

Instrument Performance Evaluation Report

Urine analyzer (dry chemical method)

Model: BW-300 Urine analyzer from Bioway

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1. Purpose and content

Objective: To evaluate whether the performance indicators of the urine analyzer produced by Bioway Biological technology Co., Ltd. meet the technical requirements of the products and meet the clinical needs.

Content: This report submitted the analysis performance evaluation data of urine analysis test paper (hereinafter referred to as test paper) (dry chemical method), and the performance indicators of the machine, including working environment, appearance, loading, accuracy, repeatability, and inter-batch difference. The detection limit and analysis specificity were tested separately.

2. Urine analysis test strip determination kit related information

2.1 Experimental instruments

The instrument used for performance evaluation is BIOWAY BW-300 urine analyzer

2.2 Batch number and specifications

Applicable specifications and models of the instrument: URS-10H, URS-11H, URS-12H, URS-14H, URS-8H, URS-4H

Instrument detection model: URS-14H

The urine analysis test paper model used for performance evaluation is URS-14H, and the batch numbers are 2019020701, 2019020901 and 2019021101. This product is designed with a variety of packaging specifications. The test strips of various models are completely the same in terms of raw materials, production processes, reaction principles, and inspections. The individual tests are relatively independent and do not interfere with each other. There is no difference in performance on the same item. The applicable urine analyzer has no effect on the performance evaluation results. Therefore, the test paper model URS-14H that can cover all the testing items is selected for performance testing.

3. Analysis performance evaluation plan

3.1 Working environment conditions

Temperature 20℃～28℃, relative humidity is not more than 80%

3.2 Appearance

The appearance of the urine test analyzer should meet the following requirements:

(a) The outer surface of the analyzer should be flat, smooth, uniform in color, free from scratches, burrs, sharp edges, and deformation.

(b) The text of the analyzer should be clear and easy to recognize;

3.3 Maneuverability

The switches and buttons on the analyzer should be flexible and reliable, easy to operate, the data cable connection should be firm and reliable, and the actual information should be clear and stable.

3.4 Function

(a) It should be able to start the self-test and identify customs declaration errors

(B) The result unit has at least an international unit system

(C) Should have an output port

(D) It should be able to store test data

(E) The machine should have a correction function

3.5 Accuracy

When the test paper is tested with artificial standard urine at the concentration listed in Table 1, each test item is measured three times at each specification point, and the difference between the test result and the reference solution label concentration is calculated, and the test result is different from the corresponding reference solution label value. No more than one order of magnitude in the same direction, no reverse phase difference is allowed. Negative results shall not appear in positive reference solutions, and positive results shall not appear in negative reference solutions.

Table 1 Accuracy test table

Test items	Inspection concentration and marked value				
	Neg	±	+	++	+++
LEU (cells/μl)	0	15	70	125	500
NIT (μmol/l)	0	—	18.12	—	—
URO (μmol/l)	3.3(±)	16	33	66	133
PRO (g/l)	0	0.15	0.3	1.0	3.0
BLD (cells/μl)	0	10	25	80	200
KET (mmol/l)	0	0.5	1.5	3.9	7.8
VC (mmol/l)	0	0.6	1.4	2.8	5.6
BIL (μmol/l)	0	—	17	50	100
GLU (mmol/l)	0	5.5	14	28	55

CAL (g/l)	0	—	0.15	0.3	0.5
CRE (g/l)	0	—	10	20	30
MAL (g/l)	0	—	0.15	—	—
pH	5.0、 6.0、 7.0、 8.0、 9.0				
SG	1.010、 1.020、 1.030				

3.6 Repeatability

Randomly draw 20 test strips of the same batch number, and use any positive artificial standard urine whose concentration is not less than "+" shown in Appendix A as the test solution to calculate the consistency of the test results of each test item. The consistency is not less than 90%.

The calculation results are consistent; calculate the results according to formula (1).

$$V (\%) = N/20 \times 100\% \quad \text{-----} \quad (1)$$

In the formula:

V: Degree of consistency of repeatability test results within a test item batch

N: The number of consistent results of a test item = the total number of repeated measurements of a test item — the number of times the result of the test is inconsistent

3.7 Detection limit

Randomly draw 20 test strips of the same batch number, and configure the first non-negative level of artificial standard urine of each item (except specific gravity and pH value) according to the method in Appendix A of the product technical requirements. Each artificial standard urine Repeat the test 20 times each, and the first non-negative magnitude of each test item should be detectable.

3.8 Analysis specificity

3.8.1 Anti-interference

According to the method in Appendix A of product technical requirements, configure the artificial standard urine listed in Table 2. Each artificial standard urine test is repeated 3 times, and the test result should meet the "marked value after interference".

Table 2 Specific detection table

Item	Analyte	Marked	Interferer	Interference	Marked value
------	---------	--------	------------	--------------	--------------

	concentration	value		concentration	after interference
GLU	5.5mmol/l	±	Acetoacetate	0.5mmol/l	±
BIL	0	NEG	Pyridine	5μl/ml	NEG
KET	0	NEG	Sunset yellow	20μg/ml	NEG
SG	—	1.020	Bovine serum albumin	0.02mg/ml	1.020
BLD	200cells/μl	+++	Sodium chloride	2mg/ml	++~+++
PRO	0	NEG	Sodium hydroxide	0.5mg/ml	NEG
URO	0.2	±	formaldehyde	10μl/ml	±
NIT	18.12μmol/l	+	Sodium chloride	10mg/ml	+
LEU	500 cells/μl	+++	oxalic acid	0.05mg/ml	+++
MAL	0	NEG	Sodium hydroxide	0.5mg/ml	NEG

3.8.2 Anti-vitamin C interference

Randomly draw 10 test strips of the same batch number, and configure each artificial standard urine added with vitamin C according to the method in Appendix A of product technical requirements. Each artificial standard urine is tested 10 times, and each item of the test paper is resistant to the interference of 2.8 mmol/l vitamin C.

3.9 Difference between batches

Randomly draw 3 test papers of different batch numbers, draw 20 strips from each batch, and use any of the positive artificial standard urine whose concentration is not less than "+" shown in Appendix A as the test fluid to calculate the test result level of each item between batches The difference between the test results does not exceed one order of magnitude, and positive results must not appear negative.

4. Analyze performance evaluation data and results

4.1 Working environment conditions

Temperature 20℃~28℃, relative humidity is not more than 80%

4.2 Appearance

Urine analyzer: The outer surface of the analyzer is flat and smooth, uniform in color, free of scratches, burrs, sharp edges, and deformation. The text of the analyzer should be clear and easy to

recognize; it should meet the technical requirements of the product.

Test strip:

Lot number: 2019020701 (a) The surface of the urine test strip is flat, and the edges of the polyester film are free of burrs; (b) The test block and the polyester film are tightly fixed, without defects or falling off; (c) The test block has a neat appearance, uniform color and no color Spots or stains. Meet the technical requirements of the product.

Lot number: 2019020901 (a) The surface of the urine test strip is flat, and the edges of the polyester film are free of burrs; (b) The test block is tightly fixed with the polyester film, without defects or falling off; (c) The test block has a neat appearance, uniform color and no color Spots or stains. Meet the technical requirements of the product.

Lot number: 2019021101 (a) The surface of the urine test strip is smooth, and the edges of the polyester film are free of burrs; (b) The test block is tightly fixed with the polyester film, no defects or shedding; (c) The test block is neat, uniform in color, and no color Spots or stains. Meet the technical requirements of the product.

4.3 Loading

Lot number: 2019020701, 100 pieces/box, in line with product technical requirements;

Batch number: 2019020901, 100 pieces/box, in line with product technical requirements;

Batch number: 2019021101, 100 pieces/box, in line with product technical requirements.

4.4 Accuracy

Batch number: 2019020701, the inspection result meets the product technical requirements.

Test items	Inspection concentration and result					Test items	Inspection concentration and result				
	concentra tion	mark	1	2	3		concent ration	mark	1	2	3
URO	3.3	±	±	±	±	GLU	0	NEG	NEG	NEG	NEG
	16	±	±	±	±		5.5	±	±	±	±
	33	+	+	+	+		14	+	+	+	+
	66	++	++	++	++		28	++	++	++	++
	133	+++	+++	+++	+++		55	+++	+++	+++	+++
BIL	0	NEG	NEG	NEG	NEG	SG	1.010	1.010	1.010	1.010	1.010

	17	+	+	+	+		1.020	1.020	1.020	1.020	1.020
	50	++	++	++	++		1.030	1.030	1.030	1.030	1.030
	100	+++	+++	+++	+++						
KET	0	NEG	NEG	NEG	NEG	pH	5.0	5.0	5.0	5.0	5.0
	0.5	±	±	±	±		6.0	6.0	6.0	6.0	6.0
	1.5	+	+	+	+		7.0	7.0	7.0	7.0	7.0
	3.9	++	++	++	++		8.0	8.0	8.0	8.0	8.0
	7.8	+++	+++	+++	+++		9.0	9.0	9.0	9.0	9.0
BLD	0	NEG	NEG	NEG	NEG	VC	0	NEG	NEG	NEG	NEG
	10	±	±	±	±		0.6	±	±	±	±
	25	+	+	+	+		1.4	+	+	+	+
	80	++	++	++	++		2.8	++	++	++	++
	200	+++	+++	+++	+++		5.6	+++	+++	+++	+++
URO	0	NEG	NEG	NEG	NEG	CRE	0	NEG	NEG	NEG	NEG
	0.15	±	±	±	±		10	+	+	+	+
	0.3	+	+	+	+		20	++	++	++	++
	1.0	++	++	++	++		30	+++	+++	+++	+++
	3.0	+++	+++	+++	+++						
NIT	0	NEG	NEG	NEG	NEG	MALB	0	NEG	NEG	NEG	NEG
	18.1 2	+	+	+	+		0.15	+	+	+	+
LEU	0	NEG	NEG	NEG	NEG	CA	0	NEG	NEG	NEG	NEG
	15	±	±	±	±		0.15	+	+	+	+
	70	+	+	+	+		0.3	++	++	++	++
	125	++	++	++	++		0.5	+++	+++	+++	+++
	500	+++	+++	+++	+++						

Batch number: 2019020901, the inspection result meets the product technical requirements.

Test items	Inspection concentration and result					Test items	Inspection concentration and result				
	concentra tion	mark	1	2	3		concent ration	mark	1	2	3
URO	3.3	±	±	±	±	GLU	0	NEG	NEG	NEG	NEG
	16	±	±	±	±		5.5	±	±	±	±
	33	+	+	+	+		14	+	+	+	+
	66	++	++	++	++		28	++	++	++	++
	133	+++	+++	+++	+++		55	+++	+++	+++	+++
BIL	0	NEG	NEG	NEG	NEG	SG	1.010	1.010	1.010	1.010	1.010
	17	+	+	+	+		1.020	1.020	1.020	1.020	1.020
	50	++	++	++	++		1.030	1.030	1.030	1.030	1.030
	100	+++	+++	+++	+++						
KET	0	NEG	NEG	NEG	NEG	pH	5.0	5.0	5.0	5.0	5.0
	0.5	±	±	±	±		6.0	6.0	6.0	6.0	6.0
	1.5	+	+	+	+		7.0	7.0	7.0	7.0	7.0
	3.9	++	++	++	++		8.0	8.0	8.0	8.0	8.0
	7.8	+++	+++	+++	+++		9.0	9.0	9.0	9.0	9.0
BLD	0	NEG	NEG	NEG	NEG	VC	0	NEG	NEG	NEG	NEG
	10	±	±	±	±		0.6	±	±	±	±
	25	+	+	+	+		1.4	+	+	+	+
	80	++	++	++	++		2.8	++	++	++	++
	200	+++	+++	+++	+++		5.6	+++	+++	+++	+++
URO	0	NEG	NEG	NEG	NEG	CRE	0	NEG	NEG	NEG	NEG
	0.15	±	±	±	±		10	+	+	+	+
	0.3	+	+	+	+		20	++	++	++	++
	1.0	++	++	++	++		30	+++	+++	+++	+++

	3.0	+++	+++	+++	+++						
NIT	0	NEG	NEG	NEG	NEG	MALB	0	NEG	NEG	NEG	NEG
	18.1						0.15	+	+	+	+
	2	+	+	+	+						
LEU	0	NEG	NEG	NEG	NEG	CA	0	NEG	NEG	NEG	NEG
	15	±	±	±	±		0.15	+	+	+	+
	70	+	+	+	+		0.3	++	++	++	++
	125	++	++	++	++		0.5	+++	+++	+++	+++
	500	+++	+++	+++	+++						

Lot number: 2019021101, the inspection result meets the product technical requirements.

Test items	Inspection concentration and result					Test items	Inspection concentration and result				
URO	concentration	mark	1	2	3	GLU	concentration	mark	1	2	3
	3.3	±	±	±	±		0	NEG	NEG	NEG	NEG
	16	±	±	±	±		5.5	±	±	±	±
	33	+	+	+	+		14	+	+	+	+
	66	++	++	++	++		28	++	++	++	++
	133	+++	+++	+++	+++		55	+++	+++	+++	+++
BIL	0	NEG	NEG	NEG	NEG	SG	1.010	1.010	1.010	1.010	1.010
	17	+	+	+	+		1.020	1.020	1.020	1.020	1.020
	50	++	++	++	++		1.030	1.030	1.030	1.030	1.030
	100	+++	+++	+++	+++						
KET	0	NEG	NEG	NEG	NEG	pH	5.0	5.0	5.0	5.0	5.0
	0.5	±	±	±	±		6.0	6.0	6.0	6.0	6.0
	1.5	+	+	+	+		7.0	7.0	7.0	7.0	7.0
	3.9	++	++	++	++		8.0	8.0	8.0	8.0	8.0

	7.8	+++	+++	+++	+++		9.0	9.0	9.0	9.0	9.0
BLD	0	NEG	NEG	NEG	NEG	VC	0	NEG	NEG	NEG	NEG
	10	±	±	±	±		0.6	±	±	±	±
	25	+	+	+	+		1.4	+	+	+	+
	80	++	++	++	++		2.8	++	++	++	++
	200	+++	+++	+++	+++		5.6	+++	+++	+++	+++
URO	0	NEG	NEG	NEG	NEG	CRE	0	NEG	NEG	NEG	NEG
	0.15	±	±	±	±		10	+	+	+	+
	0.3	+	+	+	+		20	++	++	++	++
	1.0	++	++	++	++		30	+++	+++	+++	+++
	3.0	+++	+++	+++	+++						
NIT	0	NEG	NEG	NEG	NEG	MALB	0	NEG	NEG	NEG	NEG
	18.1 2	+	+	+	+		0.15	+	+	+	+
LEU	0	NEG	NEG	NEG	NEG	CA	0	NEG	NEG	NEG	NEG
	15	±	±	±	±		0.15	+	+	+	+
	70	+	+	+	+		0.3	++	++	++	++
	125	++	++	++	++		0.5	+++	+++	+++	+++
	500	+++	+++	+++	+++						

4.5 Repeatability

Batch number: 2019020701, the test results meet the product technical requirements

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	SG	PH	VC	CRE	CA	MALB
Mark	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
1	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
2	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
3	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
4	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
5	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
6	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
7	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
8	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
9	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
10	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
11	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
12	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
13	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
14	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
15	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
16	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
17	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
18	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
19	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
20	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
Uniform	`100 %	`100 %	`100 %	`100 %	`100 %	`100 %	`100 %	`100 %	`100 %	`100 %	`100 %	`100 %	`100 %	`100 %

Batch number: 2019020901, the test results meet the product technical requirements

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	SG	PH	VC	CRE	CA	MALB
Mark	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
1	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
2	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
3	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
4	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
5	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
6	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
7	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
8	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
9	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
10	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
11	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
12	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
13	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
14	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
15	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
16	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
17	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
18	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
19	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
20	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
Unifor m	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

Batch number: 2019021101, the test result meets the product technical requirements

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	SG	PH	VC	CRE	CA	MALB
Mark	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
1	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
2	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
3	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
4	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
5	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
6	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
7	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
8	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
9	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
10	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
11	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
12	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
13	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
14	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
15	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
16	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
17	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
18	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
19	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
20	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
Uniform	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%	100%

4.6 Detection limit

Batch number: 2019020701, the test results meet the product technical requirements

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	VC	CRE	CA	MALB
Mark	±	+	±	±	±	+	±	±	±	+	+	+
1	±	+	±	±	±	+	±	±	±	+	+	+
2	±	+	±	±	±	+	±	±	±	+	+	+
3	±	+	±	±	±	+	±	±	±	+	+	+
4	±	+	±	±	±	+	±	±	±	+	+	+
5	±	+	±	±	±	+	±	±	±	+	+	+
6	±	+	±	±	±	+	±	±	±	+	+	+
7	±	+	±	±	±	+	±	±	±	+	+	+
8	±	+	±	±	±	+	±	±	±	+	+	+
9	±	+	±	±	±	+	±	±	±	+	+	+
10	±	+	±	±	±	+	±	±	±	+	+	+
11	±	+	±	±	±	+	±	±	±	+	+	+
12	±	+	±	±	±	+	±	±	±	+	+	+
13	±	+	±	±	±	+	±	±	±	+	+	+
14	±	+	±	±	±	+	±	±	±	+	+	+
15	±	+	±	±	±	+	±	±	±	+	+	+
16	±	+	±	±	±	+	±	±	±	+	+	+
17	±	+	±	±	±	+	±	±	±	+	+	+
18	±	+	±	±	±	+	±	±	±	+	+	+
19	±	+	±	±	±	+	±	±	±	+	+	+
20	±	+	±	±	±	+	±	±	±	+	+	+

Batch number: 2019020901, the test results meet the product technical requirements

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	VC	CRE	CA	MALB
Mark	±	+	±	±	±	+	±	±	±	+	+	+
1	±	+	±	±	±	+	±	±	±	+	+	+
2	±	+	±	±	±	+	±	±	±	+	+	+
3	±	+	±	±	±	+	±	±	±	+	+	+
4	±	+	±	±	±	+	±	±	±	+	+	+
5	±	+	±	±	±	+	±	±	±	+	+	+
6	±	+	±	±	±	+	±	±	±	+	+	+
7	±	+	±	±	±	+	±	±	±	+	+	+
8	±	+	±	±	±	+	±	±	±	+	+	+
9	±	+	±	±	±	+	±	±	±	+	+	+
10	±	+	±	±	±	+	±	±	±	+	+	+
11	±	+	±	±	±	+	±	±	±	+	+	+
12	±	+	±	±	±	+	±	±	±	+	+	+
13	±	+	±	±	±	+	±	±	±	+	+	+
14	±	+	±	±	±	+	±	±	±	+	+	+
15	±	+	±	±	±	+	±	±	±	+	+	+
16	±	+	±	±	±	+	±	±	±	+	+	+
17	±	+	±	±	±	+	±	±	±	+	+	+
18	±	+	±	±	±	+	±	±	±	+	+	+
19	±	+	±	±	±	+	±	±	±	+	+	+
20	±	+	±	±	±	+	±	±	±	+	+	+

Batch number: 2019021101, the test result meets the product technical requirements

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	VC	CRE	CA	MALB
Mark	±	+	±	±	±	+	±	±	±	+	+	+
1	±	+	±	±	±	+	±	±	±	+	+	+
2	±	+	±	±	±	+	±	±	±	+	+	+
3	±	+	±	±	±	+	±	±	±	+	+	+
4	±	+	±	±	±	+	±	±	±	+	+	+
5	±	+	±	±	±	+	±	±	±	+	+	+
6	±	+	±	±	±	+	±	±	±	+	+	+
7	±	+	±	±	±	+	±	±	±	+	+	+
8	±	+	±	±	±	+	±	±	±	+	+	+
9	±	+	±	±	±	+	±	±	±	+	+	+
10	±	+	±	±	±	+	±	±	±	+	+	+
11	±	+	±	±	±	+	±	±	±	+	+	+
12	±	+	±	±	±	+	±	±	±	+	+	+
13	±	+	±	±	±	+	±	±	±	+	+	+
14	±	+	±	±	±	+	±	±	±	+	+	+
15	±	+	±	±	±	+	±	±	±	+	+	+
16	±	+	±	±	±	+	±	±	±	+	+	+
17	±	+	±	±	±	+	±	±	±	+	+	+
18	±	+	±	±	±	+	±	±	±	+	+	+
19	±	+	±	±	±	+	±	±	±	+	+	+
20	±	+	±	±	±	+	±	±	±	+	+	+

4.7 Analysis specificity

4.7.1 Anti-interference analysis

Lot number: 2019020701. The test results meet the technical requirements of the product.

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	SG	MALB
Mark	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG
1	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG
2	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG
3	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG

Lot number: 2019020901. The test results meet the technical requirements of the product.

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	SG	MALB
MARK	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG
1	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG
2	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG
3	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG

Lot number: 2019021101. The test results meet the technical requirements of the product.

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	SG	MALB
mark	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG
1	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG
2	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG
3	±	NEG	NEG	+	NEG	+	++	±	1.020	NEG

4.7.2 Anti-vitamin C interference

Lot number: 2019020701. The test results meet the technical requirements of the product.

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	CA	SG	MALB
mark	+	+	+	+	+	+	+	+	+	+	+
1	+	+	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+	+	+

Lot number: 2019020901. The test results meet the technical requirements of the product.

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	CA	SG	MALB
mark	+	+	+	+	+	+	+	+	+	+	+
1	+	+	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+	+	+

Lot number: 2019021101. The test results meet the technical requirements of the product.

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	CA	SG	MALB
mark	+	+	+	+	+	+	+	+	+	+	+
1	+	+	+	+	+	+	+	+	+	+	+
2	+	+	+	+	+	+	+	+	+	+	+
3	+	+	+	+	+	+	+	+	+	+	+
4	+	+	+	+	+	+	+	+	+	+	+
5	+	+	+	+	+	+	+	+	+	+	+
6	+	+	+	+	+	+	+	+	+	+	+
7	+	+	+	+	+	+	+	+	+	+	+
8	+	+	+	+	+	+	+	+	+	+	+
9	+	+	+	+	+	+	+	+	+	+	+
10	+	+	+	+	+	+	+	+	+	+	+

4. 8 LOT differences

LOT NO.: 2019020701

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	SG	PH	VC	CRE	CA	MALB
Mark	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
1	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
2	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
3	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
4	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
5	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
6	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
7	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
8	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
9	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
10	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
11	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
12	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
13	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
14	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
15	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
16	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
17	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
18	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
19	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
20	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+

LOT NO.: 2019020901

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	SG	PH	VC	CRE	CA	MALB
Mark	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
1	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
2	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
3	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
4	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
5	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
6	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
7	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
8	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
9	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
10	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
11	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
12	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
13	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
14	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
15	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
16	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
17	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
18	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
19	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
20	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+

LOT NO.: 2019021101

Test items	URO	BIL	KET	BLD	URO	NIT	LEU	GLU	SG	PH	VC	CRE	CA	MALB
Mark	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
1	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
2	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
3	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
4	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
5	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
6	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
7	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
8	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
9	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
10	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
11	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
12	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
13	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
14	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
15	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
16	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
17	++	+++	+++	+++	+++	+	+++	+++	1.020	9.0	+	++	+	+
18	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
19	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+
20	+	+++	+++	+++	+++	+	+++	+++	1.020	8.0	+	++	+	+

After batch-to-batch comparison of three batches of products, the test results meet the product technical requirements.

5. Analysis performance evaluation summary

Experimental results of urine analysis test strip (dry chemical method) on Yantai Baowei BW-300 urine analyzer:

Inspection environment: temperature 20℃~28℃, relative humidity not more than 80%

Appearance: (a) The surface of the urine test strip should be flat, with no burrs on the edges of the polyester film. (b) The test block and the polyester film should be tightly fixed without defects or fallout; (c) The test block has a neat appearance, uniform color, and no stains or stains. Meet the technical requirements of the product.

Capacity: 100 pieces/box, in line with product technical requirements.

Accuracy: The difference between the test result and the corresponding reference solution mark is no more than one order of magnitude in the same direction, and there is no reverse phase difference, which meets the technical requirements of the product.

Repeatability: The same batch of test papers are repeatedly tested on the same positive specimen, and the consistency of the test results is not less than 90%, which meets the technical requirements of the product.

Detection limit: each artificial standard urine test is repeated 20 times. The first non-NEG level of each Test item should be detectable, which meets the technical requirements of the product.

Analysis specificity: (1) Anti-interference substance: The test result should meet the product index "post-interference mark", (2) Each test item of the test paper can resist the interference of 2.8 mmol/l vitamin C. All meet the product technical requirements.

Inter-batch difference: The three batches of test papers are repeatedly tested on the same specimen, and the difference between the test results does not exceed one order of magnitude, which meets the product technical requirements.

6. Conclusion

As the above tests show, BW-300 analyzer and the specified reagents have good precision, accuracy and stable performance, and meet the claimed specifications and practical clinical applications

