



Certificate of Analysis

Product Name	Strep A Test <input type="checkbox"/> Strip <input type="checkbox"/> Cassette <input checked="" type="checkbox"/> Uncut Sheet	Catalog No.	U03-19-422		
Lot No.	SA-9010K02	Quantity	1300	Shelf Life	2022-03
Store	2-30°C	Release Date	2020-10		
Appearance	<input type="checkbox"/> Strip 3mm Single test, Sealed in desiccated aluminum pouch				
	<input type="checkbox"/> Cassette Single test, Sealed in desiccated aluminum pouch				
	<input checked="" 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 type="checkbox"/> Cassette	<input checked="" type="checkbox"/> Uncut Sheet	
Width	3±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	Strep A inactivated Positive Sample	Positive	Pass
	1: 10 diluted	Positive	
	1: 100 diluted	Positive	
	1: 1000 diluted	Positive	
Specificity	Negative enhancement sample	Negative	Pass
	Strep A diluted	Negative	

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

Safety Certification:

- 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.
- This lot has been manufactured and packaged in accordance with the relevant regulations for diagnostic and medical devices industry in Canada.
- 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: 2020-10