Siemens Healthcare Diagnostics, a global leader in clinical diagnostics, provides healthcare professionals in hospital, reference, and physician office laboratories and point-of-care settings with the vital information required to accurately diagnose, treat, and monitor patients. Our innovative portfolio of performance-driven solutions and personalized customer care combine to streamline workflow, enhance operational efficiency, and support improved patient outcomes.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

Order No. A91DX-121448-XC1-4A00
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How can I combine reliable Chlamydia trachomatis and Neisseria gonorrhoeae detection with the power to do more?

VERSANT CT/GC DNA 1.0 ASSAY (kPCR)

With the reliable and efficient CT/GC assay for the VERSANT kPCR Molecular System

Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) infections are common sexually transmitted diseases that represent major public health threats. Lower genital tract infections in men and women caused by CT and/or GC are often asymptomatic and represent a silent epidemic around the world. Without diagnosis and proper treatment, infected individuals serve as as reservoir for spreading infections and are at risk for serious sequelae such as pelvic inflammatory disease, ectopic pregnancy and infertility for women, and epididymitis, urethritis and sterility for men. Diagnostic tests are necessary to specifically identify patients infected with these diseases so that proper anti-microbial therapy can be initiated to prevent morbidity and reduce medical costs. Nucleic acid amplification tests (NAAT) are not only more sensitive than other methods, but also effective for screening non-invasive clinical samples such as first catch urine. NAAT assays, designed to operate on high-throughput platforms, are sensitive for screening programs to identify infected individuals.

Answers for life.

CT/GC multiplex detection and the power to do more

The VERSANT® CT/GC DNA 1.0 Assay* (kPCR) is a kinetic polymerase chain reaction assay for detection of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (GC) in both symptomatic and asymptomatic individuals. This assay is performed on the VERSANT® kPCR Molecular System* and provides:

Outstanding Assay Performance

- Increased DNA recovery and reproducibility through proprietary sample extraction technology
- Unique external quality control materials using heat labile CT and GC cells mimic specimen
- Reduces risk of false negative results with internal control (IC) to monitor PCR inhibition
- Minimal sample input volume of 250 uL facilitates repeat testing

System Reliability

- Uracil-N-glycosylase (UNG) chemical contamination control reduces risk of contamination
- Accurate liquid delivery with unique TADM (Total Aspiration and Dispense Monitoring) technology

Workflow Efficiency

- Multiple testing options with dual detection of both CT and GC or CT only
- 188 patient results per shift
- Universal sample preparation for urine and swab specimens
- No centrifugation or offline processing of specimens

Optimal Sensitivity

The sensitivity (LoD) of the VERSANT CT/GC DNA 1.0 Assay (kPCR) was unchanged when samples with low copy numbers of either CT or GC were in the presence of high copy numbers of the opposite analyte.

	Analyte Detection Rate								95% one-sided Lower CI	
	Lot 1		Lot 2		Lot 3		Lots Combined		Lots Combined	
	Urine	Swab	Urine	Swab	Urine	Swab	Urine	Swab	Urine	Swab
CT	98.88% (88/89)	98.92% (92/93)	100% (94/94)	97.87% (92/94)	100% (94/94)	100% (94/94)	99.64% (276/277)	98.93% (278/281)	98.30%	97.26%
GC	98.92% (88/89)	98.92% (92/93)	100% (94/94)	100% (92/94)	100% (94/94)	100% (94/94)	99.64% (276/277)	99.64% (278/281)	98.32%	98.32%

Data from Nexus Global Solutions: Jan 2009.

Assay Workflow

Hands-on time
40-65 minutes

VERSANT kPCR SP Module Sample Extraction
3.0 hours

VERSANT kPCR AD Module Amplification and detection
1.75 hours

Total run time to result = 94 samples in 5.5 to 6 hours
Next run can start when PCR plate is transferred to the VERSANT® kPCR AD Module

Method Comparison: Siemens VERSANT CT/GC DNA 1.0 Assay (kPCR) versus Gen-Probe APTIMA Combo 2® Assay

The VERSANT CT/GC DNA 1.0 Assay (kPCR) has > 99% agreement with the APTIMA Combo 2 Assay.

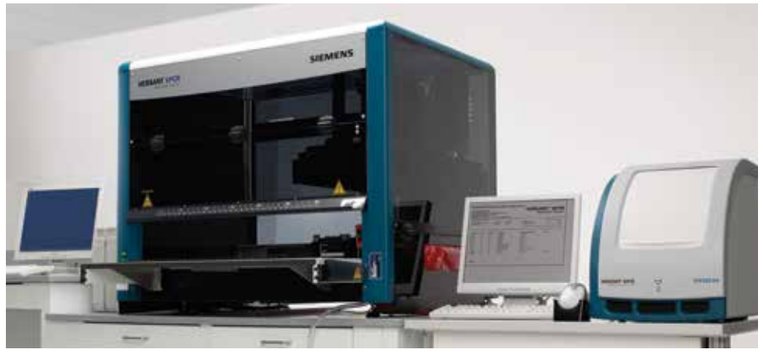
CT Urine		APTIMA	
		+	–
Siemens	+	160	0
	–	6	1291
Percent Agreement:		99.6%	
Positive Percent Agreement:		96.4%	
Negative Percent Agreement:		100%	

CT Swab		APTIMA	
		+	–
Siemens	+	161	1
	–	13	1283
Percent Agreement:		99.0%	
Positive Percent Agreement:		92.5%	
Negative Percent Agreement:		99.9%	

GC Urine		APTIMA	
		+	–
Siemens	+	59	2
	–	0	1397
Percent Agreement:		99.9%	
Positive Percent Agreement:		100%	
Negative Percent Agreement:		99.9%	

GC Swab		APTIMA	
		+	–
Siemens	+	60	2
	–	1	1394
Percent Agreement:		99.8%	
Positive Percent Agreement:		98.4%	
Negative Percent Agreement:		99.9%	

Data Source: Siemens Healthcare Diagnostics 2009 CE-Mark Registration Clinical Trial Data



Ordering Information*

Catalog No.	Description
10470126	VERSANT CT/GC 1.0 Assay (kPCR) Kit, including Extraction
10467524	VERSANT kPCR Molecular System
10489960	VERSANT Urine Transport Kit (UTK)
10378895	VERSANT Urine Transport Replacement Green Cap Kit
10486166	VERSANT Female Swab Collection Kit
10486167	VERSANT Male Swab Collection Kit
10378896	VERSANT Swab Transport Replacement Cap Kit

*IVDD, CE marked. Not available for sale in the U.S. Product availability varies from country to country and is subject to local regulatory requirements.

For additional information, contact your Siemens Healthcare Diagnostics representative.

VERSANT CT/GC DNA 1.0 Assay (kPCR) Performance and Specifications†

Target Region

- CT Cryptic plasmid outside of 377 bp deletion; detects Swedish variant
- GC pivNG gene - highly-conserved, multiple-copy gene results in high sensitivity and specificity

Sensitivity

- CT 342 copies/mL (0.34 IFU/mL)
- GC 137 copies/mL (2.3 cells/mL)

High Specificity

- No cross-reactivity with 178 organisms††

Potentially Interfering Substances

- No interference with 21 substances

Inclusivity

- 100% detection of 15 CT serovars and 46 GC strains

High Throughput

- 188 patient results per shift

Specimen Types

- Endocervical
- Patient-collected vaginal
- Male urethral swabs
- Male and female urines

Collection Devices

- VERSANT Urine Transport Kit (UTK)
- VERSANT Female Swab Collection Kit
- VERSANT Male Swab Collection Kit
- Commercially-available M4RT

†Specifications are from Siemens Healthcare Diagnostics R&D testing during development as well as from the CE Registration clinical trial.
††Several strains of N. cinerea were tested and gave negative results. However, cross-reactivity may occur when genetic recombination results in strains of N. cinerea that include some or all of the pivNG gene.