

Status

Flu A&B



An *in vitro* rapid qualitative test that detects influenza type A and type B antigens directly from nasal swab, nasopharyngeal swab and nasal aspirate/wash specimens*

FLU FEARS US. YOU WILL LOVE US!



THEY CAN RUN BUT CANNOT HIDE

- Meets the new FDA reclassification performance criteria
- CLIA WAIVED for swab specimens
- Includes Positive and Negative control swabs
- Innovative flip design with onboard sample extraction
- Differentiates between Influenza A and B
- Pre-measured developer solution capsule for increased accuracy and ease of use
- Flocked nasal swabs for improved patient comfort and superior specimen collection

ORDERING INFORMATION		
PRODUCT	# OF TESTS	ITEM #
Status Flu A & B	25	36025
Nasal Aspirate Kit	25	510AS



Proudly made in the USA

For more information or to place an order, contact:

lifeSign

A PBM Group Company

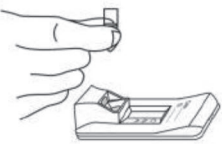
85 Orchard Road • Skillman • New Jersey • 08558
800.526.2125 • 732.246.3366 • Fax: 732.246.0570 • www.lifesignmed.com

*nasal aspirate/wash specimens – non waived

Simple Procedure for Swab Specimens

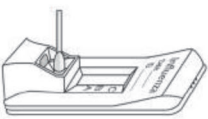
Extract

Fill extraction well with reagent




Incubate

Insert collection swab and incubate for 1 minute




Flip

Tip device allowing liquid to flow



Read

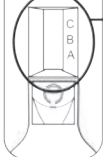
Interpret results at 10 to 15 minutes




**See Package Insert For Details


Interpretation of Results


Influenza
Date _____
ID _____




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


A line:
Influenza type A





B line:
Influenza type B


A & B lines:
Influenza type A & B

C Line only
NEGATIVE



No C Line
INVALID



Repeat with new sample and device.

Proven Clinical Performance

Status Flu A & B vs. PCR

	Influenza A	Influenza B
Positive Percent Agreement (PPA)	89.2 % (95% CI: 83.0 - 93.4%)	86.4 % (95% CI: 80.1 - 90.9%)
Negative Percent Agreement (NPA)	99.4 % (95% CI: 97.7 - 99.8%)	99.0 % (95% CI: 97.1 - 99.7%)

Wide Influenza strain coverage: 49 strains including A/CA/2009(H1N1v), A/Minesota/2010(H3N2v), H5NX and H7N9.

CPT CODE

INFLUENZA A 87804QW

INFLUENZA B 87804QW-59