

## Clinical Study Report of Chlamydia Rapid Test

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ACRO BIOTECH, INC

## Clinical Study Report of Chlamydia Rapid Test

### 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 Chlamydia rapid test produced by ACRO Biotech Inc 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 Chlamydia rapid test produced by our company (abbreviated as ACRO 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 ACRO test device and the contrast device.

### 3 .Study method

The Chlamydia Rapid Test Cassette (Swab/Urine) has been evaluated with specimens obtained from a population of symptomatic and asymptomatic individuals. PCR served as the reference method for the Chlamydia Rapid Test Cassette (Swab/Urine). The specimen was considered positive if PCR results were positive. The specimen was also considered negative if the PCR results were negative. The lot of ACRO Chlamydia Rapid Test is CHL14050001-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.

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

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### 5. Result of the clinical test

#### 5.1 Result of all specimens

ICH-502 Lot: CHL14050001-T

#### Female Cervical Swab Specimen

Method		PCR Result		Total
Chlamydia Rapid Test Cassette	Results	Positive	Negative	
	Positive	42	4	46
	Negative	3	156	159
Total Results		45	160	205

Sensitivity Agreement: 93.3% (95%CI\*: 81.7%-98.6%)

Specificity Agreement: 97.5% (95%CI\*: 93.7%-99.3%)

Overall Accuracy: 96.6% (95%CI\*: 93.1%-98.6%)

Kappa=0.90

#### Male Urethral Swab Specimen

Method		PCR Result		Total
Chlamydia Rapid Test Cassette	Results	Positive	Negative	
	Positive	50	5	55
	Negative	8	115	123
Total Results		58	120	178

Sensitivity Agreement: 86.2% (95%CI\*: 74.6%-93.9%)

Specificity Agreement: 95.8% (95%CI\*: 90.5%-98.6%)

Overall Accuracy: 92.7% (95%CI\*: 87.8%-96.1%)

Kappa=0.83

#### Male Urine Specimen

Method		PCR Result		Total
Chlamydia Rapid Test Cassette	Results	Positive	Negative	
	Positive	35	0	35
	Negative	2	60	62
Total Results		37	60	97

Sensitivity Agreement: 94.6% (95%CI\*: 81.8%-99.3%)

Specificity Agreement: >99.9% (95%CI\*: 95.1%-100%)

Overall Accuracy: 97.9% (95%CI\*: 92.7%-99.7%)

Kappa=0.96

### **5.2 Discussion and conclusion**

Clinical test has been conducted on altogether 205 Female Cervical Swab specimens. The ACRO tests were parallel comparison studied with the PCR, and after consistency test on the Kappa value of the result, the total conformity rate of the test result of ACRO test and the PCR comparison is 96.6%, the consistency test result of Kappa is 0.90, and this indicate that the two has got high conformity in the respect of Chlamydia Rapid test.

Clinical test has been conducted on altogether 178 Male Urethral Swab specimens. The ACRO tests were parallel comparison studied with the PCR, and after consistency test on the Kappa value of the result, the total conformity rate of the test result of ACRO test and the PCR comparison is 92.7%, the consistency test result of Kappa is 0.83, and this indicate that the two has got high conformity in the respect of Chlamydia Rapid test

Clinical test has been conducted on altogether 97 Male Urine specimens. The ACRO tests were parallel comparison studied with the PCR, and after consistency test on the Kappa value of the result, the total conformity rate of the test result of ACRO test and the PCR comparison is 97.9%, the consistency test result of Kappa is 0.96, and this indicate that the two has got high conformity in the respect of Chlamydia Rapid test