P0362

Paper Poster Session II

Urogenital and sexually transmitted infections

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

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Objectives. *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections are the most common bacterial sexually transmitted diseases (STDs) worldwide, representing important problems of public health. Nucleic acids amplification techniques (NAATs), widely considered the "Gold standard" tests, have been shown to be reliable, fully-automated, and high-throughput methods.

Here we investigated the clinical performance of the novel artus® CT/NC 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. 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.

First the specimens were tested by the VERSANT® assay, then they were analyzed by the artus® CT/NC 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.

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.

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. Considering all the specimens (i.e. clinical and external quality control samples), the agreement between the artus® CT/NC QS-RGQ assay and the VERSANT® CT/GC DNA 1.0 assay was 99.2%, when *C. trachomatis* data were considered, while it rose to 99.8%. when *N. gonorrhoeae* data were analysed.

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.

Conclusion. NAATs have become the reference method for *C. trachomatis* and *N. gonorrhoeae* detection both on urogenital and extra-genital specimens. Considering the excellent ease of use and automation, the high samples throughput and its very good sensitivity and specificity, the artus® CT/NC QS-RGQ assay could represent an outstanding choice as screening test for the laboratory diagnosis of chlamydia and gonorrhoea infections.