Participant flow

Study assessed was observational in design and utilised remnant specimens (leftover or archived) taken for purposes of routine STI diagnostic testing through a swab or urine sample from male and female subjects (n=1163). As such no participants were directly involved.

Baseline Characteristics

Characteristic	**Details**
Age	≥18 years
Specimen Type no.	
Urine	733
Urogenital swab	178
Oral swab	128
Rectal swab	60
Lesion swab	32

Overall Outcome Measures

Primary Study Outcome (all sample matrices)	Device								
	CT/NG-*fle*X qPCR QP10704		HSV1/HSV2/TP-*fle*X qPCR QP10705			MG/TV-*fle*X qPCR QP10706		MH/UU-*fle*X qPCR QP10707	
Method Correlation	99.54%		99.14%			99.41%		97.14%	
Diagnostic Sensitivity	CT: 100%	NG: 100%	HSV1: 98.55%	HSV2: 100%	TP: 98%	MG: 97.87%	TV: 94.59%	MH: 98.43%	UU: 88.89%
Diagnostic specificity	CT: 99.41%	NG: 99.62%	HSV1: 98.84%	HSV2: 98.75%	TP: 99.89%	MG: 99.34%	TV: 99.77%	MH: 97.66%	UU: 99.29%
Positive Predictive Value (PPV)	CT: 93.02%	NG: 92.16%	HSV1: 87.18%	HSV2: 82.81%	TP 98.00%:	MG: 88.46%	TV: 94.59%	MH: 89.29%	UU: 97.87%
Negative Predictive Value (NPV)	CT: 100.00%	NG: 100.00%	HSV1: 99.88%	HSV2: 100.00%	TP: 99.89%	MG: 99.89%	TV: 99.77%	MH: 99.68%	UU: 96.03%
Positive Likelihood Ratio	CT: 169.33	NG: 262.25	HSV1: 85.25	HSV2: 80.09	TP: 866.32	MG: 149.09	TV: 409.59	MH: 42.06	UU: 124.67
Negative Likelihood Ratio	CT: 0	NG: 0	HSV1: 0.01	HSV2: 0	TP: 0.02	MG: 0.02	TV: 0.05	MH: 0.02	UU: 0.11
Diagnostic Accuracy	CT: 99.45%	NG: 99.64%	HSV1: 98.82%	HSV2: 98.82%	TP: 99.79%	MG: 99.27%	TV: 99.56%	MH: 97.79%	UU: 96.48%

CT: *Chlamydia trachomatis, NG: Neisseria gonhorroeae; HSV1:* Herpes Simplex Virus 1, HSV2: Herpes Simplex Virus 1, TP: *Treponema pallidum*; MG: *Mycoplasma genitalium*, TV: *Trichomonas vaginalis*; MH: *Mycoplasma hominis*, UU: *Ureaplasma urealyticum*

Adverse Events

No subject enrolment in the study was carried out as the clinical study was observational in design and utilised remnant specimens. Such study design posed no additional risks to test subjects or potential for adverse event(s).