

Visby Medical Sexual Health Click Test



Product Specifications Sheet

Product	Visby Medical Sexual Health Click Test		
Orderable Part (Kit)	Visby Medical Sexual Health Click - 20 devices per case		
Orderable SKU Number	SKU: PS-000688 (Case equals two purple boxes)		
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, geographically diverse clinical isolates and strains with known mutations	TV: evaluated against a panel of 17 different strains
Complexity	CLIA-Waived		
Instrument	None needed		
Results	Individual Qualitative result for Chlamydia, Gonorrhoeae and Trichomonas visually interpreted on the Visby Medical Sexual Health Click 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)	28 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 and 86°F (2°C and 30°C) Humidity: 30% and 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		
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)		

