



黎明生物
南京黎明生物制品有限公司
Nanjing Liming Bio-Products Co., Ltd.

统一社会信用代码 Tax No.: 9132010272837745XD

地址: 江苏省南京市玄武区花园路 12 号

邮编: 210042

Add: No.12, Huayuan Road, Xuanwu District, Nanjing, Jiangsu, P.R. China, 210042

Tel: +86-25-85476723/+86-25-85288506

Fax: +86-25-85476387

E-mail: sales@limingbio.com

Web: www.limingbio.com

Testing Report and in Silico Analysis for StrongStep® SARS-CoV-2

Antigen Rapid Test on Different SARS-CoV-2 Variant

SARS-CoV-2 has now evolved several mutations with serious consequences, some like B.1.1.7, B.1.351, B.1.2, B.1.1.28, B.1.617, Including the **omicron mutant strain(B1.1.529)** reported in recent days.

As an IVD reagent manufacturer, we always pay attention to the development of relevant events, check the changes of relevant amino acids and evaluate the possible impact of mutations on reagents. And we also tested from the lowest detection limit with the recombinant antigen and virus samples.

1. Purpose:

To confirm whether StrongStep® SARS-CoV-2 Antigen Rapid Test can detect different SARS-CoV-2 variant.

2. Testing Report and Silico Analysis:

Part I: Sequence alignment

2019-nCoV		40th-54th
N-std	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-B.1.351	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
Mu-N-B.1.621	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-B.1.526.1	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-P.2	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
nCoV-N-P.1	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-B.1.525	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-B.1.1.318	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-C.36.3	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-R1	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-B.1.2	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-B.1.526.2	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-C.1.2	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-B.1.1.529	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-B.1.1.7	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-B.1.617.2	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-B.1.617.3	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	
N-B.1.617.1	MSDNGPQNQRNAPRITFGGSPDSTGSNQNGERSGARSKRRPQGLPNNTASWFTALTQHG	

2019-nCoV		100th-120th
N-std	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-B.1.351	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
Mu-N-B.1.621	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-B.1.526.1	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-P.2	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
nCoV-N-P.1	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-B.1.525	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-B.1.1.318	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-C.36.3	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-R1	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-B.1.2	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-B.1.526.2	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-C.1.2	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-B.1.1.529	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-B.1.1.7	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-B.1.617.2	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-B.1.617.3	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	
N-B.1.617.1	KEDLKFRGGQVPIINSSPDDQIGYYRATRRIRGGDGMMKDLSPRWYFYFLGTGPEAG	

2019-nCoV		121th-130th
N-std	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-B.1.351	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
Mu-N-B.1.621	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-B.1.526.1	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-P.2	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
nCoV-N-P.1	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-B.1.525	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-B.1.1.318	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-C.36.3	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-R1	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-B.1.2	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-B.1.526.2	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-C.1.2	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-B.1.1.529	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-B.1.1.7	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-B.1.617.2	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-B.1.617.3	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	
N-B.1.617.1	LPYGANKDGLIWVATEGALNTPKDHIGTRNPANNAIVLQLPGQTTLPGGFYAEGRSGGS	

2019-nCoV QASSRSSRSRNSRNSSTPGSSRGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-seed QASSRSSRSRNSRNSSTPGSSRGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-B.1.351 QASSRSSRSRNSRNSSTPGSSRGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
Mu-N-B.1.621 QASSRSSRSRNSRNSSTPGSSRGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-B.1.526.1 QASSRSSRSRNSRNSSTPGSSRGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-P.2 QASSRSSRSRNSRNSSTPGSSRGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
nCoV-N-P.1 QASSRSSRSRNSRNSSTPGSSRGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-B.1.525 QASSRSSRSRNSRNSSTPGSSRGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-B.1.1.318 QASSRSSRSRNSRNSSTPGSSKRTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-C.36.3 QASSRSSRSRNSRNSSTPGSSKRTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-R1 QASSRSSRSRNSRNSSTPGSSKRTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-B.1.2 QASSRSSRSRNSRNSSTPGSSRGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-B.1.526.2 QASSRSSRSRNSRNSSTPGSSRGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-C.1.2 QASSRSSRSRNSRNSSTPGSSKRTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-B.1.1.529 QASSRSSRSRNSRNSSTPGSSKRTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-B.1.1.7 QASSRSSRSRNSRNSSTPGSSKRTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-B.1.617.2 QASSRSSRSRNSRNSSTPGSSMGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-B.1.617.3 QASSRSSRSRNSRNSSTPGSSMGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ
N-B.1.617.1 QASSRSSRSRNSRNSSTPGSSMGTS ParmagNGGDAALALLLLDRLNQLESKMSGKGQQ

2019-nCoV QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-std QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-B-1.351 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
Mu-N-B-1.621 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-B-1.526.1 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-P.2 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
nCoV-N-P.1 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-B.1.525 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-B-1.1.318 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-C.36.3 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-R1 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-B.1.2 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-B-1.526.2 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-C.1.2 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-B-1.1.529 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-B.1.1.7 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-B.1.617.2 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-B.1.617.3 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH
N-B.1.617.1 QQQGQVTVTKKSAAEASKKPQKQRTATKAYNVTAQFGRGGEPEQTQGNFGDQELIRQGTDYKH

2019-nCoV
N-std
N-B.1.351
Mu-N-B.1.621
N-B.1.526.1
N-P.2
nCoV-N-P.1
N-B.1.525
N-B.1.1.318
N-C.36.3
N-R1
N-B.1.2
N-B.1.526.2
N-C.1.2
N-B.1.1.529
N-B.1.1.7
N-B.1.617.2
N-B.1.617.3
N-B.1.617.1

name	Mutant strains	GenBank ID
2019-nCoV	WT	GenBank:NC_045512.2
B.1.351	nCoV-N-B.1.351 (Beta)	GenBank: FR990755.1
N-B.1.2	nCoV-N-B.1.2 (P67S, P199L)	GenBank: MT811485.1
N-P.1	nCoV-N-P.1 (Gamma P80R)	GenBank: MZ427312.1
N-B.1.1.7	nCoV-N-B.1.1.7 (Alpha D3L S235F)	GenBank:MZ773903; MZ773924
N-std	The standard sequence	GenBank:NC_045512.2
N-P.2	nCoV-N-P.2 (A119S, M234I)	GenBank:FR992894.1;MW338781.1
N-B.1.617.2	nCoV-N-B.1.617.2 (Delta R203M, D377Y)	GenBank:MW891333.1
N-B.1.617.3	nCoV-N-B.1.617.3	GenBank:MZ779752.1



黎明生物

南京黎明生物制品有限公司
Nanjing Liming Bio-Products Co., Ltd.

LIMING BIO

统一社会信用代码 Tax No.: 9132010272837745XD

地址: 江苏省南京市玄武区花园路 12 号

邮编: 210042

Add: No.12, Huayuan Road, Xuanwu District, Nanjing, Jiangsu, P.R. China, 210042

Tel: +86-25-85476723/+86-25-85288506

Fax: +86-25-85476387

E-mail: sales@limingbio.com

Web: www.limingbio.com

	(P67S, R203M, D377Y)	
N-B.1.617.1	nCoV-N-B.1.617.1 (Kappa)	GenBank:LC633761.1;MW932634.1
N-B.1.525	nCoV-N-B.1.525 (Eta)	GenBank:MW571191.1
Mu-N-B.1.621	nCoV-N-B.1.621 (Mu)	GenBank:MZ141872.1;MZ233528.1
N-B.1.1.318	nCoV-N-B.1.1.318	GenBank: OK183381.1
N-C.36.3	nCoV-N-C.36.3	GenBank: OU194093.1
N-B.1.526.1	nCoV-N-B.1.526.1(Lota)	GenBank: MW424878.1
B.1.526.2	nCoV-N-B.1.526.2(Lota)	GenBank: MW689815.1
N-R1	nCoV-N-R1	GenBank:MZ141771.1;MZ182023.1
N-C.1.2	nCoV-N-C.1.2	GenBank:OK433429.1
N-B.1.1.529	B.1.1.529(P13L,DEL31-31,R203K,G204R)	EPI_ISL_6704875

Conclusion: We selected two monoclonal antibodies. The first antibody corresponds to an antigen labeled from 40th to 54th amino acid, called 33HB(As shown in the first image above); The other antibody corresponds to an antigen labeled from amino acid 100th to amino acid 130th, called 22M(As shown in the first image above). According to the sequence alignment results, no mutation occurred in the 33HB epitope;there was only one amino acid change(A119S mutation) in the mutations named P.2 of the 22M epitope, **We have been fully confirm that the test kits have not been affected, including omicron mutant strain(B1.1.529).**

Part II: Recombinant protein testing

Method: Produce recombinant nucleocapsid protein from different SARS-CoV-2 variant, dilute those protein into 0.5ng/ml, with solutions Supplied with the kit test those dilutions with StrongStep® SARS-CoV-2 Antigen Rapid Test.

Material:

Different recombinant nucleocapsid protein are produced from different SARS-CoV-2 variant list below.

Cat No.	Mutation site	variant	Subtype of name
HP811-5K	Wt	Wt	Wt
HP811-8K	D3L、 S235F	B.1.1.7	Alpha
HP811-9K	R203K、 G204R	P.3	Theta
HP811-10K	P67S, P199L	B.1.2	Beta
HP811-11K	P80R	P.1.1	Gamma
HP811-12K	A119S、 M234I	P.2	\
HP811-13K	R203M、 D377Y	B.1.617.1	Kappa
HP811-14K	P67S、R203M、 D377Y	B.1.617.3	\
HP811-15K	P13L、 R203K、	C37.Mu.(Lambda)	Lambda



黎明生物

南京黎明生物制品有限公司
Nanjing Liming Bio-Products Co., Ltd.

LIMING BIO

统一社会信用代码 Tax No.: 9132010272837745XD

地址: 江苏省南京市玄武区花园路 12 号

Add: No.12, Huayuan Road, Xuanwu District, Nanjing, Jiangsu, P.R. China, 210042

Tel: +86-25-85476723/+86-25-85288506

E-mail: sales@limingbio.com

邮编: 210042

Fax: +86-25-85476387

Web: www.limingbio.com

	G204R、G214C		
HP811-16K	D3L、R203K、G204R、S235F	B.1.1.7	Alpha
HP811-17K	T205I	B.1.351	Beta、Mu
HP811-18K	P80R、R203K、G204R	B.1.1.28	Gamma
HP811-19K	D63G、R203M、D377Y	AY.2	Delta
HP811-20K	D63G、R203M、G215C、D377Y	B.1.617.2	Delta
HP811-21K	S2Y、del3、A12G、T205I	B.1.525	Eta
HP811-22K	T205I、M234I	B.1.526.1	Iota
HP811-23K	P13L、S202R	B.1.526.Mu.	Iota
HP811-24K	S187L、R203K、G204R、Q418H	\	R1 Mu.
HP811-25K	P13L、R203K、G204R、Q384H	\	C.1.2 Mu.
HP811-26K	D63G、A119S、R203M、G215C、D377Y	B.1.617.2	Delta
HP811-27K	P67S、A119S、R203M、D377Y	B.1.617.3	\
HP811-28K	P13L、DEL31-33、R203K、G204R etc.	B.1.1.529	Omicron

Step:

- 1) Dilute above protein into 0.5ng/ml with dilution buffer in the kit.
- 2) Test above diluted protein with StrongStep® SARS-CoV-2 Antigen Rapid Test (batch number: 2101004) and read the results at 15 minutes.

Results:

Cat No.	result	Cat No.	result
HP811-5K	+	HP811-18K	+
HP811-8K	+	HP811-19K	+
HP811-9K	+	HP811-20K	+
HP811-10K	+	HP811-21K	+
HP811-11K	+	HP811-22K	+
HP811-12K	+	HP811-23K	+
HP811-13K	+	HP811-24K	+
HP811-14K	+	HP811-25K	+
HP811-15K	+	HP811-26K	+
HP811-16K	+	HP811-27K	+



黎明生物

南京黎明生物制品有限公司
Nanjing Liming Bio-Products Co., Ltd.

LIMING BIO

统一社会信用代码 Tax No.: 9132010272837745XD

地址: 江苏省南京市玄武区花园路 12 号

邮编: 210042

Add: No.12, Huayuan Road, Xuanwu District, Nanjing, Jiangsu, P.R. China, 210042

Tel: +86-25-85476723/+86-25-85288506

Fax: +86-25-85476387

E-mail: sales@limingbio.com

Web: www.limingbio.com

HP811-17K	+	HP811-28K	+
-----------	---	-----------	---

Conclusion: StrongStep® SARS-CoV-2 Antigen Rapid Test can detect all above recombinant protein from different variant at 0.5ng/ml, we confirm that the test kits have not been affected by current SARS-CoV-2 Variant.

Part III: Lab wet testing

Method: Collect different SARS-CoV-2 variant from other institute, dilute the virus into series dilution to check the sensitivity on the StrongStep® SARS-CoV-2 Antigen Rapid Test and StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit.

Material:

1) Different SARS-CoV-2 variant from other institute list below.

Virus strain name	variant	Subtype of name
CZ34	B.1.617	Delta
CBR04	B.1.1.28	gamma
CG01	B.1.2	Beta
CZ02	WT	WT

2) Reagent used in this testing

StrongStep® SARS-CoV-2 Antigen Rapid Test (batch number: 2101004).

StrongStep® Novel Coronavirus (SARS-CoV-2) Multiplex Real-Time PCR Kit (batch number: G2105011)

Step:

3) Dilute above variant with dilution buffer in the kit in 10 fold one by one, from 10 fold to 10⁷ fold.

4) Test 10³-10⁶ fold diluted variant with tests above and read the results according to tests' IFU.

Results:

Sample Diluted multiples	CZ34		CBR04		CG01		CZ02	
	PCR (copies/ml)	Antigen Rapid Test	PCR (copies/ml)	Antigen Rapid Test	PCR (copies/ml)	Antigen Rapid Test	PCR (copies/ml)	Antigen Rapid Test
10 ³	2.39 × 10 ⁶	+++	7.36 × 10 ⁶	+++	1.25 × 10 ⁷	+++	1.36 × 10 ⁷	+++
10 ⁴	1.48 × 10 ⁵	++	4.14 × 10 ⁵	++	8.57 × 10 ⁵	++	1.36 × 10 ⁶	++
10 ⁵	2.21 × 10 ⁴	+	7.06 × 10 ⁴	+	1.29 × 10 ⁵	+	1.36 × 10 ⁵	+
10 ⁶	2.65 × 10 ³	-	7.44 × 10 ³	-	1.39 × 10 ⁴	-	1.36 × 10 ⁴	-

Conclusion: StrongStep® SARS-CoV-2 Antigen Rapid Test can detect all above variants around 1.0 × 10⁵copies/ml, we confirm that the test kits have not been affected by current SARS-CoV-2 Variant.

3. Discussion and Conclusion:

StrongStep® SARS-CoV-2 Antigen Rapid Test detect nucleocapsid protein antigen from SARS-CoV-2 in human Nasal swab from patients who are suspected of COVID-19 infection. From results above(Sequence alignment, Recombinant protein testing, different variant lab wet testing), we can conclude that StrongStep SARS-CoV-2 Antigen Rapid Test showed no drop off in sensitivity



®

黎明生物

南京黎明生物制品有限公司

Nanjing Liming Bio-Products Co., Ltd.

LIMING BIO

统一社会信用代码 Tax No.: 9132010272837745XD

地址: 江苏省南京市玄武区花园路 12 号

邮编: 210042

Add: No.12, Huayuan Road, Xuanwu District, Nanjing, Jiangsu, P.R. China, 210042

Tel: +86-25-85476723/+86-25-85288506

Fax: +86-25-85476387

E-mail: sales@limingbio.com

Web: www.limingbio.com

when compared with the wild type with respect to the following variants -B.1.1.7; B.1.351; B.1.2; B.1.1.28 ;B.1.617; **B.1.1.529** and current variants list above.

We will continue to pay attention to the latest changes of virus. Once the mutations may affect the detection ability of the product, we will inform customers of the possible risks immediately. we will change the design of product, study and verify the detection performance of the latest mutant strains, and submit the research verification report.

