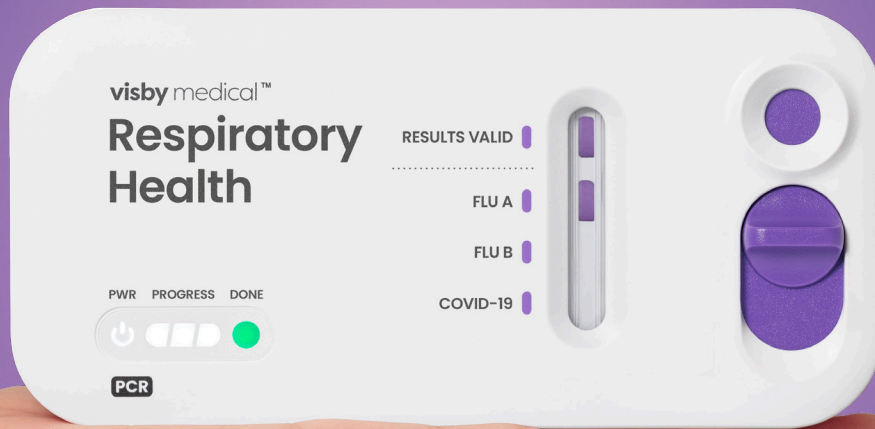


# The power of PCR in your hands

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

<b>Product</b>	Visby Medical Respiratory Health Test			
<b>Orderable Part (Case)</b>	Visby Medical Respiratory Health (2 inner boxes of 10 devices)			
<b>Orderable SKU Number</b>	SKU: PS-400380 (Case equals two purple boxes)			
<b>Technology</b>	Reverse Transcription Polymerase Chain Reaction (RT-PCR)			
<b>Targets</b>	<i>Influenza A</i>	<i>Influenza B</i>	<i>SARS-CoV-2</i>	
<b>Target Details</b>	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	
<b>Complexity</b>	EUA for use in CLIA-waived point-of-care settings			
<b>Instrument</b>	None needed			
<b>Results</b>	Qualitative results - visual colorimetric indicator next to the target pathogen			
<b>Device Use</b>	Single Use			
<b>Sample Extraction</b>	None Needed			
<b>Precision Pipetting</b>	Not required			
<b>Turnaround Time (TAT)</b>	30 minutes			
<b>Internal Control</b>	Process Control			
<b>Limit of Detection (LOD)</b>	<i>Influenza A</i>	<i>Influenza B</i>	<i>SARS-CoV-2</i>	
<b>Nasopharyngeal Swab</b>	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	
<b>Positive Percent Agreement (PPA)*</b>	96.2%	96.9%	93.2%	
<b>Negative Percent Agreement (NPA)*</b>	98.9%	100%	98.9%	
<b>Swab Stability* *in Visby Buffer</b>	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)			
<b>Kit and Device Storage</b>	Temperature: 36°F - 86°F (2°C - 30°C), Humidity: 5% - 80%			

\* Data is a combination of prospective fresh specimens, banked frozen specimens, and surrogate specimens

This product has not been FDA cleared or approved, but has been authorized for emergency use by FDA under an EUA for use by authorized laboratories. This product has been authorized only for the detection and differentiation of nucleic acid from SARS-CoV-2, influenza A, and influenza B, not for any other viruses or pathogens; and the emergency use of this product is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3(b)(1), unless the declaration is terminated or authorization is revoked sooner.