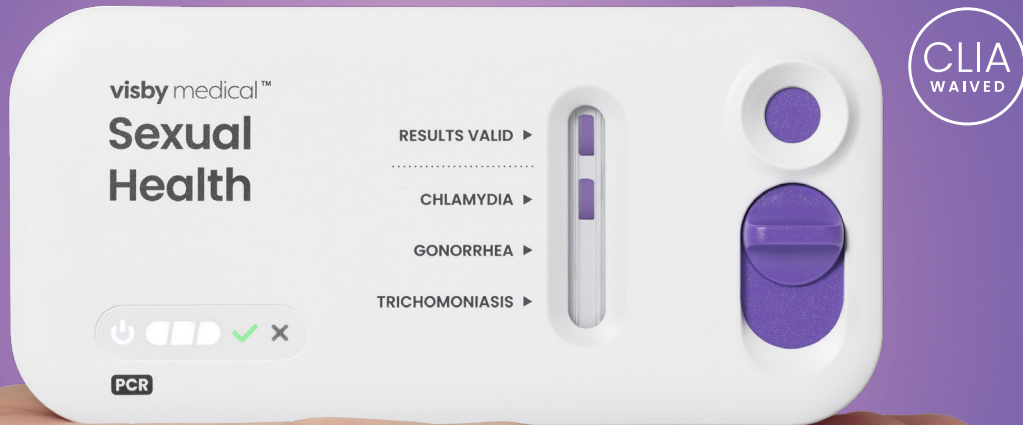


The power of PCR in your hands

Get point-of-care STI results in under 30 minutes



Test, talk and treat – in the same visit.

Visby Medical Sexual Health Test:

- ✓ CLIA waived PCR test for three STIs: Chlamydia, Gonorrhea, Trichomoniasis
- ✓ Delivers ~97% accuracy* in under 30 minutes
- ✓ Vaginal self-collected swab
- ✓ Improves antibiotic stewardship

visby medical™

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* See Instructions For Use for details.



PL-000077 Rev C

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	<i>Chlamydia trachomatis</i> (CT)	<i>Neisseria gonorrhoeae</i> (NG)	<i>Trichomonas vaginalis</i> (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* <small>*in Visby Sexual Health Buffer</small>	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† <small>†(sold separately)</small>	SKU: PS-000288			
External Controls	Refer to Instructions for Use ZeptoMetrix external controls: NATCTNGTV-POS-IVD, NATCTNGTV-NEG-IVD			