

Certificate of Analysis

Product: mö-screen Corona Antigen Test
Catalog-No.: 0230005

LOT No.: 2009100
Expiration Date: 2022-08
Batch Quantity: 20000 Tests

CONTROLS		SPECIFICATION	TEST RESULT	CONCLUSION
Negative Control (N1-N5)		T-Line should be negative at 15 min	Negative	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Buffer Control		C-Line should be visible within 3 min T-Line should be negative at 15 min	Negative	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Clinical Samples		T-Line should be negative at 15 min	Negative	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Positive Controls	P-H	T-Line should be positive at 15 min	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	P-M	T-Line should be positive at 15 min	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	P-L	T-Line should be positive at 15 min	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
	Uniformity P-J	T-Line should be positive at 15 min and the color difference should be within 1 gradient	Positive	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail
Pouch Leakage		No leakage	No leakage	<input checked="" type="checkbox"/> Pass <input type="checkbox"/> Fail

Pass All results meet QC standard
 Fail

This product is manufactured and checked according to IVD 98/78/EG as well as IN ISO 13485:2003.

QC Supervisor



Date: 2020-10-01

