

# **Clinical Study Report of hCG Pregnancy Rapid Test**

**(Cut-off:25mIU/ml&20mIU/ml&10mIU/ml)**

Test company: Guangxi zhuang autonomous region,  
Institute of skin disease prevention and  
control

Company applying for the test: Hangzhou AllTest Biotech Co., Ltd

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# Clinical Study Report of hCG Pregnancy Rapid Test

(Cut-off:25mIU/ml&20mIU/ml&10mIU/ml)

## 1 Purpose of the test

Through testing on certain quantity of representative specimens, and through scientific and reasonable statistic analysis on the results, thus evaluate the consistency between test results of hCG pregnancy rapid test produced by Hangzhou AllTest Biotech Co., Ltd and the contrast test device, and evaluate its clinical application ability.

## 2 Overall design of the test

Parallel-group test is adopted, and the already launched product with the same theory is taken as contrast device. The hCG pregnancy rapid test produced by our company (abbreviated as AllTest test device in the following) and the contrast test device will do parallel test on the same clinical specimen. We'll record the results respectively, and do hypothesis testing on the enumeration data by a 2x2 contingency table, thus evaluate the consistency between AllTest test device and the contrast device.

## 3 Study methods

### 3.1 specimen size and confirming basis

According to "Guiding principle of clinical study technique of in vitro diagnostic device", this product belongs to in vitro diagnostic device category II. In order to follow the guiding principle, and in the meantime inspect in a wider range the function of AllTest device. The target total specimen size of this clinical test is confirmed as 916 cases. The target urine specimen size of this clinical test is confirmed as 608 cases. The target serum/plasma specimen size of this clinical test is confirmed as 308 cases.

### 3.2 Specimen selection

hCG test device (Colloidal gold method) applies to qualitative test on hCG antigen in human urine, and assist diagnose whether the specimen provider is pregnant. Patients who are under outpatient service, emergency treatment, and who remain in hospital for further observation or be hospitalized, in order to test whether they pregnant should be selected. Suitable specimen for AllTest device and the contrast device is urine, serum, or plasma. The collection of specimens should be operated strictly following the requirements of the instructions of AllTest device and the contrast device. The testing on the specimens and the judgment of the results will also strictly follow the requirements of the instructions of AllTest device and the contrast device.

In order to protect the privacy of specimen providers, no name of specimen providers will appear on the test records.

### 3.3 The selection of contrast device and the confirming method

There are products in the same category already launched presently, and the similar device which was approved by CE registration, the test device produced by ABON Biopharm (Hangzhou) Co., Ltd is taken as contrast device for this test. In case of different test results out of AllTest device and the contrast device, the method Elisa will be adopted for confirmation.

The AllTest devices Cut-off: 25mIU/ml is:

hCG Pregnancy Rapid Test Dipstick(Urine): Lot#HCG14010001-T, Lot#HCG14010046-T;

hCG Rapid Test Cassette(Urine): Lot#HCG14010004-T, Lot#HCG14010049-T;

hCG Rapid Test Midstream(Urine): Lot#HCG14010007-T, Lot#HCG14010052-T;

hCG Rapid Test Dipstick(Serum/Plasma/Urine): Lot# HCG14010028-T;

hCG Rapid Test Cassette(Serum/Plasma/Urine): Lot# HCG14010031-T;

The ABON devices Cut-off: 25mIU/ml is:

hCG Rapid Test Cassette(Serum/Plasma/Urine): Lot# HCG3120035

The AllTest devices Cut-off: 20mIU/ml is:

hCG Pregnancy Rapid Test Dipstick(Urine): Lot#HCG14010010-T, Lot#HCG14010055-T;

hCG Rapid Test Cassette(Urine): Lot#HCG14010013-T, Lot#HCG14010058-T;

hCG Rapid Test Midstream(Urine): Lot#HCG14010016-T, Lot#HCG14010061-T;

hCG Rapid Test Dipstick(Serum/Plasma/Urine): Lot# HCG14010034-T;

hCG Rapid Test Cassette(Serum/Plasma/Urine): Lot# HCG14010037-T;

The ABON devices Cut-off: 20mIU/ml is:

hCG Rapid Test Cassette(Serum/Plasma/Urine): Lot# HCG3110011

The AllTest devices Cut-off: 10mIU/ml is:

hCG Pregnancy Rapid Test Dipstick(Urine): Lot#HCG14010019-T, Lot#HCG14010064-T;

hCG Rapid Test Cassette(Urine): Lot#HCG14010022-T, Lot#HCG14010067-T;

hCG Rapid Test Midstream(Urine): Lot#HCG14010025-T, Lot#HCG14010070-T;

hCG Rapid Test Dipstick(Serum/Plasma/Urine): Lot# HCG14010040-T;

hCG Rapid Test Cassette(Serum/Plasma/Urine): Lot# HCG14010043-T;

The ABON devices Cut-off: 10mIU/ml is:

hCG Rapid Test Cassette(Serum/Plasma/Urine): Lot# HCG3120048

#### 4 Statistic analysis techniques of the test results

This test adopts statistic analysis on matched numeration data, and it is recorded and analyzed in the form of fourfold tables. Refer to the following:

Table 1 Fourfold table evaluating the diagnostic device

		Contrast device		Total
		Positive	Negative	
Tested device	Positive	a	b	r1
	Negative	c	d	r2
Total		C1	C2	N

Positive coincidence rate =  $[a/(a+c)] \times 100\%$

Negative coincidence rate =  $[d/(b+d)] \times 100\%$

Total coincidence =  $[(a+d)/(a+b+c+d)] \times 100\%$

Kappa consistency test is conducted on the results, and the Kappa value is between 0-1. The closer the Kappa value is to 1, it means better consistency between the results of the two devices.

Normally consistency is approved when Kappa value is greater than 0.75.

$$\text{Kappa} = \frac{N(a+d) - (\gamma_1 C_1 + \gamma_2 C_2)}{N^2 - (\gamma_1 C_1 + \gamma_2 C_2)}$$

## 5 Result of the clinical test for urine specimen

### 5.1 Cut-off: 25mIU/ml

Among altogether 608 cases of urine specimens, HCG: 231 positive cases and 377 negative cases were detected by AllTest device. Refer to below table

Table – Fourfold table of hCG test result

		ABON device HCG3120035		Total
		Positive	Negative	
AllTest Dipstick	Positive	231	0	231
HCG14010001-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120035		Total
		Positive	Negative	
AllTest Cassette	Positive	231	0	231
HCG14010004-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120035		Total
		Positive	Negative	
AllTest Midstream	Positive	231	0	231
HCG14010007-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120035		Total
		Positive	Negative	
AllTest Dipstick	Positive	231	0	231
HCG14010046-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120035		Total
		Positive	Negative	
AllTest Cassette	Positive	231	0	231
HCG14010049-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120035		Total
		Positive	Negative	
AllTest Midstream	Positive	231	0	231
HCG14010052-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120035		Total
		Positive	Negative	
AllTest Dipstick	Positive	231	0	231
HCG14010028-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120035		Total
		Positive	Negative	
AllTest Cassette	Positive	231	0	231
HCG14010031-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Among altogether 308 cases of serum/plasma specimens, HCG: 68 positive cases and 240 negative cases were detected by AllTest device. Refer to below table

Table – Fourfold table of hCG test result

		ABON device HCG3120035		Total
		Positive	Negative	
AllTest Dipstick	Positive	68	0	68
HCG14010028-T	Negative	0	240	240
Total		68	240	308

Positive coincidence rate= $68 / (68+0) * 100\% = 100.0\%$

Negative coincidence rate= $240 / (0+240) * 100\% = 100.0\%$

Total coincidence rate= $(68+240) / (68+0+0+240) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120035		Total
		Positive	Negative	
AllTest Cassette HCG14010031-T	Positive	68	0	68
	Negative	0	240	240
Total		68	240	308

Positive coincidence rate= $68 / (68+0) * 100\% = 100.0\%$

Negative coincidence rate= $240 / (0+240) * 100\% = 100.0\%$

Total coincidence rate= $(68+240) / (68+0+0+240) * 100\% = 100.0\%$       Kappa=1

According to above tables, the positive coincidence rate between AllTest device and the contrast device is 100.0%, negative coincidence rate is 100.0%, and total coincidence rate is 100.0%. Kappa value reaches 1.

## 5.2 Cut-off: 20mIU/ml

Among altogether 608 cases of urine specimens, HCG: 231 positive cases and 377 negative cases were detected by AllTest device. Refer to below table

Table – Fourfold table of hCG test result

		ABON device HCG3110011		Total
		Positive	Negative	
AllTest Dipstick HCG14010010-T	Positive	231	0	231
	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$       Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3110011		Total
		Positive	Negative	
AllTest Cassette HCG14010013-T	Positive	231	0	231
	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$       Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3110011		Total
		Positive	Negative	
AllTest Midstream HCG14010016-T	Positive	231	0	231
	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$       Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3110011		Total
		Positive	Negative	
AllTest Dipstick	Positive	231	0	231
HCG14010055-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3110011		Total
		Positive	Negative	
AllTest Cassette	Positive	231	0	231
HCG14010058-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3110011		Total
		Positive	Negative	
AllTest Midstream	Positive	231	0	231
HCG14010061-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3110011		Total
		Positive	Negative	
AllTest Dipstick	Positive	231	0	231
HCG14010034-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3110011		Total
		Positive	Negative	
AllTest Cassette	Positive	231	0	231
HCG14010037-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Among altogether 308 cases of serum/plasma specimens, HCG: 68 positive cases and 240 negative cases were detected by AllTest device. Refer to below table

Table – Fourfold table of hCG test result

		ABON device HCG3110011		Total
		Positive	Negative	
AllTest Dipstick HCG14010034-T	Positive	68	0	68
	Negative	0	240	240
Total		68	240	308

Positive coincidence rate= $68 / (68+0) * 100\% = 100.0\%$

Negative coincidence rate= $240 / (0+240) * 100\% = 100.0\%$

Total coincidence rate= $(68+240) / (68+0+0+240) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3110011		Total
		Positive	Negative	
AllTest Cassette HCG14010037-T	Positive	68	0	68
	Negative	0	240	240
Total		68	240	308

Positive coincidence rate= $68 / (68+0) * 100\% = 100.0\%$

Negative coincidence rate= $240 / (0+240) * 100\% = 100.0\%$

Total coincidence rate= $(68+240) / (68+0+0+240) * 100\% = 100.0\%$  Kappa=1

According to above tables, the positive coincidence rate between AllTest device and the contrast device is 100.0%, negative coincidence rate is 100.0%, and total coincidence rate is 100.0%. Kappa value reaches 1.

### 5.3 Cut-off: 10mIU/ml

Among altogether 608 cases of urine specimens, HCG: 231 positive cases and 377 negative cases were detected by AllTest device. Refer to below table

Table – Fourfold table of hCG test result

		ABON device HCG3120048		Total
		Positive	Negative	
AllTest Dipstick HCG14010019-T	Positive	231	0	231
	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120048		Total
		Positive	Negative	
AllTest Cassette HCG14010022-T	Positive	231	0	231
	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1



Table – Fourfold table of hCG test result

		ABON device HCG3120048		Total
		Positive	Negative	
AllTest Midstream	Positive	231	0	231
HCG14010025-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120048		Total
		Positive	Negative	
AllTest Dipstick	Positive	231	0	231
HCG14010064-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120048		Total
		Positive	Negative	
AllTest Cassette	Positive	231	0	231
HCG14010067-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120048		Total
		Positive	Negative	
AllTest Midstream	Positive	231	0	231
HCG14010070-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120048		Total
		Positive	Negative	
AllTest Dipstick	Positive	231	0	231
HCG14010040-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$  Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120048		Total
		Positive	Negative	
AllTest Cassette	Positive	231	0	231
HCG14010043-T	Negative	0	377	377
Total		231	377	608

Positive coincidence rate= $231 / (231+0) * 100\% = 100.0\%$

Negative coincidence rate= $377 / (0+377) * 100\% = 100.0\%$

Total coincidence rate= $(231+377) / (231+0+0+377) * 100\% = 100.0\%$       Kappa=1

Among altogether 308 cases of serum/plasma specimens, HCG: 68 positive cases and 240 negative cases were detected by AllTest device. Refer to below table

Table – Fourfold table of hCG test result

		ABON device HCG3120048		Total
		Positive	Negative	
AllTest Dipstick	Positive	68	0	68
HCG14010040-T	Negative	0	240	240
Total		68	240	308

Positive coincidence rate= $68 / (68+0) * 100\% = 100.0\%$

Negative coincidence rate= $240 / (0+240) * 100\% = 100.0\%$

Total coincidence rate= $(68+240) / (68+0+0+240) * 100\% = 100.0\%$       Kappa=1

Table – Fourfold table of hCG test result

		ABON device HCG3120048		Total
		Positive	Negative	
AllTest Cassette	Positive	68	0	68
HCG14010043-T	Negative	0	240	240
Total		68	240	308

Positive coincidence rate= $68 / (68+0) * 100\% = 100.0\%$

Negative coincidence rate= $240 / (0+240) * 100\% = 100.0\%$

Total coincidence rate= $(68+240) / (68+0+0+240) * 100\% = 100.0\%$       Kappa=1

According to above tables, the positive coincidence rate between AllTest device and the contrast device is 100.0%, negative coincidence rate is 100.0%, and total coincidence rate is 100.0%. Kappa value reaches 1.

## 6 Conclusions:

There are clinical tests on total 916 cases of specimens, and parallel-group study is conducted on AllTest device and the contrast device. Through Kappa consistency check on the results, the total coincidence rate between the test results of AllTest device and ABON contrast device is 100.0%, and Kappa consistency test result is 1, which means the two has got high coincidence in the aspect of hCG test.

Confirming of the test company:  
Guangxi zhuang autonomous region,  
Institute of skin disease prevention and control

Date: May.19.2014

Confirming of the applying  
Hangzhou AllTest Biotech Co., Ltd

Date: May.20.2014