

Effects of Sample Volume 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		2020.04.01	
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

Labelling 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. Seal 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).

Test 3 drops, 4 drops, 5 drops, and 6 drops of samples respectively to study the influence of sample volume 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 for selection of sample volume

Sample no.	Testing results of different sample volumes			
	3 drops	4 drops	5 drops	6 drops
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

When the sample volume is three drops, the sample volume is small and the chromatography is insufficient. When the test sample volume is 4 drops, 5 drops, and 6 drops, there is a significant difference between negative and positive samples, and the color intensity of positive samples with different concentrations is basically the same, indicating that the sample volume of 4 drops, 5 drops, and 6 drops has no significant effect on the product performance, but the sample volume of 5~6 drops is too much, and the sample inlet overflows, so select 4 drops for sample volume.