

# ***Trichomonas vaginalis* detection by NAAT: the analytical performance of the CE-IVD PRESTO TV 200 in comparison to an in house TV PCR**

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## **Introduction:**

*Trichomonas vaginalis* (TV) causes the most common non-viral sexual transmitted infection (STI) with annually 248 million new cases world-wide. Detection by NAAT assay is of importance for treatment and to prevent late complications.

## **Aim:**

To test the analytical performance of the new PRESTO TV200 in comparison to an in-house PCR

## **Results:**

### Analytical sensitivity

Concentration TV	Ct (mean ± SD; n = 20)
0.1 copies/ µl	34.71 ± 0.64
0.05 copies/ µl	36.28 ± 1.24
0.01 copies/ µl	16/20 Ct < 40

### Analytical specificity

All organisms gave negative results without cross reaction.

Actinomyces israelii	Epstein-Barr Virus	Neisseria mucosa
Bacteroides fragilis	Escherichia coli	Neisseria perflava
Branhamella catarrhalis	Gardnerella vaginalis	Neisseria polysaccharea
Candida albicans	Haemophilus influenzae	Neisseria sicca
Candida glabrata	Herpes simplex virus 1	Neisseria subflava
Candida krusei	Herpes simplex virus 2	Neisseria dentrificans
Candida parapsilosis	Klebsiella pneumoniae	Peptostreptococcus species
Candida tropicalis	Lactobacillus species	Proteus mirabilis
Chlamydia trachomatis	Legionella pneumophila	Pseudomonas aeruginosa
Citrobacter freundii	Morganella morganii	Serratia marcescens
Clostridium perfringens	Neisseria cinerea	Staphylococcus aureus
Cryptococcus neoformans	Neisseria elongata	Staphylococcus epidermidis
Cytomegalovirus	Neisseria flavescens	Streptococcus agalactiae
Enterobacter cloacae	Neisseria gonorrhoeae	Streptococcus pneumoniae
Enterococcus faecalis	Neisseria lactamica	Streptococcus pyogenes
Enterococcus faecium	Neisseria meningitidis	Yersinia enterocolitica

Microorganisms tested for specificity analyses



**PRESTO TV200**  
(Available Q1 2018)

## **Methods:**

### Analytical sensitivity:

A quantified stock culture from Vircell (14000 copies/µl) was used to make serial dilutions. To determine the limit of detection (LOD) 20 replicates were tested at the concentrations of 0.1, 0.05 and 0.01 copies/µl, see table 1.

### Analytical specificity

37 bacteria, 5 yeast, 1 protozoa and 4 viral strains that may be isolated from the urogenital tract were used.

### Assay Comparison

190 TV positive samples were collected between 2005 and 2016 at IZORE. 25 samples were from men (21 urines), most female samples were either Cervix/Vagina/Urethra (116) or urines (31). The in-house TV PCR of IZORE was compared on these TV positive samples to the CE-IVD certified PRESTO TV 200 (Goffin Molecular Technologies, NL).

## **Results**

### Assay comparison

13 samples were neg. in both assays mainly due to low titres. The other 177 samples were positive in both assays. Cp values between the two assays were very comparable (<1 CP) except for one sample (20vs32)

## **Conclusion:**

The CE IVD certified PRESTO TV 200 Assay had a 100% concordance with the in-house PCR. A large group of TV negative samples is currently being tested.

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