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IVD AND POCT PRODUCTS MANUFACTURER

SARS-CoV-2 antigen IVD kit NASAL Product

Open Bag Stability Test Report



1. Purpose

This report is intended to evaluate the product open bag stability of SARS-CoV-2 antigen IVD kit NASAL .

2. Reference

2.1 Colloidal Gold Immunochromatography Assay Kit 2018-07-10 .

2.2 Guidance for the technical review of registration of pathogen-specific M-type immunoglobulin qualitative detection reagents.

2.3 "Key Points of Technical Review of SARS-CoV-2 Antigen Detection Reagent Registration in 2019 (Trial)"

3. Material

Table 1:Material List

Product	Spec	Lot	Manufacturer	Note
SARS-CoV-2 antigen IVD kit NASAL	20Cards/box	20201018 20201019 20201020	Shenzhen Reagent Technology Co.,Ltd.	Kits to be tested

4. Acceptance Criteria

4.1 Appearance

Out package should be completed without any damaged. Labelling should be clear. Test Strip should be clean, complete, without any damage or contamination. Sample Extraction Buffer should be transparent liquid, without any floccule or sediment.

4.2 Strip width

Strip width should be no less than 2.5mm.

4.3 Liquid migration velocity

Liquid migration velocity should be no less than 10mm/min.

4.4 Detection Limit

Use manufacturer's reference perform test. Results of L01, L02 reference should be

negative. Results of L05, L06 reference should be positive. Results of L03, L04 reference can either negative or positive.

4.5 Negative reference consistency rate

Use manufacturer's negative reference perform test. All test results should be negative. Negative consistency rate is (-/-)10/10.

4.6 Positive reference consistency rate

Use manufacturer's positive reference perform test. All test results should be positive.

Positive consistency rate is (+/+)5/5

4.7 Repeatability

Use manufacturer's negative reference R01 and manufacturer's weakly positive reference R02 test 20 times respectively. Negative consistency range and positive consistency rate should be no less than 95%.

5. Test Method

Because high temperature and high humidity will affect strip performance, this evaluation is focus on these two aspects. Choose 3 lots test strips. Take out Sample Extraction Buffer, open and close cap immediately, stored at 4~30°C. Take out strips from foil pouch, then put the strips at different temperature/humidity condition for 0min, 10min, 20min, 30min. Test appearance, strip width, liquid moving velocity, detection limit, negative consistency range, positive consistency rate and repeatability.

Environment condition are as below:

- (1) RH 50%, 25°C;
- (2) RH 50%, 40°C;
- (3) RH 90%, 25°C

6. Test Result

Table 2-test Result

20201018													
Environment		25℃,RH50%				40℃,RH50%				25℃,RH90%			
Time		0min	10min	20min	30min	0min	10min	20min	30min	0min	10min	20min	30im
/	Appearance	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Strip width(mm)	3.00	3.02	3.00	3.00	3.02	3.00	3.02	3.00	3.00	3.02	3.00	3.02
	Liquid migration velocity(mm/min)	19.6	20.1	19.5	19.9	18.9	18.7	19.0	18.8	19.2	18.9	19.3	19.2
Detection Limit	L01	-	-	-	-	-	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-	-	-	-	-	-
	L03	-	-	-	-	-	-	+	-	+	-	+	+
	L04	+	-	+	-	+	-	+	-	-	+	-	-
	L05	+	+	+	+	+	+	+	+	+	+	+	-
	L06	+	+	+	+	+	+	+	+	+	+	+	+
Negative Reference Consistency Rate	N01	-	-	-	-	-	-	-	-	-	-	-	-
	N02	-	-	-	-	-	-	-	-	-	-	-	-
	N03	-	-	-	-	-	-	-	-	-	-	-	-
	N04	-	-	-	-	-	-	-	-	-	-	-	-
	N05	-	-	-	-	-	-	-	-	-	-	-	-
	N06	-	-	-	-	-	-	-	-	-	-	-	-
	N07	-	-	-	-	-	-	-	-	-	-	-	-
	N08	-	-	-	-	-	-	-	-	-	-	-	-
	N09	-	-	-	-	-	-	-	-	-	-	-	-
	N10	-	-	-	-	-	-	-	-	-	-	-	-

Positive Reference Consistency Rate	P01	+	+	+	+	+	+	+	+	+	+	+	+
	P02	+	+	+	+	+	+	+	+	+	+	+	+
	P03	+	+	+	+	+	+	+	+	+	+	+	-
	P04	+	+	+	+	+	+	+	+	+	+	+	+
	P05	+	+	+	+	+	+	+	+	+	+	+	+
Repeatability	R01	20/20(-)	20/20(-)	20/20(-)	20/20(-)	20/20(0(-))	20/20(-)	20/20(-)	20/20(-)	20/20(0(-))	20/20(-)	20/20(-)	20/20(-)
	R02	20/20(+)	20/20(+)	20/20(+)	20/20(+)	20/20(0(+))	20/20(+)	20/20(+)	20/20(+)	20/20(0(+))	20/20(+)	20/20(+)	20/20(+)

20201019

Environment		25°C,RH50%				40°C,RH50%				25°C,RH90%			
Time		0min	10min	20min	Time	0min	10min	20min	Time	0min	10min	20min	Time
/	Appearance	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Strip width(mm)	3.00	3.00	3.02	3.00	3.00	3.02	3.02	3.00	3.02	3.02	3.00	3.00
	Liquid migration velocity(mm/min)	19.2	19.9	19.6	19.8	18.8	18.5	19.2	18.9	19.1	18.7	19.2	19.0
Detection Limit	L01	-	-	-	-	-	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-	-	-	-	-	-
	L03	+	-	-	-	+	-	-	-	-	-	-	-
	L04	+	+	+	-	-	+	+	-	+	+	+	-
	L05	+	+	+	+	+	+	+	+	+	+	+	-
	L06	+	+	+	+	+	+	+	+	+	+	+	+
Negative Reference Consistency Rate	N01	-	-	-	-	-	-	-	-	-	-	-	-
	N02	-	-	-	-	-	-	-	-	-	-	-	-
	N03	-	-	-	-	-	-	-	-	-	-	-	-
	N04	-	-	-	-	-	-	-	-	-	-	-	-
	N05	--	-	-	-	-	-	-	-	-	-	-	-
	N06	-	-	-	-	-	-	-	-	-	-	-	-
	N07	-	-	-	-	-	-	-	-	-	-	-	-
	N08	-	-	-	-	-	-	-	-	-	-	-	-

	N09	-	-	-	-	-	-	-	-	-	-	-	-
	N10	-	-	-	-	-	-	-	-	-	-	-	-
Positive Reference Consistency Rate	P01	+	+	+	+	+	+	+	+	+	+	+	+
	P02	+	+	+	+	+	+	+	+	+	+	+	+
	P03	+	+	+	+	+	+	+	+	+	+	+	+
	P04	+	+	+	+	+	+	+	+	+	+	+	-
	P05	+	+	+	+	+	+	+	+	+	+	+	+
Repeatability	R01	20/20(-)	20/20(-)	20/20(-)	20/20(-)	20/20(0(-))	20/20(-)	20/20(-)	20/20(-)	20/20(0(-))	20/20(-)	20/20(-)	20/20(-)
	R02	20/20(+)	20/20(+)	20/20(+)	20/20(+)	20/20(0(+))	20/20(+)	20/20(+)	20/20(+)	20/20(0(+))	20/20(+)	20/20(+)	20/20(+)

20201020

Environment		25°C,RH50%				40°C,RH50%				25°C,RH90%			
Time		0min	10min	20min	Time	0min	10min	20min	Time	0min	10min	20min	Time
/	Appearance	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass	Pass
	Strip width(mm)	3.02	3.00	3.00	3.00	3.02	3.02	3.02	3.00	3.00	3.02	3.02	3.00
	Liquid migration velocity(mm/min)	19.5	19.7	20.1	19.5	19.2	18.9	19.1	18.7	19.0	19.2	19.0	19.3
Detection Limit	L01	-	-	-	-	-	-	-	-	-	-	-	-
	L02	-	-	-	-	-	-	-	-	-	-	-	-
	L03	-	-	-	-	-	+	-	-	-	-	-	+
	L04	+	+	+	+	+	-	+	+	+	+	+	-
	L05	+	+	+	+	+	+	+	+	+	+	+	+
	L06	+	+	+	+	+	+	+	+	+	+	+	+
Negative Reference Consistency Rate	N01	-	-	-	-	-	-	-	-	-	-	-	-
	N02	-	-	-	-	-	-	-	-	-	-	-	-
	N03	-	-	-	-	-	-	-	-	-	-	-	-
	N04	-	-	-	-	-	-	-	-	-	-	-	-
	N05	-	-	-	-	-	-	-	-	-	-	-	-
	N06	-	-	-	-	-	-	-	-	-	-	-	-

	N07	-	-	-	-	-	-	-	-	-	-	-	-
	N08	-	-	-	-	-	-	-	-	-	-	-	-
	N09	-	-	-	-	-	-	-	-	-	-	-	-
	N10	-	-	-	-	-	-	-	-	-	-	-	-
Positive Reference Consistency Rate	P01	+	+	+	+	+	+	+	+	+	+	+	+
	P02	+	+	+	+	+	+	+	+	+	+	+	+
	P03	+	+	+	+	+	+	+	+	+	+	+	+
	P04	+	+	+	+	+	+	+	+	+	+	+	+
	P05	+	+	+	+	+	+	+	+	+	+	+	+
Repeatability	R01	20/20(-)	20/20(-)	20/20(-)	20/20(-)	20/20(0(-))	20/20(-)	20/20(-)	20/20(-)	20/20(0(-))	20/20(-)	20/20(-)	20/20(-)
	R02	20/20(+)	20/20(+)	20/20(+)	20/20(+)	20/20(0(+))	20/20(+)	20/20(+)	20/20(+)	20/20(0(+))	20/20(+)	20/20(+)	20/20(+)

Note: Take example as 100% (20/20-),100% means positive rate,“20/20-”means 20 test results are negative in 20 tests .

According to table 2, SARS-CoV-2 antigen IVD kit NASAL meet acceptance criteria at each environment condition within open 20 minutes.After open 20 minutes,test results failed when humidity is 90%.

7. Conclusion

After open the foil bag, SARS-CoV-2 antigen IVD kit NASAL meet requirements after opened within 20 minutes. But test results will fail after opened 30 minutes.

Therefore, the open bag stability is defined as 10 minutes.