DEPARTMENT OF
Biomedical Engineering
UNIVERSITY OF WISCONSIN-MADISON

Vaginal Self-Swab to Minimize Contact Contamination

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Client: Dr. Jean Riquelme
Advisor: Prof. Randolph Ashton
Date: 10/04/2024

Presentation Overview

- Background Information
- Problem Statement
- Product Design Specifications
- Specific Semester Goals
- Preliminary Designs
- Design Matrix
- Future Work
- References and Acknowledgements

Problem Statement

- Current vaginal self-swabbing methods contaminate the testing environment
    - Various contamination sources
        - Insertion and swabbing the vaginal canal
        - Transferring the swab to the culture media
    - Contamination causes 67% of women to receive a false positive [1].

- Provide a convenient, accessible method of vaginal testing for bacterial vaginosis, yeast infections, and sexually transmitted infections
    - 96.6% of women prefer self-sampling in a medical setting over a home-based screening because of contamination stress [2].

Background Information

Client: Dr. Jean Riquelme

- Family medicine doctor based in Madison
  - UW Health, Department of Family Medicine and Community Health
- Requests a vaginal self-swabbing device that can screen for bacterial vaginosis, yeast infections, and sexually transmitted infections (STIs)
- Goal is to promote safer, more accurate vaginal self-testing

Figure 1: The client, Dr. Jean Riquelme [3]

Background Information

- STIs are under-tested especially in young women
  - Only 27% of sexually experienced females (15-25) reported being tested for an STD [4].
  - 32% of adolescents have had at least one STI [5].
  - Long term complications if untreated
    - Increased risk of pelvic inflammatory disease, certain cancers, and infertility [6]
- Past semesters' designs
  - Device to hold the swab to decrease contamination through hands
  - Lock mechanism
  - Cut the swab at the perforated line
    - Not always accurate

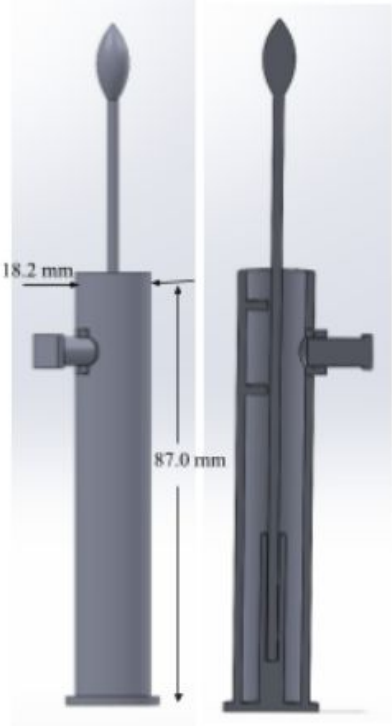


Figure 2: Spring 2024 Final Three Point Bending Design

Product Design Specifications

01 Accuracy:

- Leak prevention
- Holding device will be durable enough to break the swab consistently

02 Safety:

- All materials will be biocompatible and nontoxic
- Toxicology risk assessment outlined by ISO-10993-17

03 Ergonomics:

- Minimal and easily handheld
- Designed for one-time use
- Clear 5 cm mark on swab

04 Budget:

- $250

05 Patient:

- Increase reliable testing accessibility
- User friendly with clear instructions

06 Quantity:

- One prototype

Specific Semester Goals

INCREASE TESTING ACCURACY

- By the reduction of the risk of cross-contamination and consistent swab breakage

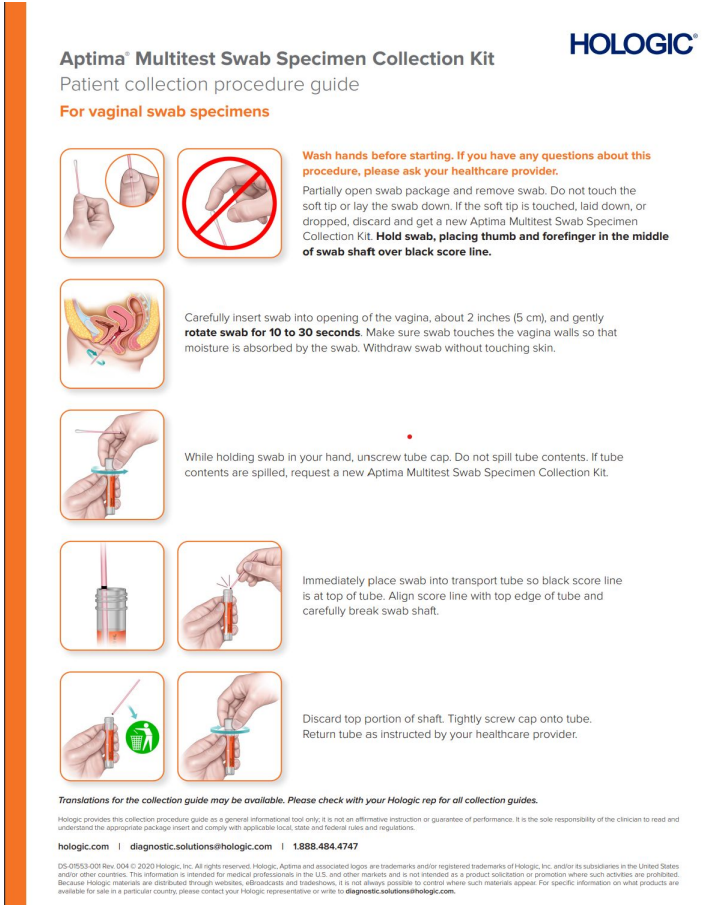
REDUCE RISK OF CONTAMINATION

- Device should limit the swab from external surface contact
- Prevention of the transport medium from leaking by providing stability

Figure 3: Aptima STI self swab and solution medium [7]

Competing Designs

- Hologic Aptima
  - Two components
  - Inconsistent snapping
  - Higher potential for contamination



HOLOGIC

Aptima® Multitest Swab Specimen Collection Kit

Patient collection procedure guide

For vaginal swab specimens

Wash hands before starting. If you have any questions about this procedure, please ask your healthcare provider.

Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. **Hold swab, placing thumb and forefinger in the middle of swab shaft over black score line.**

Carefully insert swab into opening of the vagina, about 2 inches (5 cm), and gently **rotate swab for 10 to 30 seconds**. Make sure swab touches the vagina walls so that moisture is absorbed by the swab. Withdraw swab without touching skin.

While holding swab in your hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, request a new Aptima Multitest Swab Specimen Collection Kit.

Immediately place swab into transport tube so black score line is at top of tube. Align score line with top edge of tube and carefully break swab shaft.

Discard top portion of shaft. Tightly screw cap onto tube. Return tube as instructed by your healthcare provider.

Translations for the collection guide may be available. Please check with your Hologic rep for all collection guides.

Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

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Figure 4: Hologic multitest swab specimen collection kit instructions [7].

Design 1: Altered Bend Design

Features:

- Large base
  - Stability
  - Splash Prevention
- Easy fabrication
  - 3D Printing - PLA
- Low-cost
  - Approximately 40 g
  - About $2.00

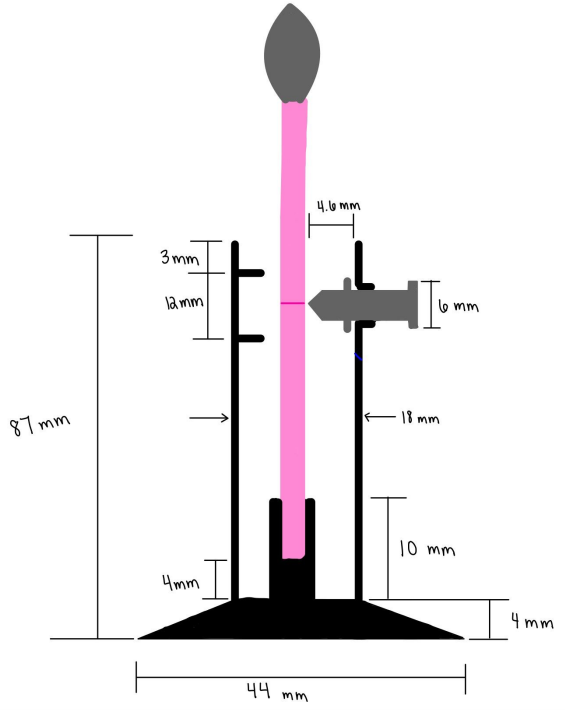


Figure 5: Altered Bend Design sketch

Design 2: Tilt-and-Break

Features:

- Easy snapping of swab
- Secure, threaded design
  - Avoid media leakage
- Simple fabrication
  - 3D-printing - PLA
- Low-cost
  - Approximately 55 g
  - About $2.75

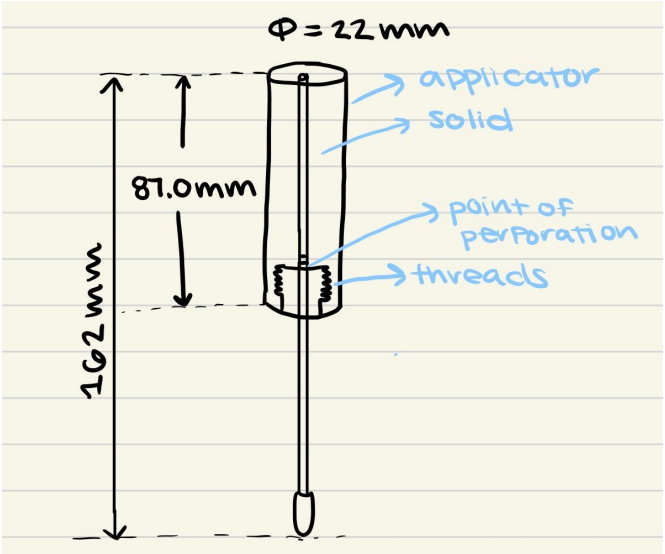


Figure 6: "Tilt-and-Break" design sketch.

Design 3: The Tunnel

Features:

- Wide base
- Pinch to break swab
- Easy fabrication
  - 3D Printing - PLA
- Low-cost
  - Approximately 47 g
  - About $2.35

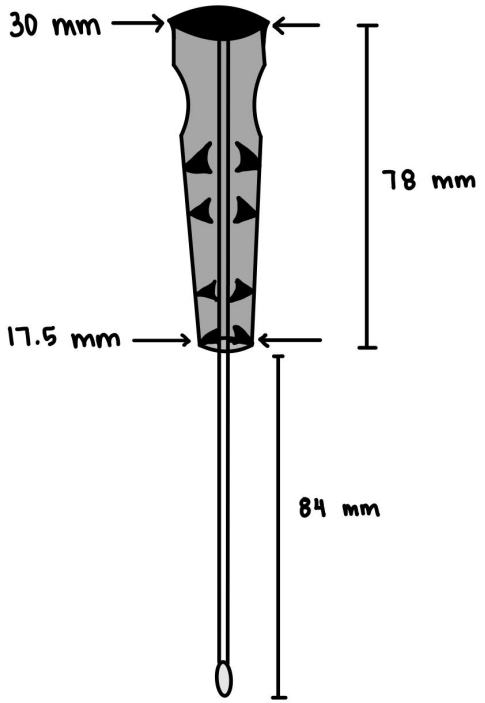


Figure 7: The Tunnel Design sketch

Design Matrix 1:
Table Attachment

1. "Altered-Bend"
   a. Difficult fabrication
2. "Tilt-and-Break"
   a. Good leakage prevention
   b. High ease of use
   c. Simple fabrication
3. "The Tunnel"
   a. Difficult to use
   b. Low ease of fabrication
   c. Low safety

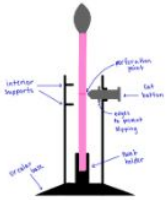
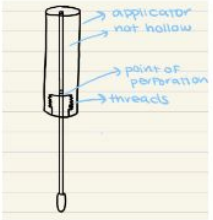
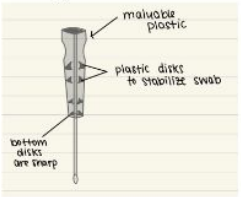
Design Criteria (weight)	Design 1: Altered Bend Design		Design 2: Tilt - and - Break		Design 3: The Tunnel	
						
Limiting Contamination (30)	4	24	4	24	4	24
Leakage Prevention (25)	4	20	5	25	4	20
Ease of Use (15)	4	12	5	15	3	9
Ease of Fabrication (10)	3	6	4	8	2	4
Patient Comfort (10)	5	10	5	10	5	10
Safety (5)	4	4	5	5	2	2
Cost (5)	5	5	5	5	5	5
Total Score (100)		81		92		74

Table 1. Design matrix for Table Attachment

Final Design - “Tilt-and-Break”

- Good leakage prevention
- High ease of use
- High patient comfort
- Safe and affordable
- Relatively easy to fabricate

Final score: 92/100

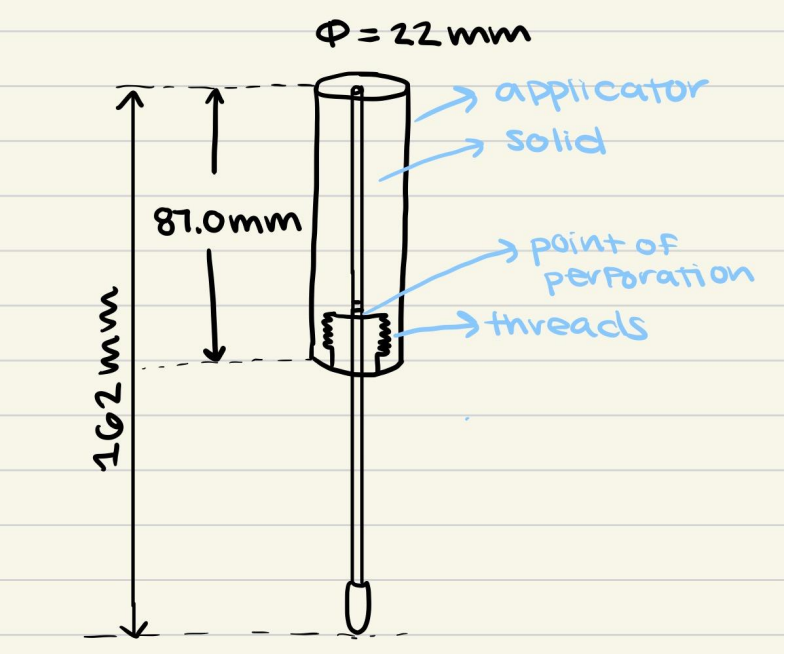


Figure 8: The final design sketch

Final Design - “Tilt-and-Break”

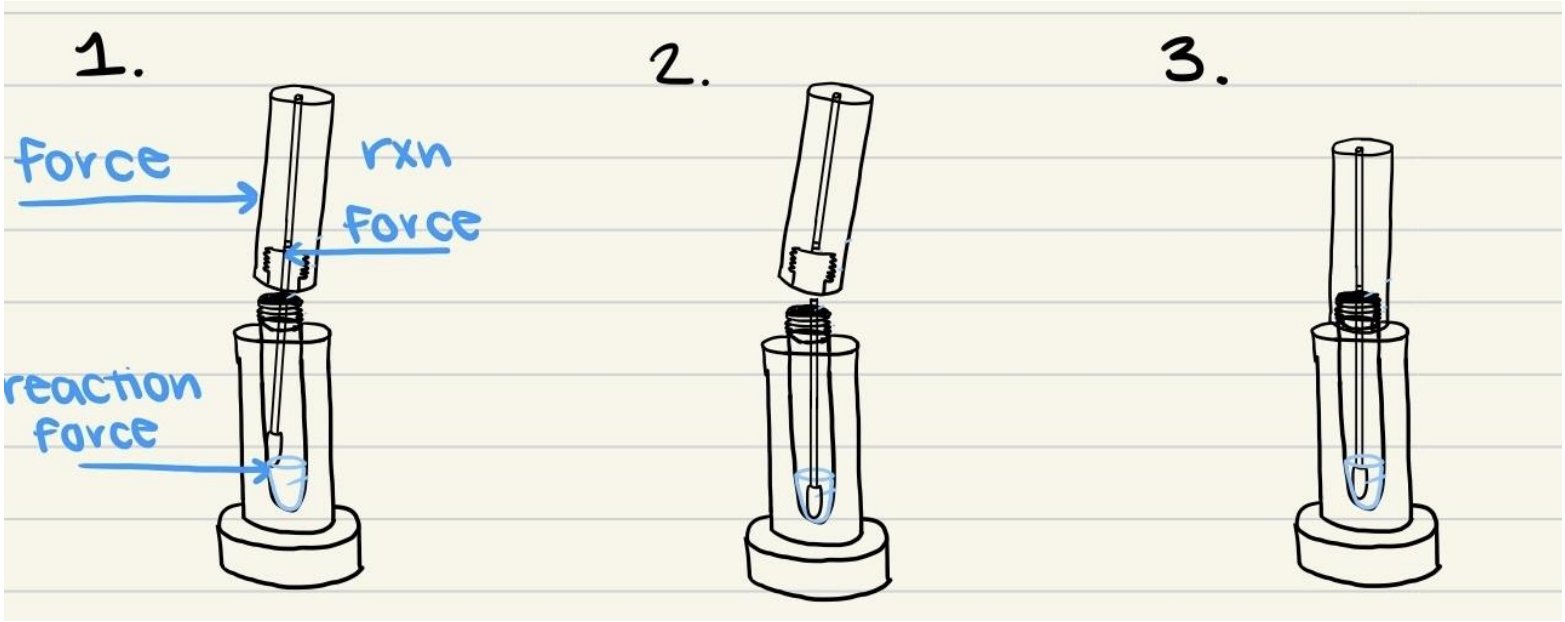


Figure 9: “Tilt-and-Break” mechanism sketch

Future Work

- **Creating SolidWorks models**
  - Testing theoretical mechanical strength via SolidWorks simulation.
- **Testing of the device**
  - Testing accuracy of swab-breaking.
  - Testing mechanical strength properties of the device.
- **Potential patent**
  - Meeting with lab managers required.

Acknowledgements

- Professor Randolph Ashton, UW Madison, Department of Biomedical Engineering
- Dr. Jean Riquelme, UW Health, Department of Family Medicine and Community Health

References

[1] M. Toepfe, B. Hermann, M. Sansone, C. Lilja, and P. Nolskog, “Environmental contamination by Chlamydia trachomatis RNA can cause false-positive test results in clinical samples,” Sexually Transmitted Diseases, vol. Publish Ahead of Print, Oct. 2020, doi: https://doi.org/10.1097/olq.0000000000001323.

[2] J. Sormani et al., “Exploring Factors Associated with Patients Who Prefer Clinician-Sampling to HPV Self-Sampling: A Study Conducted in a Low-Resource Setting,” Int J Environ Res Public Health, vol. 19, no. 1, p. 54, Dec. 2021, doi: 10.3390/ijerph19010054.

[3] Nelson, “Agnesian HealthCare Welcomes Family Medicine Physician To Waupun Clinic – Hometown Broadcasting.” Available: https://hometownbroadcasting.com/2021/04/agnesian-healthcare-welcomes-family-medicine-physician-to-waupun-clinic/. [Accessed: Oct. 04, 2024]

[4] K. M. Cuffe, A. Newton-Levinson, T. L. Gift, M. McFarlane, and J. S. Leichliter, “Sexually Transmitted Infection Testing Among Adolescents and Young Adults in the United States,” Journal of Adolescent Health, vol. 58, no. 5, pp. 512–519, May 2016, doi: 10.1016/j.jadohealth.2016.01.002.

[5] I. P. Monteiro, C. F. G. Azzi, J. P. Bilibio, P. S. Monteiro, G. C. Braga, and N. Nitz, “Prevalence of sexually transmissible infections in adolescents treated in a family planning outpatient clinic for adolescents in the western Amazon,” PLoS One, vol. 18, no. 6, p. e0287633, Jun. 2023, doi: 10.1371/journal.pone.0287633.

[6] O. of I. D. and H. Policy (OIDP), “Sexually Transmitted Infections (STIs).” Accessed: Sep. 29, 2024. [Online]. Available: https://www.hhs.gov/programs/topic-sites/sexually-transmitted-infections/index.html

[7] “Aptima-Multitest Patient Vaginal Collection Guide,” *HOLOGIC*. Available: https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab#4257225834-3862873779

QUESTIONS?