

Visby Medical Sexual Health Click Test

Product Specifications Sheet

Product	Visby Medical Sexual Health Click Test			
Orderable Part (Kit)	Visby Medical Sexual Health, Click - 10 Pack x 2			
Orderable SKU Number	PS-000688			
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 14 serovars, including new or Swedish variant (nvCT)	NG: evaluated against a panel of 30 different strains from WHO, geographically diverse clinical isolates and strains with known mutations	TV: evaluated against a panel of 15 different strains	
Complexity	CLIA-Waived			
Instrument	N/A, None needed			
Results	Qualitative results - visual colorimetric indicator next to the target pathogen			
Device Use	Single Use			
Sample Extraction	N/A, None needed			
Precision Pipetting	Not required			
Turnaround Time (TAT)	28 minutes			
Internal Control	Process Control			
Limit of Detection (LOD)	CT (Serovar)	NG (Strain)	TV (Strain)	
Patient Collected Vaginal Swab (F)	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%	
Negative Percent Agreement (NPA)	97.8%	99.1%	96.7%	
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 and 86°F (2°C and 30°C) Humidity: 30% and 80% Pressure: ~98ft-5400ft			
Sample Collection Kit	Visby Medical Sexual Health, Vaginal Specimen Collection Kit, 50 Pack			
Sample Collection Kit P/N	PS-000715			
Commercial Controls	Refer to Instructions for Use or Contact Visby Customer Experience Team Email: support@visby.com; Phone: 1-833-GoVisby (1-833-468-4729)			