INTRODUCTION & PURPOSE

Rapid diagnostics for *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG) are necessary to guide therapeutic decision-making. The Xpert CT/NG assay is a 90-min real-time PCR test for CT and NG detection in urine and genital samples collected in the Cepheid transport medium.

In many laboratories, the eSwab with Amies transport medium (1 ml) (Copan) is used to collect genital specimens and to maintain bacterial viability throughout the transport process. This collection system offers the advantage of performing molecular tests and bacterial cultures on the same sample. However, the sample volume (1 ml) needed to perform the Xpert CT/NG test requires a dilution of eSwab samples.

Therefore, this study aims to validate the Xpert CT/NG assay for CT and NG detection in genital eSwab samples diluted 1:2 with saline (0.45% NaCl).

METHODS

- **The analytical performance** of the Xpert CT/NG assay for CT/NG detection in diluted eSwab samples was determined by limit of detection (LOD with 95% hit rate), accuracy and precision. Accuracy and precision was monitored by the analysis of external quality control samples.
- **The rate of invalid results** in this medium was assessed by analyzing 166 diluted genital samples in daily routine.
- An alternative sample pretreatment procedure was evaluated to minimize the occurrence of invalid results and to avoid costly repeat testing. Subsequently, the impact of this procedure on the LOD of the assay was analyzed.

RESULTS

- **Analytical performance**

  The LOD of the Xpert CT/NG assay was 25 copies/ml and 312 copies/ml for CT and NG, respectively.

  The 2013 QCMD panel for detection of CT and NG was used to check for **accuracy** and the obtained results correlated excellently with the reference results.

  The **precision** of the assay was high between runs with standard deviations lower than 1 Ct for weak positive samples (i.e. 10x LOD). These samples were tested in triplicate on two different days.

  - The Xpert CT/NG assay had an **invalid rate** of 15.7% (26/166) over a 2-month period of routine use.
  - A one-time **freeze-thaw cycle** with a freezing step at -70°C of at least 15 min markedly reduced these invalids by 81% without any impact on the LOD of the assay.

CONCLUSION

1. Because of the sample volume (1 ml) required for the Xpert CT/NG assay, eSwab samples have to be diluted 1:2 with saline (0.45% NaCl).
2. The Xpert CT/NG assay is **highly sensitive** for the detection of CT and NG in genital specimens collected by eSwab in Amies transport medium.
3. Invalid results can be avoided by subjecting all samples to a one-time **freeze-thaw cycle** with a pre-analytical freezing step (-70°C) of at least 15 min. This does not affect the LOD.