Viral Nucleic Acid Extraction Kit (Silica-Based Spin Column)

Performance Evaluation Report

1. Purpose

This kit was used to evaluate the accuracy of swab, culture liquid and serum samples.

2. Reference standards and regulations

(1) EN 13612:2002/AC:2002 Performance evaluation of in vitro diagnostic medical devices

(2) CLSI EP15-A2: User verification of performance for precision and trueness; Approved Guideline-Second Edition.

(3) ISO3534-1 2006: Statistics -- Vocabulary and symbols -- Part 1: General statistical terms and terms used in probability.

(4) Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline—Second Edition This. EP17-A2 Vol. 32 No. 8 Replaces EP17-A Vol. 24 No. 34.

(5) CLSI EP12-A2: User Protocol for Evaluation of Qualitative Test Performance, 2nd Edition

3. Test materials

3.1 Detection reagent

Batch code：20190501;20190502;20190601
Specification：50T

3.2 Reference

120 Samples，including 40 throat swab、40 virus culture 和 40 serum clinical sample

4. Evaluation result

4.1 Student's T test

Student's T test was used for statistical analysis of CT values of 90 positive samples from 120 samples, and the analysis results were as follows:

Paired sample statistics

		Mean value	N	SD	SE Mean
Throat swab	ssbio	27.4277	30	4.28732	.78275
	Qiagen	27.4907	30	4.21556	.76965
Virus culture	ssbio	27.4770	30	4.35802	.79566
	Qiagen	27.3843	30	4.24547	.77511
Serum	ssbio	27.5510	30	4.17129	.76157
	Qiagen	27.5883	30	4.20412	.76756

Correlation coefficients of paired samples

		N	correlation coefficient	Sig.
Throat swab	ssbio & Qiagen	30	.995	.000
Virus culture	ssbio & Qiagen	30	.994	.000
Serum	ssbio & Qiagen	30	.997	.000

Paired sample test

		Difference in pairs					t	df	Sig. (double side)
		Mean value	SD	SE Mean	95% Confidence interval for the difference Lower limit	Upper limit			
Throat swab	ssbio - Qiagen	-.06300	.44667	.08155	-.22979	.10379	-.773	29	.446
Virus culture	ssbio - Qiagen	.09267	.46685	.08523	-.08166	.26699	1.087	29	.286
Serum	ssbio - Qiagen	-.03733	.34002	.06208	-.16430	.08963	-.601	29	.552

After statistical analysis，the CT value of nucleic acid extraction by this kit and QIAGEN viral nucleic acid extraction kit，Swab sample P=0.446＞0.05，Virus culture samples P=0.286＞0.05，Serum sample P=0.552＞0.05，There was no significant difference between the three different types of samples for the two kits.

4.2 Consistency test

CT values of 120 clinical samples were statistically analyzed using 2×2 contingency table，

The analysis results are as follows:

Qiagen* ssbio cross tabulation

Count

		ssbio		Total
		Positive	Negative	
Qiagen	Positive	90	0	90
	Negative	0	30	30
Total		90	30	120

Chi-square test

	Value	df	Progressive Sig. (Two Side)	Accuracy Sig.(Two Side)	Accuracy Sig.(Single Side)
Pearson chi-square	120.000[a]	1	.000		
Continuous correction [b]	114.726	1	.000		
Likelihood ratio	134.960	1	.000		
Fisher's exact test				.000	.000
Linear and linear combinations	119.000	1	.000		
McNemar'test				1.000[c]	
N in effective cases	120				

a. The expected count for the cell (.0%) is less than 5. The minimum expectation count is 7.50.

b. Only for table 2x2

c. Binomial-distribution

Symmetric metric

		Value	Asymptotic standard error[a]	Approximate value T[c]	Approximate value Sig.
According to the interval in sequence	Pearson' R	1.000	.000[b]		
	Spearman correlation	1.000	.000[b]		
Consistent measurement	Kappa	1.000	.000	10.954	.000
N in effective cases		120			

a. Not assuming the null hypothesis

b. Based on the normal approximation

c. assume the null hypothesis using the asymptotic standard error

After statistical analysis, ssbio's Viral RNA Nucleic Acid Extraction Kit & Qiagen Viral Nucleic Acid Extraction

（1）Positive coincident rate：90/（90+0）×100%= 100 %

（2）Negative coincident rate：30/（0+30）×100%= 100%

（3）Total coincident rate：（90+30）/（90+0+0+30）×100%= 100%

（4）Kappa value： K=（Pa-Pe）/（1-Pe）=1.00

Kappa value 1.00>0.75 It indicated that the results of viral nucleic acid extraction by Ssbio and Qiagen viral nucleic acid extraction kit are consistent. The above results showed that there was no significant difference in the test results between the two extraction methods -- Ssbio viral nucleic acid extraction kit and Qiagen viral nucleic acid extraction kit, which are equivalent.