

Effects of Different Temperatures on Product Performance

1. Basic information:

Basic information			
Manufacturer		Beijing Hotgen Biotech Co., Ltd.	
Experiment Site	Hotgen Biotech laboratory	Operator	5.1.2e
Date of Initiation and completion		2020.04.03	
Study protocol			
Samples		5 positive samples 5 negative samples	
Storage condition and Test interval		2~8°C	

2. Source and information of samples

2.1 Source of samples

Virus cultures: Academy of Military Medical Sciences

2.2 Preparation of samples

2.2.1 Collection of negative samples

Anterior nasal swabs of multiple healthy subjects shall be collected according to the sample collection method as specified in the IFU, diluted with the sample extraction buffer and then used as negative samples.

2.2.2 Preparation of positive samples

Dilute virus cultures with the sample extraction buffer 50, 100, 200, 400 and 800 times respectively to be used as positive samples 1~5.

3. Study protocol

Labeling process: Add 20 μ L of 2% potassium carbonate into 1mL of colloidal gold prepared from 0.04% chloroauric acid. Antibody concentration shall be labeled as 20 μ g/mL, and the labeling time is 10min. Block with 0.1% BSA for 5min.

Coating process: C-line: Goat anti Mouse IgG: 2.0 mg/mL; T-line: Antibody: 2.0 mg/mL. Coating buffer: 0.01M PB (pH7.2)

Under the condition of humidity <85%, test positive and negative samples at the temperature of 10°C, 20°C and 30°C respectively to study the influence of different temperature on product performance.

4. Acceptance criteria

Testing results of negative and positive samples are obviously different, and positive samples with different concentrations have color gradients.

5. Testing results

Table 1 Testing results under different temperature conditions

Sample no.	Testing results under different temperature conditions		
	10°C	20°C	30°C
Positive sample 1	+++	+++	+++
Positive sample 2	++	++	++
Positive sample 3	++	++	++
Positive sample 4	+	+	+
Positive sample 5	+	+	+
Negative sample 1	-	-	-
Negative sample 2	-	-	-
Negative sample 3	-	-	-
Negative sample 4	-	-	-
Negative sample 5	-	-	-

6. Conclusions

Negative and positive samples had significant differences at 10°C, 20°C and 30°C and the coloration intensity of positive samples with different concentrations basically kept at the same level, indicating that tests at 10°C~30°C had no significant effects on product performance.