

**Clinical Study Report of  
Urinalysis Reagent Strips (Urine for Animals)**

## Clinical Study Report of Urinalysis Reagent Strips (Urine for Animals)

### 1 .Purpose of the test

Through test on certain quantity of representative clinical specimens, scientific and rational statistic analysis on the test result, evaluate the consistency of the visual result and test with Urinalysis Reagent Strips (Urine for Animals) produced by Hangzhou Alltest Biotech and compare with TECO product, and evaluate its clinical application capacity.

### 2 .Overall design of the test

The test of parallel contrast is adopted, compared with similar product(TECO) . The Alltest urinalysis reagent strips is used for visual interpretation, and parallel test on the same specimen of the control product, the results are recorded separately for the purpose of evaluating the consistency of test results and test results. The consistent results between Alltest’s and TECO’s product were confirmed.

### 3 .Research method

This evaluation has been run as a blind study. Specimens from different animals are randomized and tested. Dip the testing Strip and contrasting Strip into the specimen with all the reagent pads be impregnated, and remove it immediately. Absorb the excess solution on the paper. Read results in scheduled time according to visual color chart, then compare the two kinds of results (testing strip and contrasting strip).

#### 3.1 Sample size:

There were a total of 130 urine samples, among which 73 were clinical urine samples from different animals. Due to the lack of clinical urine positive samples, we prepared positive samples with different analytes and concentrations according to the clinical positive samples, and these prepared positive samples were blindly numbered to give blind tests to testers.

#### 3.2 Selection of specimen

The samples were selected from medical institution with different animals(such as Dogs, cats, cattle, horses ).

#### 3.3 The selection of comparison device and confirmation method

TECO similar product is selected as the comparison method.

#### 3.4 Product information:

AllTest Urinalysis Reagent Strips: V190750001    EXP: 2021-07

TECO Urinalysis Reagent Strips: 79581                    EXP: 2020-11

### 4. Acceptance criteria:

The consistency rate between the urine analysis test paper and the control test paper was more than 90%, and the consistency rate of the test results was less than or equal to  $\pm 1$ .

### 5. The test results:

#### 5.1 Urine Reagent Strips for Animal Urinalysis of AllTest company and TECO company

##### 5.1.1 Leukocyte LEU (130 samples)

TECO result AllTest result	-	$\pm$	+	++	+++
-	96	1			
$\pm$	1	8			
+		1	6		
++			1	4	1

+++						11
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5.1.2 Urobilinogen URO (130 samples)

TECO result \ AllTest result	0.2mg/dl	1 mg/dl	2 mg/dl	4 mg/dl	8 mg/dl	12 mg/dl
0.2mg/dl	90	1				
1 mg/dl	2	6				
2 mg/dl			4	1		
4 mg/dl			1	12		
8 mg/dl				1	5	
12 mg/dl						7

5.1.3 Microalbumin ALB (130samples)

TECO result \ AllTest result	10mg/L	30mg/L	80mg/L	150mg/L
10mg/L	113	1		
30mg/L	1	4		
80mg/L			7	1
150mg/L				3

5.1.4 Protein PRO (130 samples)

TECO result \ AllTest result	-	±	+	++	+++	++++
-	92	1				
±	2	7				
+		1	1	1		
++			1	9		
+++				1	8	1
++++						5

5.1.5 Bilirubin BIL (130 samples)

TECO result \ AllTest result	-	+	++	+++
-	99	1		
+		5	2	
++			14	1
+++			1	7

5.1.6 Glucose (130 samples)

TECO result \ AllTest result	-	±	+	++	+++	++++
-	78					
±	4	5	1			
+		1	12			
++			1	9	1	
+++				1	6	
++++						11



5	19	1					
6		23	1				
6.5		2	19	1			
7			1	10	1		
7.5				2	18		
8					1	13	1
9						1	16

5.1.13 BLO (130 samples)

TECO result AllTest result	-		±		+		++		+++	
-	98									
±	2		9							
+					5		1			
++							8			
+++									7	

5.1.14 Data analysis

analytes	Results were completely consistent with the consistency rate			Results ±1 display color block consistency rate		
	conform	inconformity	coincidence rate	conform	inconformity	coincidence rate
LEU	125	5	96.2%	260	0	100%
URO	124	6	95.4%	260	0	100%
ALB	127	3	97.7%	260	0	100%
PRO	123	8	94.6%	260	0	100%
BIL	125	5	96.2%	260	0	100%
Glu	121	9	93.1%	260	0	100%
ASC	123	7	94.6%	260	0	100%
SG	115	9	93.1%	260	0	100%
KET	119	11	91.5%	260	0	100%
NIT	130	0	100%	260	0	100%
CRE	123	7	94.6%	260	0	100%
pH	118	12	90.8%	260	0	100%
BLO	127	3	97.7%	260	0	100%

6. Conclusion:

In this clinical trial, it is necessary to evaluate the equivalence between visual interpretation of urine Reagent Strips for Animal Urinalysis of Hangzhou AllTest company, as well as the equivalence between urine test paper of Hangzhou AllTest company and control company TECO company. The clinical trial results showed that:

1. There is no statistical difference between the visual interpretation of urine analysis paper and urine analyzer of Hangzhou AllTest company, showing a high degree of consistency, that is, the clinical application performance of the two interpretations is similar, which can be used for effective diagnosis of related diseases in clinical hospitals.
2. There is no statistical difference between the urine analysis test paper of Hangzhou AllTest company and the

urine analysis test paper of TECO company, showing a high degree of consistency, that is, the clinical application performance of the two kinds of urine analysis test paper is similar, which can be used for effective diagnosis of related diseases in clinical hospitals.