

SEJOY	文件名称 File Name	SARS-CoV-2&Influenza A+B Antigen&RSV Combo Rapid Test Cassette Completed Product Test Report Form 新冠&流感&合胞检测试剂盒完成品报告单	版次 Version	A/0
	文件编号 File Number	Q4-000ICA-PZ-238A	NO.	NP238A202308001

SARS-CoV-2&Influenza A+B Antigen &RSV Combo Rapid Test Cassette Completed Product Test Report Form
新冠&流感&合胞检测试剂盒完成品报告单

型号 Model	ISR-9334	批号 LOT	ISR 210207	数量 QTY	10000	规格 SPEC	1 Pcs/box
生产日期 MFG	2021-02-20		有效期 EXP	2027-02-19		色卡批号 Color card lot number	202303001
参考品 S1 Reference panel S1	SLov6220312001	参考品 S2 Reference panel S2	SLov6220312001	参考品 S3 Reference panel S3	SLov6220312001	缓冲液 LOT Lot of buffer	A230312001
FluA(H1N1) Reference panel H1N1	SH1N1 231110-01	FluA(H3N2) Reference panel H3N2	SH3N2 231110-01	FluB Reference panel FluB	SFluB 231110-01	订单号 Order	2031-2102-SP20A-10001
参考品 P1 Reference panel P1	SRV 210207-01	参考品 P3 Reference panel P3	SRV 210207-01				

项目 Project	标准要求 Standard requirements	检验结果 Test results	单项结论 Individual conclusions
物理检查 Physical inspection	产品外观应整洁完整、无毛刺、无破损、无污染；材料附着牢固； The appearance of the product should be neat and complete, free of burrs, damage and contamination; the material should be firmly attached	外观: <input checked="" type="checkbox"/> 是 <input type="checkbox"/> 否 符合要求 Appearance: <input type="checkbox"/> Yes <input type="checkbox"/> No Meet the requirements	<input checked="" type="checkbox"/> 合格 Qualified <input type="checkbox"/> 不合格 Unqualified
	C 线出现时间应不超过 120 秒，且 15 分钟时 $C \geq G8$ The C line should appear for no more than 120 seconds and $C \geq G8$ at 15 minutes	C 线出现时间 Time of appearance of C line <u>42s</u> C 线强度 C-line strength <u>G8</u>	<input checked="" type="checkbox"/> 合格 Qualified <input type="checkbox"/> 不合格 Unqualified

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功能性检 查 Functional checks	检测项目 Test items	企业参考品 Corporate reference items	检测标准 Testing standards		C/T 线符合率应为 100% (G1-G10) C/T line compliance should be 100% (G1 - G10)					单项结论 Individual conclusions
					Test 1	Test 2	Test 3	Test 4	Test 5	
阴性符合率 Negative compliance rate	阴性参考品 Negative reference	T<G3 A<G3 B<G3 T<G3	Flu A	1	1	1	1	1	<input checked="" type="checkbox"/> 合格 Qualified <input type="checkbox"/> 不合格 Unqualified	
			Flu B	1	1	1	1			
			COVID-19	1	1	1	1			
			RSV	1	1	1	1			
Flu A 阳性符合率 Flu A positive compliance rate	H1N1 Reference panelH1N1	G3≤A≤G5	Flu A	3	3	3	3	3	<input checked="" type="checkbox"/> 合格 Qualified <input type="checkbox"/> 不合格 Unqualified	
		B<G3	Flu B	1	1	1	1	1		
	H3N2 Reference panelH3N2	G4≤A≤G6	Flu A	4.5	4.5	4.5	4.5	4.5	<input checked="" type="checkbox"/> 合格 Qualified <input type="checkbox"/> 不合格 Unqualified	
		B<G3	Flu B	1	1	1	1	1		
Flu B 阳性符合率 Flu B positive compliance rate	Flu B Reference panel Flu B	A<G3	Flu A	1	1	1	1	1	<input checked="" type="checkbox"/> 合格 Qualified <input type="checkbox"/> 不合格 Unqualified	
		G4≤A≤G6	Flu B	4	4	4	4	4		
RSV 阳性符合率 RSV positive compliance rate	P1 Reference panel P1	G7≤T≤G9	RSV	8	8	8	8	8	<input checked="" type="checkbox"/> 合格 Qualified <input type="checkbox"/> 不合格 Unqualified	

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COVID-19 阳性符合率 COVID-19 positive compliance rate	Reference panel P3	G3≤T≤G5	RSV	3.5	3.5	3.5	3.5	3.5	<input checked="" type="checkbox"/> 合格 Qualified <input type="checkbox"/> 不合格 Unqualified
	Reference panel S1	T≥G7	COVID-19	8	8	8	8	8	<input checked="" type="checkbox"/> 合格 Qualified <input type="checkbox"/> 不合格 Unqualified
	Reference panel S2	T≥G4.5	COVID-19	5	5	5	5	5	
	Reference panel S3	T≥G3	COVID-19	4	4	4	4	4	
	重复性 Repeatability	参考上述检测项目，判阳性企业内部参考品检测的判读结果 <input checked="" type="checkbox"/> 是 <input type="checkbox"/> 否 一致，且显色度 <input checked="" type="checkbox"/> 是 <input type="checkbox"/> 否 均一 Referring to the above test items, the readings of the internal reference tests of the positive companies <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No are consistent and the colour rendering <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No is uniform							
综合判定 Comprehensive determination	<input checked="" type="checkbox"/> 合格 Qualified <input type="checkbox"/> 不合格 Unqualified 检验员 Inspector: <u>彭叔</u> 日期 Date: <u>2024-02-08</u> 复核员 Reviewer: <u>付冬梅</u> 日期 Date: <u>2024.3.8</u>								
备注 Remark	如检验不合格，备注是否复检，并附上复检结果。 If the test fails, make a note of whether to retest and attach the results of the retest.								