

# FlashDx<sup>®</sup> SARS-CoV-2 /FluA/FluB/RSV



<b>Test Reagent Kit</b>	SARS-CoV-2/FluA/FluB/RSV			
<b>Catalog Number</b>	CoV2P4-10			
<b>Instrument</b>	FlashDx-1000-E, SPRT™ 4T/8T/12T			
<b>Technology</b>	SPRT™ (semi-Solid Phase Real-Time PCR) technologies			
<b>Targets</b>	<b>SARS-CoV-2</b> N, E, and ORF1ab genes	<b>Flu A</b> Matrix gene	<b>Flu B</b> NEP/NS2 gene	<b>RSV</b> L gene
<b>Batch or On-Demand</b>	On-Demand			
<b>Minimum Batch Size</b>	1			
<b>Sample Types</b>	<b>Specimen:</b> Nasopharyngeal, navvhroat swabs <b>Transport Media:</b> UTM/VTM* or saline (0.9%)			
<b>Sample Extraction</b>	Fully automated/integrated			
<b>Precision Pipetting</b>	Not required			
<b>Turnaround Time</b>	<1 hour			
<b>Hands-on Time</b>	~1 minute			
<b>Control</b>	Internal Process Control			
<b>Clinical Evaluation<sup>†</sup></b>	<b>Sensitivity</b>	<b>Specificity</b>		
SARS-CoV-2	97.5% (95% CI: 87.1% - 99.6%)	100%	(95% CI: 91.2% - 100%)	
Flu A	100% (95% CI: 80.6% - 100%)	100%	(95% CI: 95.0% - 100%)	
Flu B	100% (95% CI: 88.3% - 100%)	100%	(95% CI: 94.0% - 100%)	
RSV	97.7% (95% CI: 88.2% - 99.6%)	100%	(95% CI: 92.1% - 100%)	
<b>Kit Storage</b>	2-8 °C			
<b>Commercial Controls</b>	See FlashDx Package Insert or contact FlashDx Customer Support			

\*Sample transport media with guanidine buffer is not compatible , †Compared to an FDA EUA RT-PCR assay or NMPA-approved RT-PCR assays.

