Vaginal Self-Swab Device

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Problem Statement

Bacterial vaginosis, yeast infections, and sexually transmitted infections (STIs) can be detrimental to the well-being of an individual and cause a variety of health concerns if left untreated. The vaginal self-swab device is to be utilized by patients to easily collect cervicovaginal mucus samples from the vaginal canal to diagnose infections and STIs. This device design aims to provide a convenient, accessible method of breaking the swab into the transfer tube while minimizing exogenous cross-contamination of the self-collected sample. Cross-contamination, with the surface and environment, typically occurs while transferring the sample to the culture media, which can alter the test results. In order to overcome this, the device will reduce contamination resulting from user-error by allowing the testing swab to break into the culture media solution directly, reducing swab-surface contact, and preventing media leakage.

Problem Definition

Motivation

- Only 27% of sexually-active females (aged 15-25) report being tested for a sexually transmitted disease [1].
- Serious long-term complications if untreated, including pelvic inflammatory disease, certain cancers, and even infertility [2].
- Women prefer a less invasive vaginal swab over a pelvic examination [3].
- Barriers to accessible testing, including financial cost, clinic locations, and stigmatization [4].
- Current self-swabbing methods lead to 67% of women receiving a false positive result [5].

Figure 1:Aptima Multitest Specimen Collection Kit by Hologic [6].

Background

- Device in conjunction with Aptima Multitest Swab Specimen Collection Kit, which is used by the UW-Health System clinics.
- The current device technique:
  - produces an inaccurate, inconsistent break of the swab
  - easily spills culture media (small base diameter)
  - not user-friendly
- The self-swab test is designed to detect bacterial vaginosis, yeast infections, and sexually transmitted infections.

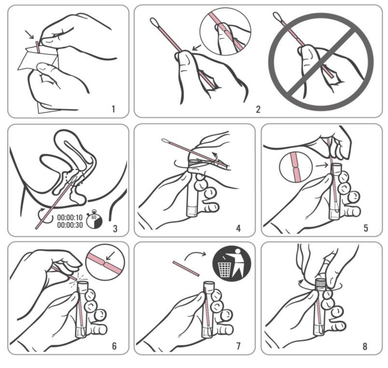

Figure 2: Instructions for using the Aptima Multitest Collection Kit [6]

Design Criteria

- Swab must be deployed at least 5 cm into vaginal canal [7].
- All materials must be biocompatible and non-toxic.
- Designed for one-time use.
- Budget of $250.
- Device must produce accurate, consistent break of the swab.
- Device must be user-friendly and promote universal testing.

Final Design

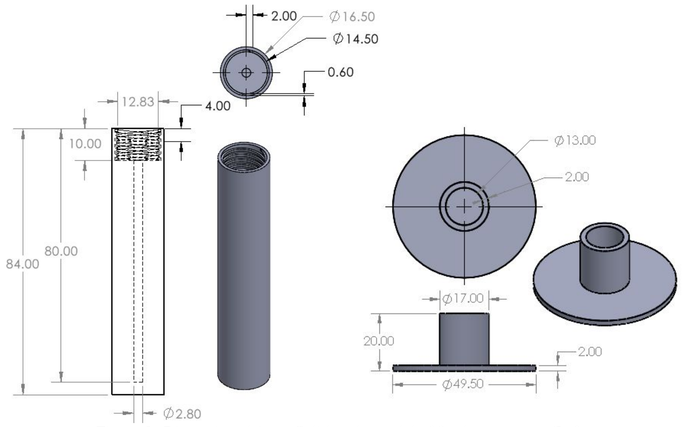

Figure 3: Dimensioned (mm) Solidworks model of final prototypes. (Left to right: Tilt and Break, Swab Holder)

Components:
- 1 Tilt-and-Break model (Clear Resin)
- 1 Swab Base Holder (PLA)

Features:
- Durability from resin
- High-precision threading
- Inexpensive Base
- Lightweight
- Portable

Item	Vendor	Cost
3D-Printed Holder Prototype - PLA	UW-Madison Makerspace	$0.33
3D-Printed Tilt and Break Prototype - Clear Resin	UW-Madison Makerspace	$4.96
Total Cost: $5.29		

Table 1: Itemized fabrication purchases for fabrication of one Tilt-and-Break model.

Testing & Results

Swab-Breaking Accuracy

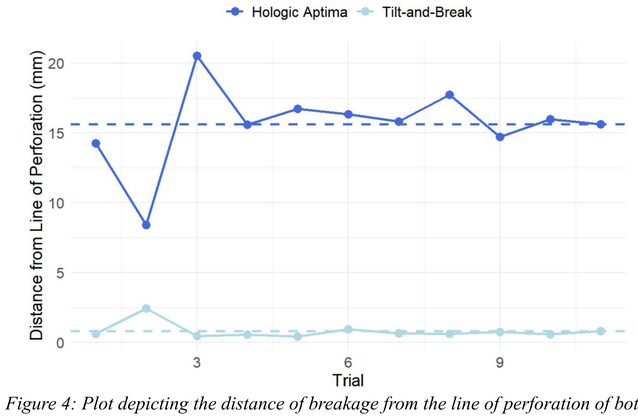

Figure 4: Plot depicting the distance of breakage from the line of perforation of both the Hologic Aptima and Tilt-and-Break devices; a dashed line of best fit is included for each condition, which represents the average distance from the line of perforation.

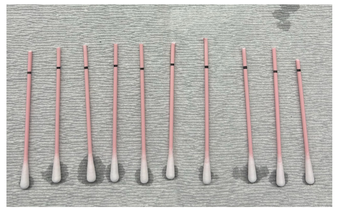

Figure 5: Image depicting swab-breakage of ten swabs using the Hologic Aptima.

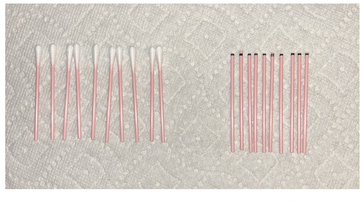

Figure 6: Image depicting sample collection end and breaking point handle of ten swabs using the Tilt and Break.

- Mean distance between the breakage point and line of perforation:
  - Hologic Aptima: 15.601 mm (Figure 4)
    - Standard deviation: 2.830 mm
  - Tilt-and-Break: 0.816 mm (Figure 4)
    - Standard deviation: 0.576 mm
- One-sided T-test p-value is 2.776e-09 (<0.05); statistically-significant.
- Can reject the null hypothesis; conclude that the Tilt-and-Break and Hologic Aptima will have a difference in swab-breaking accuracy.

Cross-Contamination Testing

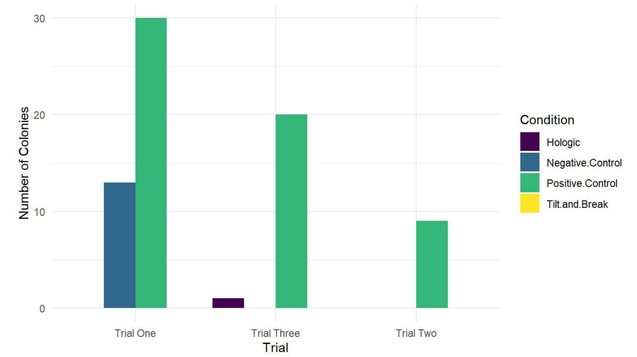

Figure 7: Bar graph displaying the number of colonies present on the agar plate for three trials of four different testing conditions.

- Average number of colonies:
  - Positive control: 19.667 (standard deviation: 10.504)
  - Negative control: 4.33 (standard deviation: 7.500)
  - Hologic Aptima: 0.33 (standard deviation: 0.570)
  - Tilt-and-Break: 0 (Standard deviation: 0)
- Two-sided T-test provided a p-value of 0.4226 (>0.05); statistically insignificant, fail to reject null hypothesis.

Conclusion

Contamination Control:
- Insufficient statistical evidence to justify that the Tilt-and-Break will reduce external cross-contamination.

Mechanical Performance:
- Efficient swab-breakage mechanism that consistently performs as intended, ensuring reliability and precision.
- Statistical evidence indicate Tilt-and-Break model achieves a break significantly closer to the perforation point.

Limitations:
- Sample size and random sampling potential effect on statistical power.
- Variability in experimental conditions.
- Nuance in user differences.

Future Work

- Create new instructions incorporating the Tilt-and-Break to include in new kits.
- Begin the patenting process.
- Clinical use requirements and legal processes (e.g. IRB and FDA regulations).
- Evaluate manufacturing processes to be used for final fabrication (e.g. injection molding).

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References

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