

## RAPID DIAGNOSTICS

# osom®

## Ultra Flu A&B Test

FOR THE DETECTION OF INFLUENZA TYPE A AND TYPE B NUCLEOPROTEIN ANTIGENS

[www.osomtests.com](http://www.osomtests.com)



✓ **ACCURATE;** CLIA Waived: Nasal and Nasopharyngeal (NP) Swabs.

CLIA WAIVED: NASAL AND NASOPHARYNGEAL (NP) SWABS <sup>1</sup>		
SWAB SAMPLES	POSITIVE PERCENT AGREEMENT (PPA)	NEGATIVE PERCENT AGREEMENT (NPA)
INFLUENZA A	89.2% 95% CI: 83.0-93.4%	99.4% 95% CI: 97.9-99.8%
INFLUENZA B	86.4% 95% CI: 80.1-90.9%	99.0% 95% CI: 97.1-99.7%

✓ **SIMPLE PROCEDURE;** Easy to use premeasured extraction buffer for swabs and unique cassette design for streamlined workflow.

✓ **CONFIDENT RESULTS;** Easy interpretation of results in 10-15 minutes.

✓ **FLEXIBLE SPECIMEN TYPE;** Accurate detection with nasal swabs, NP swab and NP aspirate/wash samples. Compatible with viral transport media.

1. Package Insert.



# osom<sup>®</sup>

## Ultra Flu A&B Test

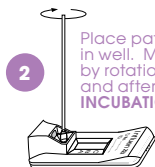
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ISO 9001 Certified, ISO 13485 Certified

### SIMPLE PROCEDURE



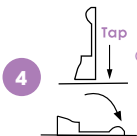
1 Add premeasured extraction buffer.



2 Place patient swab in well. Mix slightly by rotation before and after 1 MINUTE INCUBATION.



3 Raise the device upright and let stand 1-2 seconds.

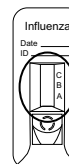


4 Gently tap and lay on flat surface.

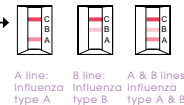


5 Start timing. Interpret Results in 10-15 minutes.

### CONFIDENT RESULTS



Any visible A and/or B Line(s) with C Line is positive.



C Line only Negative (-)



No C Line Invalid



Repeat with new sample and device.

Additional Performance Data-Moderate Complexity: NP aspirate

NP ASPIRATE SAMPLES	SENSITIVITY	SPECIFICITY
<b>INFLUENZA A</b>	95.3%	85.7%
<b>INFLUENZA B</b>	91.6%	97.5%

ORDERING INFORMATION \*\*\*

DESCRIPTION	CONFIGURATION	CATALOG #	STORAGE	CPT CODE
OSOM ULTRA FLU A&B TEST	25 TESTS 2 EXTRA FOR QC INSIDE	1006	ROOM TEMP	FLU A - 87804QW* (SWABS ONLY) 87804 (ASPIRATE ONLY) FLU B - 87804QW*-59** (SWABS ONLY) 87804-59** (ASPIRATE ONLY)
OSOM ULTRA FLU A & B CONTROL KIT	5 X POS FLU A/B SWABS 5 X NEG FLU A/B SWABS	1005	ROOM TEMP	
OSOM ULTRA FLU A & B NASOPHARYNGEAL WASH/ASPIRATE KIT	50 PIPETTES; 5ML EXTRACTION REAGENT	1007	ROOM TEMP	

\*\*QW\* modifier is added to report use of CLIA-waived test system(s) for Medicare/Medicaid claims.

\*\*\*59\* modifier used to indicate separate test.

\*\*\* Additional Accessories (Swabs and Swab With Transport Tubes) are available.

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