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Clinical Study Report of fFN Rapid Test

Testing Company: Vaxpert Inc.

Applicant: Hangzhou Alltest Biotech Co.,Ltd

Contact person: Nat Lu

Contact way: 0571-56267858

S www.vaxpert.net
E sales@vaxpert.net

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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 fFN 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 fFN 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

The fFN Rapid Test Cassette (Vaginal Discharge) has been evaluated with specimens obtained from pregnancy women. American Hologic Quickcheck fFN test served as the reference device for the fFN Rapid Test Cassette (Vaginal Discharge). The specimen was considered positive if contrast fFN test results were positive. The specimen was also considered negative if the contrast fFN test results were negative. The lot of AllTest fFN Rapid Test was FFN14090001-T, and the lot of Quickcheck fFN test was 1203018.

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 test

		Other fFN test		Total
		Positive	Negative	
Test dipstick or test cassette	Positive	a	b	r1
	Negative	c	d	r2
Total		C1	C2	N

Positive coincidence rate = [a/(a+c)]×100%

Negative coincidence rate = [d/(b+d)]×100%

Total coincidence = [(a+d)/(a+b+c+d)] ×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.

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

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5. Result of the clinical test

FFF-502 Lot: FFN14090001-T

Method		Other fFN Test		Total Results
fFN rapid test Cassette	Results	Positive	Negative	
	Positive	101	2	103
	Negative	2	148	150
Total results		103	150	253

Relative Sensitivity: 98.1% (95%CI:*93.2%-99.8%)

Relative Specificity: 98.7% (95%CI:*95.3%-99.8%)

Overall Accuracy: 98.4% (95%CI:*96.0%-99.6%)

Kappa=0.97

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6. Conclusions

Clinical test has been conducted on altogether 253 specimens. The Alltest tests were parallel comparison studied with the other fFN Test, and after consistency test on the Kappa value of the result, the total conformity rate of the test result of Alltest test and the other fFN Test comparison is 98.4%, the consistency test result of Kappa is 0.97, and this indicate that the two has got high conformity in the respect of fFN Rapid test.

Confirmation of testing company:
Vaxpert Inc.
Suite 355 Two South Biscayne Blvd.
Miami, Fl, U.S.A

Date: Feb. 26th, 2015

VAXPERT INC INCORPORATED OCTOBER 10, 2012 FLORIDA

Confirmation of applying company:

Hangzhou Alltest Biotech Co., Ltd
#550, Yinhai Street, Hangzhou
Econmic & Technological Development Area,
Hangzhou-310018, P.R.China

Date: 2015.03.04

杭州奥盛生物技术有限公司 3301180055974

T +9714 266 3030
F +9714 266 2021
S www.vaxpert.net
E sales@vaxpert.net