High-dose Hook Effect Study

1. Basic information

Basic information				
Test kit	Lot	Date of manufacture	Expiry date	Specification
Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold)	W2020040100 W2020040200 W2020040300	20200413 20200414 20200415	20211013 20211014 20211015	40 T/kit
Manufacturer		Beijing Hotgen Biotech Co., Ltd		
Experiment Site	Institute of Microbiology and Epidemiology of the Academy of Military Medical Science of the PLA, Beijing.		Operator	5.1.2e
Date of Initiation and completion		2020.04.20~2020.04.25		
Study protocol				
Anterior nasal swabs	Samples		Extraction of the novel coronavirus cultures	
	Test method		50% tissue culture infectious dose method ($TCID_{50}$)	

2. Sample source and basic information

2.1 Sample source

This experiment commissioned the Institute of Microbiology and Epidemiology of the Academy of Military Medical Sciences to cultivate the novel coronavirus and extract the virus culture.

3. Experimental protocol

The novel coronavirus (2019-nCoV) antigen test kit is used to qualitatively detect the novel coronavirus antigen in human anterior nasal swab samples *in vitro*. The high-concentration sample selected in this experiment is $1 \times 10^{6.2}$ $TCID_{50}$/mL virus culture. After the high-concentration sample is serially diluted, three lots of Novel Coronavirus 2019-nCoV Antigen Test (Colloidal Gold) are used to detect virus cultures of different concentrations. Each concentration is tested three times.

4. Acceptance criteria

In this experiment, the detection result can be judged according to the color changes. The concentration at which the color of the color band begins to decrease as the concentration increases is taken as the lowest concentration when the hook effect occurs.

5. Test results

The test results are shown in Table 1

Table 1 Test results of virus cultures at different concentrations

Lot	W2020040100	W2020040200	W2020040300
Virus concentration ($TCID_{50}$/mL)	Test result	Test result	Test result
$1\times10^{3.2}$	+	+	+
	+	+	+
	+	+	+
$5\times10^{3.2}$	+	+	+
	+	+	+
	+	+	+
$1\times10^{4.2}$	++	++	++
	++	++	++
	++	++	++
$1\times10^{5.2}$	+++	+++	+++
	+++	+++	+++
	+++	+++	+++
$1\times10^{6.2}$	+++	+++	+++
	+++	+++	+++
	+++	+++	+++

6. Conclusions

The above experimental results show that using three lots of test kits to test virus samples with different concentration gradients, the test results were all positive. As the virus concentration increases, the color signal continued to increase, and there was no color decrease. Therefore, no hook effects occur when using this kit to detects a high-titer level ($1\times10^{6.2}$ $TCID_{50}$/mL) of novel coronavirus antigen-positive samples.