

## Respiratory Viral Panel

## All the answers when you want them. Individual answers when you need them.

Current molecular solutions for respiratory panel testing often require tradeoffs between throughput, lengthy turnaround times, unnecessary scope of respiratory viruses being tested, and unsustainable costs. Stop compromising. The Solana Respiratory Viral Panel (RVP) combines two Solana respiratory assays, Solana Influenza A+B and Solana RSV + hMPV, to create a focused respiratory viral panel to detect and differentiate all four common respiratory viruses (influenza A, influenza B, respiratory syncytial virus and human metapneumovirus) from a single patient sample.

### Prompt initiation of patient management

- Four results from a single sample in just 45 minutes
- Run up to 6 patients in a single run

### True, Molecular Accuracy

- Gold standard sensitivity
- Confidence in your prescription decision
- Detect the respiratory viruses that matter most

### **Ease and Affordability**

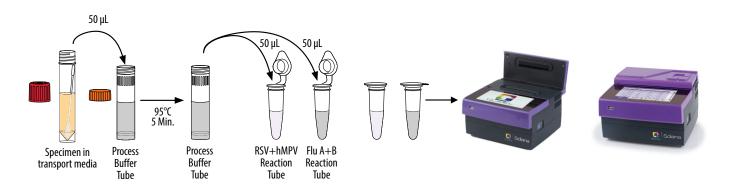
- Wide range of transport media compatibility
- Simple procedure
- Sustainable reagent pricing
- Flexible instrument placement options

The Accurate. Sustainable.

Molecular **Respiratory** Solution.

Solana

Sample Preparation Amplification Detection



### Clinical Performance

## Performance Characteristics of the Solana Influenza A+B Assay for Influenza A Compared to Culture and DSFA (Across All Sites Combined)

Source Category	N	TP	FP	TN	FN	Sensitivity % (95% CI)	Specificity % (95% CI)
Fresh	709	180	24	503	2	98.9 (96.1 to 99.7)	95.4 (93.3 to 96.9)
Frozen	699	176	27	493	3	98.3 (95.2 to 99.4)	94.8 (92.6 to 96.4)
All	1408	358	51*	996	5**	98.6 (96.8 to 99.4)	95.1 (93.7 to 96.3)

\*Of the fifty-one (51) discordant specimens (Solana Positive/Culture and DSFA Negative), twenty-eight (28) of these specimens were positive by an alternate FDA-cleared molecular assay.

\*\*Of the five (5) discordant specimens (Solana Negative/Culture and DSFA Positive), two (2) of these specimens were positive by an FDA-cleared molecular assay.

# Performance Characteristics of the Solana Influenza A+B Assay for Influenza B Compared to Culture and DSFA (Across All Sites Combined)

Source Category	N	TP	FP	TN	FN	Sensitivity % (95% CI)	Specificity % (95% CI)
Fresh	709	62	1	646	0	100 (94.2 to 100)	99.8 (99.1 to 100)
Frozen	699	23	8	668	0	100 (85.7 to 100)	98.8 (97.7 to 99.4)
All	1408	85	9*	1314	0	100 (95.7 to 100)	99.3 (98.7 to 99.6)

\*Of the nine (9) discordant specimens (Solana Positive/Culture and DSFA Negative), two (2) of these specimens were positive by an alternate FDA-cleared molecular assay.

# Performance Agreement of the Solana RSV + hMPV Assay for RSV Compared to an FDA-cleared RSV+hMPV Molecular Assay (Across All Sites Combined)

Source Category	N	TP	FP	TN	FN	PPA % (95% CI)	NPA % (95% CI)
Fresh	760	12	0	747	1	92.3 (66.7 to 98.6)	100 (99.5 to 100)
Frozen	1286	136	1	1143	6	95.8 (91.1 to 98.0)	99.9 (99.5 to 100)
All	2046	148	1*	1890	7**	95.5 (91.0 to 97.8)	99.9 (91.0 to 97.8)

\*Of the one (1) discordant specimens (Solana Positive/Comparator Negative), one (1) of these specimens were positive by an alternative FDA-cleared molecular assay.

\*\*Of the seven (7) discordant specimens (Solana Negative/ Comparator Positive), six (6) of these specimens were positive by an alternative FDA-cleared molecular assay.

# Performance Agreement of the Solana RSV + hMPV Assay for hMPV Compared to an FDA-cleared RSV+hMPV Molecular Assay (Across All Sites Combined)

Source Category	N	TP	FP	TN	FN	PPA % (95% CI)	NPA % (95% CI)
Fresh	760	24	2	733	1	96.0 (80.5 to 99.3)	99.7 (99.0 to 99.9)
Frozen	1286	62	1	1220	3	95.4 (87.3 to 98.4)	99.9 (99.5 to 100)
All	2046	86	3*	1953	4**	95.6 (89.1 to 98.3)	99.8 (99.6 to 99.9)

\*Of the three (3) discordant specimens (Solana Positive/ Comparator Negative), zero (0) of these specimens were positive by an alternative FDA-cleared molecular assay.

\*\*Of the four (4) discordant specimens (Solana Negative/ Comparator Positive), zero (0) of these specimens were positive by an alternative FDA-cleared molecular assay.

Solana Respiratory Viral Panel – 96 tests: Cat. #M925

Solana Influenza A+B - 48 tests  $\,$  I Solana RSV + hMPV - 48 tests

Solana Respiratory Viral Panel Control Set – 20 mL: Cat. #M926

Solana Influenza A+B Control Set – 20 reactions | Solana RSV + hMPV Control Set – 20 reactions Solana Instrument – Cat. #20278

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