DEPARTMENT OF
Biomedical Engineering
UNIVERSITY OF WISCONSIN–MADISON

Vaginal Self-Swab

Preliminary Report

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BME 200/300: Biomedical Engineering Design

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Abstract:

Sexually transmitted diseases (STIs) can often be asymptomatic, therefore going undiagnosed and unreported [1]. Early screening and recognition of STIs are key to preventing disease progression and receiving treatment. It is crucial for individuals to have access to accurate testing in order to ensure health and well-being. Vaginal self-swabs offer a non-invasive and less intimidating way for a greater population of women to receive testing. The vaginal self-swab created by Hologic, the Aptima Multitest Swab Specimen Collection Kit, has the intention of increasing effective screening accessibility. However, it fails to ensure a low-enough risk of contamination, which jeopardizes its accuracy. This is due to excessive external contact to the swab, inaccurate breakage of the swab shaft, and the potential for the transport media to spill. The device created by Hologic is simple and has two components: the swab and the container with the transport media. The intuitive qualities of Hologic's self-swab are present, yet there is a missing component that would ensure accurate test results. The goal of this project is to design a device to minimize contamination which the proposed final design, the "Tilt-and-Break", represents a significant advancement in doing so. This device adds a third component that would secure onto Hologic's self-swab. By doing so, external contact to the swab is eliminated, accurate breakage is ensured, and stability is given to reduce the risk of spilling. The "Tilt-and-Break" design will offer women an accurate and reliable way to get tested.

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1. Introduction

1.1. Motivation and Societal Impact

Vaginal infections are extremely undertested, especially in young women. Only 27% of sexually experienced females (15-25) reported being tested for a sexually transmitted disease [2]. Specifically, chlamydia is reported in the highest cases among young women. It is estimated that every one in 15 sexually active females (14-19) has chlamydia [3]. There can be serious long-term complications if untreated, including an increased risk of pelvic inflammatory disease, certain cancers, and even infertility [4]. However, many cases go undiagnosed due to the asymptomatic nature of these infections, which is shown in a recent study of the prevalence of bacterial vaginosis, vaginal candidiasis, and trichomoniasis. Researchers found that 48.37% of women with bacterial vaginosis were completely asymptomatic [5]. Sexually active women are recommended to be tested annually for vaginal infections, however, there are barriers to accessible testing. These barriers include the financial cost of the test, clinic locations, and even the concern of being stigmatized [6]. Although these barriers decrease the popularity of vaginal testing, one solution has been found in self-swab testing. Around 76% of women prefer a vaginal swab over a pelvic examination and 60% over a urine collection test [7]. Self-swabbing is a less invasive process that allows the patient to take control of their health without having to leave the comfort of their house. However, the self-swabbing and collection process allows for potential contamination of the testing environment and the swab itself. Possible contamination sources include the insertion and swabbing of the vaginal canal, as well as the transfer of the swab from the vaginal canal to the culture media tube. Furthermore, current vaginal self-swabbing tests require the patient to break the swab using their hands, which could lead to false positives. Overall, contamination leads to 67% of women receiving a false positive result [8]. This device will seek to combat the contamination that comes with the current vaginal self-swabbing methods.

1.2. Competing Devices

This device is unique, meaning that there are no real competing devices. The device will be used in conjunction with the Aptima Multitest Swab Specimen Collection Kit, which is the test used by the UW-Health System clinics. This kit employs the use of a swab and a transport media-filled tube. After the user has swabbed, the swab is broken at the perforated line and placed into the media tube to be sent to the lab [9]. A similar design is the Evvy Vaginal Health Test, which utilizes the same sample collection method [10]. During the transferring process, there is a high probability of contamination. For both tests, the user has to collect a sample and then navigate the process of breaking the swab at the perforated line to place it into the culture media tube. Additionally, the transfer tube could spill, the swab could be dropped, and vaginal fluid could spread to other surfaces before being placed into the culture media.

1.3. 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 vaginal 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 should allow the testing swab to break into the culture media solution directly, and to prevent media leakage.

2. Background

2.1. Background Research

This self-swab test is designed to detect bacterial vaginosis, yeast infections, and various sexually transmitted infections. The swab is used to collect vaginal fluid, which is contained in the culture media transfer tube. This fluid holds cells with vital information on the health of the patient's vaginal canal [11]. Specifically, bacterial vaginosis is a poly-microbial condition of the vaginal canal which is caused by an increase in the vaginal pH. A typical vaginal pH is acidic, with a range of 3.5 to 4.5. Bacterial vaginosis is correlated to a pH greater than 4.5, although this can vary based on ethnic groups [12]. Sexually transmitted infections require immediate attention due to severe health complications, including pelvic inflammatory disease, increased risk of getting HIV, certain cancers, and even fertility [4].

2.2. Design Research

Since this design will involve swabbing and transferring bacteria, a safe, nontoxic material must be used. Correct sterilization and decontamination processes must be followed, including the process of autoclaving. Autoclaving is used to kill bacteria and germs through heat, pressure, and saturated steam [13]. Since the main component of the self-swab design will be 3D printed, the device must be made of autoclavable plastic. A possible autoclave-safe material is polycarbonate plastics (PC). Polycarbonate is effective in protecting the safety of the swab during transfer through heat resistance, chemical resistance, and 100% recyclable properties [14]. Further, polypropylene and polypropylene copolymers can be autoclaved without losing strength and are best known for being a low-cost, durable option [15]. This device is subject to requirements for the collection and transport of samples for medical laboratory examinations [16].

2.3. Client Information

The client, Dr. Jean Riquelme, is a family medicine specialist based in Madison. Dr. Riquelme graduated from the Medical College of Wisconsin in 1993, completing her residency in family medicine at Aurora Healthcare. Intending to promote safer, more accurate vaginal self-testing, Dr. Riquelme requests a vaginal self-swab device that limits contamination. This device should test for various vaginal diseases, including bacterial vaginosis, yeast infections, and sexually transmitted infections (STIs).

2.4. Design Specifications

This device will be used in conjunction with the self-swab process, so it must be user-friendly with clear instructions, easily hand-held, and ultimately promote universal testing. The design must be durable enough to prevent leakage and strong enough to break the swab consistently. The swab must be deployed at least 5 cm into the vaginal canal to allow for adequate vaginal testing [17]. Since this will be a sterile device, all materials must be biocompatible and nontoxic, following the toxicology risk assessment outlined by ISO-10993-17. Furthermore, the design must allow for both the swabbing and storage in the media while combating contamination of the testing environment. For more information on the design specifications, see Appendix I.

3. Preliminary Designs

3.1. The "Altered Bend" Design

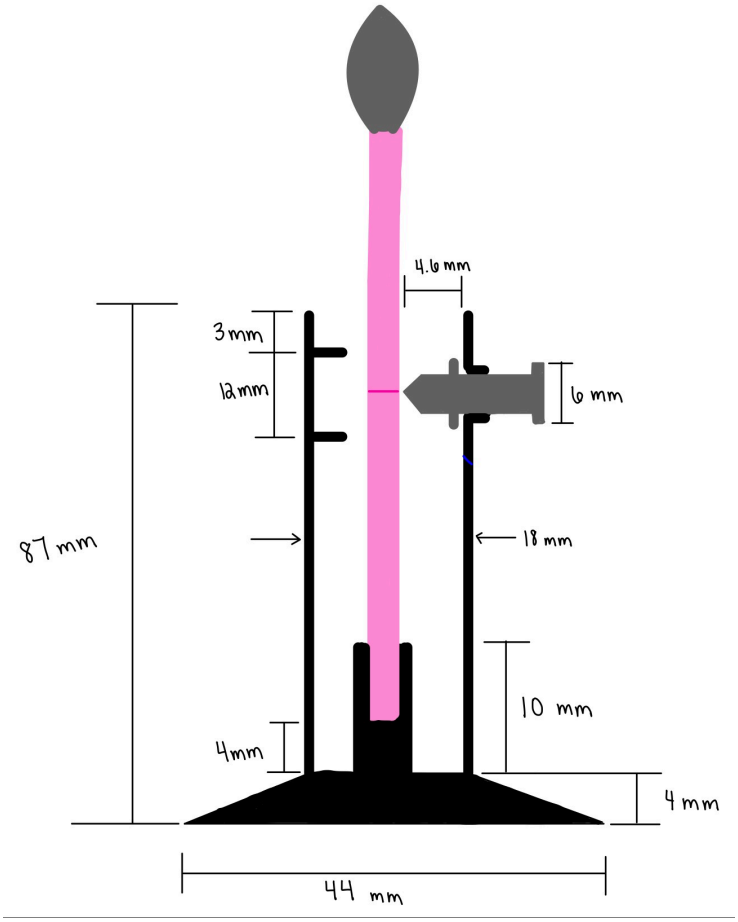


Fig. 1: The "Altered Bend" design sketch.

The first design, called the "Altered Bend" Design, is an updated and altered version of the past semesters' design. This design features a larger base, providing more stability if the patient sets the device down on a countertop after swabbing (Figure 1). It also has a wider opening surrounding the perforation point to prevent spillage of the liquid media. The button mechanism was altered to be stationary instead of rotational, in order to consistently cut the swab at an accurate length.

This device would be attached to the bottom 6 mm of the swab to hold it in place. The patient would follow the self-swabbing protocol while holding onto the bottom 87 cm handle. After swabbing, the patient will rotate the device upside down, placing the swab into the media tube. The swab should be inserted approximately 5 cm into the media tube, or up to the first interior support. Then the patient should execute the cutting mechanism by pressing the button on the side of the device. This will cut the swab directly under the perforation point. The device is wide enough to simulate an umbrella over the liquid media to prevent any possible spillage from occurring. The patient will then screw back on the provided cap to the media tube and

dispose of the device containing the bottom of the swab. The media tube will then be sent to a physicians' lab to be tested.

3.2. The "Tilt-and-Break" Design

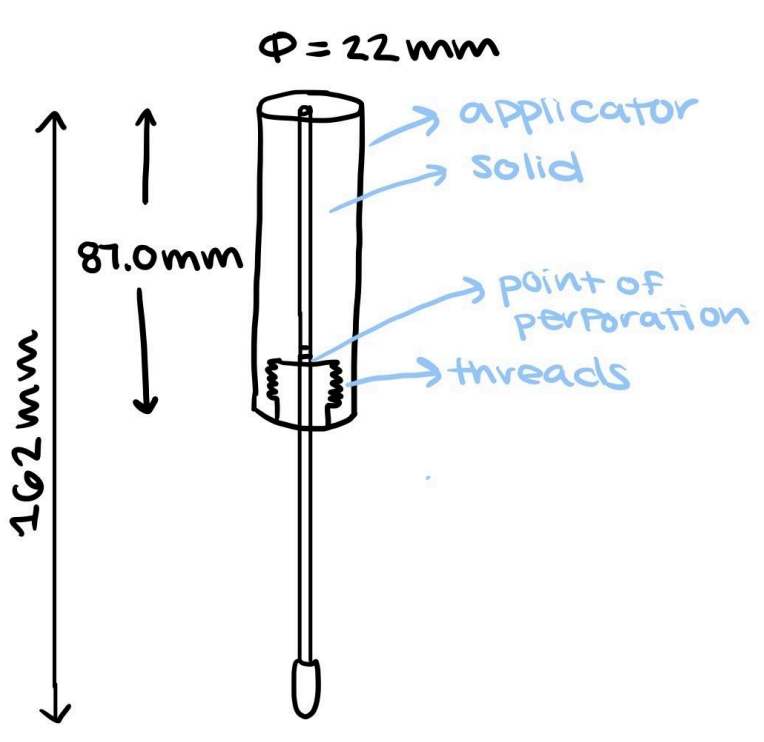


Fig. 2: Sketch of the "Tilt-and-Break" design idea.

The second design idea, named the "Tilt-and-Break", is composed of Hologic's 'Aptima' Swab and a "handle" component. The handle component is a non-hollow, solid material into which the testing swab is pressure-fit into. The solid material extends for the portion of the swab which is above the perforation line. At the perforation line, the solid material ends and there exists a hollow void with threaded "walls", into which the media container can be securely screwed into (Figure 2).

To use this device, the patient must hold the device by the "handle" while swabbing themselves (as instructed by the typical self-swabbing protocol) [9]. Following the swabbing process, the patient must insert the end of the swab into the media container. Then, before screwing the handle onto the media container, the patient must hold the media container in place while tilting the handle of the device. This motion will produce a reaction force (by the solid material of the handle) onto the line of perforation of the swab, resulting in swab breakage. Once the swab is broken, the patient may then screw the handle component onto the media container, which will allow the healthcare provider to collect the specimen and send it to the lab for further testing.

3.3. The "Tunnel" Design

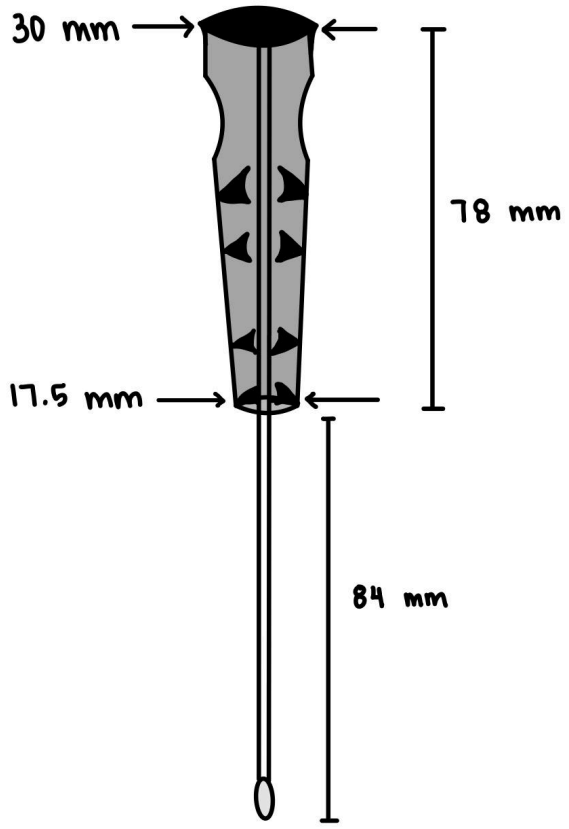


Fig. 3: The "Tunnel" Design with the swab and holder.

The third design consists of three components - the swab holder, Hologic's 'Aptima' swab, and 'Aptima' media tube. As seen in Figure 3, the swab holder is completely hollow with varying-sized disks in the interior. These disks align to stabilize the swab whilst being used to swab the vaginal canal. The base is wider than the bottom opening, serving as protection from tipping and spills. Additionally, there are cutouts at the top for ease of use for the patient.

When using this design, a patient would receive the device with the swab already placed inside the holder. In this orientation, the swab is secure in the holder and will limit contamination. The patient would then use the grips to hold the swab holder and insert the swab into the vaginal canal, collect the specimen, and remove the swab. After removing the swab from the canal, the user would then transfer the swab to the Aptima transport media tube by pinching the bottom opening to break the swab. Since the bottom-most disk is sharp, the swab will break at the perforated line due to the pressure. After the swab is broken and in the culture media, cap the tube and follow the transfer instructions. The advantages of this design include the ability to limit contamination and leakage/spillage. The holder acts as a barrier between the environment and the swab. The user can set down the swab without the risk of spreading contaminated vaginal fluids. However, this design has the opportunity to be dangerous for the user. Since the

inside contains a sharp disk, the patient could pinch or cut themselves in the swabbing and breaking process. Further, this design is not extremely user-friendly due to the force needed to break the swab by pinching.

4. Preliminary Design Evaluation

4.1: Design Matrix for Table Attachment

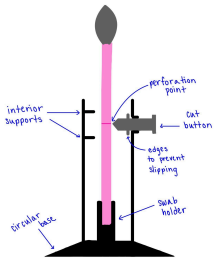
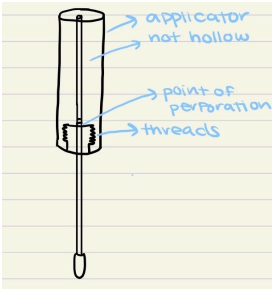
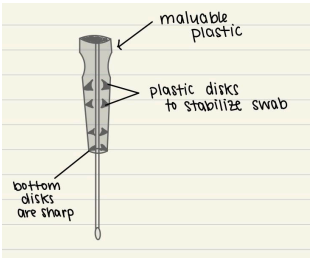
Design Criteria (weight)	Design 1: Altered Bend Design 		Design 2: Tilt - and - Break 		Design 3: The Tunnel 	
Limiting Contamination (30)	4	24	4	24	4	24
Leakage Prevention (25)	4	20	5	25	4	20
Ease of Use (15)	4	12	5	15	3	9
Ease of Fabrication (10)	3	6	4	8	2	4
Patient Comfort (10)	5	10	5	10	5	10
Safety (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 depicting the three design ideas and their respective scores.

The criteria chosen for the evaluation of the vaginal self-swab design ideas (from highest to lowest weight) include: limiting contamination (30/100 points), leakage prevention (25/100 points), ease of use (15/100 points), ease of fabrication (10/100 points), patient comfort (10/100 points), safety (5/100 points), and cost (5/100 points) (Table 1).

The first criterion, limiting contamination, refers to the ability of the device to prevent

cross-contamination of the sample by contact with an exogenous surface. All of the design ideas received the same score in this category. The second criterion, leakage prevention, is the ability of the device to prevent the leakage of media from the media-containing component. The "Tilt-and-Break" design scored the highest in this category (5/5) due to the threaded aspect of the design, which provides additional security once screwed onto the media-containing component. For ease of use, which is how intuitive it is for the patient to use the device, the design scoring the highest was the "Tilt-and-Break", due to its simplistic design and method of usage. Similarly to the previous category, due to its simplistic design, the "Tilt-and-Break" scored ⅘ points within the ease of fabrication category. All of the designs scored full points for both the patient comfort and cost categories, as they have similar swabbing protocols and are to be made of the same material. Finally, for the safety category, the design with the highest score (5/5) was the "Tilt-and-Break"; this is because unlike its counterparts, this device does not propose a potential method of pinching the patient (via buttons or internal disks).

4.4: Proposed Final Design

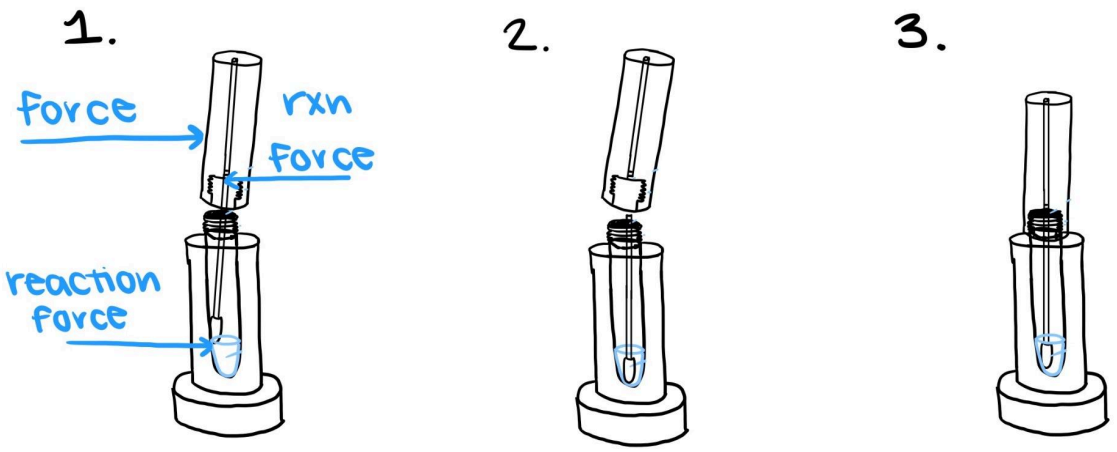


Fig. 4: Sketch of the "Tilt-and-Break" design mechanism.

Following evaluation of the design matrix criteria, the design idea with the highest overall score (92/100) to be used for the final prototype is the "Tilt-and-Break" (Table 1). This design idea is intuitive and simple, leading to its high scores for ease of use and fabrication. Without any buttons or moving components, there is reduced risk of injury to the patient, resulting in a high safety score. The threaded aspect of this design allows the device to be securely screwed onto the media container, contributing to its high leakage prevention (Figure 2). The cost of this device is estimated to be within the $250 budget given by the client.

Although this design scored relatively high in the limiting contamination category, it did not receive full points. This is due to the fact that following the swabbing process, the device is exposed, increasing the risk of exogenous contamination of the sample. This is to be mitigated

by allowing the device to "stand" on the top portion of the handle while the patient handles the media container, or by inserting the swab into the media container immediately after swabbing (Figure 4).

Similarly to the limiting contamination category, this design scored highly for ease of fabrication, yet did not receive full points. This is because although the design does not have any difficult-to-fabricate buttons or internal components, the threaded aspect of the design still poses some difficulty in fabrication, especially if this device is to be 3D-printed. Additionally, due to the handle component being solid, the high temperatures of the 3D-printing process increase the risk of the device melting.

5. Fabrication/Development Process

5.1. Materials

- **Swab:** The swab will be a dacron swab. It is a non-cotton, non-toxic, hydrophilic, synthetic fiber-wrapped swab [18]. The shaft of the swab is plastic [19]. Dacron swabs are most commonly used for STI testing due to their non-toxic and hydrophilic nature. They are both safe for patients as well as most compatible with biological samples.
- **Transport media:** A universal transport media will be used such as Vircell Transport Medium. Transport media increases the viability of the obtained specimen by keeping it in a non-dry environment and allowing the sample to be kept at room temperature [20].
- **PLA swab holder:** One of the device prototypes will be 3D printed out of polyactic acid (PLA). PLA is a thermoplastic derived from an organic source such as sugar cane or starch. It is biodegradable and has similar characteristics to petroleum-based thermoplastics such as polypropylene or polyethylene [21]. Autoclaving PLA may result in partial degeneration of the model, having a melting point of 184°C. Common autoclave processes typically run for 20 minutes at approximately 121°C [13].
- **PC swab holder:** The second device prototype will be 3D printed using polycarbonate (PC). PC is a thermoplastic with high strength, being resistant to impact and fracture. It is a recyclable, lightweight material, while also showing thermal stability up to 135°C. PC is virtually unbreakable, having a melting point of 155°C, and a toughness value between -20°C and 140°C [14].
- See Appendix III for further information regarding cost of materials.

5.2. Methods

The proposed final design was first modeled in SolidWorks. The model featured the required length and thickness specifications from the previous semesters. After the drawing of the final design was completed, it was exported as a stereolithography (STL) file to be 3D printed.

The 3D-printing process will be conducted at the UW-Madison MakerSpace using the Bambu Lab printers. The STL files will be uploaded to the MakerSpace computers so that the

MakerSpace staff members can begin the printing process. Two prototypes will be printed, one using PC filament and the other using PLA filament. Once the prototypes are finished printing, the team will sand down each design to give a smoother finish.

5.3. Final Prototype

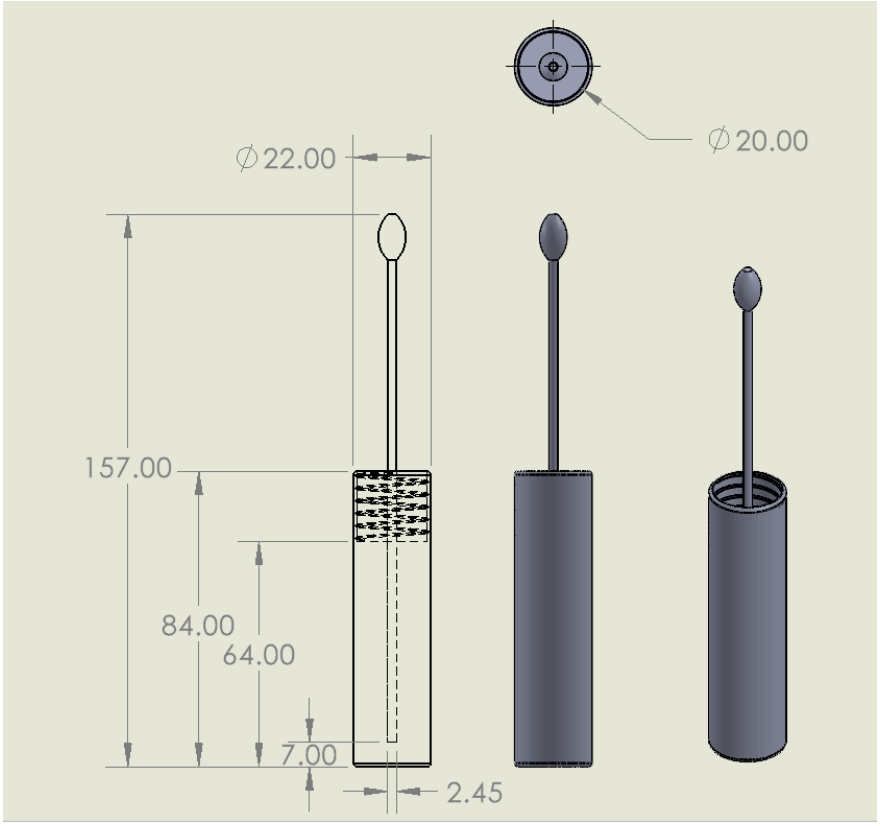


Fig. 5: "Tilt-and-Break" SolidWorks model.

6. Testing

- **Survey:** An anonymous survey will be administered to biologically female UW-Madison students. This survey will be used to gauge whether or not the participants would consider using the device, and how convenient they believe the device to be.

- **Leak Test:** A leak test will be performed to determine if, after sealing the top component of the device (containing the swab) onto the media container, any media leaks when the device is upright, tilted, or shaken. This test will be performed multiple times for the given conditions.

- **SolidWorks Simulation:** Following SolidWorks modeling of the proposed final design, a theoretical mechanical strength test will be performed via the SolidWorks simulation. The parameters of this theoretical test will include the material to be used for 3D-printing of

the prototype (PLA and PC), as well as the mechanical forces which the testing swab and handle will be potentially subjected to.

- **MTS Compressive Testing:** Compressive strength testing will be performed via MTS machine in the ECB Teaching Lab. The components of the device to be tested include both the handle component and the Aptima Swab, as well as the combined device as a whole.

7. Results

- **Survey:** For the survey portion of the testing process, the results will be analyzed with a bar graph comparing the responses from the participants.

- **Leak Test:** For the leakage test, the results will be considered as successful if there is no liquid media spillage after shaking and tilting the media tube with the device cap attached. The results will be labeled as either "pass" or "fail" depending on the outcome, and later compiled in a bar graph to visualize the results for each trial.

- **SolidWorks Simulation:** The SolidWorks simulation will directly yield the theoretical results and values associated with the material and structure of the device. These results, along with data collected from scientific literature, will then serve as a basis for the analysis of the MTS mechanical strength testing data.

- **MTS Compressive Testing:** The data from the MTS mechanical strength testing will be analyzed via MATLab to determine the mechanical properties of the device, such as Young's modulus and the ultimate strength.

8. Discussion

The design chosen for this semester's project is the "Tilt-and-Break", due to its high scores in the design matrix. After 3D-printing the first two prototypes of the "Tilt-and-Break" design (one made of PLA and one made of PC), testing will be conducted in order to decide on which material to move forward with. Testing will also allow for further assessment of the device design, potentially requiring additional adjustments to be made to the design in order to better fit the design criteria.

Since the primary goal of the project is to provide a more accessible, convenient, and accurate STI swab test for women, it is of paramount importance that the device is affordable, comfortable, and fully-functional. Providing reliable and affordable healthcare products will encourage more people to get tested. Testing of the device will ensure its reliability and functionality.

9. Conclusions

Bacterial Vaginosis, yeast infections, and sexually transmitted infections (STIs) can

threaten the health and well-being of individuals and are more common than one might think. In 2022, more than 2.5 million cases of syphilis, gonorrhea, and chlamydia were reported in the United States [22]. All of which can have devastating effects on reproduction, even in women who are asymptomatic. There is an urgent need for swift innovation and collaboration from all STI prevention. Vaginal self-swabs offer a noninvasive way for women to ensure a healthy vaginal microbiota and identify undesirable microorganisms [23].

The vaginal self swab created by Hologic, the Aptima Multitest Swab Specimen Collection Kit, has allowed for women to gain greater access to testing [9]. However, this device currently faces several challenges which have negatively impacted the accuracy of results by allowing for increased user error. This includes a higher risk of contamination due to excessive external contact to the swab, improper breakage of the swab and a greater potential for the transport media spillage. The goal of this project is to design a device to minimize contamination, preventing the spread of misinformation to women seeking healthcare.

The proposed final design, the "Tilt-and-Break", represents a significant advancement in ensuring accuracy and reducing contamination risks during the sampling process. The design addresses these issues by introducing a third hand-held component, allowing patients to handle the swab without direct contact. This should limit the risk of potentially infected vaginal fluids from spreading to other surfaces in the testing room, as well as protect the sample specimen from contamination from the hands. Additionally, the transport media container base mitigates the risk of leaking, spilling, or splashing of the media as it does not need to be picked up or moved after specimen collection. Lastly, the snug fit of the swab shaft in the durable device will ensure the swab will break at the same point every time. This will allow the nucleic acid amplification test (NAAT) to proceed seamlessly as the specimen holding swab must be a specific length [9]. The device will be fabricated using a 3D printer with either PC or PLA. Future work will focus on testing both of these materials to ensure they can be safely autoclaved. It is also a priority to verify the reliability of the 3D-printing process, ensuring the device to be error-free.

It is crucial for individuals seeking preventative screenings to have accessibility to accurate testing to optimize their health and well being. The "Tilt-and-Break" design will offer women an accurate and reliable way to get tested.

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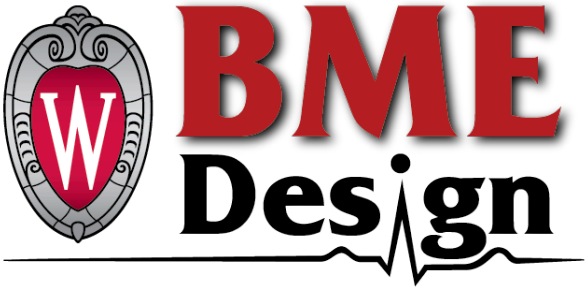
11. Appendix I

11.1. Product Design Specifications



Vaginal Self-Swab Device

BME 200/300 PDS

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Date: 09/13/2024

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Function:

The vaginal self-swab is a device to be utilized by patients to self-collect samples from the vaginal canal in the diagnosis of vaginal infections and STIs. The aim of this device design is to provide a convenient method of sample collection, while minimizing cross-contamination of the self-collected sample. Although studies have shown that vaginal self-swabbing has an accuracy similar to that of a physician-collected sample, self-swabbing poses a risk of sample cross-contamination [1]. Cross-contamination of the sample typically occurs during the process of transferring the sample to the culture media, which can alter the results. In order to overcome this, the device should allow the testing swab to directly break into the culture media solution, and to prevent media leakage.

Client Requirements:

- The vaginal self-swab should easily fit within the transfer tube.
- The base of the stand should be stable in order to withstand the general process of using the device.
- The device should limit cross-contamination resulting from transferring the sample into the culture media.
- The self-swab should directly break into the culture media solution.
- There should be no media leakage from the device.
- A budget of $250 should be observed.

Design Requirements:

1. **Physical and Operational Characteristics**
    - **a.** *Performance Requirements*:

i. The swab and holding device must be designed for one-time use and intended to function solely for the duration of the swabbing and subsequent testing process.

ii. The holding device must show sufficient durability to ensure secure containment during transport.

    a. No risk of spillage or leakage of culture media.

iii. The holding device must be capable of remaining upright autonomously, both when empty and when the swab is inserted.

iv. The swab must be easily insertable into the holding device, with a secure fit that ensures stability.

v. The support structure within the holding device should secure the swab in an upright position, minimizing the risk of cross-contamination during handling and transport.

vi. The swab head will need to be inserted at least 5 cm into the vagina in order for specimen collection [2].

b. *Safety*:

i. The swab head of the device must be 1-2 cm to collect an effective sample size without causing discomfort.

ii. The shaft must be no longer than necessary (5 cm) to prevent pushing the swab excessively into the vagina to collect an adequate sample.

iii. The transport media used must be non-toxic to prevent irritation or bodily reaction in the case that the media stand is spilled onto the skin.

iv. Materials that compose the vaginal self-swab must be biocompatible. It is

important that all components be reviewed by a toxicology risk assessment outlined by ISO-10993-17 to ensure the device does not contain harmful elements that may leach into the vaginal canal and cause irritation in any way [3].

c. *Accuracy and Reliability*:

   i. The swabs must show a sensitivity of 94.1% for Chlamydia and 96.5 % for Gonorrhea in order to ensure precision in the detection of the infections [4].

   ii. Insert the swab 5 cm into the vagina and rotate, making contact with the vaginal walls for 10 to 30 seconds to provide reliable results.

   iii. In order to guarantee accurate results, the patient must dispose of the kit and restart if the swab is touched by the skin, placed on any surface, or the contents of the tube are spilled [5].

   iv. The tip of the self-swab devices should be approximately 1 cm in length for optimal collection of vaginal discharge samples [6].

d. *Life in Service*:

   i. The swab and holding device should be designed for only one use, intended only for the swabbing and immediate testing process.

   ii. Distance traveled is undefined.

   iii. Before use, tests should be kept within a dry environment between 2-8 °C (36 – 46 °F) and out of direct sunlight [7].

   iv. After use, the sample will be sent back to the lab.

      a. The sample can be stored in the lab for 14 days at room

temperature or up to 180 days if kept frozen (-20 °C) [8].

e. *Shelf Life:*

   i. The swab sample should be stored and transported within a 50 mL centrifuge tube.

   ii. The swabs should be transported and tested within 14 days and stored in between 2-30° C [6].

   iii. To ensure the preservative liquid holding the sample remains effective, the STI kit should be used within 30 days of receiving it [9].

f. *Operating Environment*:

   i. The vaginal self-swab device should be fully-functional at room temperature (20-22°C), as it will be administered in a clinical testing environment.

   ii. The self-swab should be contained and administered in a sterile environment to prevent cross-contamination of samples.

   iii. To ensure that the device is leak-proof and structurally sound, it must withstand aqueous conditions due to the containment of the transport medium.

   iv. The swab portion of the device should withstand the acidic vaginal environment (pH 3.8-4.5) [10].

g. *Ergonomics*:

   i. The device should be user-friendly and easy to use, and the self-swab will be provided with clear instructions [5].

   ii. The self-swab should be a minimal device that can be easily handheld.

The device should provide a comfortable grip to maneuver it easily without slip.

iii. The shaft portion of the device is to be inserted 5 centimeters into the vaginal canal, which will be made clear with a stopper. It should be slender and flexible for easy insertion [5].

iv. The swab proportion of the device should be soft and large enough to collect an effective sample yet still be minimally invasive.

h. *Size*:

i. The device must be able to fit the swab comfortably, with room for support.

a. The Aptima swab measures 15 cm in length with a circumference of 3 to 5 mm [11].

b. The average depth of an unaroused vaginal canal is approximately 9 cm [12].

ii. Adequate sizing is required for the swab to fit without contamination.

iii. Device size should accommodate easy transportation.

iv. The device should be measured in comparison to the standard lab procedures and equipment found within the client's laboratory.

i. *Weight*:

i. It is necessary for the device to be lightweight with a balanced weight distribution in order for the user to be able to handle the device easily.

a. The device will have a weight of approximately 5-15 grams, including the casing and swab.

j. *Materials*:

i. The testing swab portion of the self-swab device to be used in the final prototype will utilize a pre-existing self-swab design called ‘Aptima Multitest Swab’, which is manufactured by Hologic [11].

ii. The swab containing the vaginal sample should be stored in transport media to maintain bacterial/viral viability, which allows for greater testing accuracy [13].

iii. The main component of the self-swab device, into which the swab will be broken and in which the culture medium will be contained, must be composed of an autoclavable plastic.

k. *Aesthetics*, *Appearance, and Finish*:

i. A separate slender container will be needed alongside the swab that contains transport media.

ii. The swab shaft will be slender and smooth to ensure easy insertion. The casing of the swab will be smooth and biocompatible as well to prevent pinching or irritation to the skin

iii. The shaft will have a safety stopper or marker to show the patient when they have reached 5 centimeters.

iv. The swab itself will have a soft, woven sampling brush head [14].

v. The portion of the device that the patient holds should have appropriate ridges to provide better grip.

vi. The color of the case of the self-swab should look appealing and clean to patients and the swab itself will have no color. The container holding

transport media will be clear so the patient can see inside.

2. Production Characteristics

a. *Quantity*:

i. By the end of the semester, the team will design and fabricate one usable prototype.

b. *Target Product Cost*:

i. The total budget of this project, as specified by the client, is approximately $250.

3. Miscellaneous

a. *Standards and Specifications*:

i. As defined by the FDA in the Code of Federal Regulations, Title 21, Sec. 866.2900, the vaginal sample collector is classified as a microbiological specimen collection and transport device and a Class I (general controls) medical device [15]. The media contained within the media tube is a transport culture medium and a Class I (general controls) device as specified in Sec. 866.2390 [16]. This classification means that the device is exempt from premarket notification 510(k), but is still subject to registration and listing, labeling, and good manufacturing practices.

ii. The device is subject to requirements for the collection and transport of samples for medical laboratory examinations as outlined by ISO 20658 [17].

b. *Customer*:

i. The customer would like to increase the accessibility of testing for vaginal

infections and STIs. More testing availability will decrease the prevalence of certain vaginal infections, many of which are associated with infertility. Self-collection of vaginal samples is not only as reliable as physician-collected samples, but it is arguably more accessible and convenient for the patient [1].

ii. The customer intends for the device to increase testing accuracy by the reduction of the risk of cross-contamination associated with current self-collection methods. The device should limit the swab from external surface contact, as well as prevent the transport medium from leaking from within the apparatus.

c. *Patient-related concerns*:

i. Currently, testing for HPV must be done in a healthcare facility, even if the patient collects a self sample. This could be a concern if a patient does not have access to a healthcare facility [18].

ii. Currently, screening for cervical cancer or gonococcal infection requires a cervical exam performed by a physician which cannot be done with a vaginal self-swab; vaginal self-swabs cannot test for every vaginal-related condition [19].

iii. It has been proven there is no difference in accuracy whether a person self collects versus going to an OBGYN for a test for yeast infection and bacterial vaginosis [20].

iv. Vaginal self swabs are generally used for testing for bacterial vaginosis and yeast infection and they make it a more accessible and equally as

effective process than getting a test from a healthcare professional [21].

d. *Competition*:

   i. There are self collection swabs that require transport media such OSOM rapid diagnostics COVID-19 tests [22] and BD Onclarity fecal swab [23]. However there are no other vaginal self swabs that prevent contamination through the use of transport media.

   ii. The current collection tube used by the client is from Hologic, the Aptima Multitest Swab Specimen Collection Kit. This tube requires the patient to break off the swab head into the collection tube with transport media and secure it with a screwable lid [24].

      a. There are plenty of companies that make vaginal self-swabs for testing bacterial vaginosis and yeast infection, however, they differ from Hologic's Aptima Test because they do not require the patient to snap the swab head into the collection tube.

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12. Appendix II

12.1. Original Design Matrices

Vaginal Self Swab - BME 300/200

Design Matrix

September 26, 2024

Section 312

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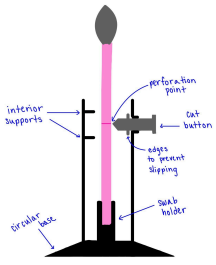
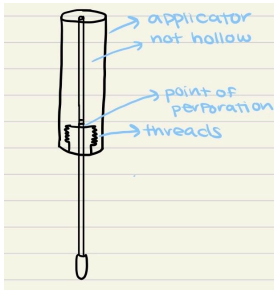
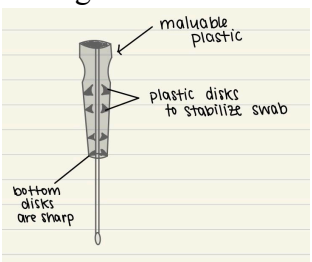
Table 2. Design matrix

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	4	20	5	25	4	20

Prevention (25)						
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

Determination of Criteria and Weights:

Limiting Contamination (30): Leaking contamination refers to the ability to inhibit the spread of microorganisms from biological fluids or the testing environment. This criterion was discussed in the *Accuracy and Reliability* section of the PDS, and was assigned a weight of 30/100 due to its significance of being an accurate measurement. The device must demonstrate a consistent snapping mechanism while transporting the swab into the culture media. This requires the minimization of contamination caused by the patient's own bacterium, such as their hands, or from the environmental bacterium, such as a countertop.

Leakage Prevention (25): Leakage prevention refers to the degree to which spilling of contained culture media is prevented. This criterion was assigned a weight of 25/100 because it is of paramount importance that the culture media does not leak. Leakage of the contained culture media can lead to inaccurate testing results, due to partial loss of the sample or external contamination. Additionally, skin contact with the culture media should be avoided, as it could lead to injury of the patient.

Ease of Use (15): This section focused on the simplicity of the process using the device. Relevant information was covered in the *Life in Service* and *Shelf Life* sections of the PDS. This criterion was given a weight of 15/100 because it is important that a patient would be able to understand and correctly use the device. A simple testing process is essential since the self-swab would be done without a doctor or physician's guidance.

Ease of Fabrication (10): This criterion assesses the ease of fabricating the insertion and stand mechanism, including the production and assembly of its components. Ease of fabrication was given a 10/100 because it's crucial that the design is feasible within the given time frame, both for prototyping and potential commercial manufacturing. A higher score in this category reflects a design that aligns with our fabrication skills and can be more readily scaled for commercial production.

Patient Comfort (10): Patient comfort refers to the comfort level of the patient while using the product, notably to which degree discomfort and pain are avoided. This criterion was assigned a weight of 10/100, as it is not an essential component of device functionality, but it is vital in the marketability and convenience of the product. Due to its convenience, patients are more likely to self-swab than to obtain a physician-collected sample [1].

Safety (5): Safety refers to risks (specifically to the user) associated with the product. This category ensures that the shaft portion of the swab can only be inserted 5 cm to prevent mechanical-induced tissue injury to the user [2]. Every material to be used is known to be biocompatible with the human body to reduce the risk of hypersensitivity [3].

Cost (5): The cost portion of the matrix is used to determine whether the cost of the materials are justifiable and within the client's budget. Points off in this category indicate costs exceeding the budget.

Justification of Assigned Scores:

Limiting Contamination (30): The "Altered Bend" design scored a ⅘ because although the base was extended to provide more stability, the device still has the potential of being knocked over, which could lead to contamination if the swab comes into contact with an external surface. The "Tunnel" design scored a ⅘ in limiting contamination because the mechanism is made out of malleable plastic, meaning it could tip easier without the added weight. Similarly to the other two design concepts, the "Tilt-and-Break" design received a score of ⅘. This is because although the design consists of a solid "handle" (as compared to the hollow "handles" of the other two designs) making it less prone to tipping over, there is still the possibility of the device being knocked over and becoming contaminated after unintentionally coming into contact with a surface.

Leakage Prevention (25): The "Altered Bend" design scored a ⅘ in the leaking prevention category because of its inability to screw onto the device containing the transportation medium. The patient could accidentally knock over the tube containing the medium, leading to the potential spilling of viable bacterium through the crevices of the device. Similarly to the "Altered Bend" design, there is a possibility for tipping with the "Tunnel" design, so it is ranked a ⅘. Since there is no solid divide between the swab-holder and the tube, the culture media could spread throughout the hollow holder and escape the container. The "Tilt-and-Break" design scored full points in this category, because the "handle" component of the device is solid, and has no hollow voids for fluid to seep into if the device is not upright. Additionally, this design utilizes threads to allow for a secure, "screw-on" tightening of the two components.

Ease of Use (15): The "Altered Bend" design was given a score of ⅘ for ease of use because the button mechanism could malfunction, leading to inconclusive results. The "Tunnel" design was ranked the lowest, with a ⅗, because of the need to apply substantial, and variable (due to the user), pressure in order to break the swab. Finally, the "Tilt-and-Break" design scored full points in this category. This is because the device solely consists of a simple "screwing-on" mechanism, making it simple to use.
Ease of Fabrication (10): When it comes to the ease of fabrication, the "Altered Bend" design was assigned a score of ⅗ because, in previous semesters, the button had issues with rotating, providing an inaccurate breaking of the swab (either too long or too short). Fabricating a "button" mechanism and assembling it in a non-rotational manner would be difficult. Ranked ⅖, the "Tunnel" design would be difficult to fabricate due to the incorporation of sharp inserts within the holder used to stabilize the swab. Lastly, the "Tilt-and-Break" design was given a score of ⅘; this device would be relatively easy to fabricate due to its simplistic design, but it may be difficult to create a "handle" into which the swab can be sufficiently pressure-fit. Additionally, the "Tilt-and-Break" design utilizes threads, which is an added component of difficulty with regard to the ease of fabrication.
Patient Comfort (15): Each of the designs scored full points for patient comfort because all of the designs have a similar mechanism in terms of specimen collection by the patient. During the process, the patient must insert the swab 5 cm into the vaginal canal, which provides little-to-no discomfort to the patient if done correctly [2].
Safety (5): The "Altered Bend" design received a score of ⅘ for safety because the button could potentially malfunction and pinch the user if not pressed correctly. The "Tunnel" design ranked the lowest, with a ⅖, due to the sharp insert at the bottom of the holder. This can be dangerous to the user during the swabbing process, as well as while breaking the swab. The simplistic design of the "Tilt-and-Break" mechanism leaves little room for the user to injure themselves, which is why this design received a full score in this category.
Cost (5): Each of the designs received full points within the cost category because all of the proposed design ideas require a minimal amount of material for fabrication, leading to affordability. All of the costs required to manufacture either device are anticipated to be within the $250 budget of the client.

13. Appendix III

13.1. Expense Spreadsheet

Table 3: Projected materials and their costs

Material	Cost	Quantity	Price Estimate	Expected Vendor
PLA	$0.05/gram	55g/1 holder	$2.75	Makerspace
PC	$0.05/gram	55g/1 holder	$2.75	Makerspace
Dacron Swab	Free	-	-	Provided by client
Transport Media	Free	-	-	Provided by client
Total Cost: $5.50				