

CLIA
WAIVED
FOR SWAB
SPECIMENS

Differentiates between Influenza A and B

INCLUDES:



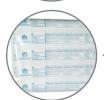
POSITIVE AND NEGATIVE CONTROL SWABS



INNOVATIVE FLIP DESIGN WITH ONBOARD SAMPLE EXTRACTION



PRE-MEASURED
DEVELOPER SOLUTION
CAPSULE for increased
accuracy and ease of use



FLOCKED NASAL SWABS for improved patient comfort and superior specimen collection



www.germainelabs.com





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BioSign® 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*

SIMPLE PROCEDURE FOR SWAB SPECIMENS



EXTRACT

Fill extraction well with reagent.

INCUBATE

Insert collection swab and incubate for 1 minute.

EI ID

Tip device for 1-2 seconds allowing liquid to flow.

READ RESULTS IN 10 TO 15 MINUTES.

READING RESULTS¹

| VALID TEST RESULTS | | | | INVALID TEST RESULTS | | |
|--------------------|--------------------------------|--------------------------------|--|------------------------|----------------|------------------------|
| NEGATIVE C B A | POSITIVE C B A | POSITIVE C B A | POSITIVE C B A | INVALID C B A | INVALID C B A | INVALID C B A |
| | A LINE: Influenza type A | B LINE: Influenza type B | A & B LINE: Influenza type A & B | Repeat with | n new sample | and device. |

PROVEN CLINICAL PERFORMANCE

(BioSign® Flu A & B vs. PCR)

| | INFLUENZA A | INFLUENZA B |
|-------------------------|------------------------------|------------------------------|
| POSITIVE % AGREEMENT | 89.2% (95% CI:83.0-93.4%) | 86.4% (95% CI:80.1-90.9%) |
| NEGATIVE % AGREEMENT | 99.4% (95% CI:97.7-99.8%) | 99.0% (95% CI:97.1-97.7%) |

BioSign® Flu A + B, 25 tests/kit, REF #BSP-510-25

CPT CODE: Influenza A 87084QW......Reimbursement \$15.39² Influenza B 87084QW-59......Reimbursement \$15.39²

THE TESTS YOU WANT.
THE ACCURACY YOU NEED!

