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Validation of the OSOM Flu SARS-CoV-2 Combo Home Test

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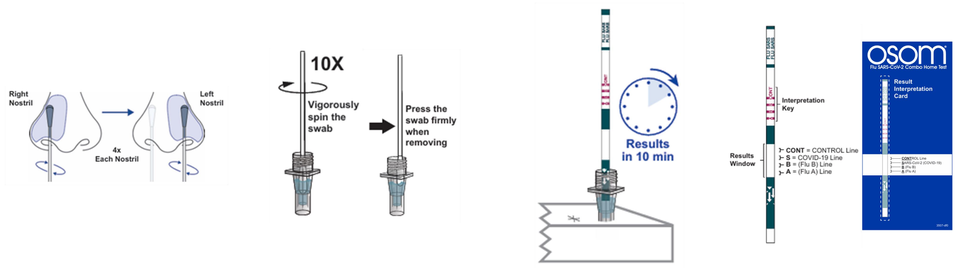
Background :

COVID-19 and Influenza respiratory infections often cause similar symptoms, however, treatment is different for each infection. Delay in diagnosis can be fatal in some cases, therefore rapid detection and differentiation are critical for appropriate medical treatment. The OSOM Flu SARS-CoV-2 Combo Home Test is a lateral flow immunoassay intended for the qualitative and differential detection of nucleocapsid protein from SARS-CoV-2 and influenza A/B proteins. Intended for non-prescription home use with self-collected anterior nares nasal swab specimens from individuals aged 14 years or older, or with adult-collected anterior nasal swab specimens from individuals two (2) years or older. An interpretation card, included with the test, is used to reliably distinguish among possible testing results.

Testing Procedure

1. Swab collection | 2. Extraction | 3. Start test | 4. Read test



Advantages of OSOM Combo Home Test: (1) Comprehensive screening for both SARS-CoV-2 and influenza A and influenza B simultaneously simplifies the testing process. (2) Speed - results in just 10 minutes.(3) User friendly result Interpretation Card.

1. Clinical Study

A prospective study was conducted across seven (7) geographically distinct sites in the U.S. during the 2023-2024 season to assess the performance of the OSOM Flu SARS-CoV-2 Combo Home Test. Participants were across different age groups (14 years and older performed self-testing using swab samples, while samples for age groups 2-13 were collected by adults). Testing took place in a simulated at-home setting. Individuals with respiratory infection symptoms provided consent for sample collection. Each participant provided two nasal swabs following standard collection protocols. One swab was self-collected and immediately tested using the OSOM Flu SARS-CoV-2 Combo Home Test. The second swab was collected by healthcare professionals in viral transport media (VTM) at least 15 minutes after the self-collection and testing process and was tested using an FDA-cleared molecular comparator test. A total of 703 prospective samples were evaluated for SARS-CoV-2. For Flu A/B, four (4) subject samples were excluded due to unavailable comparator results, leaving 699 samples for data analysis. The comparator tests used were FDA 510(k)-cleared molecular assays.

2. Performance relative to other on-market EUA-authorized Flu/Sars-Cov-2 Combo antigen products

Limit of detection (LoD) studies were conducted across four (4) on-market products using SARS-Related Coronavirus 2 (SARS-CoV-2) JN.1 strain, Influenza A H3N2 (Influenza A/Michigan/45/15) and Influenza B (B/Florida/02/06) simultaneously to control for any sample variability .

Results :

1. Clinical study : The performance of the OSOM Flu SARS-CoV-2 Combo Home are shown in Table 1.

Table 1. Clinical Performance

	Sensitivity	Specificity
FLU A	**93.1%** 67/72 (95%CI : 84.8%-97.0%)	**99.5%** 624/627 (95%CI : 98.6%-99.8%)
FLU B	**89.1%** 41/46 (95%CI : 77.0%-95.3%)	**99.7%** 651/653 (95%CI : 98.9%-99.9%)
SARS-CoV-2	**87.0%** 80/92 (95%CI : 78.6%-92.4%) *	**99.1%** 554/559 (95%CI : 98.0%-99.6%)

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

2. Performance relative to other on-market EUA-authorized Flu/Sars-Cov-2 Combo antigen product

Table 2. Simultaneous comparative LoD across multiple products

Strain:	Dilution factor	Concentration $TCID_{50}$/mL	OSOM Combo	Product A	Product B	Product C	Product D
SARS CoV-2, Lineage JN.1: Omicron Variant	4 X	1.26E+04	3/3	NT	**20/20**	NT	NT
	3 X	9.42E+03	3/3	NT	2/3	NT	**20/20**
	2 X	6.28E+03	3/3	**20/20**	1/3	NT	1/3
	1 X	3.14E+03	**20/20**	2/3	NT	**19/20**	NT
	0.5 X	1.57E+03	1/3	NT	NT	0/3	NT
Influenza A/Michigan/45/ 2015	20x	1.62E+03	3/3	**20/20**	NT	NT	NT
	10x	8.10E+02	3/3	4/20	NT	NT	NT
	2x	1.62E+02	3/3	NT	**19/20**	**20/20**	NT
	1x	8.10E+01	**20/20**	0/3	0/3	0/3	**20/20**
	0.5x	4.05E+01	0/3	NT	NT	NT	14/20
Influenza B/Florida/02/06	3x	6.90E+03	3/3	**19/20**	**19/20**	NT	NT
	2x	4.60E+03	3/3	3/20	11/20	NT	**20/20**
	1x	2.30E+03	**19/20**	0/3	1/3	**20/20**	3/5
	0.5x	1.15E+03	1/3	NT	NT	0/3	13/20

The analytical sensitivity of the OSOM Flu SARS-CoV-2 Combo Home Test matches or exceeds that of the product with the highest sensitivity among the other products.

Conclusion :

To effectively manage the spread of respiratory infections and potential co-infections with indistinguishable symptoms, facilitating at-home rapid differential testing without healthcare assistance is crucial. The OSOM Flu SARS-CoV-2 Combo Home test demonstrates comparable sensitivity and specificity to other EUA-authorized OTC/Home test devices. Self-collected anterior nasal swabs combined with affordable lateral flow assays are pivotal for CDC-recommended serial screening in high-risk scenarios. The OSOM Flu SARS-CoV-2 Combo Home test can enhance diagnostic capabilities by detecting multiple pathogens simultaneously, improving healthcare delivery, infection control, and public health responses during outbreaks.