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™

1-833-GoVisby (1-833-468-4729) | sales@visbymedical.com | www.visbymedical.com

PL-000200 Rev A

Visby Medical Respiratory Health Test

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Product Specifications Sheet

Product	Visby Medical Respiratory Health Test		
Orderable Part (Case)	Visby Medical Respiratory Health (2 inner boxes of 10 devices)		
Orderable SKU Number	SKU: PS-400380 (Case equals two purple boxes)		
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	EUA for use in CLIA-waived point-of-care settings		
Instrument	None needed		
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*
Nasopharyngeal Swab	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)*	96.2%	96.9%	93.2%
Negative Percent Agreement (NPA)*	98.9%	100%	98.9%
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%		

** 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.