Performance of Portuguese laboratories in Labquality/PNAEQ EQA schemes for *N. gonorrhoeae* and *C. trachomatis* nucleic acid detection

Helena Correia[2]; Jonna Pelanti[1]; Rita Silva[2]; Cristina Brito[2]; Ana Faria[2]
[1]Labquality, Finland; [2]Programa Nacional de Avaliação Externa da Qualidade, Portugal

INTRODUCTION

The **National External Quality Assessment Program** (PNAEQ) includes the National Health Institute Dr. Ricardo Jorge (INSA, IP), which is legally responsible for the promotion, organization and coordination of External Quality Assessment Laboratory programs.
PNAEQ has been collaborating with the Finnish peer **Labquality**, since 2000.
In 2013 a Consortium between the two entities was signed, seeking closer working relationships, and the promotion of research and development in the area of external quality assessment.

The participation of laboratories in interlaboratory EQA schemes not only facilitates diagnosis, therapeutic monitorization, and quality assessment and guidance, but it also improves performance and increases the laboratory quality level, which will directly benefit the patient.
Proficiency testing programs play a key role in the evaluation of clinical laboratories and of manufactured tests but, in the case of molecular biology testing, it is yet complicated to evaluate EQAS programs.

The *Chlamydia trachomatis* and *Neisseria gonorrhoeae* nucleic acid detection EQA schemes were chosen for the evaluation of the performance of the Portuguese laboratories in the field of molecular biology.
C. trachomatis and *N. gonorrhoeae* are responsible for urogenital infections causing cervicitis in women and urethritis in both men and women. Infections are mainly asymptomatic (~40% of men and ~70% of women for *C. trachomatis,* and ~10% of men and ~60% of women for *N. gonorrhoeae*). Therefore, most cases remain undetected and untreated, and can progress to serious complications, especially in women, such as pelvic inflammatory disease, tubal infertility and ectopic pregnancy, justifying the need for using very sensitive molecular biology methods for their screening and diagnosis.

OBJECTIVES

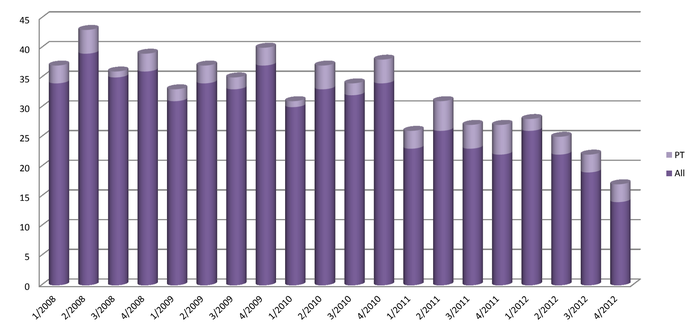
We present the performance of Portuguese laboratories participating in the Labquality/PNAEQ organized EQA for *C. trachomatis* and *N. gonorrhoeae* nucleic acid detection. We analyzed which methods were used to determine *C. trachomatis* and *N. gonorrhoeae* in the last 5 years (2008-2012) and compared performances between Portuguese participants and participants from other European countries.

METHODS

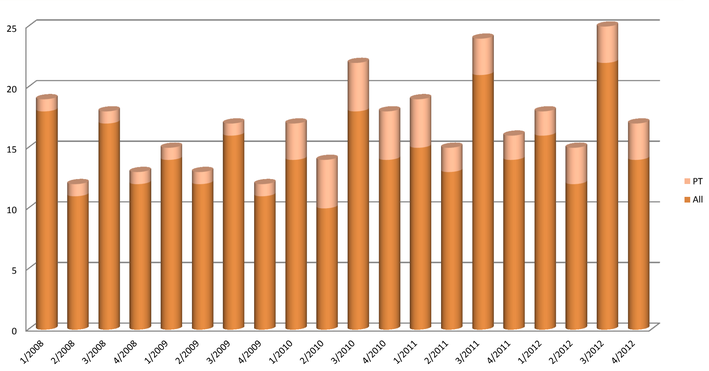
In the EQA schemes included in this retrospective study (2008-2012) three trial samples were distributed quarterly each year to the participating laboratories. Trial samples were swabs or liquid specimens, with or without *C. trachomatis* and with or without *N. gonorrhoeae*. Participating laboratories should follow a protocol provided by Labquality- PNAEQ for specimen handling, and should return their results in absorbance values and also provide the corresponding interpretation (positive/negative). In the last couple of years the participants were also asked to give information concerning positive results confirmation testing.
Labquality provided the expected results and the performance achieved to each participating laboratory, together with a global evaluation (including statistical analysis).
The results of the Portuguese laboratories regarding EQA for *C. trachomatis* and *N. gonorrhoeae* nucleic acid amplification testing were analyzed in comparison to the obtained in other countries for the same trials.

RESULTS

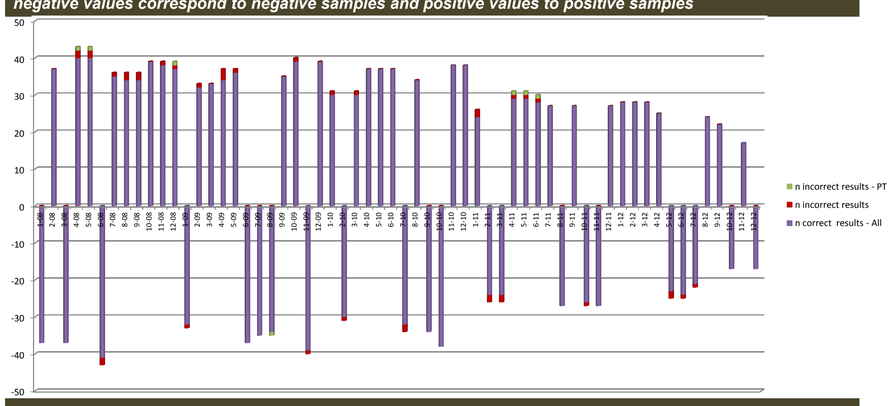
1 Participation of Portuguese laboratories for *C. trachomatis*



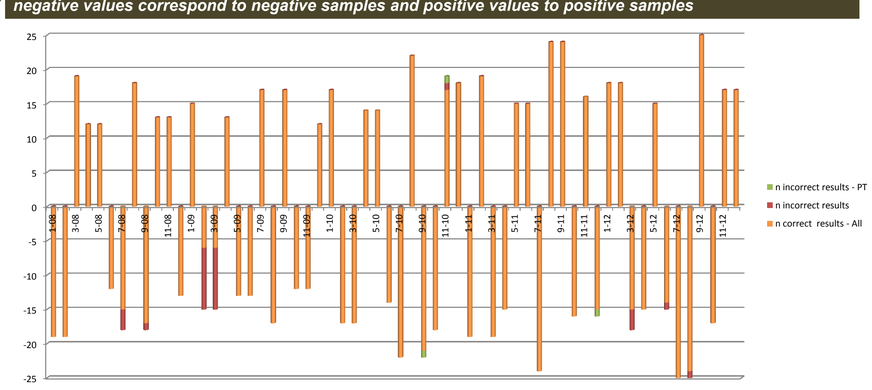
2 Participation of Portuguese laboratories for *N. gonorrhoeae*



3 Number of correct and incorrect answers for *C. trachomatis*.
negative values correspond to negative samples and positive values to positive samples



4 Number of correct and incorrect answers for *N. gonorrhoeae*.
negative values correspond to negative samples and positive values to positive samples



_In Portugal, eight laboratories participated in *C. trachomatis* and seven in *N. gonorrhoeae* nucleic acid amplification EQA schemes.
_The graphics **1** and **2** exhibit the Portuguese participation in both schemes. Graphics **3** and **4** evidence the composition of the trials (pos/neg) and the correct/incorrect results obtained for *C. trachomatis* and *N. gonorrhoeae*.
_60% incorrect results were reported for the *N. gonorrhoeae* survey, coinciding with samples containing *N. cinereae* (sample 2 and 3 of 2009)
_Portuguese participants mainly used five to six different methods for the detection of *C. trachomatis* and *N. gonorrhoeae*; for both, the Amplicor (Roche) was the most frequently used.
_The majority of the results were consistent with the composition of the trial sample.

CONCLUSIONS

Although the performance of laboratories was globally good, the number of laboratories participating in nucleic acid amplification EQA trials in Portugal is very low, emphasizing the need for a wider and nationwide participation.
The results show that PNAEQ participating laboratories performance is much similar to the observed in other countries.
All throughout the years we observed a change in the methods used among the participants from BD ProbeTec ET CT/GC and Amplicor to several different new test kits (GenProbe Aptima-combo 2 and Abbott RealTime).
The performance of participants was better for *N. gonorrhoeae* EQA trials, evidencing the need for monitoring performance in order to implement better practices that should overcome technical or personal failures.

References

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2) The epidemiology of Neisseria gonorrhoeae in europe. Yvonne van Duynhoven. Microbes and infection, 1, 1999.
3) Partner notification for Chlamydia trachomatis urogenital infections: eight years of patient referral experience in the major Portuguese sexually transmitted infections clinic, 2000-07. I Santo, J Azevedo, B Nunes, JP Gomes, MJ Borrego. International Journal of STD & AIDS 2011

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