

Comparison of the Sysmex UF-5000 urine flow cytometer to urine leukocyte esterase and urethral Gram stain in the detection of urethritis in men

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Background: Urethritis (urethral inflammation) is a common condition encountered in primary care and sexually transmitted infection (STI) clinics. Urethritis diagnosis requires evidence of inflammation. The Centers for Disease Control (CDC) recommends testing for increased white blood cells (WBCs) by urethral Gram stain smear (GSS) or the presence of leukocyte esterase (LE) by urinalysis. However, the urethral swab procedure is invasive while the LE assay is insensitive. We compared the performance of the Sysmex UF-5000 urinary flow cytometer to LE, urethral GSS, and a clinical diagnosis of urethritis.

Methods: Remnant urine specimens collected from males aged 18 and older who presented to the Bell Flower STI Clinic in Indianapolis with STI symptoms, for STI treatment, or screening were analyzed. WBC/ μL urine was determined using the UF-5000 and LE was determined by urinalysis. Demographic and clinical metadata were abstracted from the electronic medical record. Welch t-tests were performed to assess statistical significance (p -values < 0.05).

Results: Five-hundred fifty (550) specimens were included in this study. Participants' median age was 32 (range 18-74), 46% were Black, 35% were White, and 79% were non-Hispanic. 64% identified as heterosexual and 26% as men who have sex with men. The UF-5000 mean WBC count was elevated in participants who had a positive LE (676 vs 27 WBCs/ μL , $p=0.0007$), reported urethritis symptoms (162 vs 29 WBCs/ μL , $p=0.0024$), had ≥ 5 WBCs per high-power field by GSS microscopy (507 vs 39 WBCs/ μL , $p=0.0032$), and were diagnosed with urethritis (382 vs 27 WBCs/ μL , $p=0.0011$).

Conclusions and Implications: The Sysmex UF-5000 detected increased WBCs in men with confirmed urethritis and could be a rapid, non-invasive point-of care-test for urethritis. Future studies will define the assay performance (ROC curves) to identify optimal WBC cut-offs to diagnose urethritis and predict specific STIs, caused by *N. gonorrhoeae* or *C. trachomatis*.