Effects of sample extraction buffer on product performance

1. Basic information:

Basic information			
Manufacturer	Beijing Hotgen Biotech Co.,Ltd.		
Experiment Site	Hotgen biological laboratory	Operator	5.1.2e
Date of Initiation and completion	2020.04.05		
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 package insert, diluted with the sample extraction buffer and then used as negative samples.

2.2.2 Collection of positive samples

Select 3 anterior nasal swab samples from samples kept by the Academy of Military Medical Sciences.

3. Study protocol

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

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

Respectively subpackage 100 μL, 300 μL and 500μL of sample extraction buffer in sampling burettes, test swabs with positive and negative samples and study the effects of different volumes of sample extraction buffer 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 of different volume of sample extraction buffer

Sample no.	Testing results of different volume of sample extraction buffer		
	100μL	300μL	500μL
Positive sample 1	+	++	±
Positive sample 2	+	++	±
Positive sample 3	+	++	±
Negative sample 1	-	-	-
Negative sample 2	-	-	-
Negative sample 3	-	-	-
Negative sample 4	-	-	-
Negative sample 5	-	-	-

6. Conclusions

The coloration intensity of the sampling burette containing 100μL of sample extraction buffer was relatively low, which might be caused by incomplete lysis of the sample; the coloration intensity of the sampling burette containing 500μL of sample extraction buffer was generally low due to excessive sample extraction buffer and large sample dilution ratio; whereas, the coloration intensity of the sampling burette containing 300μL of sample extraction buffer was relatively higher and positive and negative samples were obviously different. Therefore, 300μL/vial has been selected to be the packing volume of the burette.