

Part 5 - COA

DN WI20-1014-RE-63
Revision 2

VivaChek Biotech (Hangzhou) Co., Ltd.

Effective Date: 2021-08-30
Page 1 of 2

VivaChek Biotech (Hangzhou) Co., Ltd.

CERTIFICATE OF ANALYSIS

Product Name: Verino® Pro SARS-CoV-2 Ag Rapid Test
Lot No.: SE2101020
Expiry Date: 2022-12-08

Inspection Item	Acceptance Criteria			Test Result
Appearance	1) The test board: no stains, assembled correctly; 2) The extraction solution: no turbidity, no precipitate for the solution, no leakage for the sealed bag and the self-sealed bag is marked; 3) The kit: clean with all components, and the label is clearly marked with correct information.			PASS
Inspection Item	Reference samples	The test results compare with the color grade		Test Result
		Evaluation criteria of C line	Evaluation criteria of T line	
Positive reference samples	P1	≥ G8	G3-G4	PASS
	P2		G4-G5	PASS
	P3		G5-G6	PASS
	P4		G6-G7	PASS
	P5		G7-G8	PASS
	P6		G8-G9	PASS
	P7		G9-G10	PASS
	P8		≥ G10	PASS
Minimum detection limit reference samples	S1	≥ G8	G5-G6	PASS
	S2		G4-G5	PASS
	S3		G3-G4	PASS
	S4		G3	PASS

VivaChek Biotech (Hangzhou) Co., Ltd

Level 2, Block 2, 146 East Chaofeng Rd, Yuhang Economy Development Zone, Hangzhou, Zhejiang 311100, China

	S5		≤ G3	PASS
	S6		G1-G2	PASS
Repeatability reference samples	R1	≥ G8	G3-G4	PASS
	R2		G5-G6	PASS
Negative reference samples	N1-N20	≥G8	G1-G2	PASS
	N21-N40			PASS
	N41-N60			PASS
Conclusion	PASS			

QC Supervisor: 胡玲燕

Signature: _____

Date: 7/30/21

