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Consistency Analysis of Detection Results of Two Herpes Simplex Virus (HSV) Type II Nucleic Acid Detection Kits

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Abstract

Objective: The objective of the study is to verify the clinical validity of the following kits with the comparative experimental analysis and evaluate whether their performance can meet the clinical requirements, *i.e.* Class III *in vitro* diagnostic reagent "Herpes Simplex Virus (HSV) Type II Nucleic Acid Detection Kit (PCR-Fluorescence Probe Method)" of Daan Gene Co., Ltd. (Daan kit for short) and "Herpes Simplex Virus (HSV) Type II Nucleic Acid Detection Kit (Fluorescence PCR Method)" of Wuhan Biot Gene Co., Ltd. (Biot kit for short). **Method:** In the study process, the samples were divided into positive and negative groups according to the control test results, and the clinical application performance of Daan kit and Biot kit was evaluated by comparing their test results. **Results:** The results show that two kits indicate the same test results, *i.e.* 26 positive and 107 negative samples in a total of 133 male urethral discharge samples, and 32 positive and 238 negative samples in a total of 270 female cervical secretion samples. **Conclusion:** It can be concluded from the clinical test that Daan and Biot Herpes Simplex Virus (HSV) Type II Nucleic Acid Test Kits are reliable, accurate, safe, convenient for use, stable and high-value in the clinical application.

Keywords

Herpes Simplex Virus (HSV) Type II, Nucleic Acid Detection Kits, Consistency Analysis

1. Introduction

Herpes simplex virus (HSV) is categorized to *a* subfamily of the Herpesviridae,

and its virus size is about 180 nm. This kind of virus can be classified as type I (HSV-I) and type II (HSV-II) based on differences in antigenicity. HSV-II can cause the cutaneous herpes below the waist and external genital herpes [1] [2], mainly in cervixes, vaginas, vulvar skins of women and penises and urethras of men. It is regarded as the main pathogenesis for the genital inflammation and herpes [3]. Herpes simplex virus (HSV) is widespread in the population, with humans being the only host and patients and carriers being the only source of infection [4]. HSV-II is mainly transmitted by the sexual intercourse [5]. It is relatively difficult to prevent such disease due to the widespread presence of carriers and occult infections, as well as the many modes of transmission and the absence of a reliable vaccine [6] [7]. Therefore, the development of diagnostic techniques that allow a rapid detection of HSV-II is of great importance for the auxiliary diagnosis of HSV-II infection, the efficacy of antiviral therapy and epidemiological studies. This technique is PCR fluorescence probe method. PCR assay has high sensitivity and specificity in detecting HSV, which is recommended by European laboratories and US Centers for Disease Control and Prevention (CDC) [8] [9].

In recent years, HSV-II detection kits based on fluorescence PCR and PCR-fluorescence probe method have been used more frequently in China. Zhao Zhao *et al.* adopted the fluorescence PCR to conduct HSV-II nucleic acid detection in 2230 patients with suspected urogenital tract herpes in Zhejiang Provincial People's Hospital from 2008 to 2017, and they found 557 HSV-II positive patients, accounting for 24.98% [10]. Yu Xueying *et al.* adopted PCR-fluorescence probe method to detect HSV-I/II in 488 patients attending the STD Clinic of Guangdong Provincial Dermatology Hospital, and they found 136 HSV-II positive and 6 HSV-I positive patients, accounting for 29.89% [11].

2. Materials and Methods

2.1. Samples

Clinically confirmed or suspected HSV-II infection cases were enrolled in this study, and there were total 403 samples, including 133 male urethral discharge samples and 270 female cervical secretion samples.

2.2. Reagents and Instruments

1) Daan Herpes Simplex Virus (HSV) Type II Nucleic Acid Detection Kit (PCR-Fluorescent Probe Method) and Biot Herpes Simplex Virus (HSV) Type II Nucleic Acid Detection Kit (Fluorescence PCR Method). DNA of all samples was extracted and detected by fluorescent PCR with two reagents, and the results were compared.

2) Extraction, amplification, and other experimental conditions are same for both reagents.

2.3. Statistical Processing

The statistics of the test results are mainly collated with fourfold tables. The test

results of two reagents were undergone the Kappa identity test and a P-value less than or equal to 0.01 would be considered statistically significant for the difference tested.

3. Results

The samples of 133 males urethral discharge (study objects) were divided into positive and negative groups according to the control test results. When comparing the test results obtained with Daan and Biot kits, it was found that they all indicated 26 positive and 107 negative samples. The test results were consistent (Table 1), which was statistically significant (Table 2). The samples of 270 females cervical secretion (study objects) were divided into positive and negative groups according to the control test results. When comparing the test results obtained with Daan and Biot kits, it was found that they all indicated 32 positive and 238 negative samples. The test results were consistent (Table 3), which was statistically significant (Table 4).

4. Discussion

According to the literature, an estimated 500 million people worldwide have genital infections with HSV-I or HSV-II, of which 90% of the pathogens of genital

Table 1. Result comparison of male urethral discharge samples with two test kits.

Test		Biot reagent		Total
		Positive	Negative	
Daan reagent	Positive	26	0	26
	Negative	0	107	107
Total		26	107	133

Table 2. Symmetric measures analysis of male urethral discharge samples with two test kits.

	Value	Asymp. Std. Error[a]	Approx. T[b]	Approx.Sig.
Measure of Agreement Kappa	1.000	0.000	11.533	0.000
N of Valid Cases	133			

[a]Not assuming the null hypothesis. [b]Using the asymptotic standard error assuming the null hypothesis.

Table 3. Result comparison of female cervical secretion samples with two test kits.

Test		Biot reagent		Total
		Positive	Negative	
Daan reagent	Positive	32	0	32
	Negative	0	238	238
Total		32	238	270

Table 4. Symmetric measures analysis of female cervical secretion samples with two test kits.

	Value	Asymp. Std. Error[a]	Approx. T[b]	Approx. Sig.
Measure of Agreement	1.000	0.000	16.432	0.000
Kappa N of Valid Cases	270			

[a]Not assuming the null hypothesis. [b]Using the asymptotic standard error assuming the null hypothesis.

herpes are HSV-II and only 10% are HSV-I [12] [13]. The incidence in China is also increasing year by year. Therefore, the early selection of appropriate laboratory diagnostic methods is important to reduce the infectiousness and pathogenicity of HSV. The current laboratory diagnostic methods of HSV-II mainly include the microscopic observation, cell culture, serological tests and PCR assay of nucleic acid detection [14]. For the high sensitivity and specificity, the PCR assay is recommended in detecting HSV. In recent years, HSV-II detection kits based on fluorescence PCR and PCR-fluorescence probe method have been used more frequently in China. However, the clinical effectiveness evaluation of HSV-II *in vitro* diagnostic kits produced by different companies in China has not yet been studied in a comparative test.

For 403 samples in this test, there were a total of 133 male urethral discharge samples. The positive and negative coincidence rate, as well as the total coincidence rate of Daan and Biot reagents were all 100%. Kappa identity test indicated that the results of Daan and Biot reagents in detecting human urogenital tract secretions were in good consistency (kappa = 1, $P < 0.001$), and of statistical significance. For 270 female cervical secretion samples, the positive and negative coincidence rate, as well as the total coincidence rate of Daan and Biot reagents were all 100%. Kappa identity test indicated that the results of Daan and Biot reagents in detecting human urogenital tract secretions were in good consistency (kappa = 1, $P < 0.001$), and of statistical significance.

5. Conclusion

The test results indicate that "Herpes Simplex Virus (HSV) Type II Nucleic Acid Detection Kit (PCR-Fluorescence Probe Method)" of Daan Gene Co., Ltd. and "Herpes Simplex Virus (HSV) Type II Nucleic Acid Detection Kit (Fluorescence PCR Method)" of Wuhan Biot Gene Co., Ltd. are reliable, accurate, safe, convenient for use, stable and high-value in the clinical application.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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