Analysis of Performance Evaluation

InSight V-CHEM

Veterinary Chemistry Analyser

1 Blank Absorbance of Reagent

1.1 Experimental Method

Take physiological saline as the sample to be tested. Operate according to the instructions of this kit and test at the biochemical analyser quality inspection interface. Read the absorbance A1 at the start of the test and the absorbance A2 after about five minutes, where A2 is the blank absorbance and continuously measure 2 once the mean value is the blank absorbance.

1.2 Experimental Results and Data Processing

Table 1-1 Reagent blank absorbance test results

	Batch No.	Blank Absorbance of Reagent	Standard
ALB	190724PD	0.419159	≤0.7000
ALP	190723C	0.865888	≤2.0000
ALT	S190718D	1.728505	≥1.0000
AMY	190709D	0.185047	≤0.3500
Ca	190528XMD	-1.20042	≤2.5000
CHOL	S190722PD	0.493224	≤1.5000
CK	S190717D	0.272196	≤0.5000
CRE	S190715D	-0.04813	≤0.5000
GLU	S190718C	0.302922	≤0.6000
TBIL	190720PC	0.007243	≤0.5000
TP	190725PC	-0.26472	≤0.7000
UREA	S190719C	4.88341	≥1.0000
AST	190912PD	1.709535	≥1.0000
LDH	S190815D	0.011916	≤0.5000
DBIL	S190724PC	0.018692	≤0.5000
GGT	190802D	0.663551	≤1.8000
CL	190527C	0.15	≤1.0000
CO2	190719C	13.4821	≥5.0000

K	190719C	4.96005	≥1.0000
Mg	S190808C	0.395794	≤1.5000
Na	190813C	0.133721	≤1.0000
P	190819D	0.61472	≤1.5000

2 Reagent Blank Absorbance Change Rate

2.1 Experimental Method

Take physiological saline as the sample to be tested. Operate according to the instructions of this kit and test on the biochemical analyser quality inspection interface. Read the absorbance A1 at the start of the test and absorbance A2 after about five minutes. A2 is the blank absorbance and measure twice continuously. Find the mean value as the blank absorbance. Calculate the absorbance change value ($|A2-A1|/t$) (t is the measurement time interval), which is the reagent blank absorbance change rate (ΔA/min) and the result should meet the requirements of 2.1.

Where: A1 is the absorbance read at the first time point

A2 is the absorbance read at the second time point

t is the time between two readings (minutes)

Table 2-1 Experimental results of blank absorbance change rate

	Batch No.	Blank Absorbance Change Rate	Standard
ALP	190723C	0.001928	≤0.005
ALT	S190718D	0.000701	≤0.004
AMY	190709D	0.000701	≤0.002
CK	S190717D	0.001314	≤0.002
UREA	S190719C	0.005257	≤0.04
AST	190819PD	0.001326	≤0.004
GGT	190802D	0.000789	≤0.005

LDH	S190815D	0.000526							≤0.002		
CL	190527C	0.002891							≤0.3		
CO2	190719C	0.017857							≤0.2		
K	190719C	0.032506							≤0.2		
Mg	S190808C	0.0467							≤0.6		
Na	190813C	0.000698							≤0.5		

3．Precision

The kits of the batch were selected as the representative and the control samples of the two levels were tested ten times each. The average value (mean) and the standard deviation (S) of the measured values of each item and each sample were calculated and the coefficient of variation (CV%) was calculated.

$$CV=\frac{S}{\overline{\overline{X}}}\times100\%；$$

Table 3-1 Experimental results of Precision

	Batch No.	Precision										
		1	2	3	4	5	6	7	8	9	10	CV
ALB	190724PD	41	41	43	42	41	42	41	41	42	42	1.43%
ALP	190723C	163	166	158	163	169	169	172	173	178	177	3.74%
ALT	S190718D	35	32	33	33	34	32	34	36	35	36	4.25%
AMY	190709D	76	74	74	74	75	74	75	76	76	76	1.27%
Ca	190528XMD	2.22	2.16	2.17	2.31	2.19	2.19	2.18	2.06	2.23	2.15	2.94%
CHOL	S190722PD	3.92	3.95	3.92	3.92	3.97	3.91	3.9	3.99	3.91	3.94	0.75%
CK	S190717D	189	182	185	185	187	183	190	188	191	184	1.63%
CRE	S190715D	123	123	122	121	122	126	125	125	122	123	1.22%
GLU	S190718C	5.91	5.94	5.94	5.92	5.94	5.94	5.94	5.95	5.94	5.96	0.24%
TBIL	190720PC	32.5	32.6	32.4	32.2	32.1	31.8	32.2	31.3	32.2	31.4	1.41%
TP	190725PC	61.7	59.6	60	61.7	61.5	61.7	60.4	62.1	60.2	61.8	1.46%

UREA	S190719C	7.47	7.56	7.47	7.6	7.32	7.51	7.36	7.45	7.44	7.47	1.10%
AST	190912PD	34.7	35.5	33.1	35.2	34.2	33.8	34.8	34.0	36.5	35.5	2.82%
DBIL	S190724PC	13.2	14.3	13.4	13.1	12.9	13.3	13.7	13.3	13.2	13.1	2.97%
GGT	190802D	51.6	52.0	55.7	53.1	52.7	53.4	55.9	54.1	54.1	47.5	4.51%
LDH	S190815D	184	186	191	185	188	192	188	182	192	180	2.20%
CL	190527C	93	96	93	93	94	93	98	92	94	95	2.80%
CO2	190719C	13.8	13.5	13.8	13.7	13.9	13.4	13.4	13.7	13.9	13.7	1.37%
K	190719C	4.1	4	4	4	4	4	4	4.1	4	4	4.20%
Mg	S190808C	0.96	0.96	0.99	0.97	0.99	1.00	0.97	0.96	0.99	0.99	1.45%
Na	190813C	134	140	147	134	134	141	139	142	137	136	2.00%
P	190819D	1.44	1.4	1.41	1.41	1.43	1.4	1.44	1.47	1.43	1.47	1.87%

4. Linearity

Preparation of the lower limit of the linearity range (Randox fixed serum %): 5.6% / (Randox serum value / linearity range lower limit);

Preparation of the upper limit of the linearity range (Randox fixed serum %): linearity range upper limit / Randox serum value × 5.6%;

Use a high value sample close to the upper limit of the linearity range (activity) and a low value sample close to the lower limit of the linearity range (activity) and mix it into 5 or 6 samples of dilution (xi) according to the following table.

$$r = \frac{\sum[(x_i - \overline{x})(y_i - \overline{y})]}{\sqrt{\sum(x_i - \overline{x})^2 \sum(y_i - \overline{y})^2}}$$

	Batch No.	Linearity						
		1:0	2:1	1:1	1:2	1:6	0:1	r
ALB	190724PD	19.1	31.7	38.2	43.3	49.9	54.4	0.9991
ALP	190723C	22	377	564	751	/	1071	0.9994
ALT	S190718D	6	402	572	767	/	1154	0.9998

AMY	190709D	6	468	685	916	/	1370	0.9999
Ca	190528XMD	1	2	3	3	/	4	0.9807
CHOL	S190722PD	2	6	8	10	/	14	0.9999
CK	S190717D	26	353	493	639	/	928	0.9994
CRE	S190715D	4	546	775	1097	/	1611	0.9994
GLU	S190718C	1.4	11.3	16.3	21.1	/	30.7	0.9999
TBIL	190720PC	3	97	145	191	/	291	0.9999
TP	190725PC	29	51.3	62.5	72.4	/	94.4	0.9998
UREA	S190719C	1	13	19	25	/	32	0.9921
AST	190912PD	5.33	299.02	496.62	651.06		948.33	0.9996
DBIL	S190724PC	1.58	39.00	56.40	75.59		117.77	0.9985
GGT	190802D	3.75	331.07	503.12	683.20		1018.62	0.9996
LDH	S190815D	20.91	250.4	367.3	446		704.9	0.9984
CL	190527C	75	100	104	119		140	0.9949
CO_2	190719C	11.13	19.06	22.04	25.07		31.32	0.9976
K	190719C	0.784	3.045	4.462	5.577		8.307	0.9991
Mg	S190808C	0.176	0.635	0.891	1.171		1.622	0.9994
Na	190813C	101.3	117.9	131.5	148.5		176.6	0.9905
P	190819D	0.251	1.171	1.713	2.127		3.16	0.9995

5. Sensitivity

	Batch No.	**Sensitivity**	standard
ALB	190724PD	2.45192	1.4000-4.2000
ALP	190723C	0.119997	0.0120-7.2000
ALT	S190718D	0.002653	0.0001-0.0100

AMY	190709D	0.000346	0.0002-0.010
Ca	190528XMD	0.223977	0.1000-1.0000
CHOL	S190722PD	0.230595	0.0500-0.8000
CK	S190717D	0.00283	0.0001-0.0100
CRE	S190715D	0.014689	0.0001-0.3000
GLU	S190718C	0.327972	0.1000-0.6000
TBIL	190720PC	0.026499	0.0010-0.0500
TP	190725PC	0.01643	0.0010-0.1000
UREA	S190719C	0.007822	0.0001-0.0100
AST	190912PD	0.002596	0.001-0.0100
DBIL	S190724PC	0.046584	0.0010-0.0500
GGT	190802D	0.00367	0.1000-0.6000
LDH	S190815D	0.007738	0.0001-0.0100
CL	190527C	0.003824	0.0001-0.3000
CO2	190719C	0.303102	0.1000-1.0000
K	190719C	0.120707	0.0001-0.3000
Mg	S190808C	0.217391	0.1000-1.0000
Na	190813C	0.000717	0.0001-0.3000
P	190819D	0.34666	0.0500-0.5000