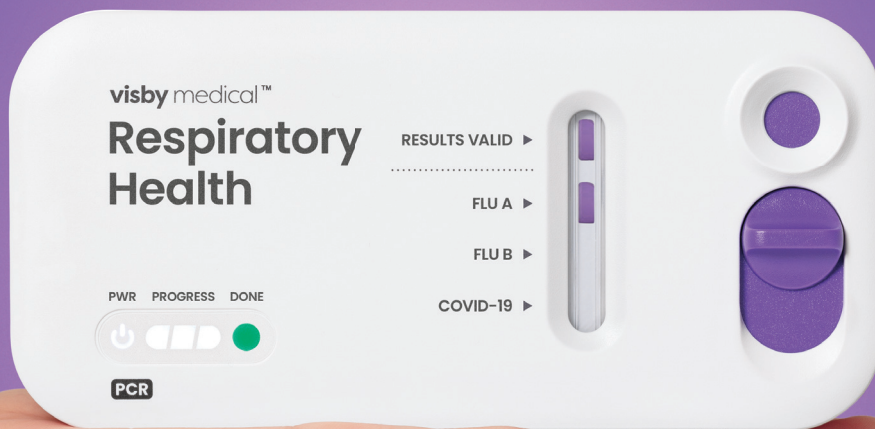


The power of PCR in your hands

COVID-19 and flu results
delivered at the point of care



Accurate results without the instrument

Visby Medical Respiratory Health Test:


- ✓ One swab, three targets: COVID-19, Influenza A and Influenza B
- ✓ Lab-quality accuracy
- ✓ No maintenance or service contracts
- ✓ Easy to run multiple patient tests simultaneously

visby medical™



Visby Medical Respiratory Health Test

Product Specifications Sheet

Product	Visby Medical Respiratory Health Test		
Orderable Part (Case)	Visby Medical Respiratory Health – 20 devices per case		
Orderable SKU Number	SKU: PS-400380 (2 inner boxes of 10 devices)		
Technology	Reverse Transcription Polymerase Chain Reaction (RT-PCR)		
Targets	Influenza A	Influenza B	SARS-CoV-2
Target Details	Flu A: Evaluated against a panel of 10 strains of influenza A H1N1 and 10 strains of Influenza A H3N2	Flu B: Evaluated against a panel of 12 strains of influenza B	Visby follows the FDA’s Policy for Evaluating Impact of Viral Mutations on COVID-19 Tests by monitoring SARS-CoV-2 sequences for mutations
Complexity	CLIA-waived		
Instrument	None needed		
Sample Type	Nasopharyngeal swab or anterior nasal swab (patient or provider collected)		
Results	Qualitative results – visual colorimetric indicator next to the target pathogen		
Device Use	Single use		
Sample Extraction	None needed		
Precision Pipetting	Not required		
Turnaround Time (TAT)	30 minutes		
Internal Control	Process control		
Limit of Detection (LOD)	Influenza A	Influenza B	SARS-CoV-2
	Influenza A/H1N1 2009, Brisbane/02/18 106 copies/swab Influenza A/H3N2, Kansas/14/2017 125 copies/swab	Influenza B/Washington/02/19 728 copies / swab Influenza B/Oklahoma/10/2018 778 copies / swab	SARS-CoV-2 (USA-WA1/2020) 100 copies / swab
Positive Percent Agreement (PPA)	96.9%	100.0%	97.2%
Negative Percent Agreement (NPA)	99.4%	99.8%	99.0%
Swab Stability in Visby Buffer	Up to 120 minutes (2 hours) at room temperature 59°F – 86°F (15°C – 30°C) Up to 48 hours at refrigerated temperature 36°F – 46°F (2°C – 8°C)		
Kit and Device Storage	Temperature: 36°F – 86°F (2°C – 30°C), Humidity: 5% – 80%		
Power Adapter (sold separately)	SKU: PS-000288		
External Controls	Refer to Instructions for Use or Contact Visby Customer Experience Team Email: support@visby.com; Phone: 1-833-GoVisby (1-833-468-4729)		