Artron Certificate of Analysis

Product Name	Covid-19 Antigen Test	**Catalog No.**	A03-50-422S5
Lot No.	SR230008	Expired Date	2025-09-01
Store	2-30°C	**Release Date**	2023-11-07
Appearance	Single cassette test, sealed in desiccated aluminum pouch.		

Applicable Inspection and Evaluation of specification:

Physical Inspection:

1. The components of the kit are complete, and no components are missing. No liquid leakage. Packaging labels should be clear and accurate. The catalog number, lot number, and expiration date are correct.
2. The packaging aluminum foil bag is completely sealed, no cracks, no scratches.
3. The appearance of the cassette is neat and complete, no damage, no deformation, no stains, the components of the test strip are firmly attached.
4. The sample extraction buffer are transparent, no precipitates, no suspended materials.
5. The filling volume of sample extraction buffer meet the 300μL fill line.

Performance Characteristic Inspection:

6. General Requirement

Test	Specification	Results
	Cassette	Pass
Width of line	**1.0 ± 0.2mm**	Pass
TC distance	**4.8-5.0mm**	Pass
Time for sample to get onto test membrane	**2”-1’**	Pass
Time for sample to flow over test membrane	**15”-1’**	Pass
Time for background color to disappear	**15’-30’**	Pass
Time for test line to appear	**Not be later than 15 minutes**	Pass

7. Performance Evaluation

Sensitivity	Covid-19 Antigen Test QC Positive Panel (Covid-19 Ag 2020)		T line (color grade)		C line
	P1		++		Strong
	P2		+		Strong
	P3		+++		Strong
	P4		++		Strong
	P5		+		Strong
Specificity	Covid-19 Antigen Test Negative Panel	Sample (N)	Test Results	C line	Specificity (%)
	N1-N18	18	-	Strong	100%
	10 negative swab Specimens (N19-N28)	10	-	Strong	100%
	Sample extraction buffer	1	-	Strong	100%
Precision	Panel Member	Runs	T line	C line	
	P4	10	++	≥7	

	P5	10	+	≥7

Note: All data are from QC testing unless otherwise indicated.

Safety Certification:

1. **Appropriate inspection has been applied to this lot, and to our knowledge, specific defects do not exceed the maximum allowable quantities as listed in the applicable specifications.**
2. **This lot has been manufactured and packaged in accordance with the relevant regulations for diagnostic and medical devices industry in Canada.**
3. **There are no biohazard materials utilized in this product. No radioactive materials, no narcotic reagents, neither their derivatives, no virus neither their reagent nor metabolic by-products.**

Approved by QC Manager: **Date:** 2023-11-07