WOODLEY
EQUIPMENT COMPANY LTD.

InSight V-CHEM®

Veterinary Chemistry Analyser

Correlation Study – Liver Panel

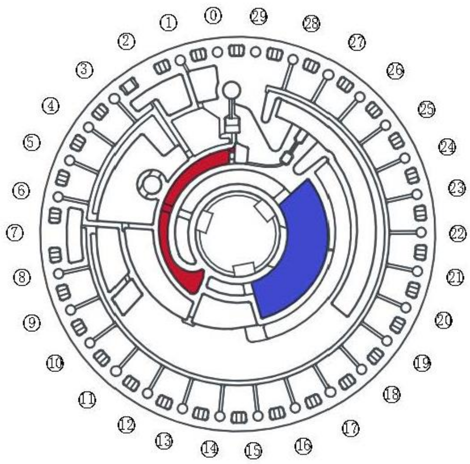
Contents

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

1. Clinical Evaluation Purposes

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

2. Product Introduction



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

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

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

The InSight V-CHEM Liver Panel is used to quantitative test the concentration of the eight 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 colored 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.

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

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

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) 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.

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

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

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.

e) Gamma Glutamyl Transferase (GGT)

The addition of sample containing gamma glutamyl tranferase to the substrates L-γ-glutamyl-3-carboxy-4-nitroanilide and glycylglycine causes the formation of L-γ-glutamyl- glycylglycine (glu-gly-gly) and 5-Amino-2-nitrobenzoate.

$$\text{L-}\gamma\text{-glutamyl-3-carboxy-4-nitroanilide+ glycylglycine} \xrightarrow{\text{GGT}} \text{Glu-gly-gly + 5-Amino-2 - nitrobenzoate}$$

The absorbance of this rate reaction is measured at 405/505 nm. The production is directly proportional to the GGT activity in the sample.

f) 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.

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

g) 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.

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

h) Direct Bilirubin (DBIL)

In the enzymatic procedure, the soluble bilirubin complex (direct bilirubin) is oxidised by bilirubin oxidase (BOD) into biliverdin.

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

Direct Bilirubin is quantitated as the difference in absorbance between 450 nm and 546 nm. The initial absorbance of this end point reaction is determined from the direct bilirubin blank cuvette and the final absorbance is obtained from the direct bilirubin test cuvette. The amount of direct bilirubin in the sample is proportional to the difference between the initial and final absorbance measurements.

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
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
GGT	Dog: 0 ~ 7U/L	Dog: 0 ~ 7U/L
	Cat: 0 ~ 2U/L	Cat: 0 ~ 2U/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
DBIL	Dog: 0 ~ 3.4μmol/L	Dog: 0 ~ 0.2mg/dL
	Cat: 0 ~ 3.4μmol/L	Cat: 0 ~ 0.2mg/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 Liver Panel containing 8 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
AST	100
GGT	100
ALP	100
TBIL	100
DBIL	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):

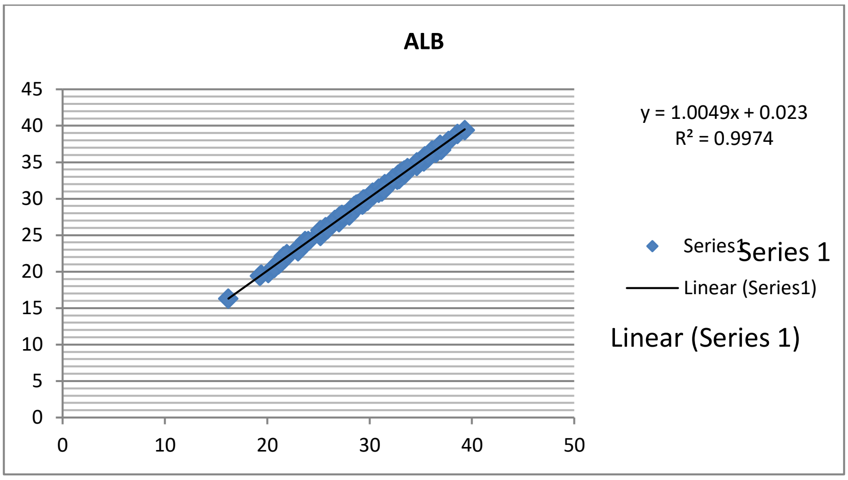
V-CHEM reagent value ALB g/L	VS2 reagent value ALB g/L	V-CHEM reagent value TP g/L	VS2 reagent value TP g/L	V-CHEM reagent value TBIL umol/L	VS2 reagent value TBIL umol/L	V-CHEM reagent value ALT U/L	VS2 reagent value ALT U/L	V-CHEM reagent value AST U/L	VS2 reagent value AST U/L	V-CHEM reagent value GGT U/L	VS2 reagent value GGT U/L	V-CHEM reagent value DBIL umol/L	VS2 reagent value DBIL umol/L	V-CHEM reagent value ALP U/L	VS2 reagent value ALP U/L
23.7	23.9	61	61.5	3.32	3.15	48	50	41	43	0.5	0.6	1.58	1.8	24	26
19.4	19.6	92.8	93.3	12.42	12.6	62	64	50	52	1.4	1.5	6.06	6.31	23	25
30.4	30.5	62.2	62.7	80.73	80.85	38	39	32	33	0.4	0.4	44.31	44.58	56	57
21.1	21.2	58.5	58.9	5.13	5.02	67	68	33	34	1.1	1.1	0.57	0.68	160	161
29.4	29.3	64.1	64	2.39	2.67	89	88	21	20	1.7	1.6	1.2	1.06	58	57
25.2	24.9	48.6	48.5	3.56	3.71	985	982	222	221	1.3	1.2	1.3	1.13	66	65
38.6	38.9	83.7	83.8	7.66	7.56	111	114	61	62	0.1	0.1	3.53	3.71	24	25
33.4	33.9	73.4	73.5	9.22	9.12	87	92	42	44	1.2	1.3	3.68	3.8	30	32
23.7	24.2	60.7	60.6	4.72	4.86	716	721	104	106	1.8	1.7	0.73	0.62	27	29
27	27.5	68.4	68.9	5.69	5.97	40	45	22	24	0.3	0.3	2.43	2.71	60	62
25.7	26.1	67.9	68.3	3.52	3.67	39	43	41	45	1.1	1.2	0.62	0.76	16	17
25.3	25.2	69.9	69.8	13.89	14.13	264	263	87	86	1.5	1.5	6.55	6.85	18	17
21.1	21	84.6	84.5	6.3	6.52	37	36	16	15	1.2	1.1	2.8	2.9	20	19
37.7	37.9	64.5	64.6	3.48	3.68	41	43	17	19	0.8	0.9	1.2	1.32	14	16
32.1	32.3	79.4	79.5	3.32	3.46	67	69	27	29	0.3	0.3	1.08	1.28	152	154
31.2	31	81.6	81.5	2.89	2.79	66	64	48	46	1.7	1.6	1.16	1.38	30	28
31.5	32	68.1	68.6	5.5	5.74	25	30	27	29	0.4	0.4	2.67	2.87	20	22
30.3	30.8	57.7	58.2	3.97	4.19	28	33	23	25	1.8	1.9	1.41	1.64	24	26
27.1	27.6	62.3	62.8	3.85	4.05	43	48	14	16	0.4	0.5	1.64	1.76	63	65
28.9	29.3	64.3	64.7	17.77	17.91	13	17	72	76	1.5	1.5	5.39	5.53	32	33
32.7	32.6	67.9	68	2.21	2.39	84	83	41	40	1.8	1.9	0.09	0.27	32	31
34.6	34.5	68.6	68.7	5.07	5.17	26	25	72	71	0.1	0.1	1.98	2.08	50	49
36.5	36.3	68.8	68.7	2.74	2.98	71	69	38	36	0.8	0.7	0.02	-0.08	59	57
23.1	23.3	75.8	76.3	4.99	5.21	53	55	16	18	0.5	0.6	2.26	2.46	151	153

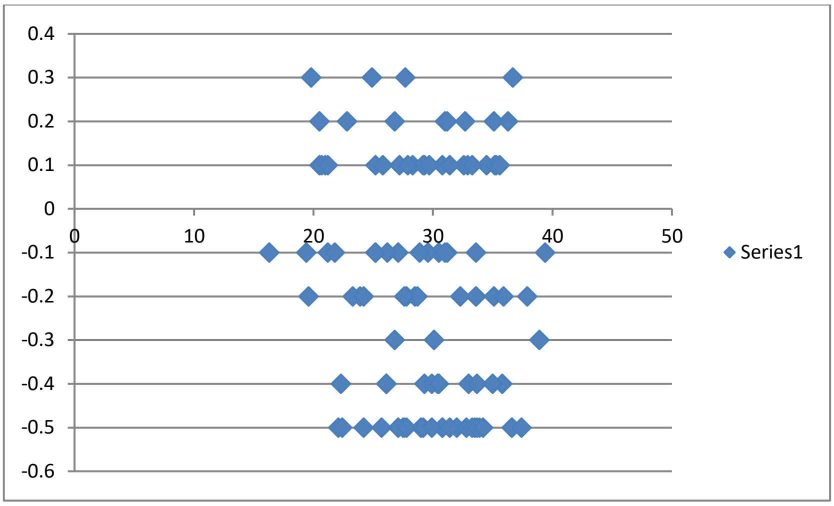
30.9	30.8	60.7	61.2	2.58	2.78	47	46	21	20	1.4	1.5	1.01	1.29	122	121
33.4	33.6	71.8	71.9	3.42	3.56	77	79	80	82	0.8	0.8	0.41	0.51	14	16
30	30.4	69.9	70.3	2.86	2.99	47	51	36	40	1.1	1.2	1	1.13	53	54
32.6	33	66.8	67.2	8.61	8.71	50	54	12	16	1.5	1.6	4.02	4.12	25	26
20.1	19.8	51.1	50.8	63.09	62.77	239	236	61	58	0.9	0.9	38.74	38.42	121	118
29.5	29.6	72.3	72.4	3.93	4.07	45	46	27	28	1.9	2	0.69	0.83	26	27
29.8	30.1	68.1	68.4	2.34	2.64	61	64	23	26	0.7	0.7	0.6	0.9	33	36
27	27.1	58.5	58.6	6.74	6.84	38	39	32	33	1.7	1.8	1.8	1.9	24	25
31.1	31.2	70.6	70.7	5.5	5.62	15	16	27	28	1.3	1.3	1.71	1.83	21	22
30.3	30.8	64.2	64.7	3.76	3.96	27	28	21	22	0.6	0.7	0.85	1.05	30	31
28.5	29	82.5	83	2.98	3.2	105	106	51	52	0.1	0.1	2.35	2.57	14	15
21.9	22.3	71.7	72.1	6.99	7.09	42	40	24	22	0.1	0.1	3.28	3.38	231	229
28.4	28.3	67.8	67.9	13.45	13.62	75	77	40	42	0.1	0.1	4.89	5.06	131	133
33	32.9	63.2	63.3	5.4	5.5	69	67	48	46	1.5	1.6	1.66	1.76	24	22
27	26.8	64	63.9	4.05	4.19	73	71	25	23	0.8	0.7	2.56	2.38	54	52
26.1	26.2	66.5	67	6.46	6.76	56	57	32	33	0.9	1	1.9	2.1	24	25
33	33.5	62.6	63.1	2.64	2.74	55	60	42	44	0.1	0.1	1.36	1.56	528	530
33.4	33.3	61.2	61.1	2.44	2.56	62	61	25	24	0.8	0.7	2.09	1.96	30	29
25.1	25.2	64.3	64.4	5.66	5.86	41	42	18	19	0.7	0.8	2.82	2.92	22	23
28.7	29.2	62.5	63	3.42	3.64	8	7	25	24	1.2	1.2	0.15	0.35	25	24
36.1	36.6	64.7	65.2	3.63	3.83	40	39	15	14	1.5	1.6	0.71	0.91	25	24
29.5	29.9	53.8	54.2	4.94	5.06	151	152	75	76	0.9	0.9	2.15	2.27	209	210
20.6	20.5	49.9	49.8	143.4	143.5	247	248	105	106	1.2	1.1	89.88	89.78	332	333
20.8	20.7	44.2	44.3	44.62	44.92	565	566	344	345	0.8	0.9	25.33	25.49	202	203
30.9	31	72.9	73	3.39	3.49	63	64	18	19	0.9	0.9	2.24	2.34	203	204
32.9	32.7	76.9	76.8	3.07	3.19	59	57	20	18	0.8	0.7	0.95	0.85	33	31
28.3	28.5	65.6	66.1	10.19	10.39	45	47	39	41	1.4	1.5	5.42	5.62	27	29
35.3	35.1	81.2	81.7	5.57	5.79	63	61	29	27	1.7	1.8	2.1	2.33	38	36
35.4	35.3	73.1	73	10.14	9.97	258	257	28	27	1.9	1.9	2.91	2.74	308	307
39.3	39.4	81.8	81.9	8.57	8.7	78	79	32	33	0.9	1	5.25	5.38	14	15
16.2	16.3	53.6	53.7	28.4	28.5	37	38	69	70	0.9	0.9	14.47	14.57	26	27
33.5	33.6	59.7	59.8	6.03	6.16	31	32	37	38	0.9	0.9	2.99	3.12	75	76
32.3	32.8	63	63.5	2.73	2.93	184	185	61	62	1.6	1.7	1.96	2.16	47	48
36.1	36.6	79.4	79.9	6.15	6.35	285	284	50	49	1.9	1.9	3.47	3.67	164	163
33.3	33.7	77.6	78	3.01	3.15	22	24	31	33	1	1.1	1.56	1.71	15	17
27.3	27.2	71.8	71.7	4.42	4.72	116	115	50	49	0.1	0.1	2.85	2.75	28	27
29.3	29.2	69.7	69.8	3.27	3.37	108	106	24	22	1.9	1.9	0.93	1.05	32	30
28	27.9	84	84.1	6.41	6.53	43	42	20	19	1	1.1	3.03	3.13	19	18
30.9	31.4	68.6	68.5	7.28	7.48	39	44	29	31	1.6	1.5	3.66	3.56	70	72

27.6	27.8	83.4	83.9	46.13	46.35	531	533	386	388	1.7	1.7	21.31	21.51	1044	1046
32.8	33.3	79.2	79.7	5.84	6.04	150	155	37	39	1.2	1.3	1.51	1.71	132	134
35.3	35.2	59.4	59.3	2.39	2.29	133	132	20	19	1	1	1.45	1.35	109	108
34.9	35.1	75	75.1	5.57	5.72	57	59	23	25	0.4	0.5	2.82	2.97	28	30
37	36.7	62.5	62.2	2.74	2.88	148	145	28	27	1	1	1.04	0.74	163	162
35.4	35.8	56.3	56.7	5.13	5.43	69	73	21	25	0.7	0.7	1.39	1.49	133	134
25.1	25.2	71.6	71.7	3.25	3.35	131	132	78	79	1.2	1.3	1.94	2.06	24	25
24	24.2	57.7	57.8	5.51	5.63	77	79	38	40	0.8	0.8	4.68	4.78	30	32
28.8	28.9	66.8	66.9	51.32	51.52	246	247	89	90	1	1.1	32.8	32.95	842	843
28.5	28.7	62.5	62.6	3.43	3.65	90	92	23	25	0.3	0.4	1.37	1.47	21	23
26.6	27.1	65.8	66.3	6.67	6.87	211	212	103	104	1.5	1.5	3.3	3.5	82	83
21.6	22.1	48.1	48.6	2.74	2.97	344	345	166	167	0.1	0.1	2.28	2.51	539	540
25.7	26.1	66	66.4	3.99	4.11	34	33	78	77	0.5	0.6	0.93	1.05	39	38
29.8	29.7	70.7	70.8	4.48	4.62	64	67	35	38	0.3	0.3	0.91	1.01	28	31
31.5	31.4	64.5	64.6	3.39	3.69	23	24	23	24	1.9	2	2.18	2.34	80	81
20.7	20.5	36.6	36.5	4.1	4.2	205	203	678	676	0.4	0.3	0.65	0.44	120	118
26.5	26.8	41.8	42.3	5.36	5.48	346	349	717	720	0.9	1	2.18	2.38	213	216
35.7	35.6	62.6	63.1	3.54	3.74	107	106	23	22	0.1	0.1	0.93	1.13	18	17
33.2	33.7	75.6	76.1	5.89	6.11	166	171	35	37	1.2	1.3	3.25	3.45	58	60
36.9	37.4	79.8	80.3	8.37	8.57	77	82	47	49	1.7	1.7	3.84	4.04	130	132
30.1	30.5	69.2	69.6	12.86	13	313	317	50	54	1.2	1.2	5.84	6.05	25	26
27.4	27.6	56.5	56.6	5.72	6.02	33	35	87	89	1.9	2	2.78	2.99	30	32
29.4	29.9	67.8	68.3	7.96	8.06	31	36	23	25	0.5	0.5	3.23	3.37	28	30
31.4	31.2	67	66.9	4.77	4.89	28	26	29	27	0.3	0.2	1.83	2.13	30	28
21.7	21.8	51.9	52	76.7	76.9	77	78	92	93	0.1	0.1	46.81	46.91	232	233
19.3	19.4	65.2	65.3	2.95	3.17	16	17	23	24	0.1	0.1	0.72	0.84	27	28
25.2	25.7	44	43.9	3.08	3.28	397	402	671	673	1.9	1.8	1.08	1.28	109	111
21.3	21.2	40.8	41.3	2.18	2.41	241	240	566	565	0.6	0.7	1.2	1.42	76	75
33.4	33.6	61.8	62.3	2.13	2.25	48	50	38	40	0.1	0.1	1.29	1.49	18	20
28	27.7	68.8	68.5	2.46	2.6	64	61	46	45	0.4	0.4	1.02	1.25	21	20
25.9	25.8	54.8	54.7	2.62	2.52	39	38	22	21	1.8	1.7	1.19	1.31	52	51
21.9	22.4	63.8	64.3	3.47	3.68	70	75	50	52	0.6	0.6	1.84	1.98	24	26
27.3	27.8	73	73.5	3.03	3.28	80	85	17	19	0.9	1	2.42	2.67	26	28
34.6	35	71.7	72.1	2.18	2.33	216	220	40	44	1.1	1.1	1.34	1.49	73	74
35.7	35.9	72.2	72.3	3.84	3.97	43	45	123	125	0.7	0.8	2.48	2.61	18	20
33.7	34.2	64.9	65.4	5.42	5.68	70	75	32	34	1.3	1.3	2.26	2.52	74	76
23	22.8	62.9	62.8	9.03	8.93	36	34	46	44	1	0.9	4.44	4.34	118	116

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

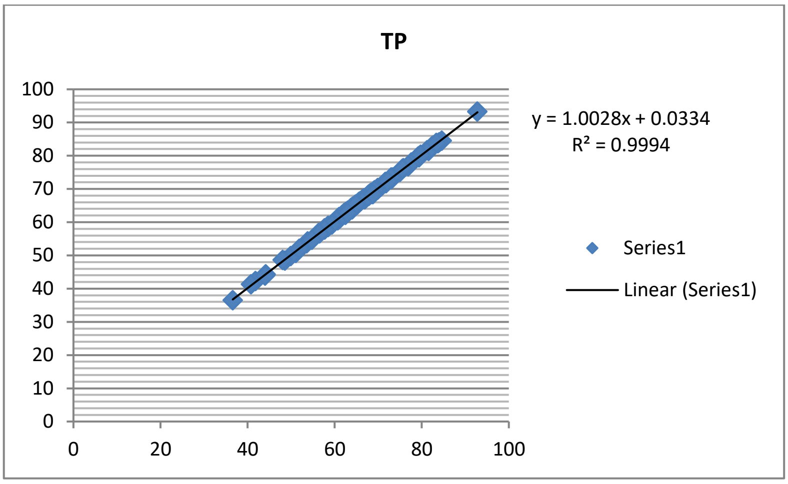
Calculated regression equation y = 1.0049x + 0.023

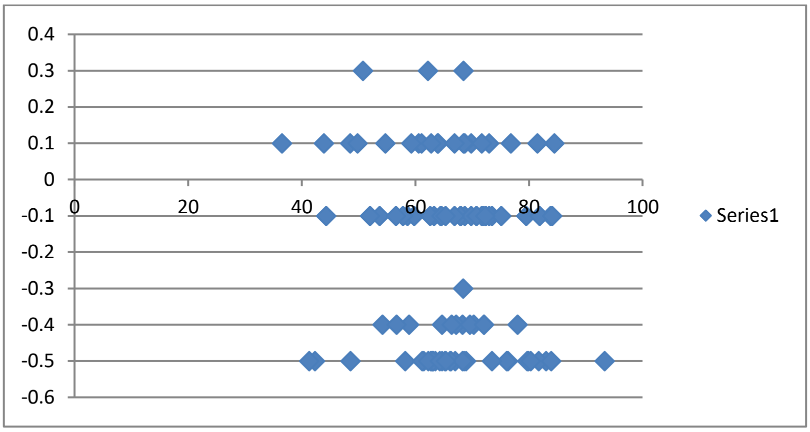
5.2.3. Statistical Analysis

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, and there was 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

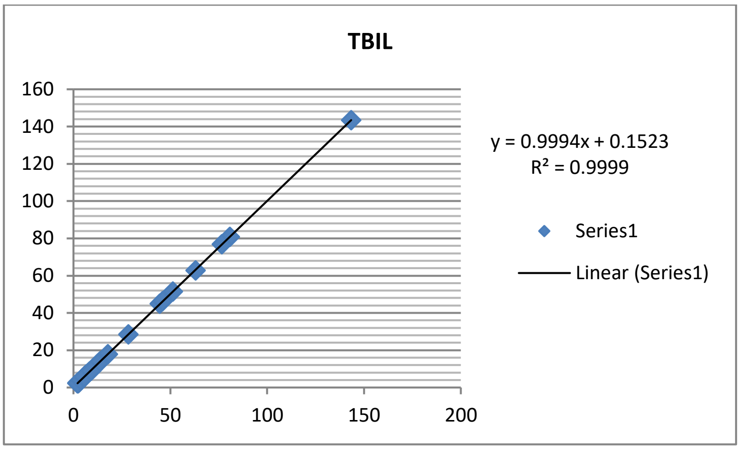
Calculated regression equation y = 1.0028x + 0.0334

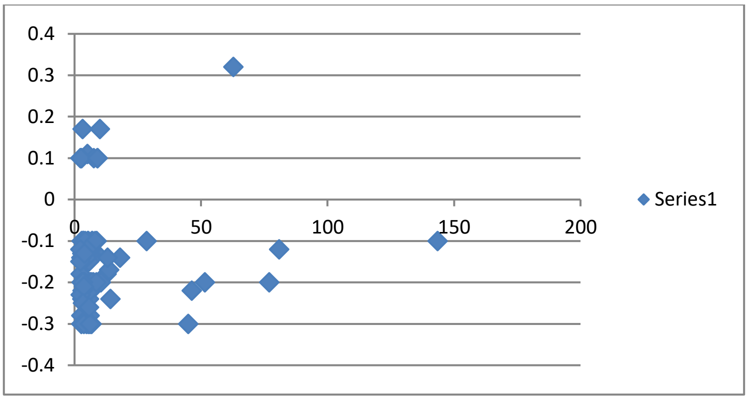
5.3.3. Statistical Analysis

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 and there was 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

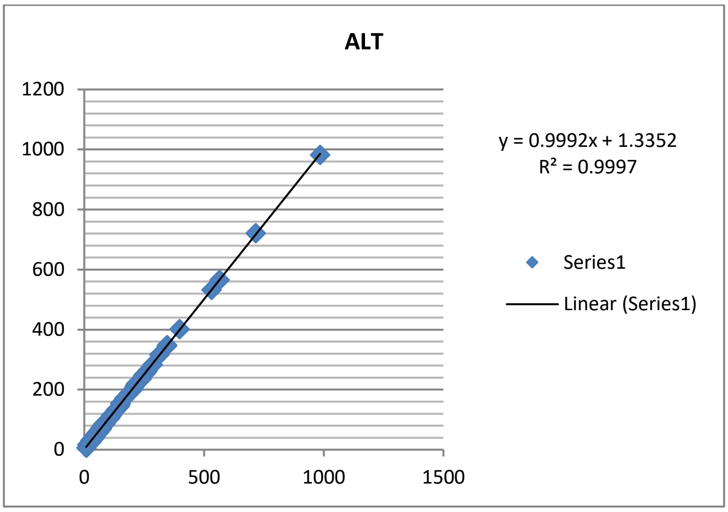
Calculated regression equation $y = 0.9994x + 0.1523$

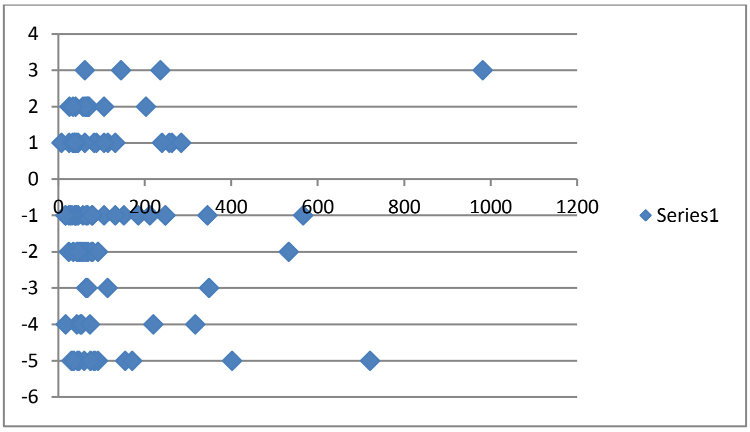
5.4.3. Statistical Analysis

The t-test was performed on the linear regression equations of the test system and the control system, and the t value was > $t_{0.05}$, $P < 0.05$. There was a good linear relationship between the two groups of data and there was 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

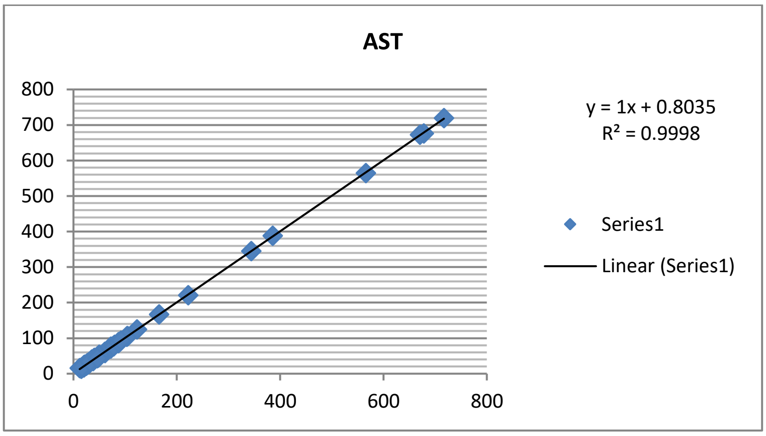
Calculated regression equation y = 0.9992x + 1.3352

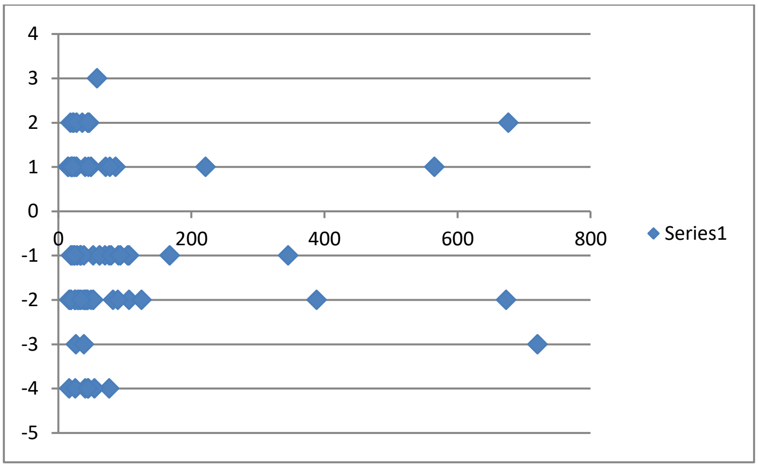
5.5.3. Statistical Analysis

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 and there was no significant difference.

5.6. 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.





5.6.1. 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

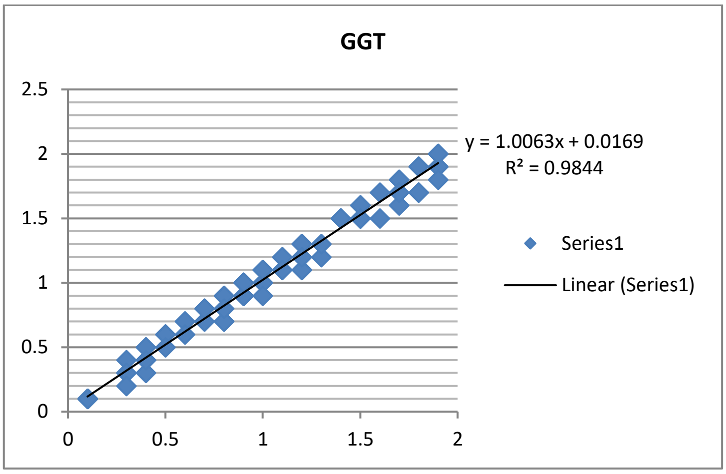
Calculated regression equation $y = 1x + 0.8035$

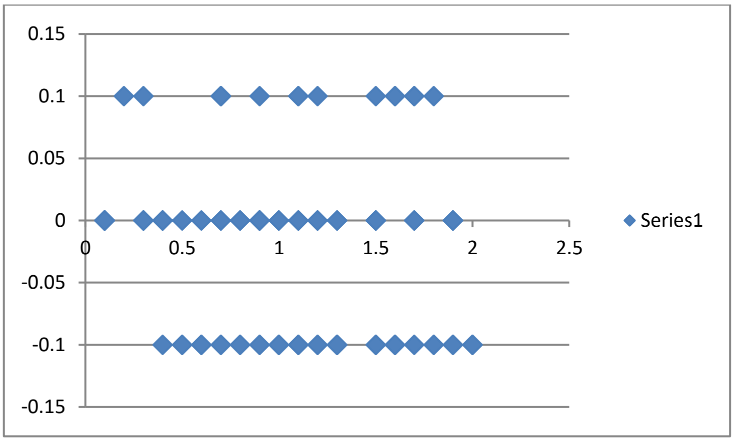
5.6.3. Statistical Analysis

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

5.7. Results Statistics and Analysis (GGT)

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=0.9921, 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

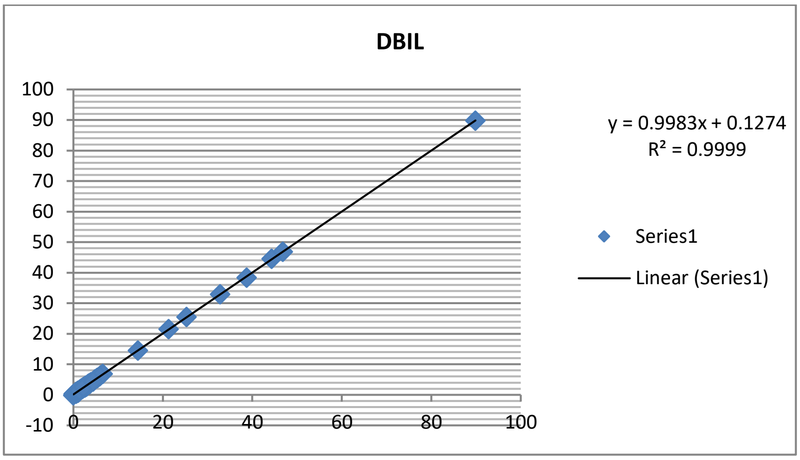
Calculated regression equation y = y = 1.0063x + 0.0169

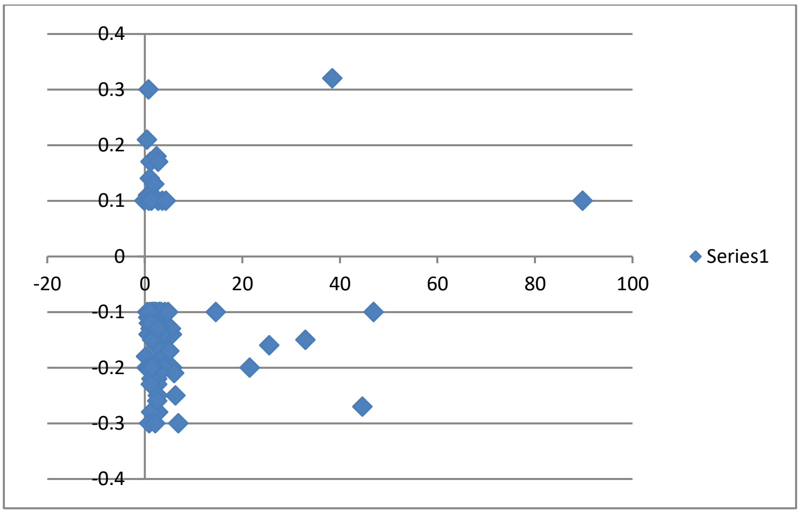
5.7.3. Statistical Analysis

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 and there was no significant difference.

5.8. Results Statistics and Analysis (DBIL)

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=0.9999, 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

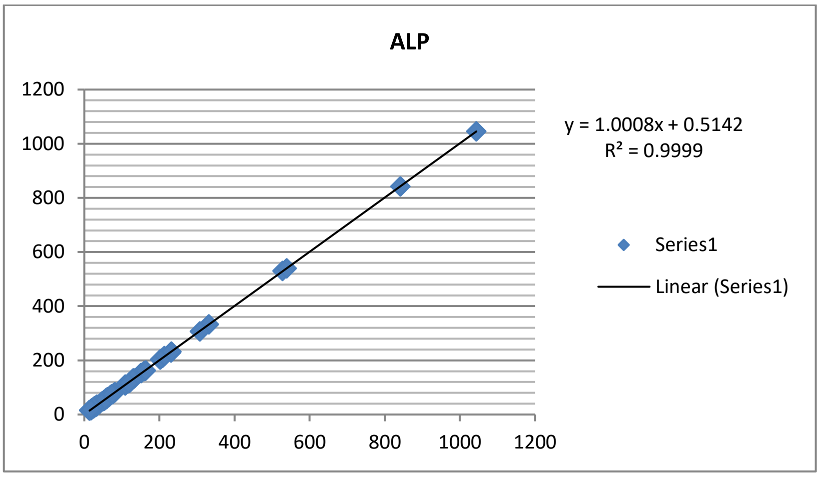
Calculated regression equation $y = 0.9983x + 0.1274$

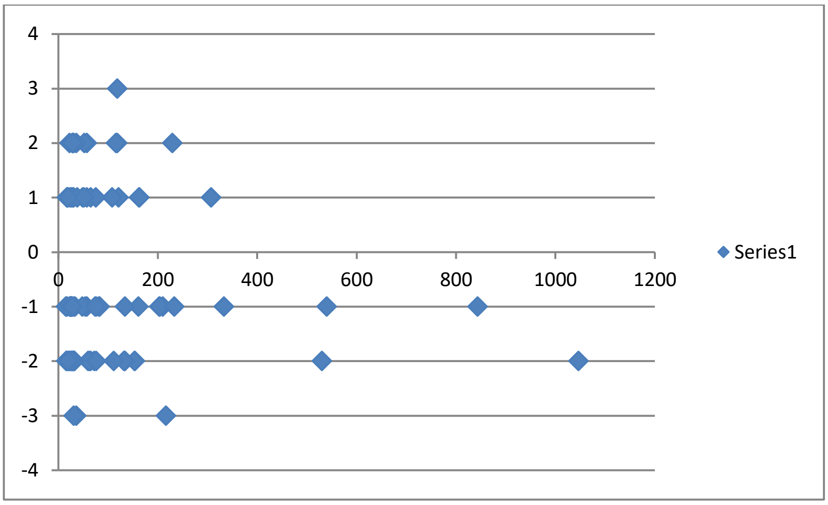
5.8.3. Statistical Analysis

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

5.9. 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.





5.9.1. 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 $y = 1.0008x + 0.5142$

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.

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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