WOODLEY EQUIPMENT COMPANY LTD.

InSight V-CHEM®

Veterinary Chemistry Analyser

Correlation Study – Preanaesthetic Plus Panel

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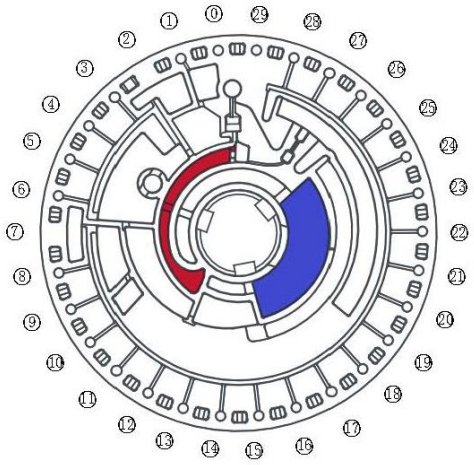
Approved By: _____ **Date:** 10/9/2021

1. Clinical Evaluation Purposes

This clinical evaluation trial is a set of comparison experiments to investigate the equivalence of Preanesthetic Panel Plus 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 Preanaesthetic Panel Plus is used to quantitative test the concentration of the nine 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) 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.

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

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

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.

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.

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

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

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) 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.

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

e) 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.

f) 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.

g) 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.

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

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

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.

h) 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.

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

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

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

i) Lactate Dehydrogenase (LDH)

Lactate dehydrogenase (LDH) catalyses the oxidation of L-lactate to pyruvate with the concurrent reduction of nicotinamide adenine dinucleotide (NAD^+) to reduced nicotinamide adenine dinucleotide (NADH). The NADH is then oxidised with the simultaneous reduction of INT in a reaction catalysed by diaphorase. The intensity of the highly coloured formazan is measured bichromatically at 505/800 nm and is directly proportional to the concentration of triglycerides in the sample.

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

$$NADH + H^+ + \text{INT} \xrightarrow{\text{Diaphorase}} NAD^+ + \text{Formazan}$$

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
ALT	Dog: 10 ~ 118U/L	Dog: 10 ~ 118U/L
	Cat: 8.2 ~ 100U/L	Cat: 8.2 ~ 100U/L
AST	Dog: 8.9 ~ 48.5U/L	Dog: 8.9 ~ 48.5U/L
	Cat: 9.2 ~ 39.5U/L	Cat: 9.2 ~ 39.5U/L
ALP	Dog: 20 ~ 150U/L	Dog: 20 ~ 150U/L
	Cat: 10 ~ 90U/L	Cat: 10 ~ 90U/L
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
CK	Dog: 20 ~ 200U/L	Dog: 20 ~ 200U/L
	Cat: 50 ~ 450U/L	Cat: 50 ~ 450U/L
LDH	Dog: 40 ~ 400U/L	Dog: 40 ~ 400U/L
	Cat: 0 ~ 800U/L	Cat: 0 ~ 800U/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 Preanaesthetic Panel Plus containing 9 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
ALT	100
AST	100
ALP	100
CRE	100
BUN	100
GLU	100
CK	100
LDH	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 TP g/L	VS2 reagent value TP g/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
61	61.5	48	50	24	26	5.86	6.06	45	47
92.8	93.3	62	64	23	25	7	7.2	216	218
62.2	62.7	38	39	56	57	5.83	5.93	92	93
58.5	58.9	67	68	160	161	2.83	2.93	31	32
64.1	64	89	88	58	57	21.2	21.1	168	167
48.6	48.5	985	982	66	65	5.44	5.14	63	60
83.7	83.8	111	114	24	25	4.22	4.52	45	48
73.4	73.5	87	92	30	32	4.25	4.75	72	77
60.7	60.6	716	721	27	29	20.5	21	172	177
68.4	68.9	40	45	60	62	7.88	8.38	119	124
67.9	68.3	39	43	16	17	4.82	5.22	117	121
69.9	69.8	264	263	18	17	11.5	11.4	74	73
84.6	84.5	37	36	20	19	3.98	3.88	85	84
64.5	64.6	41	43	14	16	6.9	7.1	85	87
79.4	79.5	67	69	152	154	8.11	8.31	115	117
81.6	81.5	66	64	30	28	2.55	2.35	65	63
68.1	68.6	25	30	20	22	4.42	4.92	44	49

57.7	58.2	28	33	24	26	6.1	6.6	80	85
62.3	62.8	43	48	63	65	24.6	25.1	366	371
64.3	64.7	13	17	32	33	14	14.4	160	164
67.9	68	84	83	32	31	29.9	29.8	235	234
68.6	68.7	26	25	50	49	18.9	18.8	187	186
68.8	68.7	71	69	59	57	4.09	3.89	67	65
75.8	76.3	53	55	151	153	7.37	7.57	78	80
60.7	61.2	47	46	122	121	14	13.9	131	130
71.8	71.9	77	79	14	16	4.48	4.68	89	91
69.9	70.3	47	51	53	54	8.36	8.76	153	157
66.8	67.2	50	54	25	26	6.62	7.02	188	192
51.1	50.8	239	236	121	118	29.5	29.2	328	325
72.3	72.4	45	46	26	27	2.14	2.24	43	44
68.1	68.4	61	64	33	36	4.46	4.76	99	102
58.5	58.6	38	39	24	25	6.29	6.39	68	69
70.6	70.7	15	16	21	22	6.34	6.44	145	146
64.2	64.7	27	28	30	31	4.4	4.5	131	132
82.5	83	105	106	14	15	7.11	7.21	160	161
71.7	72.1	42	40	231	229	15.9	15.7	167	165
67.8	67.9	75	77	131	133	6.12	6.32	138	140
63.2	63.3	69	67	24	22	4	3.8	64	62
64	63.9	73	71	54	52	6.5	6.3	45	43
66.5	67	56	57	24	25	5	5.1	73	74
62.6	63.1	55	60	528	530	7.64	8.14	152	157
61.2	61.1	62	61	30	29	13.2	13.1	90	89
64.3	64.4	41	42	22	23	7.66	7.76	64	65
62.5	63	8	7	25	24	2.69	2.59	68	67
64.7	65.2	40	39	25	24	3.29	3.19	57	56
53.8	54.2	151	152	209	210	7.33	7.43	111	112
49.9	49.8	247	248	332	333	11.9	12	203	204
44.2	44.3	565	566	202	203	8.72	8.82	218	219
72.9	73	63	64	203	204	6.86	6.96	132	133
76.9	76.8	59	57	33	31	1.01	0.81	40	38
65.6	66.1	45	47	27	29	9.04	9.24	138	140
81.2	81.7	63	61	38	36	6.3	6.1	39	37
73.1	73	258	257	308	307	4.16	4.06	98	97

81.8	81.9	78	79	14	15	29.4	29.5	327	328
53.6	53.7	37	38	26	27	5.03	5.13	116	117
59.7	59.8	31	32	75	76	6.63	6.73	134	135
63	63.5	184	185	47	48	9.29	9.39	154	155
79.4	79.9	285	284	164	163	7.76	7.66	234	233
77.6	78	22	24	15	17	4.91	5.11	81	83
71.8	71.7	116	115	28	27	15.3	15.2	313	312
69.7	69.8	108	106	32	30	3.88	3.68	31	29
84	84.1	43	42	19	18	3.15	3.05	102	101
68.6	68.5	39	44	70	72	7.07	7.57	112	117
83.4	83.9	531	533	1044	1046	9.47	9.67	118	120
79.2	79.7	150	155	132	134	7.35	7.85	146	151
59.4	59.3	133	132	109	108	8.39	8.29	228	227
75	75.1	57	59	28	30	3.2	3.4	101	103
62.5	62.2	148	145	163	162	12.2	11.9	95	92
56.3	56.7	69	73	133	134	5.04	5.44	97	101
71.6	71.7	131	132	24	25	34.2	34.3	288	289
57.7	57.8	77	79	30	32	4.32	4.52	73	75
66.8	66.9	246	247	842	843	9.02	9.12	239	240
62.5	62.6	90	92	21	23	32.2	32.4	314	316
65.8	66.3	211	212	82	83	5.6	5.7	67	68
48.1	48.6	344	345	539	540	17.8	17.9	347	348
66	66.4	34	33	39	38	7.16	7.06	122	121
70.7	70.8	64	67	28	31	6.61	6.91	59	62
64.5	64.6	23	24	80	81	8.58	8.68	84	85
36.6	36.5	205	203	120	118	19.2	19	267	265
41.8	42.3	346	349	213	216	28.2	28.5	393	396
62.6	63.1	107	106	18	17	8.79	8.69	180	179
75.6	76.1	166	171	58	60	9.27	9.77	145	150
79.8	80.3	77	82	130	132	5.99	6.49	76	81
69.2	69.6	313	317	25	26	34.9	35.3	231	235
56.5	56.6	33	35	30	32	9.16	9.36	44	46
67.8	68.3	31	36	28	30	8.84	9.34	114	119
67	66.9	28	26	30	28	15.3	15.1	184	182
51.9	52	77	78	232	233	8.02	8.12	50	51
65.2	65.3	16	17	27	28	7.14	7.24	101	102

44	43.9	397	402	109	111	7.25	7.75	105	110
40.8	41.3	241	240	76	75	17.4	17.3	280	279
61.8	62.3	48	50	18	20	28.1	28.3	86	88
68.8	68.5	64	61	21	20	9.37	9.07	84	81
54.8	54.7	39	38	52	51	4.76	4.66	65	64
63.8	64.3	70	75	24	26	10.2	10.7	79	84
73	73.5	80	85	26	28	10.5	11	149	154
71.7	72.1	216	220	73	74	1.95	2.35	37	41
72.2	72.3	43	45	18	20	29.3	29.5	253	255
64.9	65.4	70	75	74	76	6.38	6.88	76	81
62.9	62.8	36	34	118	116	4.05	3.85	92	90

V-CHEM reagent value GLU	VS2 reagent value GLU	V-CHEM reagent value CK U/L	VS2 reagent value CK U/L	V-CHEM reagent value AST U/L	VS2 reagent value AST U/L	V-CHEM reagent value LDH U/L	VS2 reagent value LDH U/L
5.73	5.56	197	202	41	43	214	213
5.61	5.29	196	192	50	52	118	119
5.4	5.19	183	181	32	33	150	152
14.59	14.51	570	571	33	34	234	237
14.62	14.02	546	551	21	20	172	170
14.66	14.89	569	572	222	221	126	127
11.06	11.31	285	281	61	62	230	232
5.94	6.27	206	213	42	44	266	265
6.17	6.6	96	92	104	106	695	696
13.25	13.17	59	66	22	24	180	182
6.52	5.86	96	93	41	45	519	515
5.26	5.81	143	149	87	86	134	135
6.15	5.56	156	156	16	15	171	170
6.32	5.73	34	34	17	19	234	235
3.91	3.79	95	96	27	29	134	136
11.93	12.38	523	522	48	46	126	125
7.32	7.84	96	92	27	29	289	290
2.82	2.51	164	161	23	25	178	178

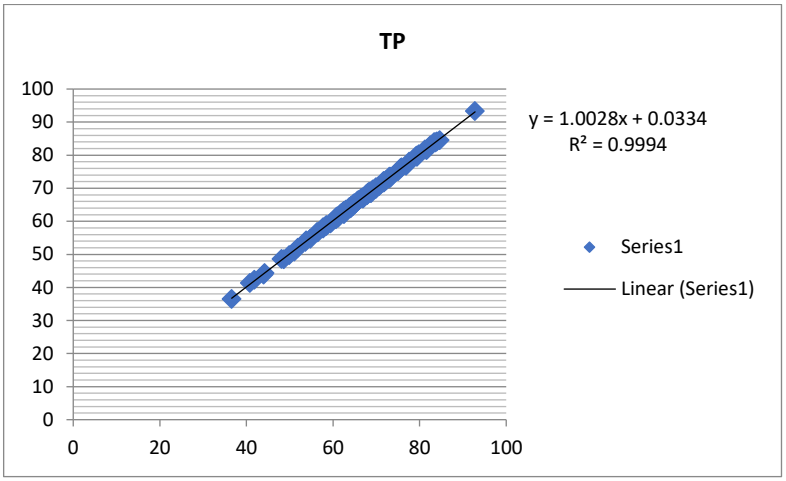
12.19	12.8	399	395	14	16	152	151
6.85	7.36	341	343	72	76	92	91
16.23	16.58	259	264	41	40	165	167
7.68	7.63	213	220	72	71	392	393
7.48	6.94	240	245	38	36	237	236
5.65	5.53	180	175	16	18	169	172
5.84	6.03	200	199	21	20	240	239
6.47	6.97	75	77	80	82	213	214
6.43	6.99	200	207	36	40	200	201
4.75	5.05	185	186	12	16	158	159
4.79	4.57	239	238	61	58	188	188
5	5.35	68	70	27	28	246	247
6.47	6.15	166	163	23	26	260	257
5.3	5.58	428	428	32	33	1290	1291
8.1	7.57	147	146	27	28	191	193
22.51	21.9	579	582	21	22	119	117
4.96	4.33	102	103	51	52	303	302
6.25	6.17	277	284	24	22	284	285
3.12	3.41	48	52	40	42	131	130
4.42	4.92	99	105	48	46	239	237
5.39	5.97	94	97	25	23	120	121
6.2	5.64	184	181	32	33	166	168
8.16	8.35	538	544	42	44	265	257
6.19	6.53	83	88	25	24	202	203
6.49	6	225	221	18	19	118	116
5.82	6.1	113	117	25	24	130	131
5.76	5.43	90	85	15	14	1213	1215
4.54	4.64	202	202	75	76	385	386
5.85	5.5	104	102	105	106	280	278
6.9	7.03	388	390	344	345	177	178
5.96	5.66	142	149	18	19	222	225
5.67	6.17	154	161	20	18	231	230
5.12	5.06	114	116	39	41	228	229
5.93	5.39	164	166	29	27	209	207

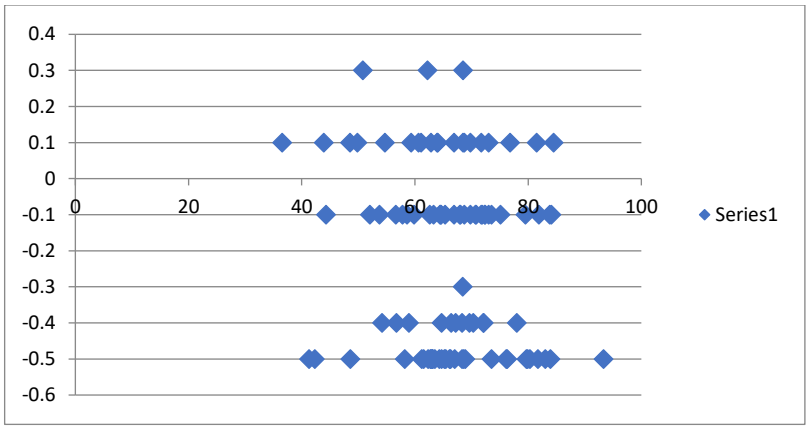
5.35	4.89	642	649	28	27	143	140
3.73	3.83	93	97	32	33	211	211
5.56	5.05	136	143	69	70	106	107
7.31	6.74	230	237	37	38	482	483
5.35	5.63	71	70	61	62	845	847
7.78	7.72	230	234	50	49	118	119
7	6.87	116	118	31	33	131	130
10.86	11.44	184	187	50	49	1235	1236
6.58	6.81	83	79	24	22	117	119
8.5	9.05	119	122	20	19	194	196
5.16	4.67	191	188	29	31	424	428
15.74	16.05	57	53	386	388	144	142
6.63	6.71	118	116	37	39	117	118
6.1	5.5	45	40	20	19	772	778
4.26	3.73	64	63	23	25	377	378
6.26	6.71	116	123	28	27	140	142
4.91	5.28	142	143	21	25	426	424
6.25	6.42	32	28	78	79	1410	1411
4.96	4.98	154	155	38	40	152	150
5.21	5.2	109	114	89	90	377	375
5.67	5.75	218	220	23	25	25	26
5.36	5.18	209	216	103	104	177	175
4.84	5.25	87	90	166	167	395	398
5.38	5.98	32	32	78	77	690	692
5.51	5.18	300	298	35	38	3128	3139
4.85	4.77	187	192	23	24	125	126
11.47	11.64	740	740	678	676	816	815
6.12	6.32	177	177	717	720	90	89
5.51	5.4	304	309	23	22	181	182
6.14	6.68	156	159	35	37	536	535
6.45	6.08	36	33	47	49	700	693
5.85	6.37	367	367	50	54	526	526
4.71	5.28	153	148	87	89	690	695
7.84	7.56	282	283	23	25	540	546

4.55	4.43	105	109	29	27	306	305
7.54	7.88	298	298	92	93	625	624
5.57	5.39	176	182	23	24	832	826
16.66	16.51	429	430	671	673	502	502
3.22	2.97	370	372	566	565	390	392
9.23	8.67	137	135	38	40	709	712
5.47	5.81	189	193	46	45	286	286
6.45	6.27	690	691	22	21	390	388
9.59	10.21	429	424	50	52	260	262
5.94	5.33	61	60	17	19	512	513
8.95	8.8	704	701	40	44	636	636
5.82	6.06	70	74	123	125	434	438
14.57	14.96	394	401	32	34	628	625
4.37	4.26	143	139	46	44	771	772

5.2. 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.





5.2.1. 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 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.

5.2.2. Linear Regression Analysis

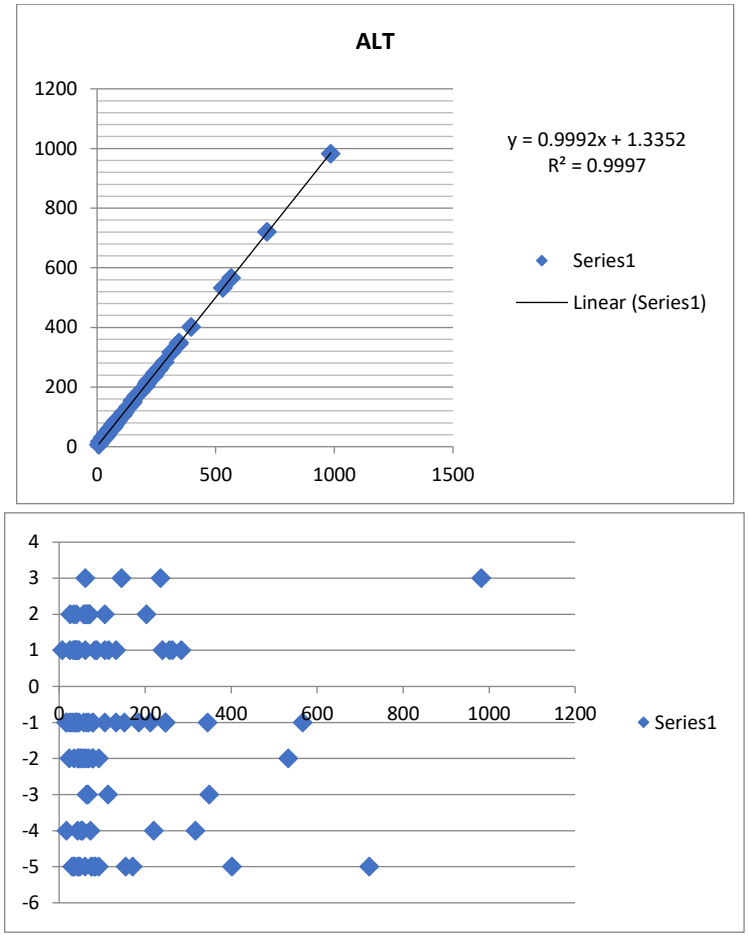
Calculated regression equation y = 1.0028x + 0.0334

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 (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.



5.3.1. 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.

5.3.2. Linear Regression Analysis

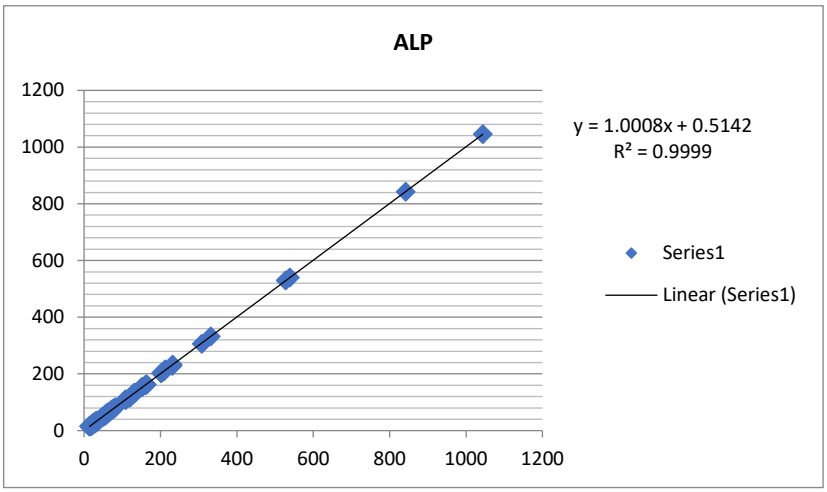
Calculated regression equation y = 0.9992x + 1.3352

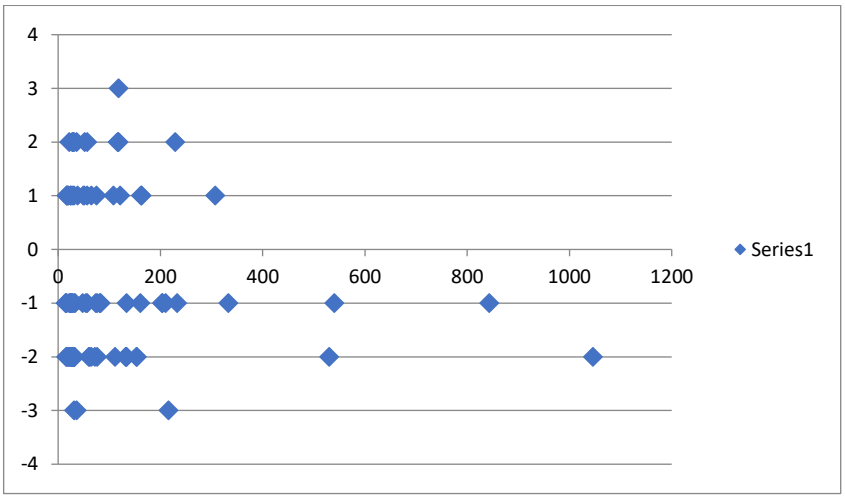
5.3.3. Statistical Analysis

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 (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.





5.4.1. 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

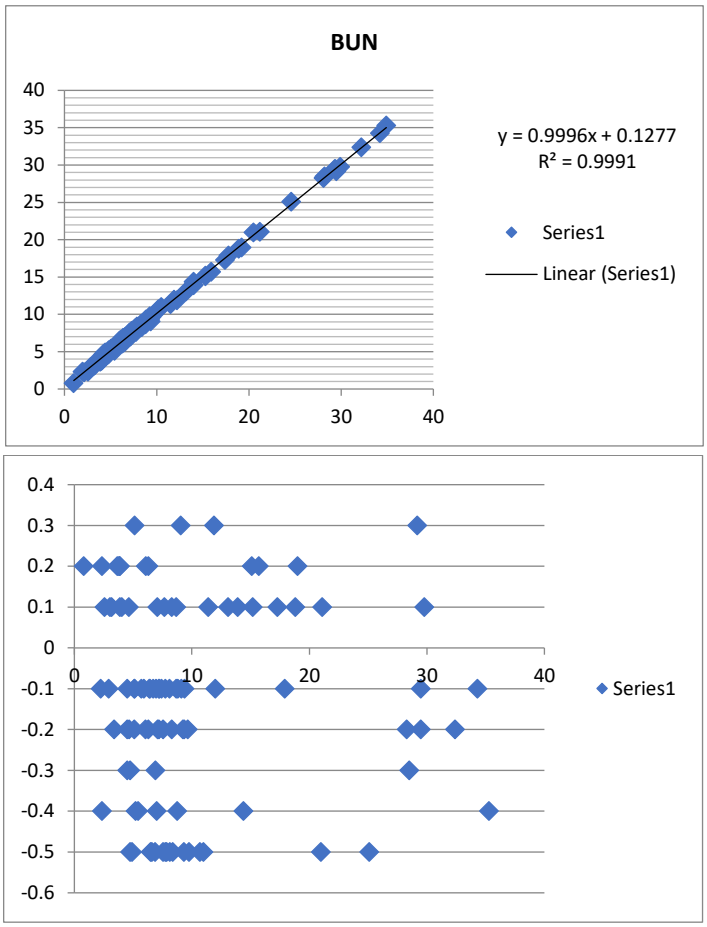
Calculated regression equation y = 1.0008x + 0.5142

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 (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.



5.5.1. 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=0.9995, 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

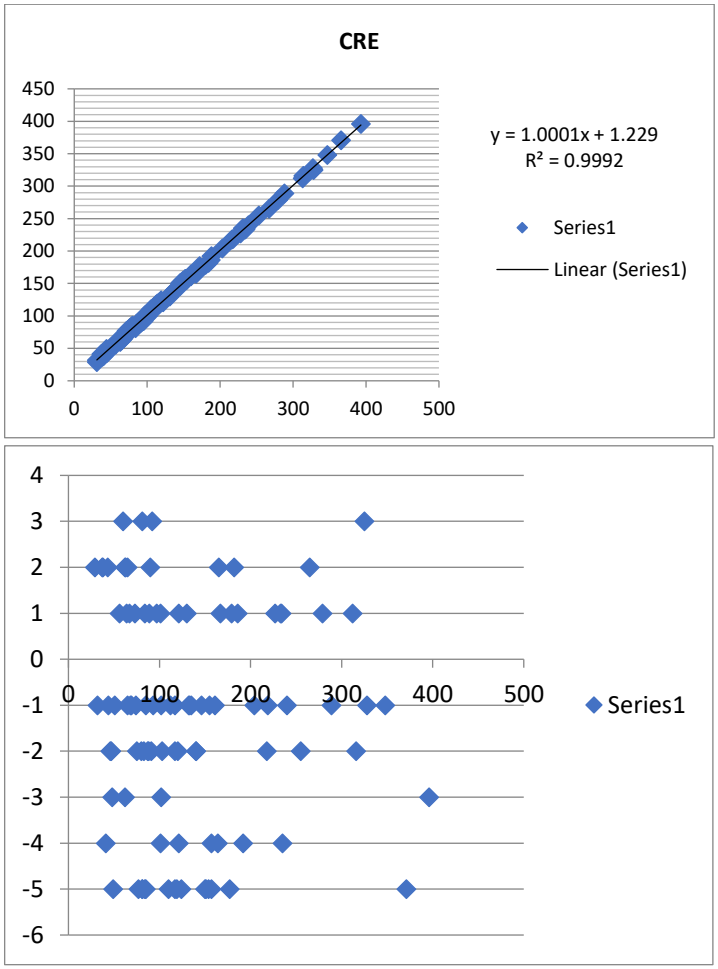
Calculated regression equation y = 0.9996x + 0.1277

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 (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.



5.6.1. 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=0.9996, 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

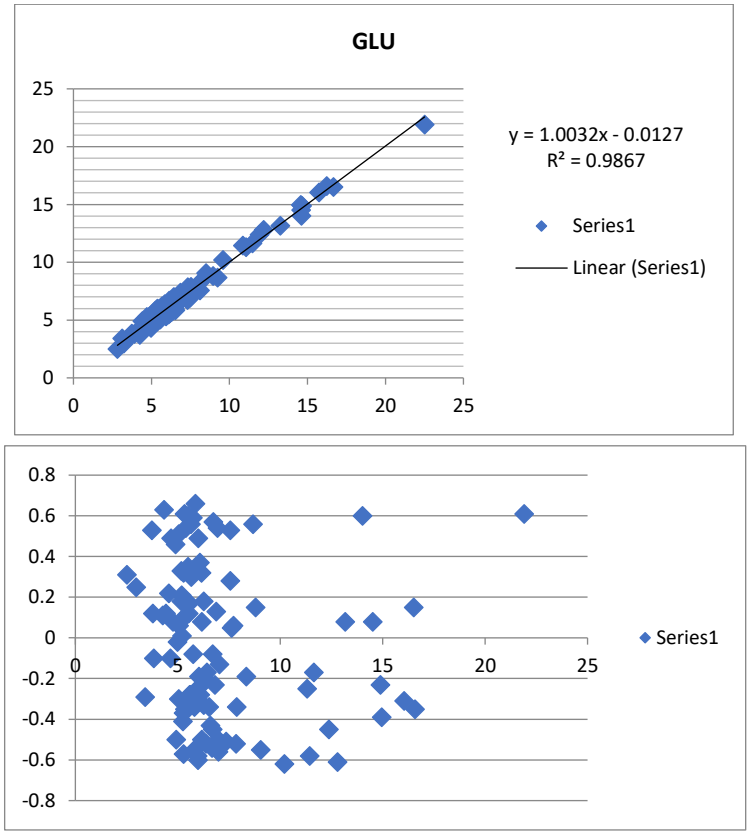
Calculated regression equation y = 1.0001x + 1.229

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 (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.



5.7.1. 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=0.9932, 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 = 1.0032x - 0.0127

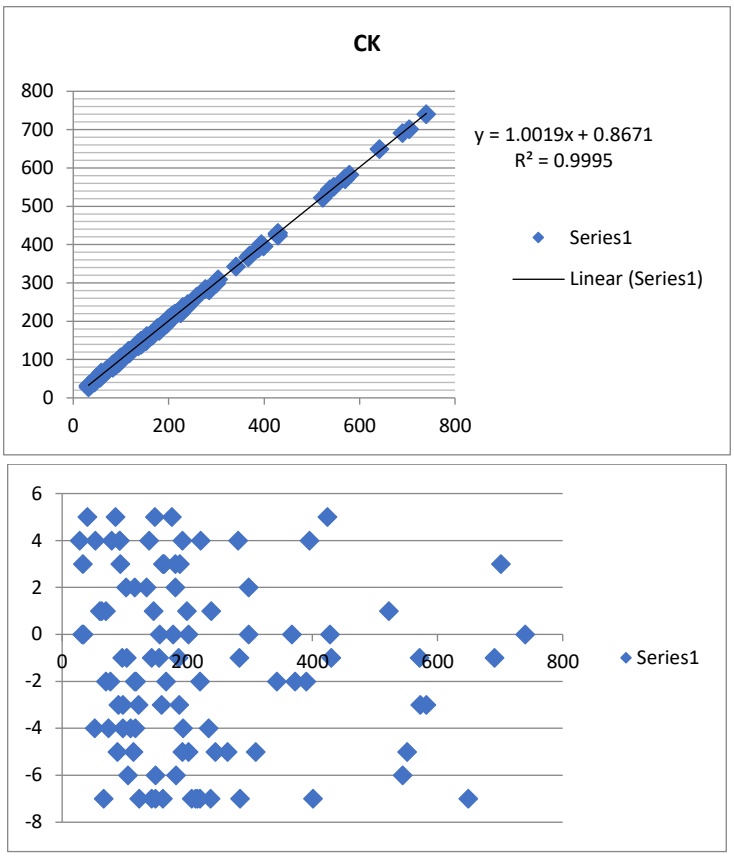
5.7.3. Statistical Analysis

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

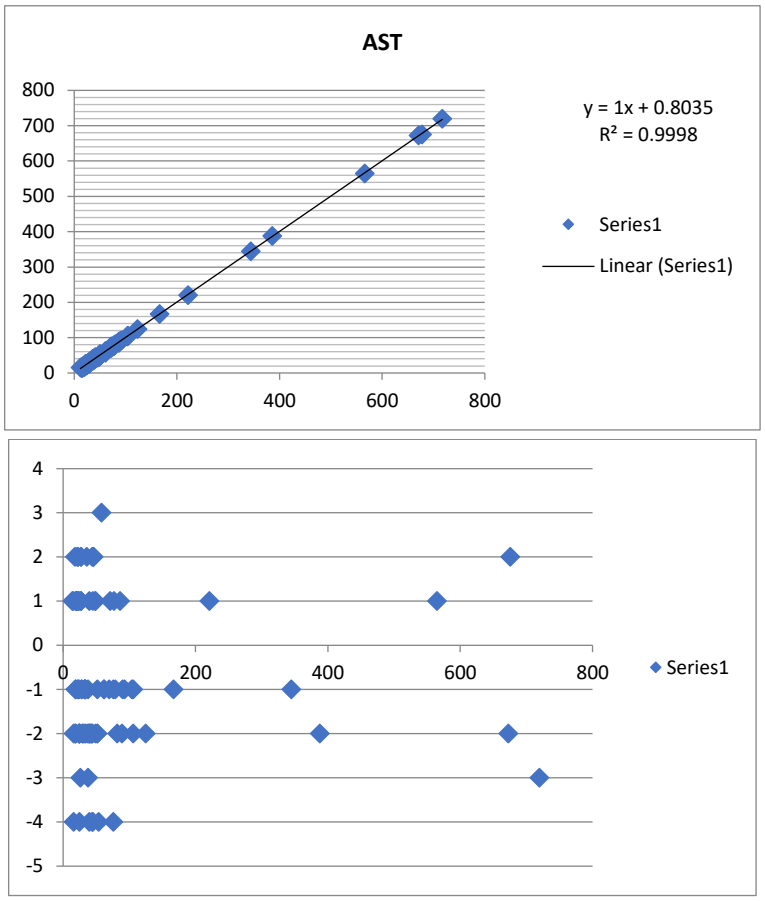
Calculated regression equation y = 1.0019x + 0.8671

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 (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.



5.9.1. 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 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.

5.9.2. Linear Regression Analysis

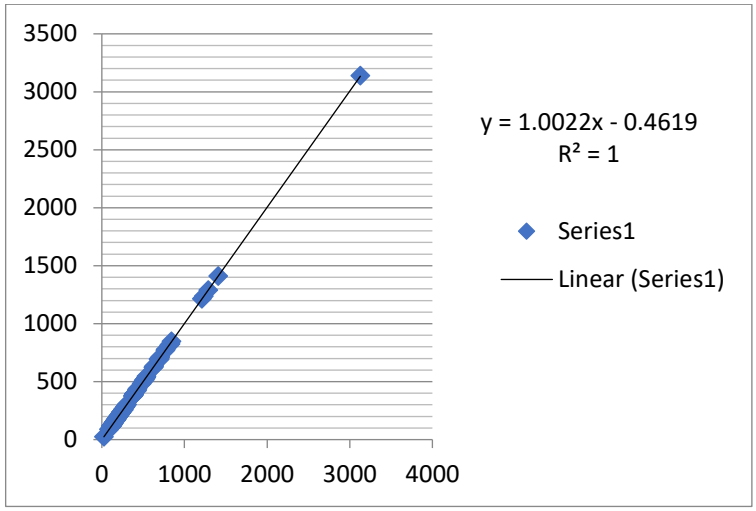
Calculated regression equation y = 1x + 0.8035

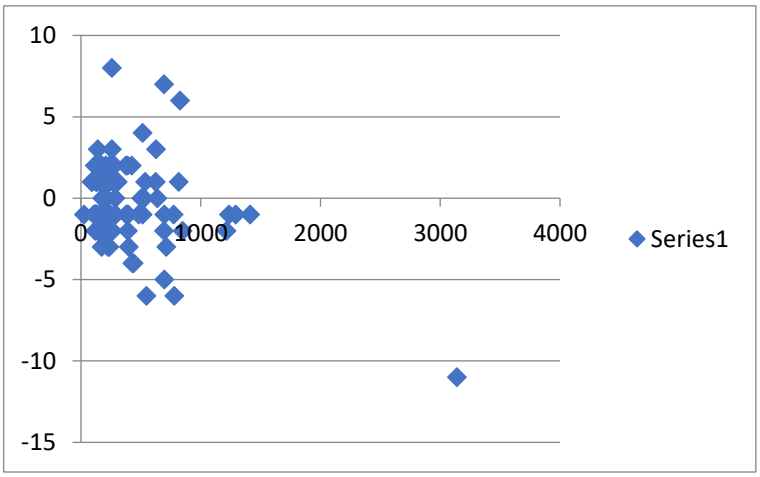
5.9.3. Statistical Analysis

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 (LDH)

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=1, 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 = 1.0022x - 0.4619

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.

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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