Evaluation of the novel *artus*® CT/NG QS-RGQ assay (QIAGEN) for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

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Introduction and purpose.

Chlamydia trachomatis and *Neisseria gonorrhoeae* are the agents of the two most prevalent bacterial sexually transmitted infections (STIs) worldwide reported. Therefore, access to diagnostic tools that facilitate identification of these infections is critical to sexually transmitted infection control efforts. Nucleic acid amplification tests (NAATs) are now recommended as the tests of choice. Here we investigated the clinical performance of the novel *artus*® CT/NG QS-RGQ assay (QIAGEN) in comparison to the VERSANT® CT/GC DNA 1.0 assay (Siemens), at present the screening method of choice in the Microbiology Laboratory of St. Orsola University Hospital, Bologna.

Methods.

Study group. A total of 467 unselected consecutive specimens, submitted for routine *C. trachomatis* and *N. gonorrhoeae* testing to the Microbiology Laboratory of St. Orsola University Hospital, were retrospectively studied. In particular, 225 specimens were obtained from patients attending the STDs Outpatients Clinic of St. Orsola University Hospital, whereas 242 samples were obtained from patients attending gynaecologic clinics or general practitioners offices.

NAATs. The specimens were first tested by the VERSANT® assay then, within a week, they were analyzed by the *artus*® CT/NG QS-RGQ assay. The *artus*® kit has been designed to be used with the QIAsymphony RGQ, providing a complete CE-IVD-compliant workflow, from sample to result.

QIAsymphony RGQ MDx is a modular system for cost-effective handling of entire laboratory workflows. The three modules are QIAsymphony SP for sample preparation, QIAsymphony AS for assay setup, and QIAGEN's real-time PCR detection platform Rotor-Gene Q MDx

The samples scored reactive for chlamydia or gonococcus by at least one of the two commercial NAATs were then analyzed with home-made methods. In particular, for chlamydia a RFLP analysis of the amplified gene *omp1* was chosen, while for *N. gonorrhoeae* a PCR targeting *porA* gene was used.

For a more comprehensive overview of the performance of the two commercial kits, samples belonging to the panels of QCMD 2014 *C. trachomatis* DNA EQA Programme B and QCMD 2014 *N. gonorrhoeae* DNA EQA Programme B, respectively (www.QCMD.org) were tested.

QCMD 2014 Chlamydia trachomatis DNA EQA Programme B - Individual Report

Thank you for participating in this QCMD EQA Programme. Listed below are the panel codes and sample contents of the EQA panel you received.

Expected results of the programme in order of sample content

Sample	Matrix *	Sample Content	Qualitative †	Copies/ml †	Ct values †
CT14B-03	Urine	C.trachomatis (LGV)	Pos 2/3 (66.7%)	537	38.73
CT14B-05	Urine	C.trachomatis (LGV)	Pos 0/3 (0%)	LoD	ND
CT14B-04	Urine	C.trachomatis (Non LGV)	Pos 3/3 (100%)	4980	35.44
CT14B-01	Urine	C.trachomatis Swedish strain	Pos 3/3 (100%)	1410000	27.10
CT14B-02	Urine	C.trachomatis Negative	Neg 3/3 (100%)	-	-
CT14B-06	Urine	C.trachomatis (LGV)/N.gonorrhoeae	Pos 3/3 (100%)	8620	34.63
CT14B-09	Sim.Swab	C.trachomatis (LGV)	Pos 3/3 (100%)	424	38.58
CT14B-08	Sim.Swab	C.trachomatis (LGV)	Pos 2/3 (66.7%)	79	41.07
CT14B-07	Sim.Swab	C.trachomatis (LGV)	Pos 0/3 (0%)	LoD	ND
CT14B-10	Sim.Swab	C.trachomatis Negative	Neg 3/3 (100%)	-	-

QCMD 2014 Neisseria gonorrhoeae DNA EQA Programme B - Individual Report

Thank you for participating in this QCMD EQA Programme. Listed below are the panel codes and sample contents of the EQA panel you received.

Expected results of the programme in order of sample content

Sample	Matrix *	Sample Content	Qualitative †	Copies/ml †	Ct values †
NG14B-02	Urine	N.gonorrhoeae (S149226)	Pos 2/2 (100%)	6854	37.50
NG14B-05	Urine	N.gonorrhoeae (S149226)	Pos 2/2 (100%)	4361	37.74
NG14B-03	Urine	N.gonorrhoeae (S149226)	Pos 0/2 (0%)	LoD	ND
NG14B-04	Urine	N.gonorrhoeae (LvI Ng PorA))	Pos 2/2 (100%)	1999	39.01
NG14B-01	Urine	N.gonorrhoeae Negative	Neg 2/2 (100%)	-	-
NG14B-08	Sim.Swab	N.gonorrhoeae Negative	Neg 2/2 (100%)	-	-
NG14B-09	Sim.Swab	N.gonorrhoeae (S149226)	Pos 2/2 (100%)	59814	33.27
NG14B-06	Sim.Swab	N.gonorrhoeae (S149226)	Pos 2/2 (100%)	8581	36.68
NG14B-10	Sim.Swab	N.gonorrhoeae (S149226)	Pos 2/2 (100%)	7153	36.45
NG14B-07	Sim.Swab	N.gonorrhoeae (S149226)	Pos 2/2 (100%)	439	40.61

Results.

Out of the clinical 467 specimens, 26 (5.6%) and 13 (2.8%) were found positive by both the two NAATs, for *C. trachomatis* and *N. gonorrhoeae*, respectively.

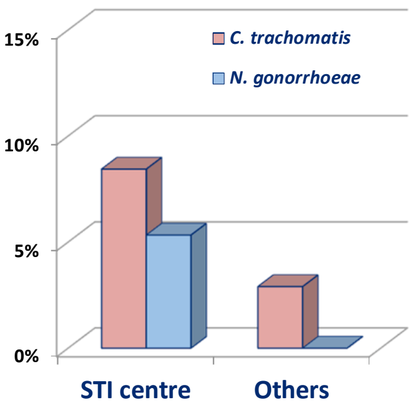
It should be underlined that no clinical samples gave inhibition problems, even if there were 16 extra-genital specimens. In particular, 5 pharyngeal and 11 rectal secretions, collected with E-Swab™ (Copan), were tested. Finally, it is worthy of note that the 451 urine specimes tested by both the NAATs were collected by using Siemens VERSANT® Urine Transport Kit and that these devices gave no interfering or inhibition problems when tested by the *artus*® kit.

C. trachomatis	artus® CT/NC QS-RGQ assay			
VERSANT® CT/GC DNA 1.0 assay		Negative	Positive	Total
	Negative	442	3	445
	Positive	1	31	32
	Total	443	34	477

***C. trachomatis*: agreement 99,2%**

N. gonorrhoeae	artus® CT/NC QS-RGQ			
VERSANT® CT/GC DNA 1.0 assay		Negative	Positive	Total
	Negative	457	1	458
	Positive	0	19	19
	Total	457	20	477

***N. gonorrhoeae*: agreement 99,8%**



Prevalence (%) of *C. trachomatis* and *N. gonorrhoeae* infections in patients attending the STI centre and in low-risk subjects, respectively.

Conclusion.

NAATs are the most sensitive assays available to date for detecting chlamydia and gonorrhea in clinical specimens and the *artus*® CT/NG QS-RGQ assay adds to the group of commercially available assays that are available to laboratories as choices for superior diagnostic performance.

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