## **XPERT® CT/NG**

## DATASHEET

Xpert® CT/NG

	СТ	NG
Test Reagent Kit	Xpert CT/NG	Xpert CT/NG
Technology	Real time PCR	Real time PCR
Targets (unique to Cepheid)	gDNA (one)	gDNA (two independent)
Batch or On Demand	On Demand	On Demand
Minimum Batch Size	1	1
Sample Extraction	Automated/Integrated	Automated/Integrated
Precision Pipetting	Not required	Not required
TAT	90 min	90 min
Hands-On Time	1 min	1 min
Limit of Detection (LoD)	Serovar (eb/ml) D H	Strain (cfu/ml) #19424 #49226
Patient Collected Vaginal swab (F) Urine (M)	84 161	1.5 1.6   2.7 1.2
Controls: Process (SPC)	$\checkmark$	$\checkmark$
Controls: Sample Adequacy (SAC)	$\checkmark$	$\checkmark$
Controls: Probe Function/Detection (PCC)	$\checkmark$	$\checkmark$
Female Swabs	СТ	NG
Patient Collected Vaginal Swabs: Sensitivity	99.5%	100%
Specificity	99.1%	99.9%
Endocervical Swabs: Sensitivity Specificity	96.0% 99.6%	100% >99.9%
Stability: in Cepheid Sample Transport Reagent	2-30°C/60 days	2-30°C/60 days
First Catch Urine		
Female Urine: Sensitivity Specificity	98.1% 99.8%	94.4% >99.9%
Stability: Neat	Room Temp. for 24 hrs or 4°C/8 days	Room Temp. for 24 hrs o 4ºC/8 days
Stability: in Cepheid Sample Transport Reagent	2-15°C/45 days or 2-30°C/3 days	2-15°C/45 days or 2-30°C/3 days
Male Urine: Sensitivity Specificity	98.5% 99.8%	98.3% 99.9%
Stability: Neat	Room Temp. for 3 days or 4°C/8 days	Room Temp. for 3 days o 4ºC/8 days
Stability: in Cepheid Sample Transport Reagent	2-30°C/45 days	2-30°C/45 days
Kit Storage	2-28°C	2-28°C
Commercial Controls	Contact Cepheid Technical Support	Contact Cepheid Technical Support

## For In Vitro Diagnostic Use.

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