



Certificate of Analysis

Product Name	COVID-19 IgM/IgG Antibody Test <input type="checkbox"/> Strip <input checked="" type="checkbox"/> Cassette <input type="checkbox"/> Uncut Sheet		Catalog No.	A03-51-322	
Lot No.	N19-500401	Quantity	28000	Shelf Life	2021-09
Store	2-30°C		Release Date	2020-04-13	
Appearance	<input type="checkbox"/> Strip 3mm Single test, Sealed in desiccated aluminum pouch				
	<input checked="" type="checkbox"/> Cassette Single test, Sealed in desiccated aluminum pouch				
	<input type="checkbox"/> Uncut Sheet Sealed in desiccated aluminum pouch				

Applicable Inspection and Evaluation of specification:

Physical Inspection:

Test	Specification			Results
	<input type="checkbox"/> Strip	<input checked="" type="checkbox"/> Cassette	<input type="checkbox"/> Uncut Sheet	
Width	3.0±0.1mm	/	/	Acceptable
Appearance	AQL=0.65	AQL=0.65	/	Acceptable
Label	AQL=0.65	AQL=0.65	AQL=0.65	Acceptable
Pouch	AQL=0.65	AQL=0.65	AQL=0.65	Acceptable
Desiccant in pouches	AQL=0.65	AQL=0.65	AQL=0.65	Acceptable

Note: AQL means Acceptance Quality Limit, quality level that is the worst tolerable process average when a continuing series of lots is submitted for acceptance sampling.

Performance Characteristic Inspection:

Test		Specification	Results
Sensitivity	COVID-19 P1 (IgM Positive)	Positive	Pass
	COVID-19 P2 (IgG Positive)	Positive	
	COVID-19 P3 (IgM/IgG Positive)	Positive	
Specificity	Negative enhancement sample	Negative	Pass
	COVID-19 Negative control, N1-N8	All negative	

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: 

Date: 2020-04-13