

Clinical Study Report of COT Oral Fluid Rapid Test

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1. Purpose of the test

Through test on certain quantity of representative clinical specimens, and scientific and rational statistic analysis on the test result, evaluate the consistency of the result of COT Rapid Test produced by Hangzhou Alltest Biotech and compare with GC/MS, and evaluate its clinical application capacity.

2. Overall design of the test

The test of parallel contrast is adopted, and GC/MS as comparison device. The COT Rapid Test produced by our company and the comparison device will parallel test on the same specimens, and the result will be recorded respectively. The enumeration data will be false inspected by 2x2 list table, for evaluating the consistency of Alltest test and the confirmed result.

3. Study method

Perform the clinical study by COT Rapid Test, and compare with GC/MS.

3.1 Specimens size and its confirmation basis

To investigate the function of product, a side-by-side comparison was conducted using The Alltest COT Rapid Test and GC/MS. Testing was performed on 230 clinical specimens previously collected from subjects present for Drug Screen Testing. Allow the test, oral fluid specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

3.2 Selection of specimen

The samples were selected from medical institution with the persons who probably abuse of COT. To protect the privacy of the specimen suppliers, the providers' name shouldn't appear in the test record.

3.3 Confirmation method

GC/MS is selected as the confirmation method. The product lot numbers are shown in table below.

Product	Alltest Product		
Cutoff	Cassette	Cup	Midstream
20ng/ml	COT14100001-T	COT14100007-T	COT14100013-T

Cutoff	Alltest Product Cassette
10ng/ml	COT14100019-T
30ng/ml	COT14100022-T

4. Statistic analysis method of test result

This test will adopt statistic analysis on pair enumeration data, and will record analysis in the form of

fourfold table, see below:

Table: fourfold table for evaluating diagnostic test

		Comparison device		Total
		positive	negative	
Test device	positive	a	b	r1
	negative	c	d	r2
total		C1	C2	N

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

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

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

We'll do Kappa consistency test on the result, and when the Kappa value is between 0-1, it means better consistency between the test results of the two devices. It is normally considered consistent when the Kappa value bigger 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. Clinical test result

5.1 Result of all the specimens

5.1.1 COT Test cassette and Cup Cut-off: 20ng/ml

Among all 230, Alltest tests get 131 positive results, and 96 negative results, see below table.

Table: fourfold table of COT20 rapid test cassette result

		GC/MS		total
		positive	negative	
COT Rapid Test Cassette (Oral Fluid)	Positive	131	2	133
	negative	1	96	97
Total		132	98	230
% Agreement		99.2%	98.0%	98.7%

Positive Agreement= $131/132 \times 100\% = 99.2\%$ (95% CI*: 95.85%~99.98%)

Negative Agreement = $96/98 \times 100\% = 98.0\%$ (95% CI*: 92.82%~99.75%)

Total Agreement= $(131+96) / (132+98) \times 100\% = 98.7\%$ (95% CI*:96.24%~99.73%)

Kappa=0.973

Table: fourfold table of COT20 rapid test cup result

		GC/MS		total
		positive	negative	
COT Rapid Test Cup (Oral Fluid)	Positive	131	2	133
	negative	1	96	97
Total		132	98	230
% Agreement		99.2%	98.0%	98.7%

Positive Agreement= $131/132 \times 100\% = 99.2\%$ (95% CI*: 95.85%~99.98%)

Negative Agreement = $96/98 \times 100\% = 98.0\%$ (95% CI*: 92.82%~99.75%)

Total Agreement= $(131+96) / (132+98) \times 100\% = 98.7\%$ (95% CI*:96.24%~99.73%)

Kappa=0.973

According to above table, the conformity rate of Alltest test with comparison device is 98.7%, negative conformity rate is 98.0%, positive conformity rate is 99.2%, and the Kappa value is 0.973.

5.1.2 COT Test Midstream Cut-off: 20ng/ml

Table: fourfold table of COT rapid test Midstream result

		GC/MS		total
		positive	negative	
COT Rapid Test Midstream (Oral Fluid)	Positive	131	3	134
	negative	1	95	96
Total		132	98	230
% Agreement		99.2%	96.9%	98.3%

Positive Agreement= $131/132 \times 100\% = 99.2\%$ (95% CI*: 95.85%~99.98%)

Negative Agreement = $95/98 \times 100\% = 96.9\%$ (95% CI*: 92.82%~99.75%)

Total Agreement= $(131+95) / (132+98) \times 100\% = 98.3\%$ (95% CI*:96.24%~99.73%)

Kappa=0.964

According to above table, the conformity rate of Alltest test with comparison device is 99.2%, negative conformity rate is 96.9%, positive conformity rate is 98.3%, and the Kappa value is 0.964.

5.1.3 COT Test Cassette Cut-off: 10ng/ml

Table: fourfold table of COT10 rapid test Midstream result

		GC/MS		total
		positive	negative	
COT Rapid Test Midstream (Oral Fluid)	Positive	131	3	134
	negative	1	95	96
Total		132	98	230
% Agreement		99.2%	96.9%	98.3%

Positive Agreement= $131/132 \times 100\% = 99.2\%$ (95% CI*: 95.85%~99.98%)

Negative Agreement = $95/98 \times 100\% = 96.9\%$ (95% CI*: 91.31%~99.36%)

Total Agreement= $(131+95) / (132+98) \times 100\% = 98.3\%$ (95% CI*:95.61%~99.52%)

Kappa=0.964

According to above table, the conformity rate of Alltest test with comparison device is 99.2%, negative conformity rate is 96.9%, positive conformity rate is 98.3%, and the Kappa value is 0.964.

5.1.4 COT Test Cassette Cut-off: 30ng/ml

Table: fourfold table of COT30 rapid test Midstream result

		GC/MS	total
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		positive	negative	
COT Rapid Test Midstream (Oral Fluid)	Positive	130	2	132
	negative	2	96	98
Total		132	98	230
% Agreement		98.5%	98.0%	98.3%

Positive Agreement= $130/132 \times 100\% = 98.5\%$ (95% CI*: 95.85%~99.98%)

Negative Agreement = $96/98 \times 100\% = 98.0\%$ (95% CI*: 91.31%~99.36%)

Total Agreement= $(130+96) / (132+98) \times 100\% = 98.3\%$ (95% CI*:95.61%~99.52%)

Kappa=0.964

According to above table, the conformity rate of Alltest test with comparison device is 98.5%, negative conformity rate is 98.0%, positive conformity rate is 98.3%, and the Kappa value is 0.964.

5.2 Discussion and conclusion

Clinical test has been conducted on altogether 230 specimens. Alltest tests of Cassette and Cup were parallel comparison studied with comparison device, and after consistency test on the Kappa value of the result, the total conformity rate of the test result of Alltest test and GC/MS for comparison is 98.7%, the consistency test result of Kappa is 0.973, Alltest tests of Midstream was parallel comparison studied with comparison device, and after consistency test on the Kappa value of the result, the total conformity rate of the test result of Alltest test and GC/MS for comparison is 98.3%, the consistency test result of Kappa is 0.964, and this indicate that the two has got high conformity in the respect of COT test.