



# FlashDx<sup>®</sup> SARS-CoV-2

Test Reagent Kit	SARS-CoV-2						
Catalog Number	CoV2-10						
Instrument	FlashDx-1000-E						
Technology	Microarray-qPCR						
Targets	N, E, and ORF1ab genes						
Batch or On-Demand	On-Demand						
Minimum Batch Size	1						
Sample Types	<b>Specimen:</b> Nasopharyngeal, nasal or throat swabs <b>Transport Media:</b> UTM/VTM* or saline (0.9%)						
Sample Extraction	Fully automated/integrated						
Precision Pipetting	Not required						
Turnaround Time	< 1 hour						
Hands-on Time	~ 1 minute						
Control	Internal Process Control						
Clinical Evaluation†	<table><tr><td><b>Sensitivity</b></td><td><b>Specificity</b></td></tr><tr><td>95.2% (95% CI: 88.1% - 98.7%)</td><td>97.3% (95% CI: 90.7% - 99.7%)</td></tr><tr><td colspan="2"><i>Testing performed with 83 positives and 75 negatives†</i></td></tr></table>	<b>Sensitivity</b>	<b>Specificity</b>	95.2% (95% CI: 88.1% - 98.7%)	97.3% (95% CI: 90.7% - 99.7%)	<i>Testing performed with 83 positives and 75 negatives†</i>	
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<i>Testing performed with 83 positives and 75 negatives†</i>							
Kit Storage	2-8 °C						
Commercial Controls	See FlashDx SARS-CoV-2 Package Insert or contact FlashDx Customer Support						

\* Use recommended UTM/VTM only. Transport media with guanadine buffer is not compatible.

† Compared to an FDA EUA RT-PCR assay.



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Ver. 0.2