MolecularDiagnostics.be 2014 external quality control scheme on the molecular detection of Mycoplasma genitalium and Trichomonas vaginalis

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Mycoplasma genitalium (MG) and Trichomonas vaginalis (TV) infections are considered important emerging sexually transmitted infections potentially associated with reproductive tract sequelae, PID, preterm labor, infertility, non-gonococcal urethritis, epididymitis, and prostatitis.

No external quality assessment schemes were available in 2014 for the detection of MG and/or TV. One of the goals of the non-profit organization MolecularDiagnostics.be is to provide quality control samples especially for these parameters where QC samples are not readily available.

The current MG/TV ring test was build-up of (i) four diluted MG/TV DNA samples (Vircell Amplirun) enabling to estimate the sensitivity of the assay independently of extraction, (ii) a negative sample and (iii) six MG/TV positive clinical samples enabling to estimate the quality and efficiency of extraction and amplification.

Among the ten participating laboratories 4 different extraction robots were in use. The calculated equivalent of the original sample applied to the PCR reaction varied between 4.6µl to 100 µl. Results did not indicate that this higher input resulted in more sensitive reaction.

The target genes pdhD, MgPa, m219 and TV specific repetitive sequence, G3 hypothetical protein gene, beta tubuline gene were in use for the detection of MG and TV respectively.

All participating laboratories performed equally well in detecting 2.5 copies TV-MG DNA/µl indicating an efficient amplification process. However, considering the simulated clinical samples, where pre-analytical factors and extraction efficiency plays an additional but important role, some laboratories missed a few positive samples which is not correlated to the analytical sensitivity of the assay.