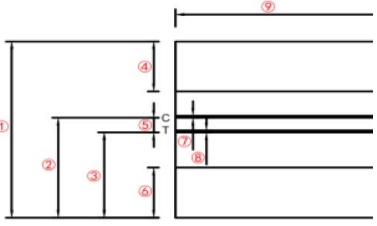


Quality Standard Agreement		
Item: Chikungunya Antigen Rapid Test Uncutsheet		Methodology: ☐ Colloidal Gold ☒ Latex ☐ Fluorescence ☐ Other _____
1	Size & Position Requirements	
1.1	Uncutsheet size	☒ 60*300mm ☐ 80*300mm ☐ Other ____ mm
1.2	Line width	0.7mm±0.1mm
1.2	C/T1/T2/T3 Position	2 lines: ☒ 34/28mm ☐ 34/29mm ☐ 41/36mm 3 lines: ☐ 36/32/28mm ☐ 37/32/27mm 4 lines: ☐ 38/34.5/31/27.5mm Other: ☐ ____ mm
1.3	Absorbent pad width	☒ 17mm ☐ 21mm ☐ 33mm ☐ 35mm ☐ Other ____ mm
1.4	NC membrane width	☐ 20mm ☐ 25mm ☐ Other ____ mm
1.5	Conjugate pad width	☒ No Requirement ☐ 6mm ☐ 8mm ☐ Other ____ mm
1.6	Sample pad width	☒ No Requirement ☐ 17mm ☐ 24mm ☐ 32mm ☐ Other ____ mm
1.7	Absorbent pad sticker	☒ No ☐ Yes, _____
1.8	Sample pad sticker	☒ No ☐ Yes, _____
2	Acceptance Criteria	
2.1	LOD	____ / ____ (CT: 28)
2.2	Method	☒ Qualitative ☐ Quantitative ☐ Semi-quantitative
2.3	Specimen type	☒ WB/S/P ☐ Swab ☐ Urine ☐ Feces ☐ Other _____
2.4	Flowing time	C-line appearance time ≤ 90 seconds; T-line appearance time ≤ 30 seconds.
2.5	Background clean time	15 min
2.6	Reading Time	15 min
3	Operation & Acceptance	
3.1	Operation	1. Cut the sheet into 3.0mm test strips and insert into cassettes. 2. Transfer 10 µL serum/plasma or 20uL whole blood into the S well using a pipette. Then take 80uL buffer into B well. 3. Start timing. 4. Read results after 15 minutes; do not interpret after 20 minutes.
3.2	Positive 1 requirement	Test 3 replicates positive 1 sample, At 15 minutes, the T line color should be ≥ L3, and the C line color should be ≥ G9
3.3	Positive 2 requirement	Test 3 replicates positive 2 sample, At 15 minutes, the T line color should be ≥ L5, and the C line color should be ≥ G9
3.4	Negative requirement	Test 10 replicates negative sample, At 15 minutes, the T line color should be < L3, and the C line color should be ≥ G9
4	Package	30pcs/bag
5	↓ 示意图 ↓	
		①Uncutsheet width ②Distance from the C line to the end of the sample pad PVC board ③Distance from T-line to the end of the sample pad PVC board ④Absorbent paper width ⑤C-T line distance ⑥Sample pad width ⑦Control line width ⑧Test line width ⑨Uncutsheet length
6	Remark	

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Version: 1.0

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