

# 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

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