Viral Transport Medium

Product Stability Performance Test Report

Date of Issue: 3 July, 2020

1. Description of Product, Specification and Pack Size

1.1 1mL/bottle: Preservation of one single piece of nasopharyngeal or oropharyngeal swab sample

1.2 2mL/bottle: Preservation of one single piece of nasopharyngeal or oropharyngeal swab sample

1.3 3mL/bottle: Preservation of one single piece of nasopharyngeal or oropharyngeal swab sample

1.4 4mL/bottle: Preservation of one single piece of nasopharyngeal or oropharyngeal swab sample

1.5 100mL/bottle: It can be packed into different sampling tubes according to different requirements of sample preservation.

1.6 200mL/bottle: It can be packed into different sampling tubes according to different requirements of sample preservation.

1.7 1000mL/bottle: It can be packed into different sampling tubes according to different requirements of sample preservation.

2. Test Method

2.1 Test Method of RNA Sample Preservation

2.1.1 Sample Preparation

The 2019-nCOV virus RNA standard positive reference sample was diluted with PBS gradient: 1/10 and 1/100, and stored at - 80 ℃ as the control for 0 days. The 2019-nCOV virus RNA standard positive reference sample was diluted with viral transport medium (simulating the state of virus preservation): diluted 1/10 and 1/100; stored at 37 ℃ for 1 day, 3 days, 7 days, 9 days, 22 days and 30 days.

2.1.2 Sample Nucleic Acid Extraction and Purification

2019-nCOV virus RNA was extracted by Bioer's MagaBio plus Virus DNA / RNA Purification Kit II. 300μL was extracted from each concentration.

2.1.3 Real Time PCR Detection of Extracted 2019-nCOV virus RNA

The reaction system was prepared according to 2019-nCOV fluorescence RT-PCR detection kit, and 2μL of extracted products were added, and then PCR amplification was carried out on Bioer 9600 Fluorescence Quantitative Detection System. The amplification results were analyzed quantitatively by sampling point

fitting method of F1 (FAM) channel.

2.1.4 Test Result

Sample Preservation Time	1 Day	1 Day		5 Days		7 Days		9 Days		22 Days		30 Days	
Concentration of Sample/ Storage Temperature	-80℃	2-8℃	37℃	2-8℃	37℃	2-8℃	37℃	2-8℃	37℃	2-8℃	37℃	2-8℃	37℃
1:10 diluted	27.17	27.42	27.56	26.65	26.21	26.70	27.56	26.69	29.02	26.71	29.97	26.54	31.67
1:10 diluted	27.06	27.41	27.59	26.56	26.21	26.75	27.43	26.78	28.64	26.74	29.91	26.51	31.78
1:100 diluted	30.37	30.92	30.68	30.60	29.63	30.74	30.67	30.39	32.27	30.42	33.63	30.15	34.58
1:100 diluted	30.53	30.90	30.56	30.32	29.59	30.51	30.73	30.40	32.39	30.57	33.65	29.97	34.00
Negative Control	--	--	--	--	--	--	--	--	--	--	--	--	--

3. Conclusion of Product Performance Test Result

The results showed that 2019-nCOV virus RNA could be stored stably for 30 days at 2-8℃ and not degraded for 7 days at 37℃. Calculated according to Arrhenius equation, 2019-nCOV virus RNA could be stably stored in Bioer's Viral Transport Medium at - 20℃ for one year.