



EZER™

Flu A+B Antigen Rapid Test



INTENDED USE

The EZER™ Flu A+B Antigen Rapid Test is an *in vitro* diagnostic test for the qualitative detection of influenza A and B nucleoprotein antigens in nasopharyngeal (NP) swab, throat swab and nasal aspirate samples, using the rapid immunochromatographic method.



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PERFORMANCE CHARACTERISTICS

Nasal aspiration

Influenza A	Cell Culture Techniques		
	+	-	Total
+	120	2	122
-	3	452	455
Total	123	454	577

Positive Percent Agreement: 97.56% (95% CI: 93.04%~99.49%)
Negative Percent Agreement: 99.56% (95% CI: 98.42%~99.95%)
Overall Percent Agreement: 99.13% (95% CI: 97.99%~99.72%)

Influenza B	Cell Culture Techniques		
	+	-	Total
+	47	1	48
-	1	528	529
Total	48	529	577

Positive Percent Agreement: 97.92% (95% CI: 88.93%~99.95%)
Negative Percent Agreement: 99.81% (95% CI: 98.95%~100.00%)
Overall Percent Agreement: 99.65% (95% CI: 98.75%~99.96%)

Nasopharyngeal swabbing

Influenza A	Cell Culture Techniques		
	+	-	Total
+	31	1	32
-	2	285	287
Total	33	286	319

Positive Percent Agreement: 93.94% (95% CI: 79.77%~99.26%)
Negative Percent Agreement: 99.65% (95% CI: 98.07%~99.99%)
Overall Percent Agreement: 99.06% (95% CI: 97.28%~99.81%)

Influenza B	Cell Culture Techniques		
	+	-	Total
+	16	1	17
-	0	302	302
Total	16	303	319

Positive Percent Agreement: 100.00% (95% CI: 79.41%~100.00%)
Negative Percent Agreement: 99.67% (95% CI: 98.18%~99.99%)
Overall Percent Agreement: 99.69% (95% CI: 98.27%~99.99%)

Throat swabbing

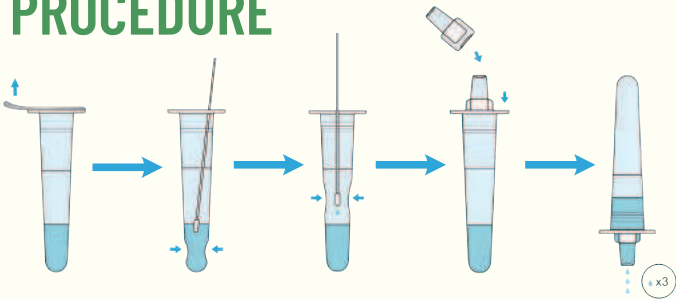
Influenza A	Cell Culture Techniques		
	+	-	Total
+	22	1	23
-	2	175	177
Total	24	176	200

Positive Percent Agreement: 91.67% (95% CI: 73.00%~98.97%)
Negative Percent Agreement: 99.43% (95% CI: 96.87%~99.99%)
Overall Percent Agreement: 98.50% (95% CI: 95.68%~99.69%)

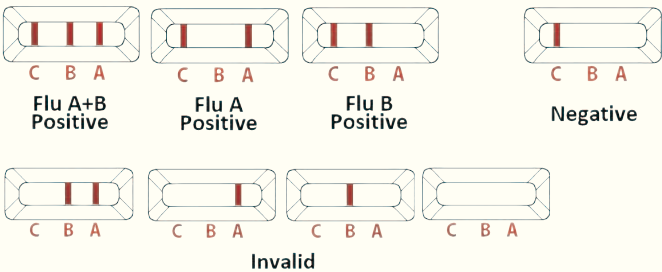
Influenza B	Cell Culture Techniques		
	+	-	Total
+	8	1	9
-	1	190	191
Total	9	191	200

Positive Percent Agreement: 88.89% (95% CI: 51.75%~99.72%)
Negative Percent Agreement: 99.48% (95% CI: 97.12%~99.99%)
Overall Percent Agreement: 99.00% (95% CI: 96.43%~99.88%)

PROCEDURE



RESULTS



AVAILABILITY

Product	EZER™ Flu A+B Antigen Rapid Test
Cat. No.	P211002
Test Device	20
Sterilized Swab	20
Extraction Tube	20
Nozzle	20
Tube Stand	1
Package Insert	1