WOODLEY
EQUIPMENT COMPANY LTD.

InSight V-CHEM®

Veterinary Chemistry Analyser

Correlation Study – Electrolytes Panel

Contents

Approved By: [signature]

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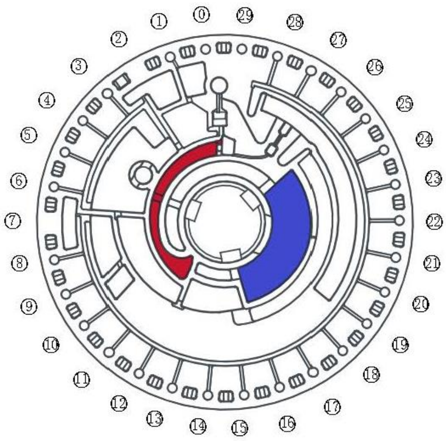
1. Clinical Evaluation Purposes

This clinical evaluation trial is a set of comparison experiments to investigate the equivalence of Electrolytes 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 Electrolytes Panel is used to quantitatively test the concentration of the seven biochemical indicators in the sample, which is based on the spectrophotometry. The principles are as follows:

a) Potassium (K^+)

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

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

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

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

b) Sodium (Na^+)

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

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

c) Chloride (Cl^-)

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

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

d) 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.

e) Magnesium (Mg^{2+})

The hexokinase (HK) activation method is described as:

$$\text{Glucose + ATP} \xrightarrow{HK,\ Mg^{2+}} \text{G-6-P + ADP}$$

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

The rate limiting reaction is the HK reaction. Magnesium from the sample activates HK which in turn catalyses the breaking down of glucose to form glucose-6-phosphate (G-6-P) and ADP. G-6-P reacts with nicotinamide adenine dinucleotide phosphate ($NADP^+$) to form reduced nicotinamide adenine dinucleotide phosphate (NADPH) and 6-phosphogluconate in the presence of glucose-6-phosphate-dehydrogenase (G-6-PDH). This is a first-order rate reaction. The rate of production of NADPH is directly proportional to the amount of magnesium present in the sample. Absorbance is measured bichromatically at 340 nm and 405 nm.

f) Phosphorus (P)

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

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

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

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

g) Carbon Dioxide (CO_2)

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

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

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

2.1. Normal Reference Ranges

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

Analyte	SI Units	Common Units
K^+	Dog: 3.7 ~ 5.8mmol/L	Dog: 3.7 ~ 5.8mmol/L
	Cat: 3.7 ~ 5.8mmol/L	Cat: 3.7 ~ 5.8mmol/L
Na^+	Dog: 138 ~ 160mmol/L	Dog: 138 ~ 160mmol/L
	Cat: 142 ~ 164mmol/L	Cat: 142 ~ 164mmol/L
Cl^-	Dog: 106 ~ 120mmol/L	Dog: 106 ~ 120mmol/L
	Cat: 112 ~ 126mmol/L	Cat: 112 ~ 126mmol/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
Mg^{2+}	Dog: 0.74 ~ 0.99mmol/L	Dog: 0.74 ~ 0.99mmol/L
	Cat: 0.82 ~ 1.03mmol/L	Cat: 0.82 ~ 1.03mmol/L
P	Dog: 0.94 ~ 2.13mmol/L	Dog: 2.9 ~ 6.6mg/dL
	Cat: 1.1 ~ 2.74mmol/L	Cat: 3.4 ~ 8.5mg/dL
CO_2	Dog: 12 ~ 27mmol/L	Dog: 12 ~ 27mmol/L
	Cat: 15 ~ 24mmol/L	Cat: 15 ~ 24mmol/L

3. Evaluation Method

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

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

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

	Comparative test of the same group of serum samples for control and test products
K^+	100
Na^+	100
Cl^-	100
CO_2	100
Ca^{2+}	100
Mg^{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, 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):

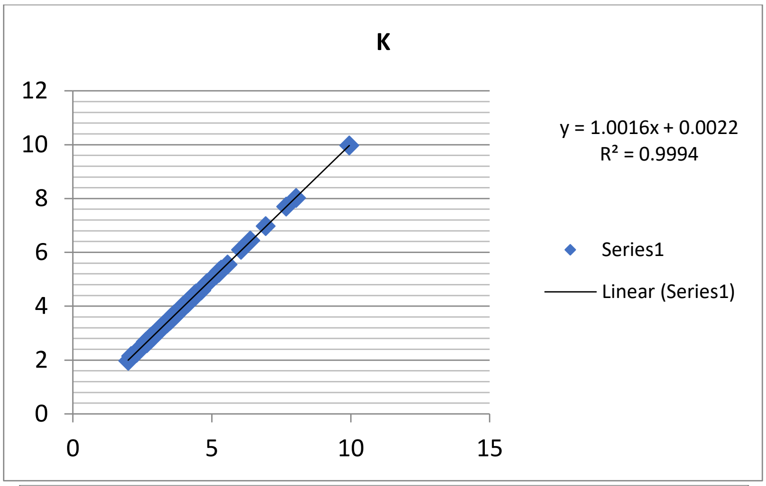
V-CHEM reagent value K^+	VS2 reagent value K^+	V-CHEM reagent value Na^+	VS2 reagent value Na^+	V-CHEM reagent value Cl^-	VS2 reagent value Cl^-	V-CHEM reagent value CO_2	VS2 reagent value CO_2	V-CHEM reagent value Ca^{2+}	VS2 reagent value Ca^{2+}	V-CHEM reagent value Mg	VS2 reagent value Mg	V-CHEM reagent value P	VS2 reagent value P
3.68	3.65	158	156	119	117	22	10	2.68	2.67	0.64	0.63	2.15	2.18
2.81	2.78	131	132	118	119	10	10	2.24	2.22	0.8	0.85	1.51	1.54
3.21	3.19	148	146	145	144	13	11	2.07	2.05	0.76	0.73	6.82	6.83
3.05	3.03	141	143	110	111	8	8	2.2	2.22	0.81	0.78	2	2.03
4.25	4.29	177	178	117	120	24	15	2.79	2.77	0.81	0.80	1.12	1.11
3.39	3.37	148	146	118	117	17	17	2.56	2.61	0.76	0.74	1.79	1.76
2.81	2.86	141	140	156	159	20	10	2.43	2.48	0.62	0.65	1.87	1.90
4.14	4.18	144	142	118	116	20	9	2.61	2.62	0.54	0.57	2.46	2.48
3.74	3.71	137	135	120	118	20	10	2.12	2.13	0.55	0.56	1.76	1.73
3.61	3.60	151	153	115	116	19	20	2.36	2.39	0.76	0.79	1.02	1.00
3.15	3.13	149	147	116	115	19	19	2.38	2.41	0.69	0.68	1.53	1.58
3.4	3.38	138	140	92	93	26	17	2.48	2.45	0.35	0.32	0.9	0.95
4.41	4.43	144	143	130	129	14	13	2.19	2.18	1.21	1.24	2.03	2.08
5.57	5.55	131	132	92	93	14	14	1.79	1.84	1.8	1.82	3.84	3.88
2.1	2.15	135	136	115	116	21	12	1.96	1.93	0.96	0.93	1.03	1.00
2.63	2.68	137	140	121	122	13	12	2.17	2.14	0.75	0.73	2.92	2.91
4.2	4.21	141	144	125	124	18	19	1.04	1.03	0.65	0.70	0.45	0.48
3.54	3.55	146	143	117	118	18	17	3.06	3.04	0.55	0.60	2.71	2.74
4.28	4.31	157	156	118	117	21	10	2.58	2.61	0.83	0.88	3.22	3.25
5.27	5.30	150	152	113	115	13	12	2.49	2.52	1.42	1.46	4.28	4.29
3.46	3.43	141	138	124	121	15	14	2.11	2.12	0.81	0.78	2.24	2.22
3.97	3.96	154	151	111	108	15	14	2.67	2.70	0.71	0.70	1.61	1.65
3.64	3.69	146	145	118	117	19	19	3.06	3.05	1.4	1.43	3.74	3.78
4.14	4.11	175	173	120	118	16	15	1.27	1.24	0.45	0.48	0.3	0.28
3.84	3.81	150	153	129	132	11	12	3.56	3.59	1.09	1.12	3.79	3.81

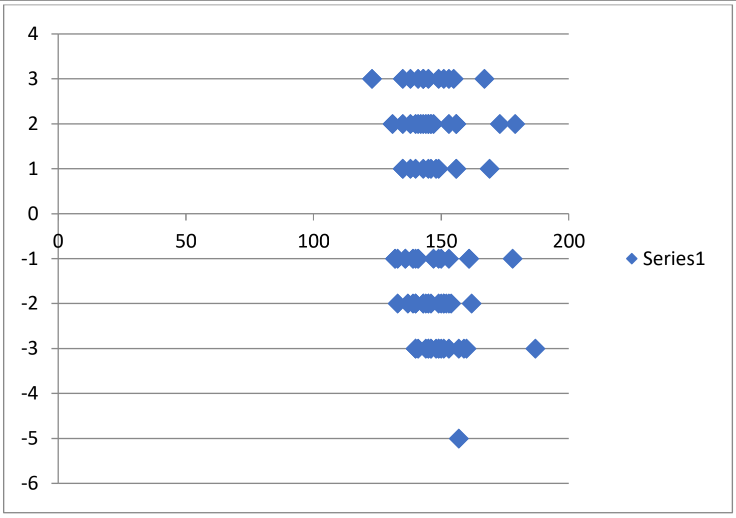
4.02	4.01	143	146	122	125	19	19	2.64	2.66	0.76	0.77	1.13	1.10
4.41	4.39	140	141	103	104	31	22	2.54	2.51	0.95	0.93	1.21	1.23
3.91	3.94	137	140	124	127	13	13	2.47	2.45	0.92	0.96	1.6	1.64
3.8	3.83	136	135	123	122	11	10	2.45	2.50	0.92	0.96	0.73	0.77
4.69	4.70	146	143	118	115	22	11	2.16	2.21	0.59	0.57	1.89	1.86
3.25	3.28	157	160	127	130	13	13	2.99	3.04	0.75	0.77	1.42	1.43
3.62	3.61	143	145	137	135	15	16	2.62	2.66	0.74	0.71	0.69	0.72
3.39	3.36	146	143	126	127	10	10	1.31	1.28	0.68	0.70	1.79	1.77
4.83	4.86	155	153	125	124	9	8	1.82	1.81	1.03	1.07	5.69	5.73
9.95	9.97	152	157	121	122	23	12	2.67	2.70	0.94	0.98	1.73	1.78
4.62	4.59	138	140	113	116	16	16	1.38	1.41	0.85	0.82	0.31	0.29
8.04	8.02	143	146	114	113	15	16	2.3	2.33	1.47	1.48	3.22	3.24
6.39	6.44	149	151	150	153	1	2	2.31	2.32	1.85	1.88	10.86	10.85
3.53	3.58	136	135	116	115	18	17	2.04	2.02	0.41	0.39	1.62	1.59
6.05	6.10	139	138	112	111	3	1	2.26	2.30	1.81	1.85	6.52	6.53
3.27	3.31	156	159	130	133	10	11	2.08	2.12	0.56	0.61	1.63	1.65
2.89	2.86	148	151	115	118	21	12	3.12	3.10	0.68	0.66	1.16	1.18
3.87	3.86	132	133	102	103	19	20	2.51	2.53	0.53	0.55	1.53	1.54
2.97	3.00	135	136	111	112	15	15	1.78	1.75	0.72	0.71	0.4	0.38
3.43	3.46	181	179	245	243	23	11	1.76	1.78	1.04	1.01	4.29	4.32
2.72	2.75	149	151	106	108	15	15	2.85	2.89	0.72	0.73	1.49	1.47
5.15	5.16	152	153	114	115	23	13	0.8	0.84	1.01	1.03	0.63	0.61
4.08	4.06	147	145	124	122	22	10	2.87	2.84	0.78	0.80	1.14	1.15
3.85	3.89	143	145	126	124	11	12	2.54	2.55	0.85	0.86	1.74	1.73
3.26	3.30	170	167	117	118	16	15	2.52	2.55	0.62	0.60	1.39	1.40
4.37	4.35	147	149	106	105	18	18	2.87	2.85	0.7	0.73	2.79	2.82
4.03	4.05	141	143	116	117	18	19	2.27	2.31	0.86	0.84	1.88	1.87
3.5	3.47	138	139	126	129	19	20	2.48	2.53	0.88	0.86	0.67	0.70
4.33	4.35	156	153	119	118	13	11	2.23	2.21	0.87	0.88	1.68	1.65
4.44	4.48	160	161	114	117	12	12	2.71	2.73	1.15	1.14	1.68	1.65
6.94	6.98	146	149	100	103	10	11	1.57	1.56	2.63	2.64	9.85	9.84
3.5	3.47	158	156	125	123	17	16	2.47	2.44	0.8	0.83	1.51	1.56
2.66	2.67	160	162	131	133	17	17	2.67	2.68	0.66	0.65	1.64	1.67
3.92	3.95	148	150	113	115	17	18	2.27	2.29	0.76	0.79	1.02	1.06
1.99	1.97	143	141	121	119	28	17	2.06	2.08	0.64	0.61	1.69	1.74
2.89	2.93	137	139	119	120	21	12	2.15	2.16	0.57	0.54	2.28	2.33
4.38	4.43	170	169	120	119	16	16	2.37	2.35	0.81	0.80	0.87	0.89
4.15	4.13	152	149	110	111	20	9	2.33	2.36	1.03	1.08	1.77	1.82
7.68	7.70	160	161	105	106	11	12	1.65	1.63	2.36	2.39	9.89	9.92

3.82	3.81	144	146	103	105	15	15	2.7	2.68	1.08	1.12	2.53	2.51
2.66	2.63	135	137	117	119	24	15	2.29	2.30	0.39	0.44	1.88	1.93
3.85	3.86	148	149	109	110	28	19	2.61	2.60	0.85	0.90	1.13	1.15
4.94	4.96	145	143	105	103	13	12	3.28	3.29	0.98	1.00	3.87	3.86
3.8	3.82	142	145	113	116	17	18	2.62	2.65	0.65	0.70	0.78	0.76
2.61	2.62	146	144	128	126	14	13	2.07	2.06	1.01	1.04	1.79	1.76
2.29	2.27	133	131	110	108	13	11	1.99	2.02	0.87	0.85	1.01	1.04
3.58	3.61	138	139	120	121	16	17	2.55	2.52	0.86	0.91	0.9	0.92
2.72	2.70	147	146	135	134	6	5	2.37	2.34	0.5	0.52	0	-0.03
5.26	5.24	140	141	93	94	14	15	2.52	2.51	1.02	1.01	0.52	0.55
3.92	3.93	154	157	118	121	17	18	2.65	2.70	1.01	0.99	1.62	1.60
3.42	3.41	157	156	124	123	25	14	2.43	2.46	0.75	0.72	1.21	1.26
3.76	3.77	145	148	125	128	22	11	2.64	2.68	0.73	0.76	1.55	1.60
3.5	3.53	148	145	114	111	18	17	2.86	2.91	0.77	0.79	1.97	2.01
3.22	3.21	158	155	115	112	18	17	3.08	3.13	0.84	0.81	1.21	1.24
3.15	3.18	149	148	123	122	14	13	2.23	2.25	0.61	0.64	1.66	1.71
3.69	3.66	149	150	122	123	21	11	2.51	2.56	0.28	0.26	1.28	1.25
3.77	3.74	142	145	114	117	21	12	2.21	2.24	0.84	0.89	1.21	1.22
4.1	4.09	149	151	122	124	20	10	3.03	3.01	0.69	0.74	2.68	2.70
3.51	3.56	139	140	112	113	19	19	2.41	2.46	0.62	0.66	1.86	1.91
2.47	2.50	144	141	114	111	23	11	1.47	1.49	0.54	0.57	2.01	1.99
4.06	4.10	152	154	122	124	17	18	2.43	2.42	1.01	1.06	2.34	2.36
2.73	2.78	131	133	112	114	21	11	1.82	1.80	0.83	0.80	2.92	2.89
3.97	4.02	138	141	116	119	14	15	2.67	2.64	0.93	0.94	1.05	1.09
5.34	5.36	142	140	115	113	5	5	2.49	2.52	1.74	1.76	5.06	5.09
2.82	2.87	146	147	102	103	20	11	2.85	2.87	0.64	0.69	0.89	0.91
3.86	3.89	138	140	110	112	18	18	2.96	2.93	0.67	0.65	2.07	2.10
2.86	2.84	150	149	119	118	19	18	2.48	2.51	0.53	0.55	1.46	1.48
3.16	3.21	147	145	128	126	10	10	2.58	2.56	1.14	1.11	4.5	4.51
3.31	3.33	138	135	108	106	21	10	2.51	2.56	0.6	0.64	1.53	1.54
4.01	4.00	146	149	118	119	19	19	0.97	1.02	0.72	0.75	0.79	0.77
4.18	4.16	142	144	132	131	13	13	2.97	3.01	0.74	0.76	1.65	1.69
3.56	3.53	126	123	121	122	17	16	2.58	2.61	0.65	0.68	2.05	2.03
4.04	4.07	184	187	132	135	13	12	1.73	1.78	0.94	0.96	2.49	2.54
3.83	3.85	140	138	116	115	20	9	2.3	2.27	0.75	0.76	1.26	1.25
4.14	4.11	147	150	116	119	12	12	2.59	2.60	0.74	0.75	1.18	1.15

5.2. Results Statistics and Analysis (K)

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





5.2.1. 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=0.9997, 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

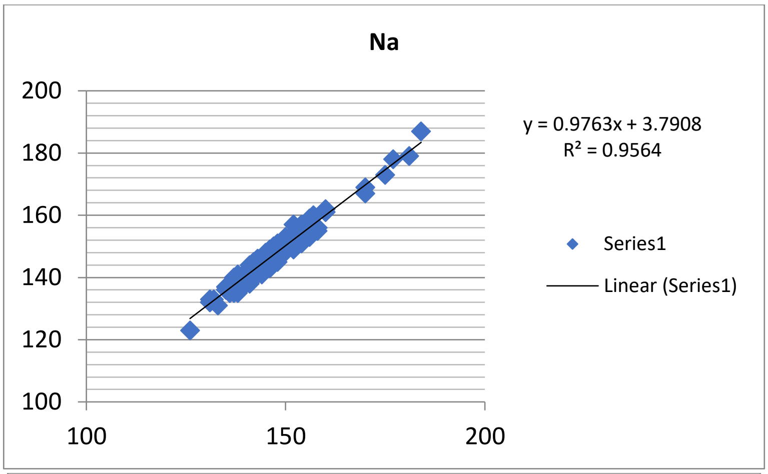
Calculated regression equation $y = 1.0016x + 0.0022$

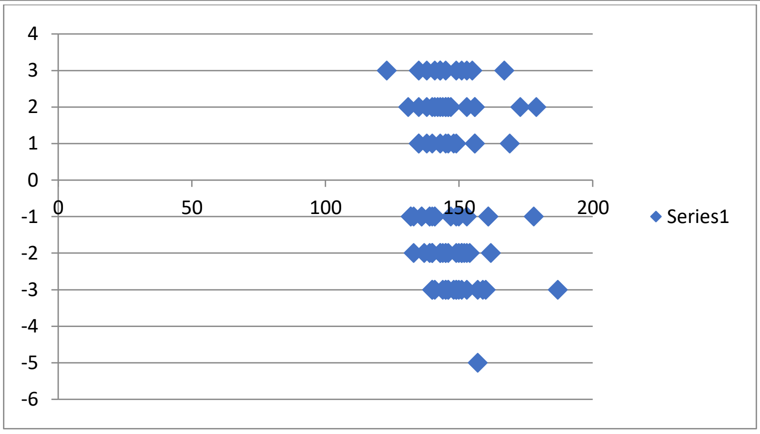
5.2.3. Statistical Analysis

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 (Na)

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





5.3.1. 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=0.9779, 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

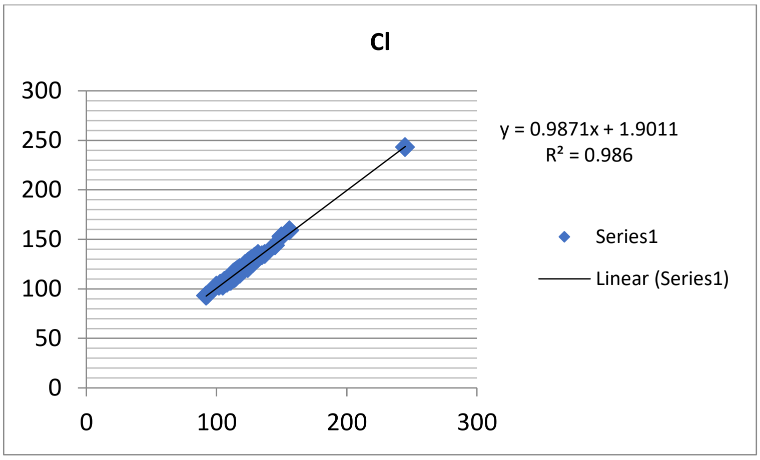
Calculated regression equation $y = 0.9763x + 3.7908$

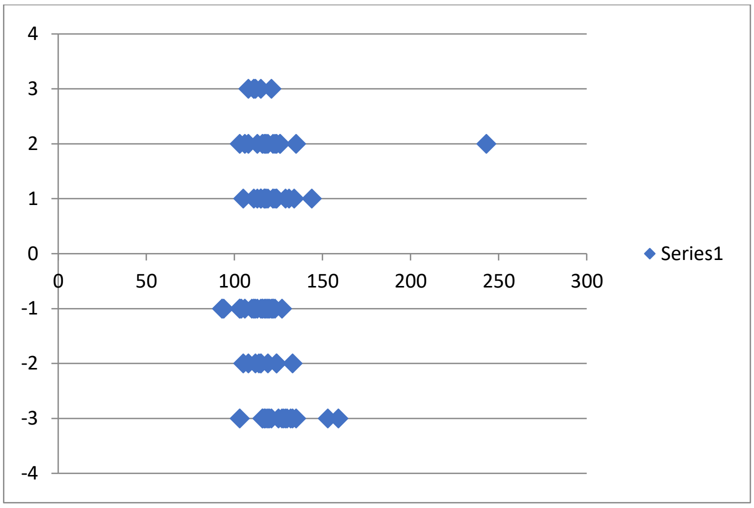
5.3.3. Statistical Analysis

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

5.4. Results Statistics and Analysis (Cl)

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





5.4.1. 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=0.9929, 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

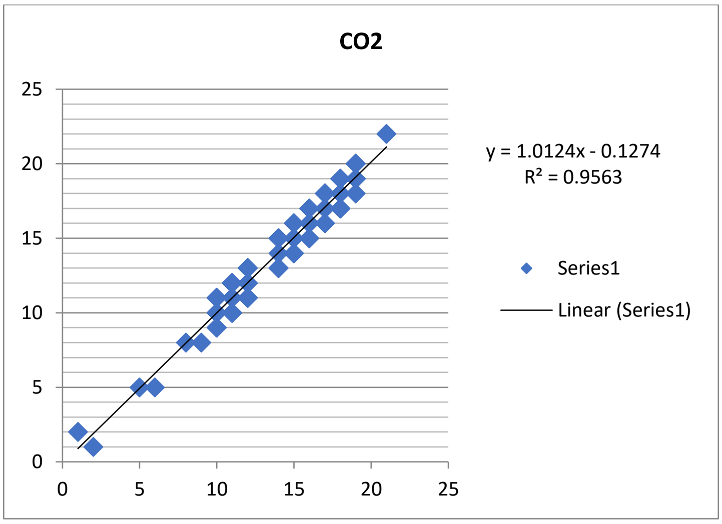
Calculated regression equation $y = 0.9871x + 1.9011$

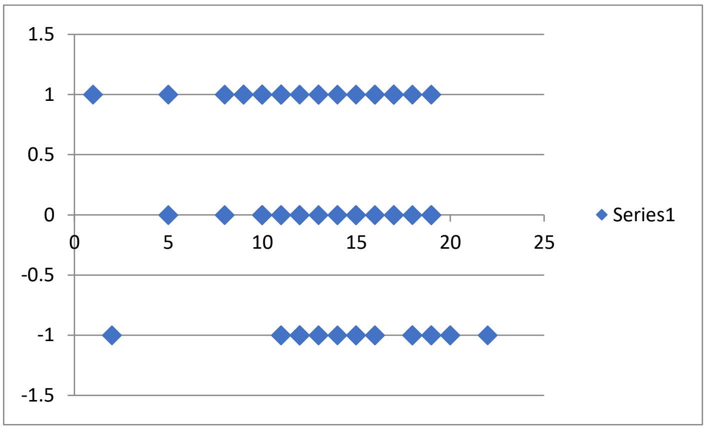
5.4.3. Statistical Analysis

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 (CO_2)

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=0.9780, 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

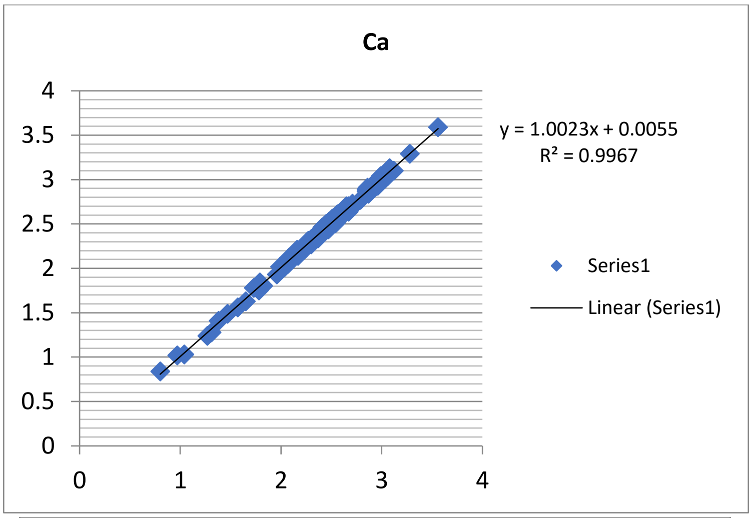
Calculated regression equation $y = 1.0124x - 0.1274$

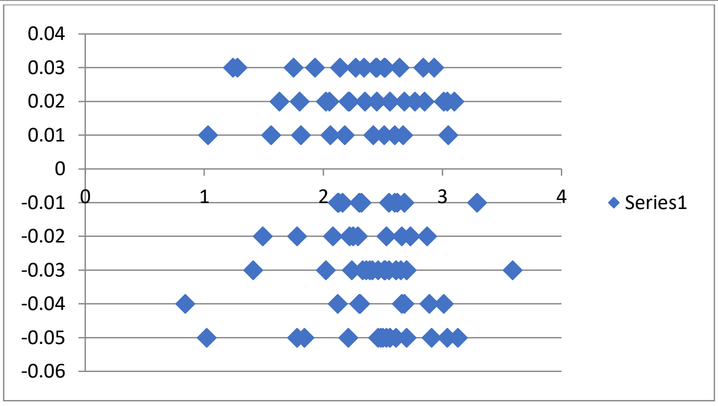
5.5.3. Statistical Analysis

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

5.6. Results Statistics and Analysis (Ca)

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





5.6.1. Visually Measure Linearity and Calculate Correlation Coefficient

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

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

5.6.2. Linear Regression Analysis

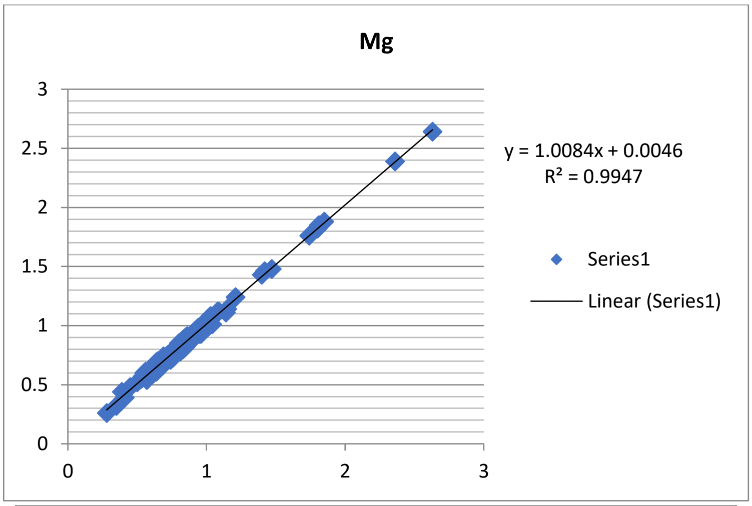
Calculated regression equation y = 1.0023x + 0.0055

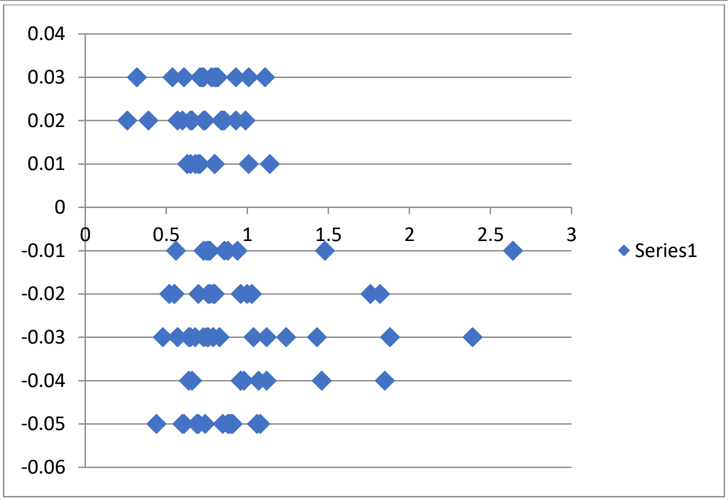
5.6.3. Statistical Analysis

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

5.7. Results Statistics and Analysis (Mg)

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 calculated to be r=0.9973, which is greater than 0.975. The range of values is appropriate and the correlation and consistency are good.

5.7.2. Linear Regression Analysis

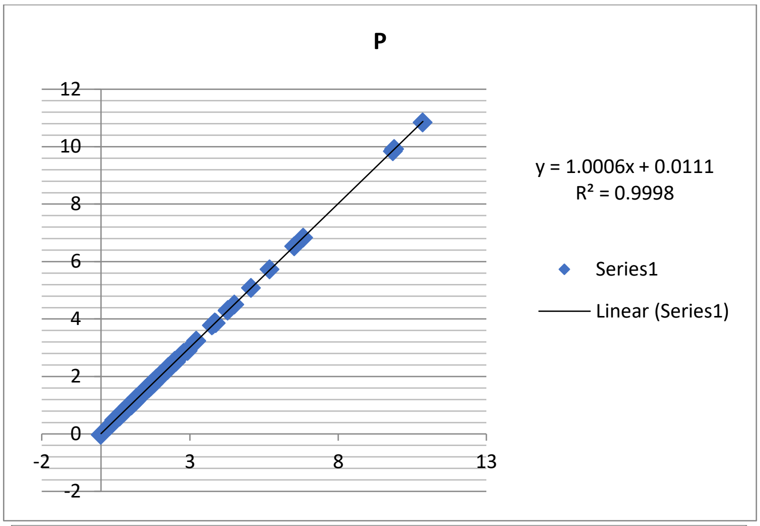
Calculated regression equation y = 1.0084x + 0.0046

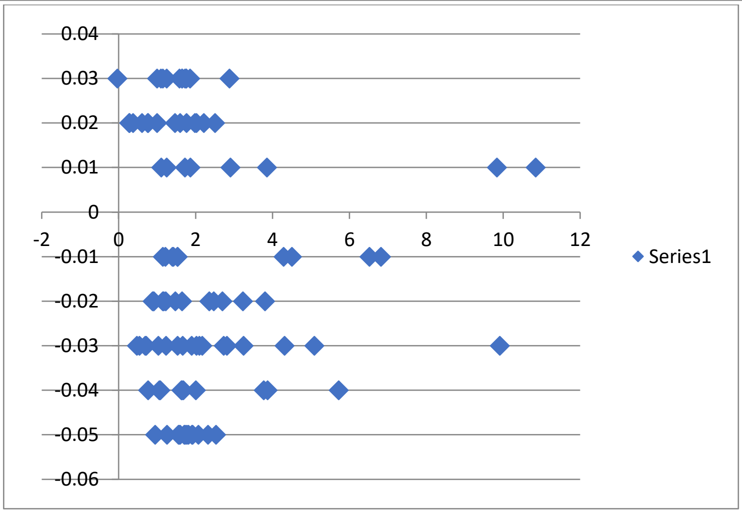
5.7.3. Statistical Analysis

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 (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.





5.8.1. 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=0.9991, 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 = 1.0006x + 0.0111

5.8.3. Statistical Analysis

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

6. Clinical Evaluation Conclusion

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

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