

Simplexa™ Flu A/B & RSV Direct Kit

Be Prepared for Flu Season

Comprehensive coverage and flexibility for
your influenza A/B and RSV testing needs

The quality of treatment starts with diagnosis.

Be Prepared for Flu Season

The broadest strain coverage for your lab's testing needs.

Commitment to performance, confidence to handle new emerging strains

Respiratory viruses mutate frequently and consistent emergence of new viral strains necessitates the need for comprehensive coverage.

DiaSorin Molecular continually monitors the major flu databases and tests newly emerging and vaccine flu strains on an ongoing basis.



Detect 92 strains

92 strains have been validated, with more strains tested regularly to provide confidence in your results.

Influenza A Viruses		Influenza B Viruses		RSV	
Subtype	Organism	Lineage	Organism	Subtype	Organism
(H1N1) pdm09	A/California/4/2009	Victoria	B/Brisbane/33/2008	N/A	ATCC-2012-1D
(H1N1) pdm09	A/California/7/2009 NYMC x-179-A	Victoria	B/Brisbane/60/2008	A	A 1997/12-35
H1N1	A/Brisbane/59/07 H1	Victoria	B/Florida/02/2006	A	A 1998/12-21
H1N1	A/Hawaii/15/2001	Victoria	B/Lee/40	A	A 1998/3-2
H2N2	A/Japan/305/57	Victoria	B/Nevada/03/2011	A	A 2000/3-4
H3N2	A/Brisbane/10/07 H3	Victoria	B/Texas/02/2013	A	A 2001/2-20
H3N2	A/California/02/2014	Victoria	B/Victoria/304/2006	A	A 2001/3-12
H5N1	A/Egypt/N03072/2010(H5N1)-PR8-IDCDC-RG29	Yamagata	B/Christchurch/33/2004	A	A Long
H5N1	A/India/NIV/2006(H5N1)-PR8-IBCDC-RG7	Yamagata	B/Florida/07/04	B	B 9320
H7N9	A/Anhui/1/2013	Yamagata	B/Florida/04/2006	B	B/Wash/18537/62
H9N2	A/Hong Kong/33982/2009(H9N2)-PR8-IDCDC_RG26	Yamagata	B/Guangdong-Liwan/1133/2014	B	B/WV/14617/B5
H1N3	A/shorebird/Delaware Bay/211/1994	Yamagata	B/Marylans/1/59		
H10N7	A/chicken/Germany/NN/49	Yamagata	B/Massachusetts/2/2012		
H16N3	A/shorebird/Delaware/172/2006	Yamagata	B/Panama/45/90		

For a full list, see MOL2650 instructions for use.

Simple and easy Flu A/B & RSV testing

- **Fast, sample-to-answer workflow:** CLIA moderate complexity without RNA extraction for results in about an hour.
- **Run as few as 1 and up to 8 samples at a time.**
- **Ready to use:** Single use reagents for no waste (24 reactions).



Reliable performance that you can count on

The Simplexa™ Flu A/B & RSV Direct assay has greater than 97% sensitivity.

Simplexa™ Flu A/B & RSV Direct Clinical Agreement Summary¹

SPECIMEN	SENSITIVITY	SPECIFICITY
INFLUENZA A	97% (66/68) 95% CI: 89.9 to 99.2%	97.9% (639/653) 95% CI: 96.4 to 98.7%
INFLUENZA B	100% (21/21) 95% CI: 84.5 to 100%	99.9% (697/698) 95% CI: 99.2 to 100%
RSV ²	97.6% (82/84) 95% CI: 91.7 to 99.3%	92.9% (592/637) 95% CI: 90.7 to 94.7%

REFERENCES: 1. MOL2650, Simplexa™ Flu A/B & RSV Direct instructions for use. 2. Mean values for these sites, but the three sites may not be statistically poolable. Specificity at the three site ranged from 84.6% to 98.2%; Sensitivity ranged from 90.0% to 100%. See package insert for details. Sites used different culture methods for comparison, but the FDA-cleared NAAT used in the discrepancy analysis was the same at all three sites.

A comprehensive offering for influenza and RSV testing

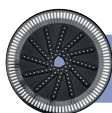


Ordering information - Simplexa™ Flu A/B & RSV Direct

CATALOG NUMBER	DESCRIPTION	REACTIONS/KIT
MOL2650	Simplexa™ Flu A/B & RSV Direct Kit*	24
MOL2660	Simplexa™ Flu A/B & RSV Positive Control Pack**	10 x 100 µL

*To be used with Direct Amplification discs (3 DAD discs, MOL1455).

** Contains Inactivated influenza A virus, Inactivated influenza B virus, Inactivated RSV.



Ordering information – Simplexa™ Flu Kits

CATALOG NUMBER	DESCRIPTION	REACTIONS/KIT
MOL2600	Simplexa™ Flu A/B & RSV Kit	100
MOL2500	Simplexa™ Influenza A H1N1 (2009) Kit	100

Other Respiratory Assays



Ordering information – Simplexa™ Direct Kits

CATALOG NUMBER	DESCRIPTION	REACTIONS/KIT
MOL2850	Simplexa™ Group A Strep Direct Kit*	24
MOL2860	Simplexa™ Group A Strep Positive Control Pack**	10 x 100 µL

*To be used with Direct Amplification discs (3 DAD discs, MOL1455).

** Contains inactivated Group A Streptococcus bacteria.



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