



# Comparison of clinical specimens collected with ESwab to Affirm collection kits for the detection of bacterial vaginosis using the the *Affirm*<sup>TM</sup> VPIII Microbial Identification assay.



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## Background

Currently molecular platforms for the detection of sexual transmitted infections use their own collection devices that are unsuitable for culture or other testing methods. Collection devices that allow multiple testing methods are practical for confirmatory testing or testing for other targets with the same specimen. ESwab, (a tube with 1.0 ml liquid Amies and a flocked swab) is a Liquid Based Microbiology device that can be used with the Walk Away Specimens Processor (WASP) and is also compatible with molecular assays. The study objective was to compare the performance of ESwab with the collection Swab supplied with the BD Affirm<sup>TM</sup> VPIII Microbial Identification Test, a DNA probe test, for the detection of *Candida* spp (C), *Gardnerella vaginalis* (GV) and *Trichomonas vaginalis* (TV)

## Methods



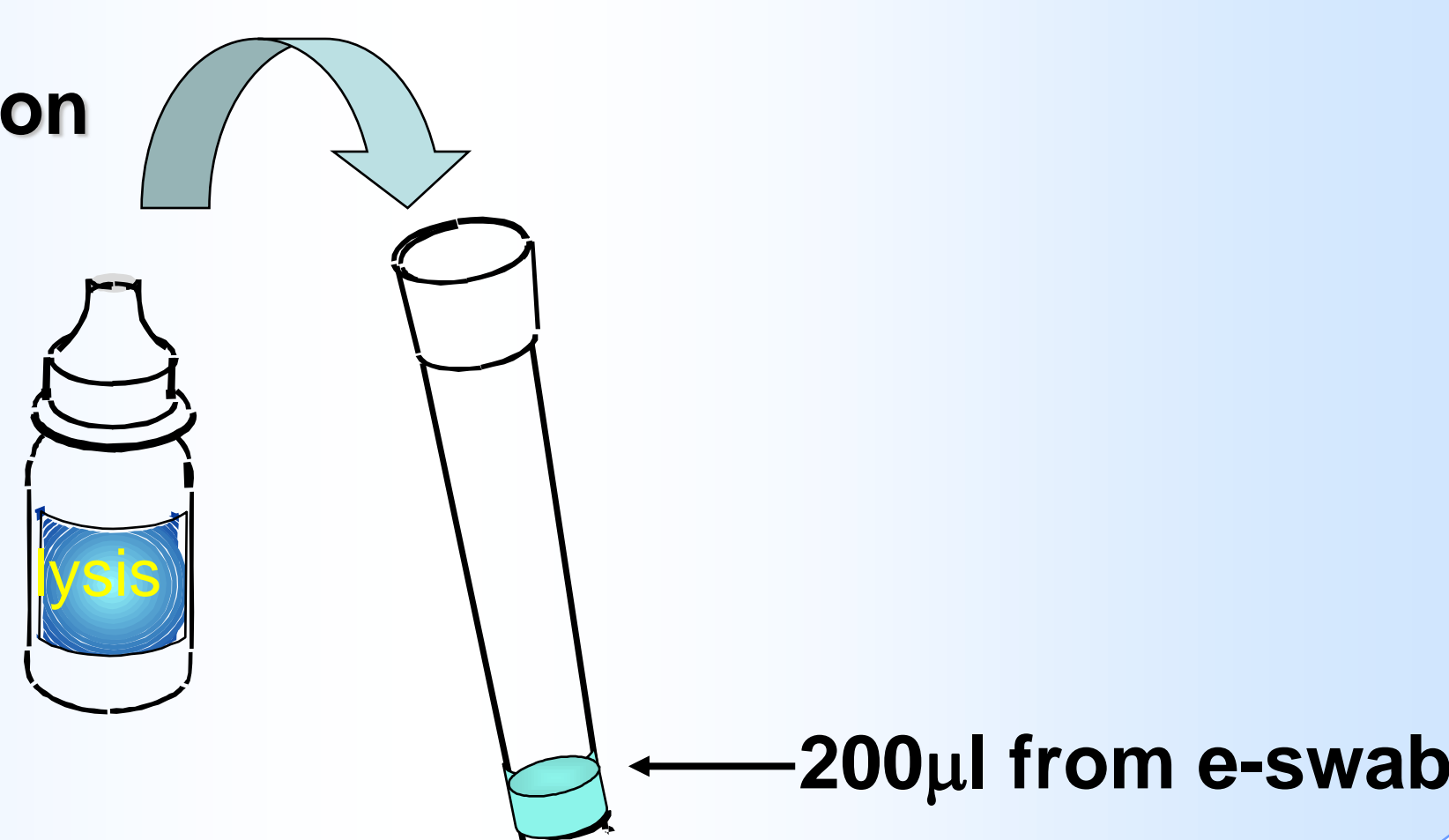
In this study were analysed 250 vaginal samples collected in duplicate, one with the Affirm kit and another with the ESwab for bacterial culture. Both samples were tested with the the *Affirm*<sup>TM</sup> VPIII.

Each positive result was confirmed by traditional culture procedure as well as by microscopic observation (that is in the case of *T.vaginalis*)

For the first 26 ESwab samples, 100µl and 200µl were tested in order to establish the optimal amount that gave the same results as the Affirm kit. Another 12 specimens were tested using the pellet obtained from 200 microliters of Amies medium. 36 specimens were used to perform the stability test: they were tested after storing at 4°C and -20°C.

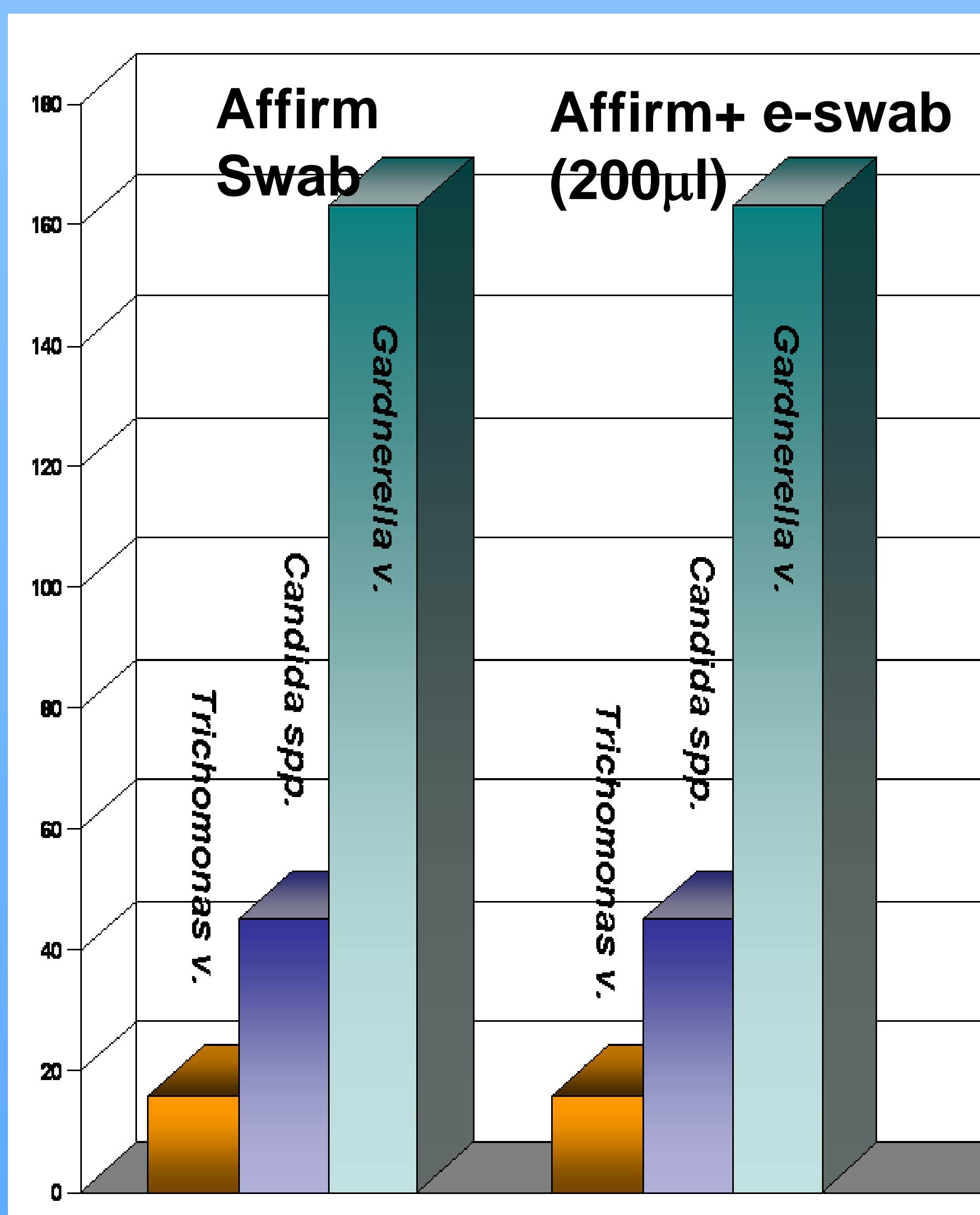
For the remaining 176 specimens, after vortexing, 200µl of ESwab sample were added to a tube containing 0.4 mL of Lysis Solution (contained in the Affirm Kit), and tested as the samples collected with the Affirm swab kit according the procedure from package insert.

0.4ml Lysis Solution



## Results

The test performed on 26 E-swab samples using 100 and 200 µl respectively, showed: 21/26 samples were positive with both the Affirm collection kit and 200 µl of ESwab, 5/26 remain negative for both system; 13/26 with 100 µl of ESwab, were concordantly positive, while 8/26 GV were not detected. Concordant results were found when stability test, within 48 hours at +4°C or stored frozen at -20°C for one week. Inhibition was found in 9 out of 12 samples when using the pellet obtained from centrifuging 200 ul of ESwab sample. In the other 174 samples tested, were found 45 CA, 16 TV, 91 GV and 24 negative with 100% concordance with both collection kits. In the other 176 samples tested, were found 45 CA, 16 TV, 91 GV and 24 negative with 100% concordance with both collection kits.



## Conclusions

- Copan ESwab can be used for the collection of vaginal specimens for the detection of C, GV and TV with the BD Affirm<sup>TM</sup> VPIII.
- Using 200ul of ESwab within 48 hours at +4°C or stored frozen at -20°C until one week proved to be the optimal testing method with the Affirm.
- Sample collected with ESwab can be used for antigen detection, Gram smear preparation and culture with manual and automated inoculation methods.

## References

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