Comparison of the FTD™ Urethritis Plus (7-Plex) detection kit with routine nucleic acid amplification testing for detection of *Neisseria gonorrhoeae* and *Chlamydia trachomatis* in urine, vaginal, pharyngeal and rectal samples

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Background/ introduction

- In the majority of UK laboratories routine testing for *Chlamydia trachomatis*/*Neisseria gonorrhoeae* (CT/NG) uses a dual nucleic acid amplification test (NAAT) (1).
- Extended multiplex testing is increasingly available in microbiology laboratories for a range of pathogens.
- The FTD™ Urethritis Plus (FTDU) NAAT detects seven pathogens associated with urethritis:

<u>Definite association</u>
- *Neisseria gonorrhoeae*
- *Chlamydia trachomatis*
- *Mycoplasma genitalium*
- *Trichomonas vaginalis*
- *Ureaplasma urealyticum*

<u>Possible association</u>
- *Mycoplasma hominis*
- *Ureaplasma parvum*

Methods

Alongside routine clinical samples, additional samples (n=729) were taken from:
- Females (vulvovaginal swabs; VVS),
- Men-who-have-sex-with-women (MSW) (urine),
- Men-who-have-sex-with-men (MSM) (rectal and pharyngeal swabs; urine).

FTDU CT/NG results were compared with routine clinic NAAT results (BD Viper).

Results

	CT					NG				
Sample type (n)	Females (306)	MSW (175)	MSM Urine (80)	MSM Rectal (81)	MSM Pharynx (85)	Females (307)	MSW (175)	MSM Urine (80)	MSM Rectal (81)	MSM Pharynx (86)
Clinic NAAT Positivity % (95% CI)	8.2 (5.1-11.3)	20.6 (14.6-26.6)	6.3 (1.0-11.6)	7.4 (1.7-13.1)	2.4 (0-5.7)	1.6 (0.2-3)	6.9 (3.1-10.7)	17.5 (9.2.-25.9)	23.5 (14.0-32.7)	19.8 (11.3-28.1)
Sensitivity % (95% CI[a])	100 (86.3-100[b])	97.2 (85.5-100)	**80.0 (28.4-99.5)**	**83.3 (35.9-99.6)**	**50.0 (1.3-98.7)**	**80.0 (28.4-99.5)**	**91.7 (61.5-99.8)**	**64.3 (35.1-87.2)**	**78.9 (54.4-93.9)**	**64.7 (38.3-85.8)**
Specificity % (95% CI[a])	99.6 (98.0-100)	98.6 (94.9-99.8)	98.6 (92.7-100)	97.3 (90.7-99.7)	100 (95.6-100[b])	99.7 (98.2-100)	100 (97.8-100[b])	100 (94.6-100[b])	87.1 (76.1-94.3)	97.1 (89.9-99.6)
Positive Predictive Value (PPV) (95% CI[a])	96.2 (80.3-100)	94.6 (81.8-99.3)	**80.0 (28.4-99.5)**	**80.0 (28.4-99.5)**	100 (2.5-100[b])	**80.0 (28.4-99.5)**	100 (71.5-100[b])	100 (66.0-100[b])	**65.2 (42.7-83.6)**	**84.6 (54.6-98.1)**
Negative Predictive Value (NPV) (95% CI[a])	100 (98.7-100[b])	99.3 (96.0-100)	98.6 (92.7-100)	97.3 (90.7-99.7)	98.8 (93.5-100)	99.7 (98.0-100)	99.4 (96.6-100)	92.5 (84.3-97.7)	93.1 (83.3-98.1)	91.8 (83.0-96.9)

[a] Binomial Exact [b]one sided, 97.5% Confidence Interval

Discussion/ Conclusions

- For CT, the FTDU had high sensitivity for genital samples in MSW and females, and fulfilled the BASHH guidelines of a PPV >90% for a NAAT to be selected (2).
- For NG, the FTDU had poor sensitivity at all sampling sites except for MSW Urine. With PPVs <90% for females and MSM extra genital sites, supplementary testing would be required to confirm a positive NG diagnosis according to BASHH guidelines.
- FTDU would not be suitable for extra-genital testing owing to its poor sensitivity and PPV for both CT and NG with the exception of the PPV for CT detection in the pharynx.
- Further work is required to establish FTDU's accuracy for detecting the other organisms on its panel.

References

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