Test to treat in a single patient visit

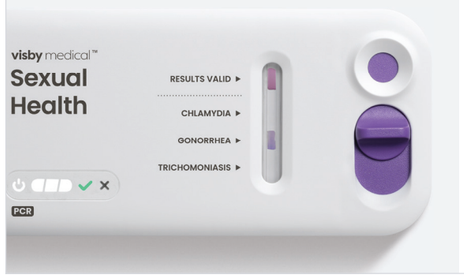
An easy-to-use workflow with <15 seconds hands-on time

Step 1

Load sample into device port

Step 2

Slide switch to close port



Step 3

Read the results

visby medical™

For more information, call 1-833-468-4729.

PL-000221 Rev A

The power of PCR in your hands

Results delivered at the point of care in under 30 minutes

True PCR results in under 30 minutes

Portable, deployable, and scalable

PCR accuracy

Instrument free - no capital investment, service contracts, maintenance or calibration

visby medical™

1-833-GoVisby (1-833-468-4729)
Visit our website at visbymedical.com or scan this QR Code.

Visby Medical Respiratory Health Test

Product Specifications Sheet

Product	Visby Medical Respiratory Health Test		
Orderable Part (Case)	Visby Medical Respiratory Health (2 boxes of 10 devices)		
Orderable SKU Number	SKU: PS-400380 (Case equals two 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		
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)*	96.8%	96.9%	96.1%
Negative Percent Agreement (NPA)*	99.0%	100%	98.2%
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%		
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)		

** Data is a combination of prospective fresh specimens (NP and AN), banked specimens (NP), and surrogate specimens (NP)*

Visby Medical Sexual Health Test

Product Specifications Sheet

Product	Visby Medical Sexual Health Test		
Orderable Part (Case)	Visby Medical Sexual Health - 20 devices per case		
Orderable SKU Number	Visby Medical SKU PS-400372: 2 inner boxes of 10 devices		
Technology	PCR		
Targets	*Chlamydia trachomatis* (CT)	*Neisseria gonorrhoeae* (NG)	*Trichomonas vaginalis* (TV)
Target Details	CT: evaluated against a panel of 16 serovars, including Swedish variant (nvCT)	NG: evaluated against a panel of 32 different strains	TV: evaluated against a panel of 17 different strains
Complexity	CLIA-Waived		
Instrument	None needed		
Results	Individual qualitative result for Chlamydia, Gonorrhea and Trichomoniasis visually interpreted on the Visby Medical Sexual Health test device		
Sample Extraction	No additional sample extraction required, raw sample added to the device		
Pipetting	Single use pipette supplied in kit		
Turnaround Time (TAT)	Under 30 minutes		
Internal Control	Combination of electronic control and assay process controls		
Limit of Detection (LOD)	CT (Serovar)	NG (Strain)	TV (Strain)
Patient Collected Vaginal Swab	Serovar H - 16.0 EB/mL Serovar D - 5.9 EB/mL	NG 19424 - 5.7 CFU/mL NG 49226 - 6.2 CFU/mL	TV 30001 - 1.2 troph/mL TV 30238 - 0.24 troph/mL
Positive Percent Agreement (PPA)	97.4%	97.8%	99.3% Sensitivity
Negative Percent Agreement (NPA)	97.8%	99.1%	96.7% Specificity
Swab Stability* *in Visby Sexual Health Buffer	2°–30°C: 4 Hours, <-15°C: 90 days		
Kit and Device Storage	Temperature: 36°F–86°F (2°C–30°C) Humidity: 5%–80%		
Sample Collection Kit	Visby Medical Sexual Health, Vaginal Specimen Collection Kit, 50 Pack		
Sample Collection Kit P/N	SKU: PS-000715		
Power Adapter† †(sold separately)	SKU: PS-000288		
External Controls	Refer to Instructions for Use ZeptoMetrix external controls: NATCTNGTV-POS-IVD, NATCTNGTV-NEG-IVD		