



# POINT-OF-CARE



## OSOM<sup>®</sup> Flu SARS-CoV-2 Combo Test

### ONE SAMPLE, ONE TEST, AND THREE STEPS TO RELIABLY DIFFERENTIATE BETWEEN SARS-COV-2, FLU A, AND FLU B

#### Features and Benefits

- **Reliable:** Proven clinical performance to help you reduce the risk of misdiagnosis & inappropriate treatment.
- **Rapid:** Differentiate between three viral infections (COVID-19, Flu A, & Flu B) in only 10 minutes, so you can facilitate immediate treatment protocols at the first patient visit.
- **Cost Efficient:** Unique QC Inside<sup>®</sup> feature which provides you with two additional tests per kit for External QC testing.
- **Simple Workflow:** Can be performed in a CLIA-waived setting & comes with ready-to-use extraction buffers to help you save time.
- **Superior Supply Chain:** Manufactured in the USA so you can avoid delays from international product shipments.

#### Performance Characteristics

	Positive Percent Agreement*	Negative Percent Agreement*	Sample Type	Limit of Detection***	Storage Temperature	Time to Result
SARS-CoV-2	87.0%**	99.1%	Anterior nasal swab	3.08 x 10 <sup>4</sup>	15-30°C/ 59-86°F	10 minutes
Flu A	93.1%	99.5%		3.53 x 10 <sup>2</sup>		
Flu B	89.1%	99.7%		9.3 x 10 <sup>1</sup>		

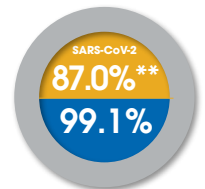
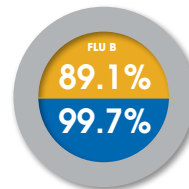
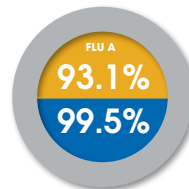
\*Combined prospective clinical RT-PCR comparator study.

\*\*Determined by a controlled analysis: Data shown is inclusion of 10% low positive samples by PCR. For all study cohort and performance at different low positive samples levels refer to IFU.

\*\*\*LOD for SARS-CoV-2 BA.5 Omicron Variant. Refer to IFU for additional LODs.



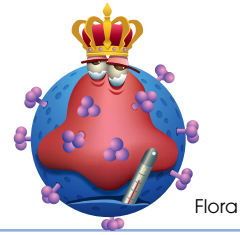
**POSITIVE PERCENT AGREEMENT**  
**NEGATIVE PERCENT AGREEMENT**



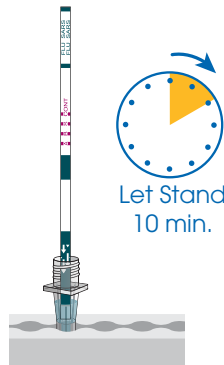
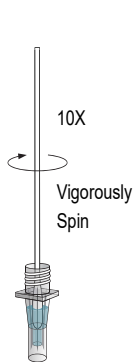
This test has not been FDA cleared or approved. It is authorized by FDA under an EUA for use by authorized laboratories. It has been authorized only for the detection of proteins from SARS-CoV-2, influenza A and influenza B, not for any other viruses or pathogens and is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C S360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

**SEKISUI**  
DIAGNOSTICS  
Because every result matters™

# OSOM® Flu SARS-CoV-2 Combo Test



Three results in only three simple steps



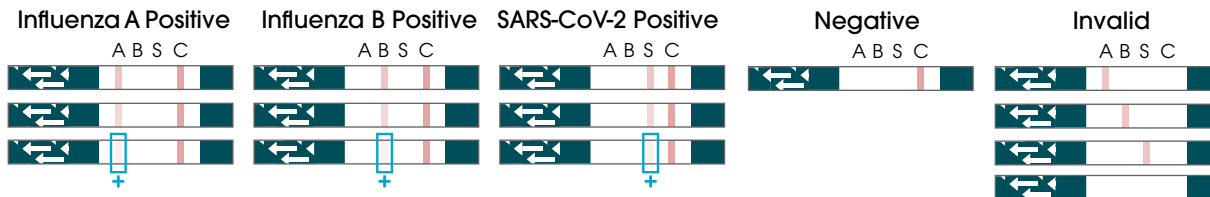
**1 MIX** the swab in the liquid by spinning it at least 10 times. Press the swab against the vial to remove any excess sample.

**2 INSERT** the test stick into the liquid of the extraction buffer vial and set a timer for 10 minutes.

**3 READ** test at 10 minutes. See Interpretation of results below.

Kit includes one Flu A/Flu B/SARS-CoV-2 positive Control Swab and one Flu A/Flu B/SARS-CoV-2 negative Control Swab

## INTERPRETATION OF RESULTS



## Ordering Information

	Configuration	Catalog Number	CPT Code
<b>OSOM FLU SARS-CoV-2 COMBO TEST</b>	25 tests per kit	1080	87428QW
<b>OSOM FLU SARS-CoV-2 COMBO CONTROL KIT</b>	5 x Flu A/Flu B/SARS-CoV-2 Positive Control Swabs 5 x Flu A/Flu B/SARS-CoV-2 Negative Control Swabs	1079	

To learn more about all of our OSOM Tests scan the QR code or go to [osomtests.com](https://osomtests.com)



### THE AMERICAS

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