

 Xpert® CT/NG Bibliography

## Performance of Xpert CT/NG

Tabrizi et al.

### **Analytical evaluation of Xpert CT/NG, the first genetic point of care assay for simultaneous detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae***

JCM 2013 00806-13

- To evaluate the analytical sensitivity and specificity of this new POC assay, in particular to evaluate cross reactivity with non-gonococcal *Neisseria* species or other closely related bacteria.
  - » All 15 serovars of CT were detectable down to 10 copies per reaction, giving a CT sensitivity of 100% (95%CI: 78.2-100%). GX CT/NG assay was able to detect the Swedish variant at the same analytical sensitivity.
  - » All 10 NG isolates were also detectable down to 10 copies per reaction, giving a NG sensitivity of 100% (95%CI: 69.2-100%). Of the 118 commensal *Neisseria* tested, all were NG negative on GX CT/NG assay, giving a NG specificity of 100% (95%CI: 96.9-100%). Three *N. mucosa* strains out of 11 strains tested and one *N. subflava* strain out of 27 strains tested showed positivity with one of two NG targets. As the assay requires positivity by both targets, these strains were interpreted as negative.

Gaydos et al.

### **Performance of Cepheid Xpert CT/NG Rapid PCR Test for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae***

JCM.03461-12, March 2013

- Objective of this study was to estimate the performance characteristics of the Xpert CT/NG using the PIS obtained by using Aptima Combo/Tigris and BD CT/NG on BD Viper.
- Xpert assay CT/NG superior diagnostic performance.
- Rapidity of the assay, valuable for clinic-based testing.
- Results can be used to immediately treat infected patients.

Tabrizi et al.

### **Assessment of direct addition of urine to GeneXpert CT/NG Assay cartridges for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae***

IUSTI Melbourne, October 2012

- The analytical sensitivity of Xpert CT/NG is not altered when urine is directly added into the Xpert cartridge.



## Impact of Xpert CT/NG on the Laboratory Workflow

[De Maria et al.](#)

### **Evaluation of a 2nd generation of real time PCR system for the rapid diagnosis of *Chlamydia trachomatis*: impact on laboratory workflow**

Poster presented at the world congress STI in Vienna in July 2013

- GX has simplified the laboratory workflow ensuring standardization, accuracy and reliability of analytical data.
- The value of SAC was relevant to support the quality of sampling in order to avoid false negative results due to insufficient cells to detect.

[Pascarella et al.](#)

### **Improvement in laboratory workflow with the new generation of real-time polymerase chain reaction (RT-PCR) test for the rapid diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae***

Publication only at ECCMID in Berlin in April 2013

- The aim of this study was to evaluate the improvement in laboratory workflow through the use of this new generation of molecular assay in comparison with current traditional Real Time PCR method used (Alert q-PCR ELitech, Nanogen).
- GeneXpert has simplified the laboratory workflow ensuring standardization, accuracy and reliability of analytical data

[Hammami et al.](#)

### **Economical and organizational interests for the acquisition of a PCR (Cepheid GeneXpert) Molecular Biology for performing laboratory tests**

RICAI Paris, November 2012

- Sensitivity and specificity on GeneXpert are better, compared with the techniques previously used in our laboratory.
- The acquisition of the GeneXpert System has proved to be profitable for STI screening and *C. difficile*, and it is interesting for the additional assays that can be used on the same instrument.
- Easy to use, easy sampling, easy storage, easy training, reduced TAT.



## Impact of Xpert CT/NG on the Management of Emergency Situations

Jauréguy et al.

### **Interest of the Cepheid Xpert CT/NG assay to rapid detection and differentiation of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) urogenital infections**

Poster presented at the world congress STI in Vienna in July 2013

- Results revealed a global prevalence (9.1 %) of CT infections, this percentage being higher in women screened for induced abortion (15.8%).
- Many clinicians tend to only request testing for C, results of this study demonstrate the value of the detection of both CT and NG by Xpert CT/NG specifically for the induced abortion population (3.4%).
- This new test allows a more rapid, accurate detection and optimizes the management of STIs by clinicians enabling targeted antibiotic treatment. Furthermore, the screening of asymptomatic population helps also to reduce the transmission and is a more cost effective alternative in screening settings.

Dubouix et al.

### **Contribution of Xpert CT/NG (GeneXpert) in the management of pelvic infection disease in women**

Poster presented at ECCMID in Berlin in April 2013

- The use of Xpert CT/NG is perfectly suitable for the rapid detection of bacteria responsible for major pelvic infections in women.
- It is perfectly adaptable in emergency situation, allowing the most appropriate antibiotic therapy accordingly.

Doucet-Populaire et al.

### **Interest of Xpert CT/NG assay for detection of simultaneous *Chlamydia trachomatis* and *Neisseria gonorrhoeae* at the time of pre-abortion consultation**

Poster presented at ECCMID in Berlin in April 2013

- Appropriate, reliable and rapid diagnostic tools should be adopted in order to improve the management of practices in pregnancy termination centers.
- The aim of the study was to evaluate the benefit of systematic C. trachomatis and N. gonorrhoeae screening by Xpert CT/NG assay at the time of pre-abortion or emergency contraception consultation.
- Xpert CT/NG is well suited for women in pre-abortion consultation due to its rapid turnaround time and easy-to-use format.
- Establish in hospital the “screen-and-treat” strategy in which all women presenting for abortion are screened for genital infections and only those with positive results are treated.



## Xpert CT/NG and Related Performance with Off Label Samples

[Jenson et al.](#)

### **Field Evaluation of the Cepheid Xpert Chlamydia trachomatis assay for Detection of Infection in a Trachoma Endemic Community in Tanzania**

PLOS Neglected Tropical Diseases, July 2013

- To determine the sensitivity, specificity, and field utility of the Cepheid Xpert Chlamydia trachomatis (CT).
- Assay (Xpert) for ocular chlamydia infection compared to Roche Amplicor CT assay (Amplicor).
- The Xpert test for *C. trachomatis* performed with high sensitivity and specificity and demonstrated excellent promise as a field test for trachoma control.

[Rebec et al.](#)

### **Comparison of two molecular platforms for the confirmation of *Neisseria gonorrhoeae* screening test positive extra-genital samples**

Poster presented at ECCMID in Berlin in April 2013

- Comparing the performance of the Xpert Chlamydia trachomatis/ *Neisseria gonorrhoeae* (CT/NG) assay and a dual target multiplex PCR run on the BDMax™ analyser against the current confirmation protocol, with the aim to determine the most suitable method for the confirmatory testing of NG screening test positive extra-genital samples for laboratory.
- The BDMax can be run in smaller batches throughout the day whereas the GeneXpert is a random access system, with no batching required. **We opted for the GeneXpert** as it was found to be the most suitable for our needs as it:
  - » fits in with the working pattern of our lab (24/7)
  - » has the highest sensitivity and NPV
  - » is easiest to use
  - » contains a comprehensive control system
  - » is a dual CT/NG assay

[Goldenberg et al.](#)

### **Performance of the Xpert CT/NG assay compared to the Aptima AC2 assay for detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* using residual Aptima rectal samples**

J. Clin. Microbiol 2012, 50(12):3867

- The Xpert CT/NG test is well suited for near patient testing due to its rapid turnaround time and ease of use.
- Despite significant dilution of samples prior to Xpert testing, the assay performed well with excellent specificity.
- The Xpert CT/NG assay appears to be sensitive and specific for use with rectal swabs.

[Dize et al.](#)

### **Comparison of the Cepheid Xpert CT/NG Assay to Roche Amplicor CT Assay and the Abbott m2000 Real-Time CT Assay for Detection of *Chlamydia trachomatis* in ocular samples from Tanzania**

ASM San Francisco, June 2012 and JCM.00519- March 2013

- Xpert CT/NG RUO Assay presented an excellent sensitivity and specificity when compared to the Roche Amplicor CT assay for the detection of *Chlamydia trachomatis* in ocular samples.
- It shows early promise as a POC field test for ocular swab specimens in Tanzania.



## Impact of Xpert CT/NG in Reducing Cross-Contamination between Different NG Species with a Dual Target for NG

Lapucci et al.

### Performance and laboratory workflow impact comparison of the Cepheid Xpert CT/NG assay on GeneXpert System and the Gen Probe Aptima Combo 2 assay on the Panther System for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*

ICAAC Denver, September 2013

- The two assays have identical performances to detect *Chlamydia trachomatis*.
- GeneXpert assay detects a *Neisseria gonorrhoeae* positive sample missed by Aptima® assay.
- GeneXpert assay voids a sample that lacks SAC, while Aptima assay gave a false negative result.
- GeneXpert assay permits to have results in almost 90 minutes compared to 4 hours of Panther® system.
- GeneXpert has simplified the laboratory workflow ensuring standardization, accuracy and reliability of analytical data.

De Barbeyrac et al.

### *Chlamydia trachomatis/Neisseria gonorrhoeae* detection in duplex: should we verify NG positive samples?

RICAI Paris, November 2012

- In confirming NG results discordant between culture and Abbott m2000 System (using GeneXpert and Roche Cobas® 4800), Cepheid Xpert CT/NG has the best performance.
- When using a test with only one target for NG, it is recommended to confirm NG PCR positive results in populations with very low prevalence (<1%).

## Health Economics

Turner et al.

### What are the costs and benefits of point of care tests for *Chlamydia trachomatis* and *Neisseria gonorrhoeae* in GUM?

Poster presented at the world congress STI in Vienna in July 2013

- Point of care test pathways could be cost-saving if implemented in GUM clinics.
- Presumptive treatment of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* accounts for a large number of unnecessary antibiotic prescriptions.
- National guidance is required to enable clinics to make informed choices about the implementation of new pathways.

Adams et al.

### Can point of care *Chlamydia trachomatis* and *Neisseria gonorrhoeae* test pathways reduce GUM costs & improve outcomes?

Poster presented at the world congress STI in Vienna in July 2013

- New patient pathways using chlamydia/gonorrhoea POC NAATs are likely to be more efficient and cost saving compared to standard pathways.
- This can offer benefits to patients who can be treated faster and more appropriately on the same day of their test.



## Women's Health Poster: Xpert GBS and Xpert CT/NG

Di Renzo et al.

### **Xpert GBS and Xpert CT/NG PCRassays as innovative tools for cervico-vaginal infections' screening?**

Poster presented at the world congress STI in Vienna in July 2013

- Real time PCR assay is a rapid and highly accurate test to identify GBS, CT and NG infections compared to culture based screening. Therefore it can be used at the time of labor reducing the work required by the personnel.
- It is easy to use; everyone of the staff can run it (senior, residents, midwives, nurses).
- It reduces the economic impact of health care costs.
- It could enhance the exact identification of candidate for antibiotic therapy, including women with preterm rupture of membranes or preterm labor.

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