ALP}} \text{Acyl phosphate + 4-NP}$$

e) Total Bilirubin (TBIL)

In the enzyme procedure, bilirubin is oxidised by bilirubin oxidase (BOD) into biliverdin. Bilirubin is quantitated as the difference in absorbance between 450nm and 546 nm. The initial absorbance of this endpoint reaction is determined from the bilirubin blank cuvette and the final absorbance is obtained from the bilirubin test cuvette. The amount of bilirubin in the sample is proportional to the difference between the initial and final absorbance measurements.

$$\text{Bilirubin + } O_2 \xrightarrow{\text{BOD}} \text{Biliverdin + } H_2O$$

f) 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 minimize the potential interference of bilirubin and ascorbic acid respectively.

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

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

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

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

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.

g) Urea Nitrogen (BUN)

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

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

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

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.

h) 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.

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

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

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.

i) Total Cholesterol (CHOL)

The reaction of CHOL is an enzymatic end-point method that uses cholesterol esterase (CE) and cholesterol dehydrogenase (CHDH). CE hydrolyses cholesterol esters to form cholesterol and fatty acids. The CHDH reaction converts cholesterol to cholest-4-en-3-one. The NADH is measured bichromatically at 340 nm and 405 nm. NADH production is directly proportional to the amount of cholesterol present. An assay-specific blank is also monitored to ensure no extraneous reactions interfere with the calculations of CHOL levels.

$$\text{Cholesterol Esters} + H_2O \xrightarrow{CE} \text{Cholesterol} + \text{Fatty Acids}$$

$$\text{Cholesterol} + NAD^+ \xrightarrow{CHDH} \text{Cholest-4-en-3-one} + NADH + H^+$$

j) 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.

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

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

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

k) Amylase (AMY)

In the coupled-enzyme reaction, amylase in the sample hydrolyses 2-chloro-4-nitrophenyl-β-1,4-galactopyranosylmaltoside (CNP-G2) to 2-chloro-4-nitrophenol (CNP) producing colour and 1,4-galactopyranosylmaltoside. The change in absorbance of the CNP is directly proportional to the amylase activity in the sample at 405nm and 505 nm.

$$\text{CNP-G2} \xrightarrow{AMY} CNP + G2$$

l) 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.

m) 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.

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

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

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

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	Dog: 5.4 ~ 8.2g/dL
	Cat: 54 ~ 82g/L	Cat: 5.4 ~ 8.2g/dL
ALB	Dog: 25 ~ 44g/L	Dog: 2.5 ~ 4.4 g/dL
	Cat: 27 ~ 45g/L	Cat: 2.7 ~ 4.5 g/dL
ALT	Dog: 10 ~ 118U/L	Dog: 10 ~ 118U/L
	Cat: 8.2 ~ 100U/L	Cat: 8.2 ~ 100U/L
ALP	Dog: 20 ~ 150U/L	Dog: 20 ~ 150U/L
	Cat: 10 ~ 90U/L	Cat: 10 ~ 90U/L
TBIL	Dog: 0 ~ 10.3µmol/L	Dog: 0 ~ 0.6mg/dL
	Cat: 0 ~ 10.3µmol/L	Cat: 0 ~ 0.6mg/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
GLU	Dog: 3.89 ~ 7.95mmol/L	Dog: 70 ~ 143mg/dL
	Cat: 4.11 ~ 8.84mmol/L	Cat: 74 ~ 159mg/dL
CHOL	Dog: 3.2 ~ 7.0mmol/L	Dog: 124 ~ 271mg/dL
	Cat: 2.3 ~ 5.3mmol/L	Cat: 89 ~ 205mg/dL
CK	Dog: 20 ~ 200U/L	Dog: 20 ~ 200U/L;
	Cat: 50 ~ 450U/L	Cat: 50 ~ 450U/L
AMY	Dog: 400 ~ 2500U/L	Dog: 400 ~ 2500U/L
	Cat: 400 ~ 2500U/L	Cat: 400 ~ 2500U/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

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 General Health Panel containing 13 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
TP	100
ALB	100
ALT	100
ALP	100
TBIL	100
CRE	100
BUN	100
GLU	100
CHOL	100
CK	100
AMY	100
Ca^{2+}	100
P	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 of this evaluation test are 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 TBIL umol/L	VS2 reagent value TBIL umol/L	V-CHEM reagent value ALT U/L	VS2 reagent value ALT U/L	V-CHEM reagent value ALP U/L	VS2 reagent value ALP U/L	V-CHEM reagent value BUN	VS2 reagent value BUN	V-CHEM reagent value CRE umol/L	VS2 reagent value CRE umol/L
23.7	23.9	61	61.5	3.32	3.15	48	50	24	26	5.86	6.06	45	47
19.4	19.6	92.8	93.3	12.42	12.6	62	64	23	25	7	7.2	216	218
30.4	30.5	62.2	62.7	80.73	80.85	38	39	56	57	5.83	5.93	92	93
21.1	21.2	58.5	58.9	5.13	5.02	67	68	160	161	2.83	2.93	31	32
29.4	29.3	64.1	64	2.39	2.67	89	88	58	57	21.2	21.1	168	167
25.2	24.9	48.6	48.5	3.56	3.71	985	982	66	65	5.44	5.14	63	60
38.6	38.9	83.7	83.8	7.66	7.56	111	114	24	25	4.22	4.52	45	48
33.4	33.9	73.4	73.5	9.22	9.12	87	92	30	32	4.25	4.75	72	77
23.7	24.2	60.7	60.6	4.72	4.86	716	721	27	29	20.5	21	172	177
27	27.5	68.4	68.9	5.69	5.97	40	45	60	62	7.88	8.38	119	124
25.7	26.1	67.9	68.3	3.52	3.67	39	43	16	17	4.82	5.22	117	121
25.3	25.2	69.9	69.8	13.89	14.13	264	263	18	17	11.5	11.4	74	73
21.1	21	84.6	84.5	6.3	6.52	37	36	20	19	3.98	3.88	85	84
37.7	37.9	64.5	64.6	3.48	3.68	41	43	14	16	6.9	7.1	85	87
32.1	32.3	79.4	79.5	3.32	3.46	67	69	152	154	8.11	8.31	115	117
31.2	31	81.6	81.5	2.89	2.79	66	64	30	28	2.55	2.35	65	63
31.5	32	68.1	68.6	5.5	5.74	25	30	20	22	4.42	4.92	44	49
30.3	30.8	57.7	58.2	3.97	4.19	28	33	24	26	6.1	6.6	80	85
27.1	27.6	62.3	62.8	3.85	4.05	43	48	63	65	24.6	25.1	366	371
28.9	29.3	64.3	64.7	17.77	17.91	13	17	32	33	14	14.4	160	164
32.7	32.6	67.9	68	2.21	2.39	84	83	32	31	29.9	29.8	235	234
34.6	34.5	68.6	68.7	5.07	5.17	26	25	50	49	18.9	18.8	187	186
36.5	36.3	68.8	68.7	2.74	2.98	71	69	59	57	4.09	3.89	67	65
23.1	23.3	75.8	76.3	4.99	5.21	53	55	151	153	7.37	7.57	78	80
30.9	30.8	60.7	61.2	2.58	2.78	47	46	122	121	14	13.9	131	130
33.4	33.6	71.8	71.9	3.42	3.56	77	79	14	16	4.48	4.68	89	91
30	30.4	69.9	70.3	2.86	2.99	47	51	53	54	8.36	8.76	153	157
32.6	33	66.8	67.2	8.61	8.71	50	54	25	26	6.62	7.02	188	192
20.1	19.8	51.1	50.8	63.09	62.77	239	236	121	118	29.5	29.2	328	325
29.5	29.6	72.3	72.4	3.93	4.07	45	46	26	27	2.14	2.24	43	44
29.8	30.1	68.1	68.4	2.34	2.64	61	64	33	36	4.46	4.76	99	102
27	27.1	58.5	58.6	6.74	6.84	38	39	24	25	6.29	6.39	68	69
31.1	31.2	70.6	70.7	5.5	5.62	15	16	21	22	6.34	6.44	145	146

30.3	30.8	64.2	64.7	3.76	3.96	27	28	30	31	4.4	4.5	131	132
28.5	29	82.5	83	2.98	3.2	105	106	14	15	7.11	7.21	160	161
21.9	22.3	71.7	72.1	6.99	7.09	42	40	231	229	15.9	15.7	167	165
28.4	28.3	67.8	67.9	13.45	13.62	75	77	131	133	6.12	6.32	138	140
33	32.9	63.2	63.3	5.4	5.5	69	67	24	22	4	3.8	64	62
27	26.8	64	63.9	4.05	4.19	73	71	54	52	6.5	6.3	45	43
26.1	26.2	66.5	67	6.46	6.76	56	57	24	25	5	5.1	73	74
33	33.5	62.6	63.1	2.64	2.74	55	60	528	530	7.64	8.14	152	157
33.4	33.3	61.2	61.1	2.44	2.56	62	61	30	29	13.2	13.1	90	89
25.1	25.2	64.3	64.4	5.66	5.86	41	42	22	23	7.66	7.76	64	65
28.7	29.2	62.5	63	3.42	3.64	8	7	25	24	2.69	2.59	68	67
36.1	36.6	64.7	65.2	3.63	3.83	40	39	25	24	3.29	3.19	57	56
29.5	29.9	53.8	54.2	4.94	5.06	151	152	209	210	7.33	7.43	111	112
20.6	20.5	49.9	49.8	143.4	143.5	247	248	332	333	11.9	12	203	204
20.8	20.7	44.2	44.3	44.62	44.92	565	566	202	203	8.72	8.82	218	219
30.9	31	72.9	73	3.39	3.49	63	64	203	204	6.86	6.96	132	133
32.9	32.7	76.9	76.8	3.07	3.19	59	57	33	31	1.01	0.81	40	38
28.3	28.5	65.6	66.1	10.19	10.39	45	47	27	29	9.04	9.24	138	140
35.3	35.1	81.2	81.7	5.57	5.79	63	61	38	36	6.3	6.1	39	37
35.4	35.3	73.1	73	10.14	9.97	258	257	308	307	4.16	4.06	98	97
39.3	39.4	81.8	81.9	8.57	8.7	78	79	14	15	29.4	29.5	327	328
16.2	16.3	53.6	53.7	28.4	28.5	37	38	26	27	5.03	5.13	116	117
33.5	33.6	59.7	59.8	6.03	6.16	31	32	75	76	6.63	6.73	134	135
32.3	32.8	63	63.5	2.73	2.93	184	185	47	48	9.29	9.39	154	155
36.1	36.6	79.4	79.9	6.15	6.35	285	284	164	163	7.76	7.66	234	233
33.3	33.7	77.6	78	3.01	3.15	22	24	15	17	4.91	5.11	81	83
27.3	27.2	71.8	71.7	4.42	4.72	116	115	28	27	15.3	15.2	313	312
29.3	29.2	69.7	69.8	3.27	3.37	108	106	32	30	3.88	3.68	31	29
28	27.9	84	84.1	6.41	6.53	43	42	19	18	3.15	3.05	102	101
30.9	31.4	68.6	68.5	7.28	7.48	39	44	70	72	7.07	7.57	112	117
27.6	27.8	83.4	83.9	46.13	46.35	531	533	1044	1046	9.47	9.67	118	120
32.8	33.3	79.2	79.7	5.84	6.04	150	155	132	134	7.35	7.85	146	151
35.3	35.2	59.4	59.3	2.39	2.29	133	132	109	108	8.39	8.29	228	227
34.9	35.1	75	75.1	5.57	5.72	57	59	28	30	3.2	3.4	101	103
37	36.7	62.5	62.2	2.74	2.88	148	145	163	162	12.2	11.9	95	92
35.4	35.8	56.3	56.7	5.13	5.43	69	73	133	134	5.04	5.44	97	101
25.1	25.2	71.6	71.7	3.25	3.35	131	132	24	25	34.2	34.3	288	289
24	24.2	57.7	57.8	5.51	5.63	77	79	30	32	4.32	4.52	73	75
28.8	28.9	66.8	66.9	51.32	51.52	246	247	842	843	9.02	9.12	239	240

28.5	28.7	62.5	62.6	3.43	3.65	90	92	21	23	32.2	32.4	314	316
26.6	27.1	65.8	66.3	6.67	6.87	211	212	82	83	5.6	5.7	67	68
21.6	22.1	48.1	48.6	2.74	2.97	344	345	539	540	17.8	17.9	347	348
25.7	26.1	66	66.4	3.99	4.11	34	33	39	38	7.16	7.06	122	121
29.8	29.7	70.7	70.8	4.48	4.62	64	67	28	31	6.61	6.91	59	62
31.5	31.4	64.5	64.6	3.39	3.69	23	24	80	81	8.58	8.68	84	85
20.7	20.5	36.6	36.5	4.1	4.2	205	203	120	118	19.2	19	267	265
26.5	26.8	41.8	42.3	5.36	5.48	346	349	213	216	28.2	28.5	393	396
35.7	35.6	62.6	63.1	3.54	3.74	107	106	18	17	8.79	8.69	180	179
33.2	33.7	75.6	76.1	5.89	6.11	166	171	58	60	9.27	9.77	145	150
36.9	37.4	79.8	80.3	8.37	8.57	77	82	130	132	5.99	6.49	76	81
30.1	30.5	69.2	69.6	12.86	13	313	317	25	26	34.9	35.3	231	235
27.4	27.6	56.5	56.6	5.72	6.02	33	35	30	32	9.16	9.36	44	46
29.4	29.9	67.8	68.3	7.96	8.06	31	36	28	30	8.84	9.34	114	119
31.4	31.2	67	66.9	4.77	4.89	28	26	30	28	15.3	15.1	184	182
21.7	21.8	51.9	52	76.7	76.9	77	78	232	233	8.02	8.12	50	51
19.3	19.4	65.2	65.3	2.95	3.17	16	17	27	28	7.14	7.24	101	102
25.2	25.7	44	43.9	3.08	3.28	397	402	109	111	7.25	7.75	105	110
21.3	21.2	40.8	41.3	2.18	2.41	241	240	76	75	17.4	17.3	280	279
33.4	33.6	61.8	62.3	2.13	2.25	48	50	18	20	28.1	28.3	86	88
28	27.7	68.8	68.5	2.46	2.6	64	61	21	20	9.37	9.07	84	81
25.9	25.8	54.8	54.7	2.62	2.52	39	38	52	51	4.76	4.66	65	64
21.9	22.4	63.8	64.3	3.47	3.68	70	75	24	26	10.2	10.7	79	84
27.3	27.8	73	73.5	3.03	3.28	80	85	26	28	10.5	11	149	154
34.6	35	71.7	72.1	2.18	2.33	216	220	73	74	1.95	2.35	37	41
35.7	35.9	72.2	72.3	3.84	3.97	43	45	18	20	29.3	29.5	253	255
33.7	34.2	64.9	65.4	5.42	5.68	70	75	74	76	6.38	6.88	76	81
23	22.8	62.9	62.8	9.03	8.93	36	34	118	116	4.05	3.85	92	90

V-CHEM reagent value Ca2+	VS2 reagent value Ca2+	V-CHEM reagent value P	VS2 reagent value P	V-CHEM reagent value GLU	VS2 reagent value GLU	V-CHEM reagent value AMY U/L	VS2 reagent value AMY U/L	V-CHEM reagent value CHOL	VS2 reagent value CHOL	V-CHEM reagent value CK U/L	VS2 reagent value CK U/L
2.68	2.67	2.15	2.18	5.73	5.56	77	78	3.86	4.05	197	202
2.24	2.22	1.51	1.54	5.61	5.29	79	80	3.88	4.18	196	192
2.07	2.05	6.82	6.83	5.4	5.19	72	74	3.65	3.14	183	181
2.2	2.22	2	2.03	14.59	14.51	327	330	7.18	7.21	570	571
2.79	2.77	1.12	1.11	14.62	14.02	328	329	7.13	7	546	551
2.56	2.61	1.79	1.76	14.66	14.89	331	330	7.18	6.53	569	572
2.43	2.48	1.87	1.90	11.06	11.31	746	741	3.12	2.93	285	281
2.61	2.62	2.46	2.48	5.94	6.27	895	891	3.52	2.88	206	213
2.12	2.13	1.76	1.73	6.17	6.6	790	787	7.29	7.61	96	92
2.36	2.39	1.02	1.00	13.25	13.17	305	309	5.33	5.45	59	66
2.38	2.41	1.53	1.58	6.52	5.86	576	574	9.45	8.92	96	93
2.48	2.45	0.9	0.95	5.26	5.81	795	798	5.47	4.88	143	149
2.19	2.18	2.03	2.08	6.15	5.56	565	568	5.31	5.36	156	156
1.79	1.84	3.84	3.88	6.32	5.73	660	662	8.19	8.66	34	34
1.96	1.93	1.03	1.00	3.91	3.79	610	606	8.62	8.65	95	96
2.17	2.14	2.92	2.91	11.93	12.38	924	927	5.15	5.2	523	522
1.04	1.03	0.45	0.48	7.32	7.84	906	903	7.63	7.49	96	92
3.06	3.04	2.71	2.74	2.82	2.51	570	574	4.38	4.37	164	161
2.58	2.61	3.22	3.25	12.19	12.8	755	753	3.29	3.36	399	395
2.49	2.52	4.28	4.29	6.85	7.36	861	863	4.66	4.39	341	343
2.11	2.12	2.24	2.22	16.23	16.58	739	740	7.09	7.15	259	264
2.67	2.70	1.61	1.65	7.68	7.63	927	928	5.8	5.6	213	220
3.06	3.05	3.74	3.78	7.48	6.94	445	446	4.66	4.55	240	245
1.27	1.24	0.3	0.28	5.65	5.53	638	639	6.46	6.73	180	175
3.56	3.59	3.79	3.81	5.84	6.03	719	717	6.24	6.52	200	199
2.64	2.66	1.13	1.10	6.47	6.97	948	946	4.91	4.65	75	77
2.54	2.51	1.21	1.23	6.43	6.99	635	637	4.54	4.32	200	207
2.47	2.45	1.6	1.64	4.75	5.05	691	693	3.23	3.61	185	186
2.45	2.50	0.73	0.77	4.79	4.57	786	791	3.13	2.69	239	238

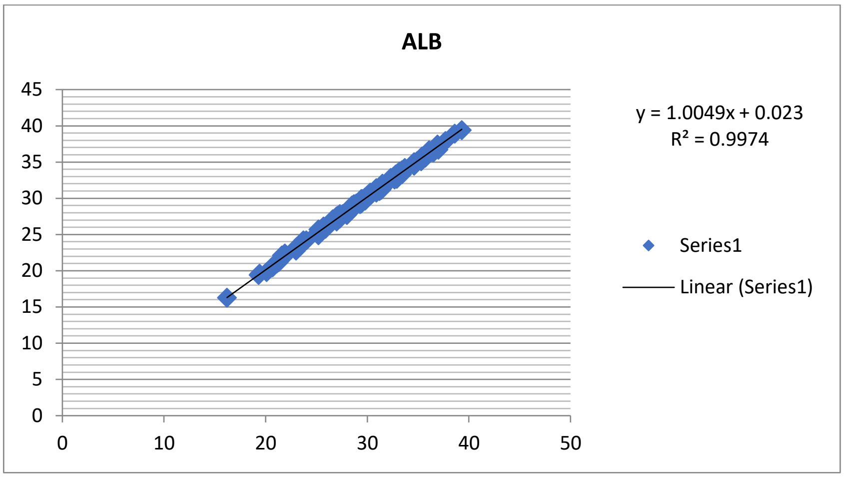
2.16	2.21	1.89	1.86	5	5.35	788	789	4.44	4.93	68	70
2.99	3.04	1.42	1.43	6.47	6.15	878	883	4.57	4.18	166	163
2.62	2.66	0.69	0.72	5.3	5.58	636	636	4.93	4.33	428	428
1.31	1.28	1.79	1.77	8.1	7.57	653	649	4.7	4.12	147	146
1.82	1.81	5.69	5.73	22.51	21.9	391	396	3.42	3.5	579	582
2.67	2.70	1.73	1.78	4.96	4.33	818	823	7.47	7.26	102	103
1.38	1.41	0.31	0.29	6.25	6.17	926	924	6.05	5.45	277	284
2.3	2.33	3.22	3.24	3.12	3.41	949	951	3.6	3.51	48	52
2.31	2.32	10.86	10.85	4.42	4.92	931	927	4.83	4.58	99	105
2.04	2.02	1.62	1.59	5.39	5.97	748	749	6.34	6.09	94	97
2.26	2.30	6.52	6.53	6.2	5.64	846	846	4.61	4.12	184	181
2.08	2.12	1.63	1.65	8.16	8.35	857	852	4.24	4.29	538	544
3.12	3.10	1.16	1.18	6.19	6.53	800	805	5.17	5.31	83	88
2.51	2.53	1.53	1.54	6.49	6	894	893	7.01	6.45	225	221
1.78	1.75	0.4	0.38	5.82	6.1	872	870	7.62	7.39	113	117
1.76	1.78	4.29	4.32	5.76	5.43	915	915	3.01	2.41	90	85
2.85	2.89	1.49	1.47	4.54	4.64	932	932	6.44	6.15	202	202
0.8	0.84	0.63	0.61	5.85	5.5	670	666	5.65	5.9	104	102
2.87	2.84	1.14	1.15	6.9	7.03	562	564	6.12	6.13	388	390
2.54	2.55	1.74	1.73	5.96	5.66	607	604	6.26	6.42	142	149
2.52	2.55	1.39	1.40	5.67	6.17	918	916	4.24	3.87	154	161
2.87	2.85	2.79	2.82	5.12	5.06	799	795	6.51	6.36	114	116
2.27	2.31	1.88	1.87	5.93	5.39	746	750	4.36	4.61	164	166
2.48	2.53	0.67	0.70	5.35	4.89	943	948	3.32	3.58	642	649
2.23	2.21	1.68	1.65	3.73	3.83	477	479	4.28	4.62	93	97
2.71	2.73	1.68	1.65	5.56	5.05	747	750	3.69	3.51	136	143
1.57	1.56	9.85	9.84	7.31	6.74	638	635	6.4	6.76	230	237
2.47	2.44	1.51	1.56	5.35	5.63	619	615	4.69	4.15	71	70
2.67	2.68	1.64	1.67	7.78	7.72	318	313	6.59	6.12	230	234
2.27	2.29	1.02	1.06	7	6.87	867	864	3.81	3.77	116	118
2.06	2.08	1.69	1.74	10.86	11.44	871	872	3.73	3.67	184	187
2.15	2.16	2.28	2.33	6.58	6.81	926	929	4.21	3.87	83	79
2.37	2.35	0.87	0.89	8.5	9.05	685	683	5.12	4.55	119	122
2.33	2.36	1.77	1.82	5.16	4.67	905	902	5.18	5.59	191	188

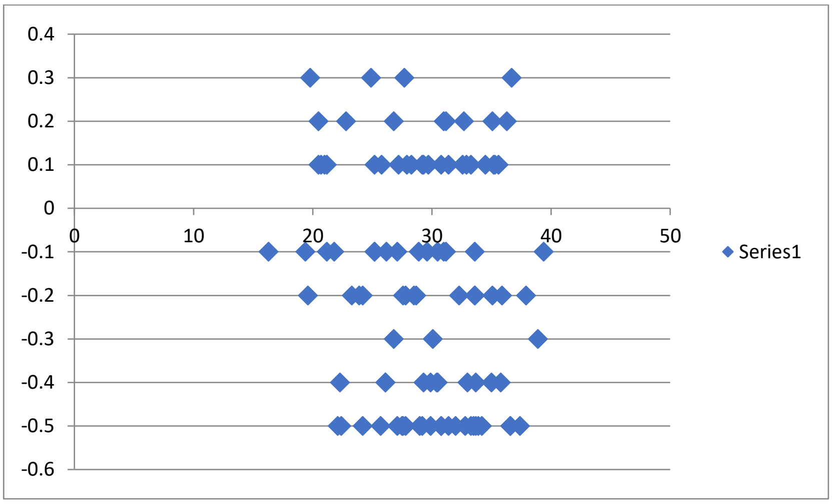
1.65	1.63	9.89	9.92	15.74	16.05	841	837	3	2.42	57	53
2.7	2.68	2.53	2.51	6.63	6.71	924	927	4.58	4.07	118	116
2.29	2.30	1.88	1.93	6.1	5.5	465	469	5.51	5.32	45	40
2.61	2.60	1.13	1.15	4.26	3.73	858	856	5.69	5.25	64	63
3.28	3.29	3.87	3.86	6.26	6.71	913	916	7.07	6.69	116	123
2.62	2.65	0.78	0.76	4.91	5.28	896	899	3.69	3.62	142	143
2.07	2.06	1.79	1.76	6.25	6.42	840	836	5.81	5.69	32	28
1.99	2.02	1.01	1.04	4.96	4.98	903	902	2.15	1.64	154	155
2.55	2.52	0.9	0.92	5.21	5.2	676	675	6.76	6.51	109	114
2.37	2.34	0	-0.03	5.67	5.75	71	70	3.48	3.95	218	220
2.52	2.51	0.52	0.55	5.36	5.18	72	74	3.28	3.62	209	216
2.65	2.70	1.62	1.60	4.84	5.25	804	805	3.72	3.44	87	90
2.43	2.46	1.21	1.26	5.38	5.98	888	886	5.83	5.63	32	32
2.64	2.68	1.55	1.60	5.51	5.18	813	813	7.91	8.14	300	298
2.86	2.91	1.97	2.01	4.85	4.77	865	862	2.81	3.04	187	192
3.08	3.13	1.21	1.24	11.47	11.64	866	869	3.47	2.88	740	740
2.23	2.25	1.66	1.71	6.12	6.32	822	825	7.6	7.44	177	177
2.51	2.56	1.28	1.25	5.51	5.4	851	848	7.44	7.27	304	309
2.21	2.24	1.21	1.22	6.14	6.68	917	917	4.45	4.55	156	159
3.03	3.01	2.68	2.70	6.45	6.08	677	676	10.61	10.91	36	33
2.41	2.46	1.86	1.91	5.85	6.37	589	592	5.85	5.67	367	367
1.47	1.49	2.01	1.99	4.71	5.28	806	807	4.54	3.93	153	148
2.43	2.42	2.34	2.36	7.84	7.56	862	860	4.55	5.08	282	283
1.82	1.80	2.92	2.89	4.55	4.43	942	940	3.65	4.14	105	109
2.67	2.64	1.05	1.09	7.54	7.88	654	652	4.35	4.78	298	298
2.49	2.52	5.06	5.09	5.57	5.39	109	111	4.59	4.05	176	182
2.85	2.87	0.89	0.91	16.66	16.51	694	694	9.52	9.7	429	430
2.96	2.93	2.07	2.10	3.22	2.97	452	453	6.61	6.02	370	372
2.48	2.51	1.46	1.48	9.23	8.67	891	892	6.28	5.89	137	135
2.58	2.56	4.5	4.51	5.47	5.81	878	877	6.86	6.45	189	193
2.51	2.56	1.53	1.54	6.45	6.27	800	800	5.45	5.21	690	691
0.97	1.02	0.79	0.77	9.59	10.21	879	883	6.18	6.04	429	424
2.97	3.01	1.65	1.69	5.94	5.33	349	347	6.54	6.62	61	60
2.58	2.61	2.05	2.03	8.95	8.8	557	552	3.34	3.03	704	701

1.73	1.78	2.49	2.54	5.82	6.06	859	862	6.48	6.99	70	74
2.3	2.27	1.26	1.25	14.57	14.96	692	690	3.35	3.08	394	401
2.59	2.60	1.18	1.15	4.37	4.26	908	908	5	4.7	143	139

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

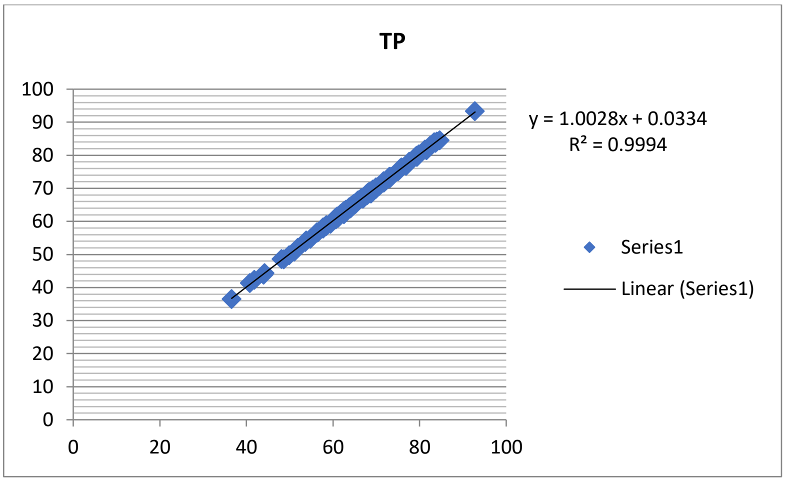
Calculated regression equation y = 1.0049x + 0.023

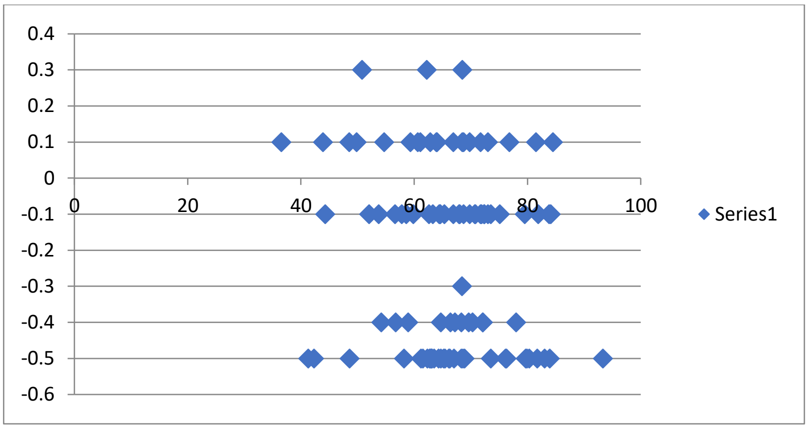
5.2.3. Statistical Analysis

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

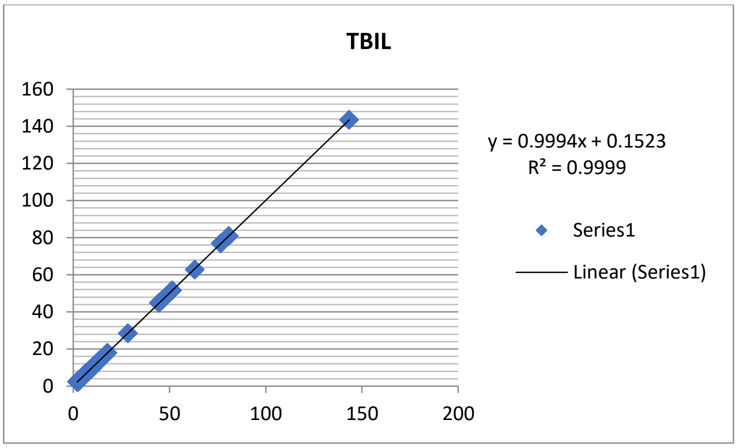
Calculated regression equation y = 1.0028x + 0.0334

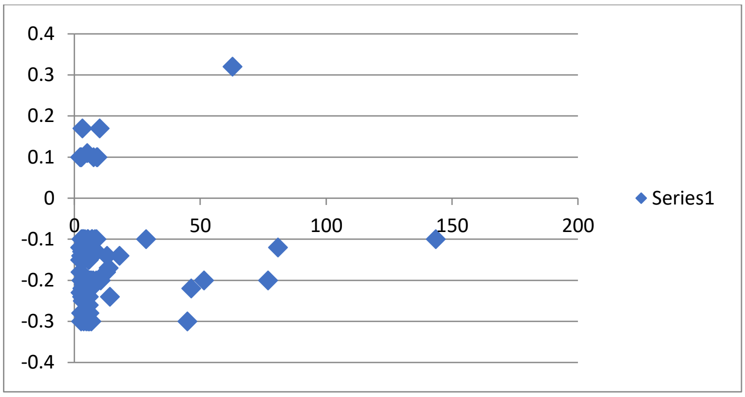
5.3.3. Statistical Analysis

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 (TBIL)

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=0.9999, 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

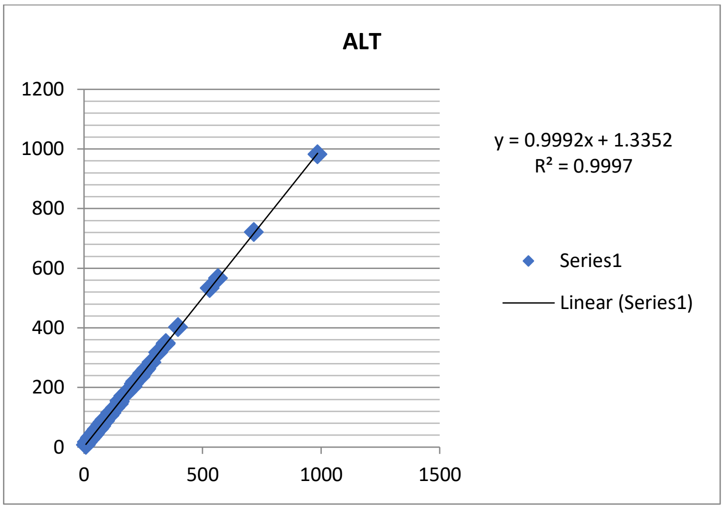
Calculated regression equation y = 0.9994x + 0.1523

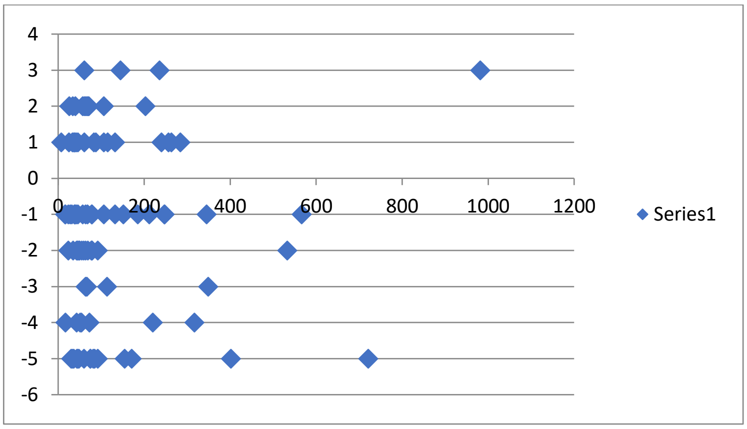
5.4.3. Statistical Analysis

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 (ALT)

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 of the test system and the control system is calculated to be r=0.9998, 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

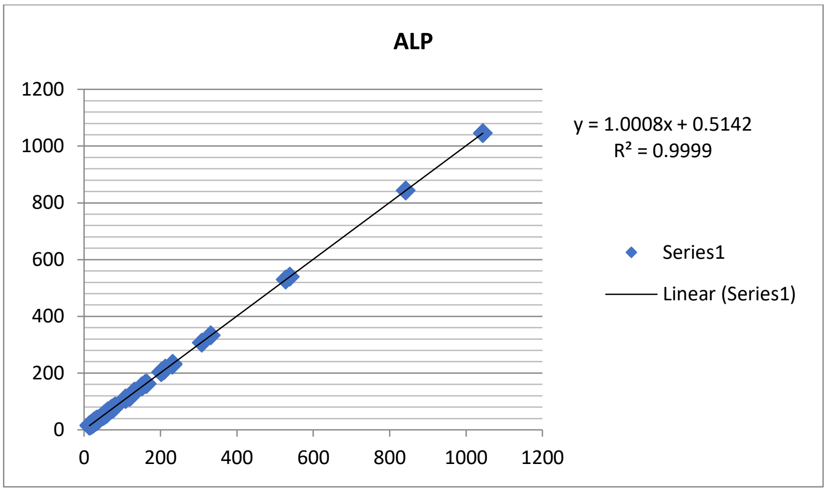
Calculated regression equation y = 0.9992x + 1.3352

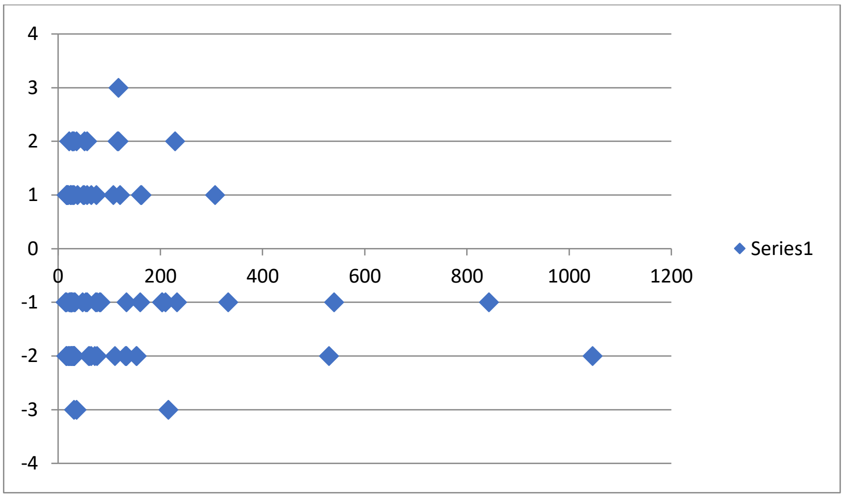
5.5.3. Statistical Analysis

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 (ALP)

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 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.

5.6.2. Linear Regression Analysis

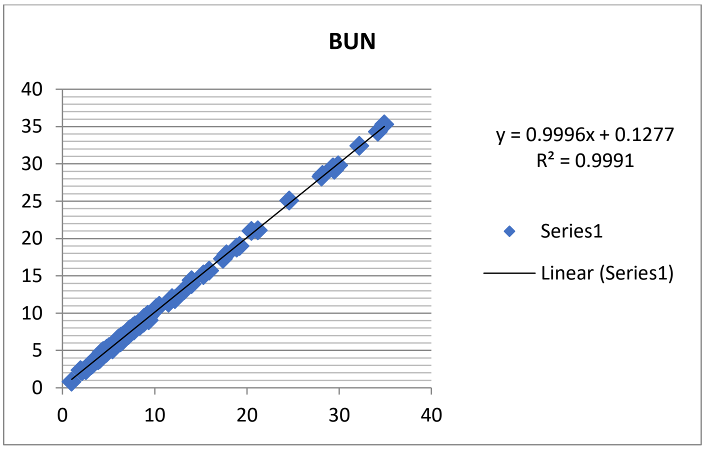
Calculated regression equation y = 1.0008x + 0.5142

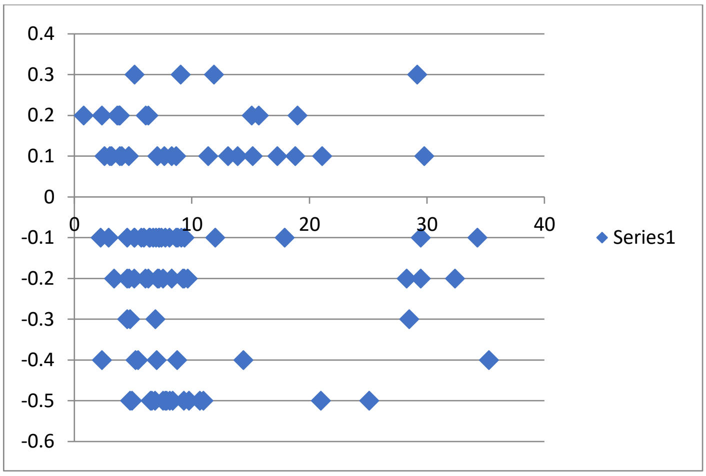
5.6.3. Statistical Analysis

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 (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.





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=0.9995, 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

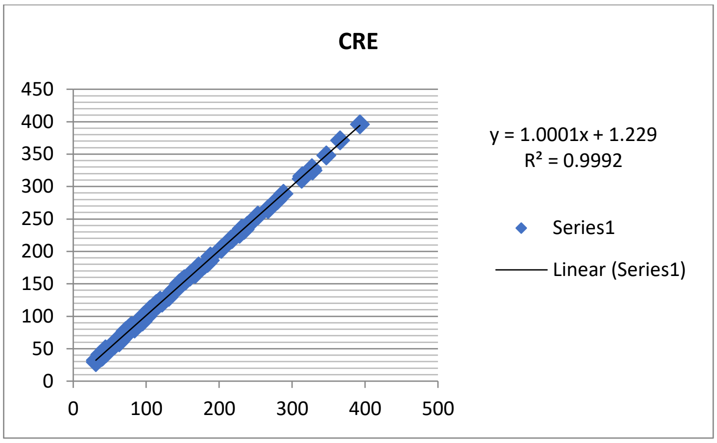
Calculated regression equation y = 0.9996x + 0.1277

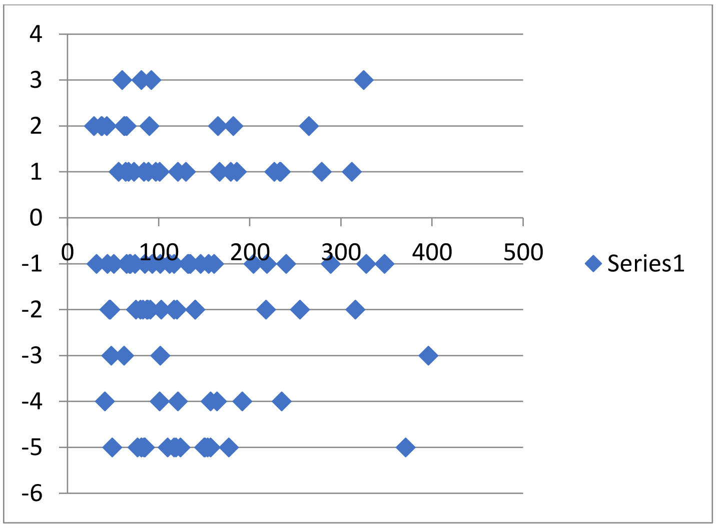
5.7.3. Statistical Analysis

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 (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.





5.8.1. 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 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.

5.8.2. Linear Regression Analysis

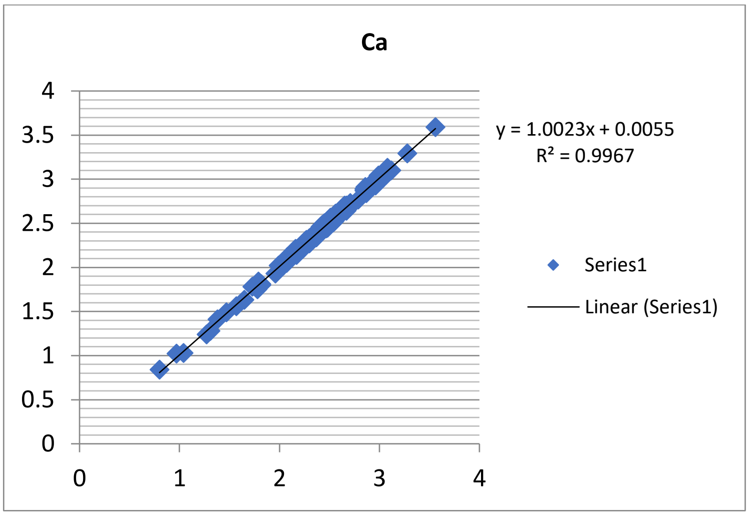
Calculated regression equation y = 1.0001x + 1.229

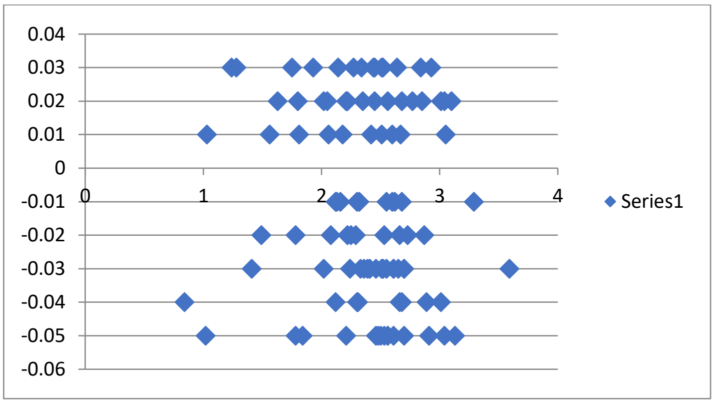
5.8.3. Statistical Analysis

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 (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.





5.9.1. 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=0.9983, 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

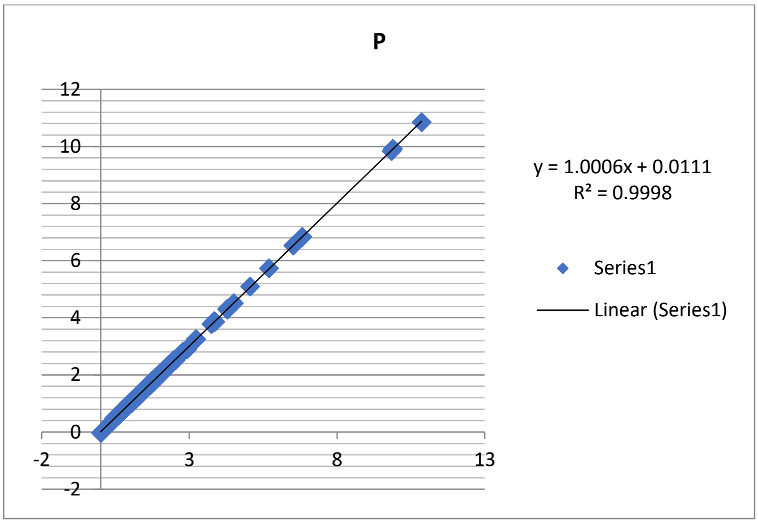
Calculated regression equation y = 1.0023x + 0.0055

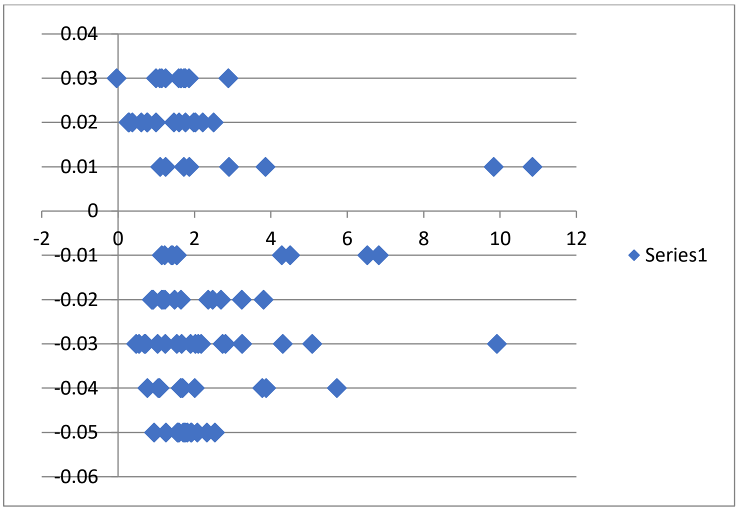
5.9.3. Statistical Analysis

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, no significant difference.

5.10. 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.





5.10.1. 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 r=0.9991, which is greater than 0.975. The range of values is suitable and the correlation and consistency are good.

5.10.2. Linear Regression Analysis

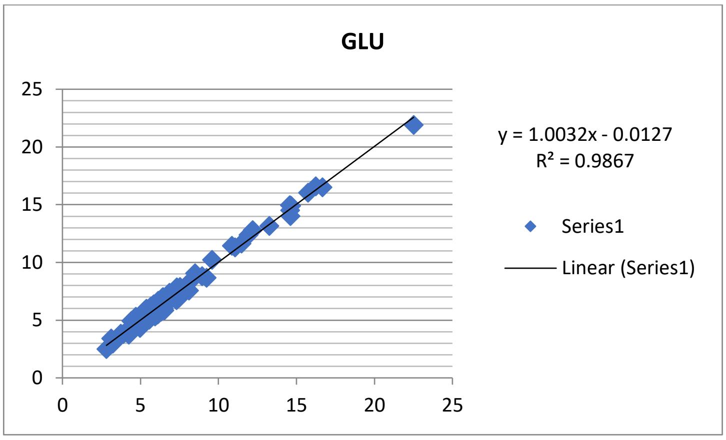
Calculated regression equation y = 1.0006x + 0.0111

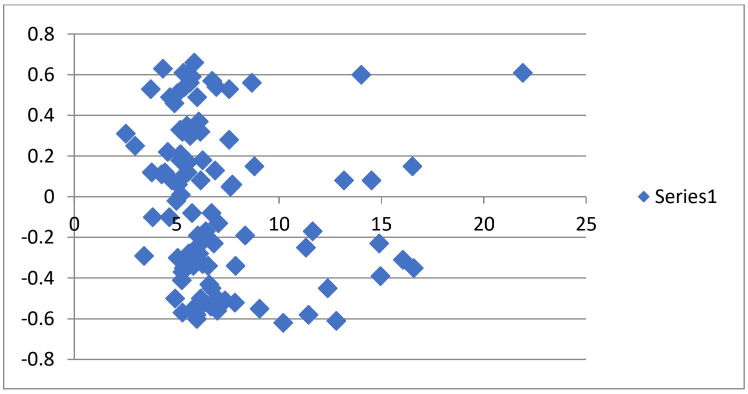
5.10.3. Statistical Analysis

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, no significant difference.

5.11. 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.





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

5.11.2. Linear Regression Analysis

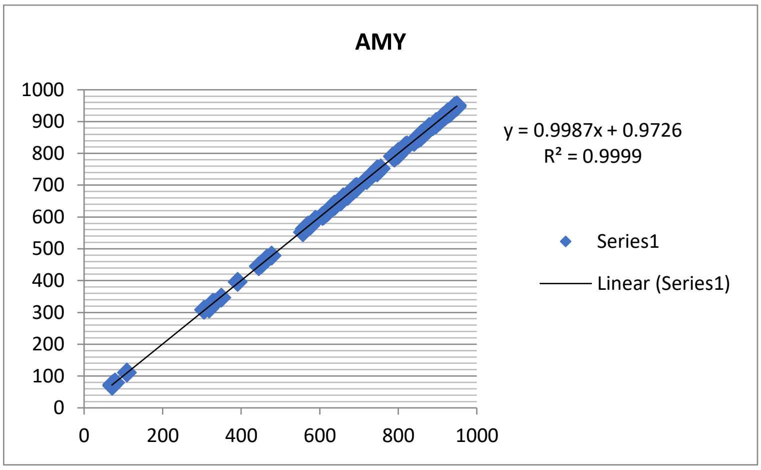
Calculated regression equation y = 1.0032x - 0.0127

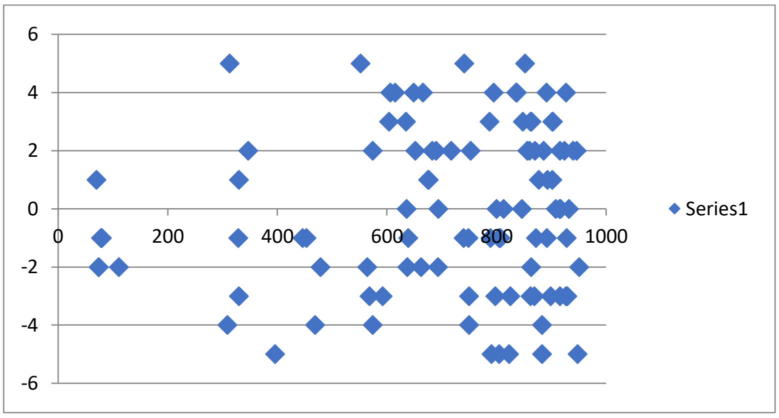
5.11.3. Statistical Analysis

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, no significant difference.

5.12. Results Statistics and Analysis (AMY)

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.





5.12.1. 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.

5.12.2. Linear Regression Analysis

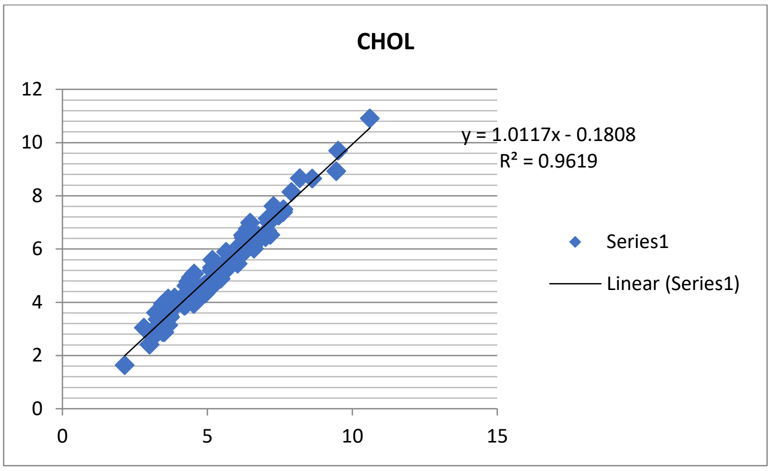
Calculated regression equation y = 0.9987x + 0.9726

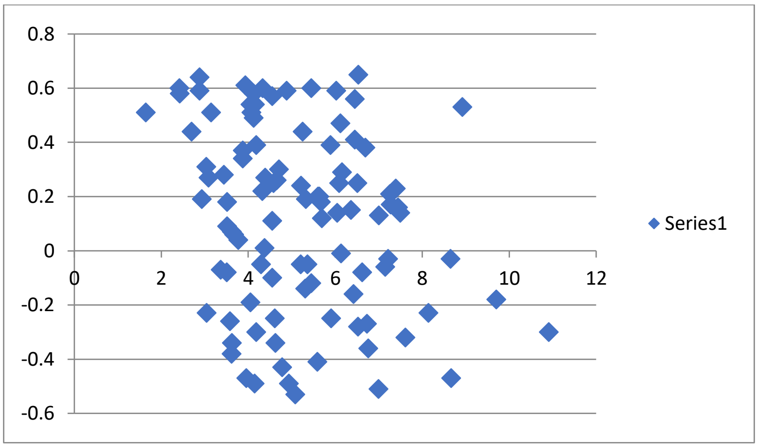
5.12.3. Statistical Analysis

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.

5.13. Results Statistics and Analysis (CHOL)

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.





5.13.1. 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=0.9807, which is greater than 0.975. The range of values is appropriate and the correlation and consistency are good.

5.13.2. Linear Regression Analysis

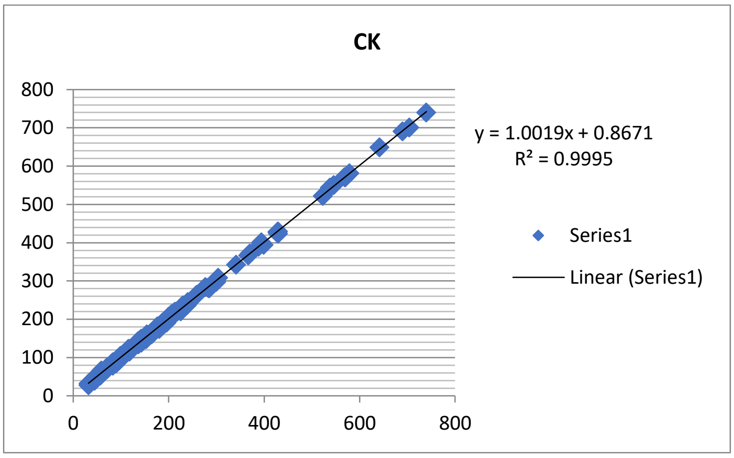
Calculated regression equation y = 1.0117x - 0.1808

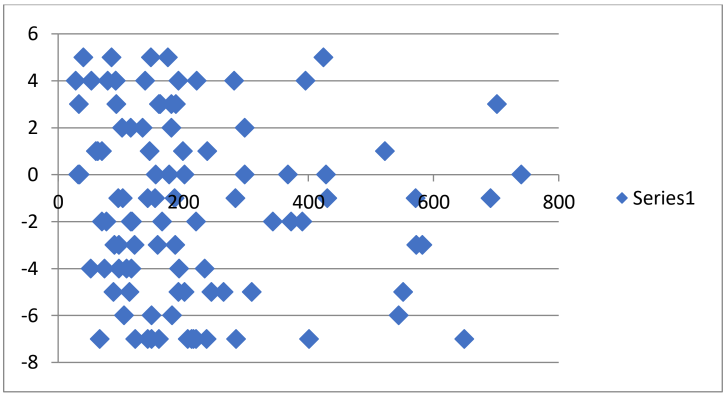
5.13.3. Statistical Analysis

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.

5.14. 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.





5.14.1. 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.

5.14.2. Linear Regression Analysis

Calculated regression equation $y = 1.0019x + 0.8671$

5.14.3. 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 > $t_{0.05}$, $P < 0.05$. 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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