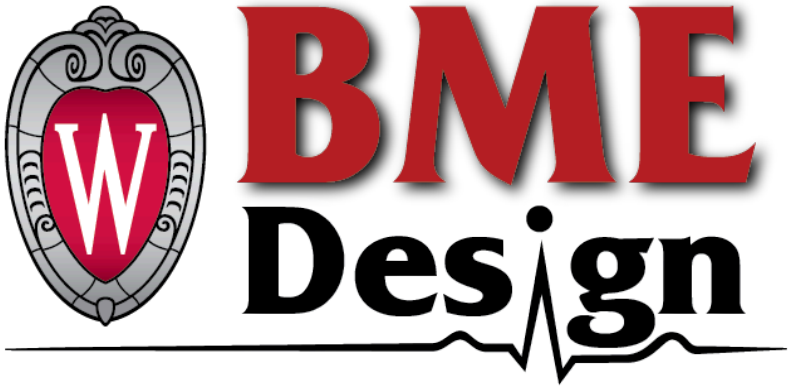

Vaginal Self-Swab Device to Minimize Contact Contamination

Final Report

Client: Dr. Jean Riquelme
Advisor: Dr. Megan McClean
TA: Stephen Foley
Lab 303

Sara Morehouse (Leader)
Cherry Qiu (Communicator)
Katherine Kafkis (BWIG and BSAC)
Adam Berdusco (BPAG)

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Abstract

Sexually transmitted infections (STIs) are often under-tested in sexually active women due to asymptomatic presentation, socioeconomic barriers, and stigma. Consequently, common infections like chlamydia and gonorrhea remain highly prevalent, with nearly two million cases of chlamydia reported in 2022 [1]. Self-administered vaginal swab tests have been found to promote routine STI testing as they minimize the discomfort patients often face with physician-administered tests [2]. During a self-swab test, a patient swabs their vaginal canal then breaks the swab into an external tube containing media. This current method poses contamination risks, as the swab or spilled media may contact testing room surfaces [2]. As a result, this project aimed to fabricate a device that limits contamination during vaginal self-swab STI testing. The fabricated device houses and breaks a Dacron swab within an external casing, leaving 6.5 cm for specimen collection. It also features three points of contact with the swab: two stationary supports on the interior and a mobile push button on the exterior, facilitating a three-point bending mechanism to break the swab at a perforation point and transfer it into the media tube. Additionally, a plastic base prevents the transport media tube from tipping over during the transfer process, minimizing spillage risks. Testing demonstrated the device's efficacy in reducing surface contamination and validated that the force required to break the swab in three point bending is less than the average woman's grip strength. Peer feedback indicated the device's aesthetic appeal, ease of use, and clarity of instructions. By simplifying the self-swabbing process and minimizing contamination, this device has the potential to enhance STI diagnostics' accuracy and promote universal testing.

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Introduction

Chlamydia is the most frequently diagnosed bacterial sexually transmitted infection in the United States, affecting an estimated 1 in 20 young women from ages 14-24. However, approximately 43% of cases go undiagnosed due to the commonly asymptomatic nature of the infection; in fact, between 50-70% of people diagnosed with chlamydia present asymptomatically [1]. Sexually active women are recommended to be tested annually for chlamydia, but barriers to testing such as lack of transportation, concerns about confidentiality, cost, and violation of privacy limit the frequency of routine testing [2][3]. Conversely, the self-swab method has been found to lower these barriers to testing. Recent studies found that 84% of women prefer the self-swab method to traditional gynecological procedures, and 94% would be more willing to routinely test for STIs if self-swabbing was available [2]. Self-swabbing allows patients to play a more autonomous role in their health and helps them feel more comfortable with a somewhat invasive process. However, one limitation of patient-collected STI samples is the potential for contamination of the testing environment and the swab itself during the collection process. In fact, one study found that 13% of testing rooms had chlamydia and gonorrhea bacteria remaining on surfaces in the room after use by a patient to self-swab [4]. The collection process involves the patient inserting a swab into the vaginal canal, which gives plenty of opportunity for potentially infected vaginal fluid to transfer from the patient's hand to other surfaces of the examination room while transferring the swab from the vagina to the media container. Furthermore, contamination of the swab, which could happen if the swab simply touches the patient's leg or a table, could lead to false positives, as other patients' samples may have contaminated the environment previously. If false positives occur, patients may be given antibiotics to treat STIs they do not have, potentially harming their gut microbiome [5].

Competing Design

Manufacturers of STI self-swabbing kits exist both in the United States and internationally, but all commonly used methods involve at least a 2-component system. The kit used in the UW-Health System clinics is the Aptima Combo 2 Assay by Hologic® (Figure 1), which employs the use of a proprietary Dacron swab for sample collection, and a small media-filled tube for sample preservation [6]. Competing design Mía by XytoTest® utilizes the same design and sample collection method [7]. During the transfer of the sample to the media tube, there is a high probability of contact contamination as the patient must first collect their sample, then hold the swab as they attempt to transfer it into the transport media. The swab could fall out of their hands, the media container could spill, or the patient could transfer vaginal fluid onto nearby surfaces as they undergo the process of handling both the sample and media at the same time, causing contact contamination. Therefore, the aim is to create a one-component device that limits contact of the patient's hands with their vaginal fluid as much as possible.

Figure 1: Aptima Multitest Specimen Collection Kit by Hologic®.

Background

Chlamydia results from infection with the *Chlamydia trachomatis* (CT) bacterium – a species of the *chlamydophila* genus [1] [8]. This bacteria is an anaerobic, gram-negative, obligate intracellular parasite that only naturally manifests in humans [9]. CT bacteria can be subclassified into 18 serologically variant strains (serovars), with serovars D-K leading to genital or neonatal infections [8]. The CT bacteria can spread during vaginal, anal, or oral sex with an infected person, and can be transferred to a newborn baby from an infected mother during childbirth [1]. CT bacteria have a unique infectious life cycle with an elementary body (EB) that is metabolically inactive and a reticulate body (RB) that is metabolically active [8]. When first coming into contact with CT bacteria, host cells take up the EB form which then differentiates into RB [8]. RB can then replicate to form additional EB and further spread the infection [8]. Chlamydia is typically asymptomatic, with only 30% of women developing symptoms [1]. Some of these symptoms include endocervical bleeding or discharge, urethritis (frequent urination), and pelvic inflammatory disease (abdominal or pelvic pain) [1]. In women, the CT bacteria initially infect the cervix but may spread to the urethra or upper reproductive tract [1]. If the bacteria spread to the uterus and fallopian tubes, pelvic inflammatory disease can develop (PID)

[1]. PID can lead to additional health complications such as chronic pelvic pain, tubal factor infertility, ectopic pregnancy, and Fitz-Hugh-Curtis Syndrome [1].

Client

The client, Dr. Jean Riquelme, is a family medicine specialist based in Madison with over 31 years of experience. Dr. Riquelme graduated from the Medical College of Wisconsin in 1993 and completed her residency in family medicine at Aurora Healthcare (Milwaukee). Dr. Riquelme has requested a vaginal self-swab device that limits contact contamination of the testing room for use in chlamydia screening. Through this project, Dr. Riquelme hopes to increase universal testing for STIs.

Design Requirements

When testing for the CT bacteria using a swabbing technique, a non-toxic material must be used. Any toxic materials can lead to bacteria death when using cell culture techniques or interference with non-culture methods like Nucleic Acid Amplification Tests (NAATs) [10]. As a result, any materials that have not been provided by a manufacturer should be tested for toxicity in cell culture and interference with non-culture testing methods [10]. The swab shaft can be made of plastic or wire, and the tip should be made of Dacron or rayon as they are absorptive materials that will not inhibit bacteria isolation during laboratory testing [11] [12]. All swab samples must be stored in a chlamydia transport media that does not contain antibiotics [11]. Samples that are inoculated within 24 hours of collection should be stored at 4℃ while samples that are to be inoculated more than 24 hours after collection should be stored at -70℃ [11]. A material that can withstand this wide range of temperatures must be used to store the sample and the media.

Given that the device is to be used as a self-swab, it must be user-friendly and should ultimately promote universal testing. The device must allow for both swabbing and storage in a media in order to mitigate the contamination of the testing room [2]. This will be accomplished by employing a design that has a contained deployment, retraction, and sealing mechanism. The swab that is within the device must be deployed at least 5 cm into the vaginal canal to allow for adequate collection of CT bacteria [13]. All components of the device must be biocompatible as they will come into contact with the vaginal canal and potentially come into contact with CT bacteria [9]. For a more detailed description of the design specifications, see Appendix A.

Ethical Considerations and Universal Design

An additional requirement for the design includes considering the ethical dimensions of the design components as well as ensuring that the design is inclusive for patients of diverse backgrounds. One such ethical dimension includes the fact that the device will be a one-time-use medical device made out of plastic. The use of the device would ultimately contribute to the

current issue of medical waste and environmental harm. To account for this, the team must use an environmentally friendly material that can be recycled or is biodegradable. Some options include compostable and 3D-printable polymer blends such as PLA/PBS or using a material other than plastic such as cardboard. Another ethical dimension of the device is that it may require a reasonable amount of mobility and dexterity to be used by the patient. To address this issue, the team must make the device as ergonomically friendly as possible and limit more difficult maneuvers such as screwing caps on. This should be done in order to make the device as accessible and easy to use as possible for patients of all levels of mobility.

Preliminary Designs

Previous Semester Design: Plunger

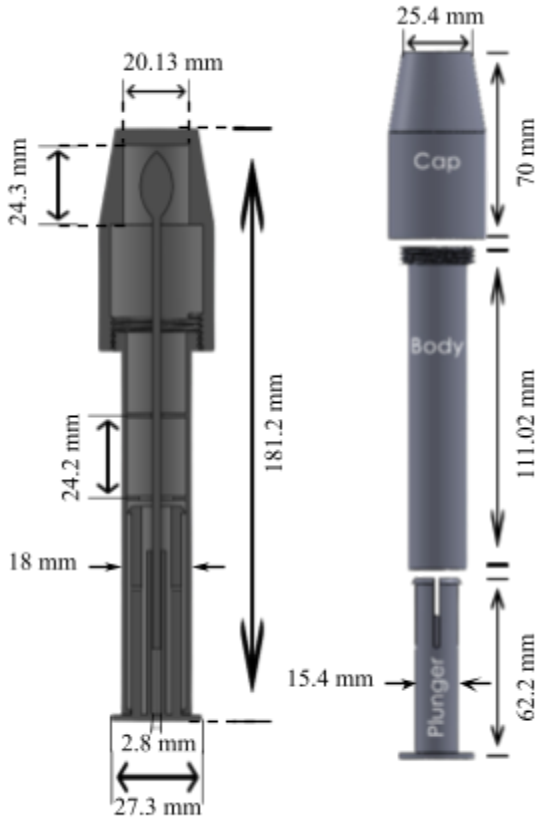


Figure 2: Dimensioned drawing of the previous prototype from fall 2023 with the plunger, body, and cap indicated.

The previous prototype from last semester, as seen in Figure 2, consisted of a plunger, body, and cap. The plunger acted as the deployment and retraction mechanism necessary to insert the swab at least 5 cm into the vagina and to remove the swab from the vagina. The plunger also had a small hole as seen in Figure 2 that was 2.8 mm in diameter and allowed for the attachment

of the swab shaft to the plunger. The body provided containment of the swab in order to limit contamination of the environment and also acted as a guide for the swab deployment path. The cap was designed to contain 2.9 ml of transport media that would be sealed off with an induction-sealed thin film. The main complication with this prototype was the leaking of fluid out of the cap, into the body, and ultimately onto surfaces through the gap between the plunger and the body. This leaking was problematic as the 2.9 ml of media is necessary to maintain the samples and may also contain bacteria that would contaminate the testing environment. Additionally, based on the survey that was conducted last semester, many respondents felt intimidated by the threading on the exterior of the body and had concerns about potential injury if the body of the device was inserted into the vagina. As a result, a design that addressed the issue of leaking and threading placement while still limiting contamination of the testing environment was necessary.

Design 1: Modified Plunger

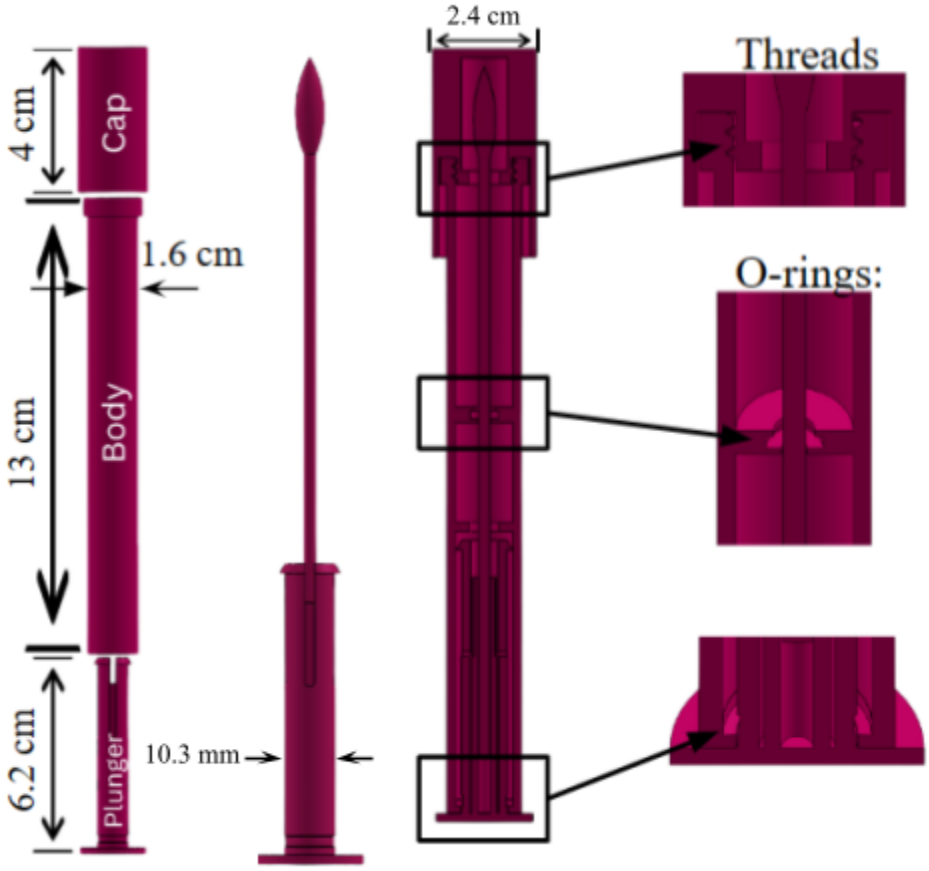


Figure 3: Modified plunger design with the cap, body, and plunger shown. A section view of the entire design with the threadings for the cap attachment on the interior of the body and two o-ring insertion sites indicated.

The first design idea, as seen in Figure 3, is a modification of the prototype completed last semester. This design idea was chosen to be modified due to its similarity to a tampon, a

device that approximately 50% of menstruating women regularly use [14]. This modified plunger design consists of the same three components – a plunger, body, and cap (Figure 3). The plunger of the design acts as the deployment and retraction mechanism necessary to insert the swab at least 5 cm into the vagina and to remove the swab after specimen collection. The body of the design acts to limit contamination of the testing environment by keeping the swab covered before and after use and providing an external casing that could be safely set down on a surface. The cap of the design is to store 2.9 mL of transport media via an induction-sealed thin film. As seen in Figure 3, there is a rim within the cap that is available for the attachment of this thin film.

When using this design, a patient would rest the top of the body against the vaginal opening, plunge the swab into the vaginal canal, grip and rotate the body to collect a sample, and then once again use the plunger to remove the swab from the vagina. The patient would then screw the cap onto the body of the device, flip the device upside down, and use the plunger one last time to puncture the thin film and soak the swab with media. To prevent leakage of media from the device, two locations for O-rings have been integrated into the body of the device. One advantage of this design is its ability to limit contamination of the testing room as the only portion of the design that will enter a potentially infected vaginal canal is to be contained by the body. Additionally, this design's use of a plunger makes it similar to a tampon, which may make the testing process a bit more comfortable when compared to conventional testing methods. While the design is suspected to reduce contamination, media may leak out of the device if the O-rings do not provide an adequate seal. If this leakage occurs, then the testing environment will inherently become contaminated. Additionally, the design will require extensive instructions to ensure that patients do not insert the body of the device into the vaginal canal and that they properly attach the cap after use.

Design 2: Snap On

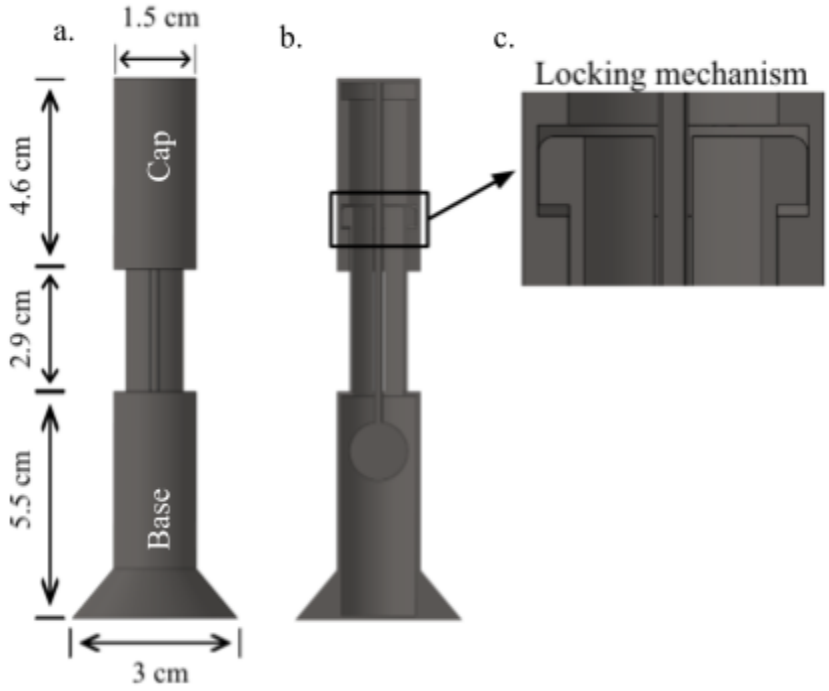


Figure 4: The Snap On design with the cap and the base. The section view shows the locking mechanism used to attach the cap to the base.

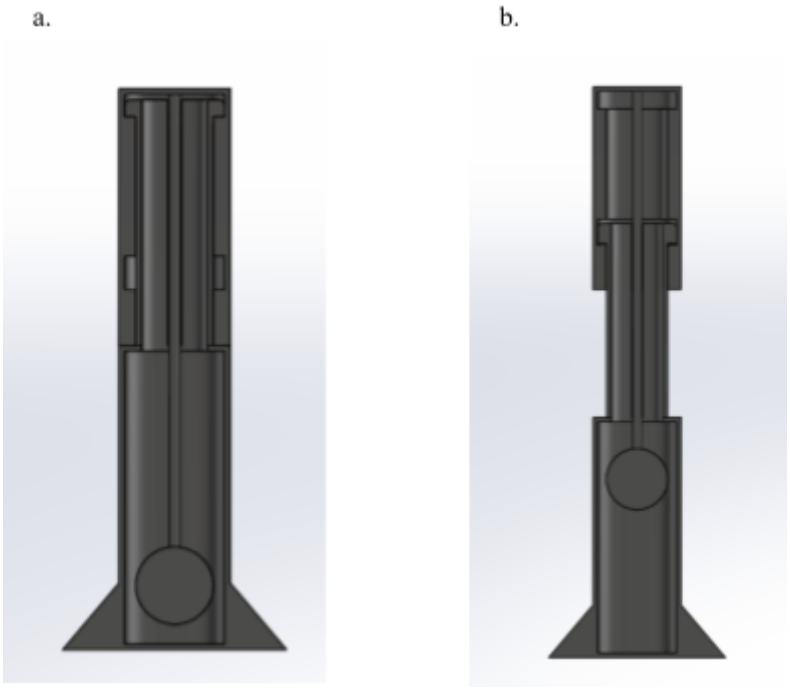


Figure 5: The Snap On design in the down position (a) and the up position (b).

The second proposed design consists of two separable components, the cap and the base. A 5 cm swab is attached to the cap, while the media is contained at the bottom of the base. As seen in Figure 4, the cap can vertically actuate in line with the base. The base has four thin vertical tabs with locking mechanisms which serve to hold the cap in a predetermined position. There are two positions the cap can be placed in, the up position and the down position (Figure 5b and 5a, respectively). The tabs are designed so that a horizontal force causes the locking mechanism to disengage, allowing the cap to slide up and down. An additional feature of this proposed design is the wide base. The wide base will allow the device to stand on its own, decreasing the likelihood of the patient laying it on its side causing contamination. Moreover, this design will not require the patient to hold any additional objects in their hands while they perform the swab, further reducing the likelihood of contamination.

To use the device, the patient would enter the testing room with the device in the up position. The patient would then push on the tabs, pulling the cap from the base. After completing the swab, the patient would push the cap into the base until the down position is reached. The head of the swab would be submerged in media and the patient could leave the room without needing to touch the device again.

Design 3: Pull-Back

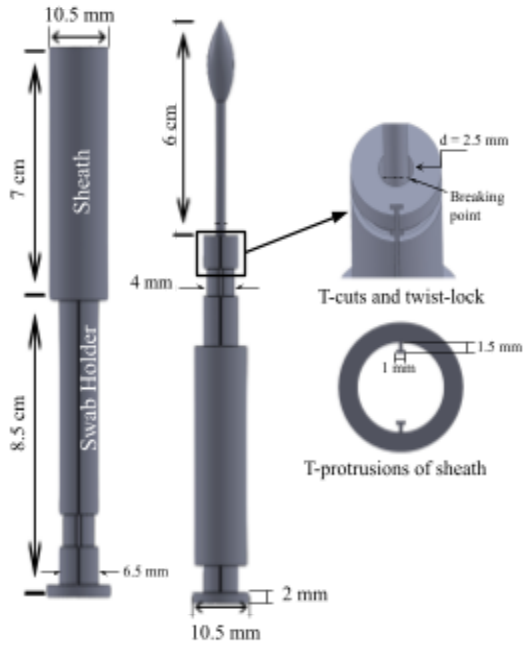


Figure 6: Pull-Back Design. From left to right: Patient received orientation with sheath locked into place. Pulled back to the second locking position, leaving 6 cm of the swab available for specimen collection. T-cuts and T-protrusion views for illustration of sliding mechanism.

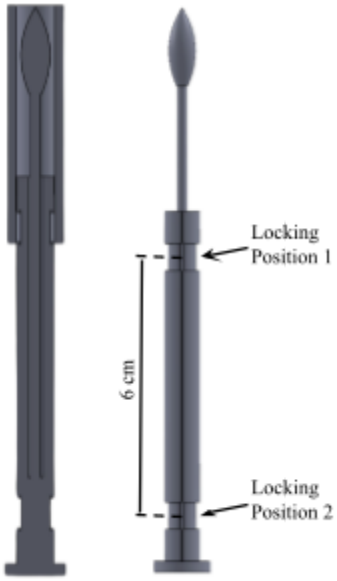


Figure 7: Section views of the Pull-Back design. From left to right: Section view with the sheath and without the sheath to indicate the two locking positions.

The third design idea consists of two components: a sliding sheath (outer cylinder) and a swab holder (inner cylinder). As seen in Figure 6, the swab holder contains two T-shaped cuts along the outer surface of its cylinder while the sheath has two T-shaped protrusions on its interior surface. These two parts – the cuts and protrusions – align to create a sliding track that is 1.5 mm in depth. The swab holder also has two secondary cuts that merge with the sliding track. These cuts allow the sheath to be twisted and locked into place at a particular location. Together, the swab holder and the sheath act to limit contamination of the testing environment as they provide complete coverage of the swab before and after use and should not be coming into contact with the vaginal canal.

When using this design, a patient would receive the device in the orientation shown in the leftmost view of Figures 6 and 7. In this orientation, the swab is completely covered and the sheath is locked in place. The patient would then twist the sheath 90 degrees counterclockwise to align the protrusions of the sheath with the cuts of the holder and pull the sheath down to the second locking position located 6 cm below the first. Once at the second locking position, the patient would rotate the sheath 90 degrees clockwise, locking it at this location and leaving 6 cm of the swab available for specimen collection (Figure 6). The patient would then use the device to insert the swab into the vaginal canal, collect the specimen, and remove the swab. After removing the swab from the vaginal canal, the patient would have to transfer the swab into the Aptima Transport Media tube by snapping it at the breaking point (Figure 6). Some advantages of this design include its ability to limit contact contamination and its relative ease of use. The sliding sheath acts as a barrier that allows the device to be set down without the risk of spreading contaminated fluids. Additionally, this design poses less risk of improper use as it is a relatively intuitive design that simply requires twisting and sliding. However, there is a risk of contamination via the spilling or splashing of media during the transport of the swab into the

secondary media container. Furthermore, the fabrication of this design may pose a challenge as its multiple fine parts must perfectly align for the design to function as intended.

Preliminary Design Evaluations

Design Criteria

The design criteria that were chosen to evaluate the preliminary design ideas include limiting contamination, leakage prevention, ease of use, ease of fabrication, patient comfort, safety, and cost. These criteria were chosen in accordance with the main client requirements and design requirements.

The first category, limiting contamination, refers to the ability of the device to prevent the spread of biological fluids and infectious species in the testing environment. A design that receives a 5/5 should completely cover the swab shaft and tip when in the retracted position, should have a method of covering the top portion of the body of the device during transport, and should also minimize the number of steps or transfers required during testing.

The leakage prevention category was added to evaluate the ability of this design iteration to keep all media contained within the device via a sealing mechanism. This was the main objective of the project for this semester and thus was given a high scoring weight. Designs that receive a 5/5 in this category should have mechanisms to actively prevent media leakage from any connection points in the design.

The ease of use category describes the overall simplicity of the device and the process for using it to collect a sample. A design that receives a 5/5, in this case, would include easy to understand instructions in addition to being simple enough for patients to get viable samples on their own. The product should be user-friendly and serve to decrease barriers to testing through increased usability for all patients.

The ease of fabrication category describes the feasibility of device fabrication by the team via 3D printing, machining, or a combination, and evaluates the complexity of the machining required to fabricate specific design components. As one of the main goals for this device is to increase the availability of universal testing, the design must be easily and reproducibly fabricated. Qualities such as simplicity, number of parts, size, and material will be taken into consideration when evaluating each design's ease of fabrication. The device must be able to be built with the technology and machines available in the TEAM Lab and Makerspace at UW-Madison.

The patient comfort category evaluates how comfortable a patient would be with using the device and considers any intimidation they may experience. A design that receives a 5/5 should allow patients to test in the testing setting and should not cause any pain or irritation within the vaginal canal.

Safety takes into account the potential biological and physical threats that are associated with device use. A design that receives a 5/5 should have material that is not abrasive/toxic to the

tissue of the vagina and especially is not abrasive or harmful to the vaginal canal tissue when rotating the swab.

Lastly, cost refers to the price of manufacturing a singular unit. A design that receives a 5/5 score would keep prototyping costs within the budget of $500 that the client provided and be inexpensive enough that it could be mass-produced.

Design Matrix

Table 1: The Design Matrix evaluating potential solutions for the Self-Swab Device.

Criteria	**Weight**	**1. Modified Plunger** 		**2. Snap On** 		**3. Pull Back** 	
Limiting contamination	30	5/5	30	3/5	18	4/5	24
Leakage Prevention	25	3/5	15	5/5	25	2/5	10
Ease of use	15	3/5	9	5/5	15	4/5	12
Ease of fabrication	10	3/5	6	5/5	10	2/5	4
Patient Comfort	10	5/5	10	4/5	8	4/5	8
Safety	5	5/5	5	5/5	5	5/5	5
Cost	5	5/5	5	5/5	5	5/5	5
Total	**100**	80		**86**		68	

Justification of Scores

For limiting contamination, designs 1 and 3 both scored the highest as they prevent any exposure of the swab with the environment; instead, they keep the head of the swab enclosed until it is inserted into the vaginal canal and then it is enclosed again after removal. By doing so, both devices limit the possibility of the swab contacting surfaces in the testing room and spreading infected vaginal fluids. However, in terms of leakage prevention, design 2 scored the highest because there is no plunger or slider that media could leak through. By eliminating this design element, the Snap On design is able to prevent the situation in which the device is upside-down and media is freely falling within the device and out any orifices, thereby reducing the risk of leakage. Additionally, eliminating the plunger or slider mechanism creates a more simplistic design that is easier to use, as it requires less moving parts, and easier to fabricate, as it does not require complex machining or threading. Therefore, design 2 scored the highest in these categories. When considering patient comfort, design 1 scored the highest due to its similarity to the tampon, a device that most female patients are familiar and comfortable with. In terms of safety, all three designs scored equally as they all require the insertion of the swab into the vaginal canal but do not require insertion of any other materials that could potentially have adverse effects. Lastly, all three designs scored equally on cost as they are all extremely inexpensive to 3D print at around $1-3 per print.

Based on the criteria and evaluations presented, the Snap On design stands out as the most well-rounded design that meets all required criteria.

Proposed Final Design

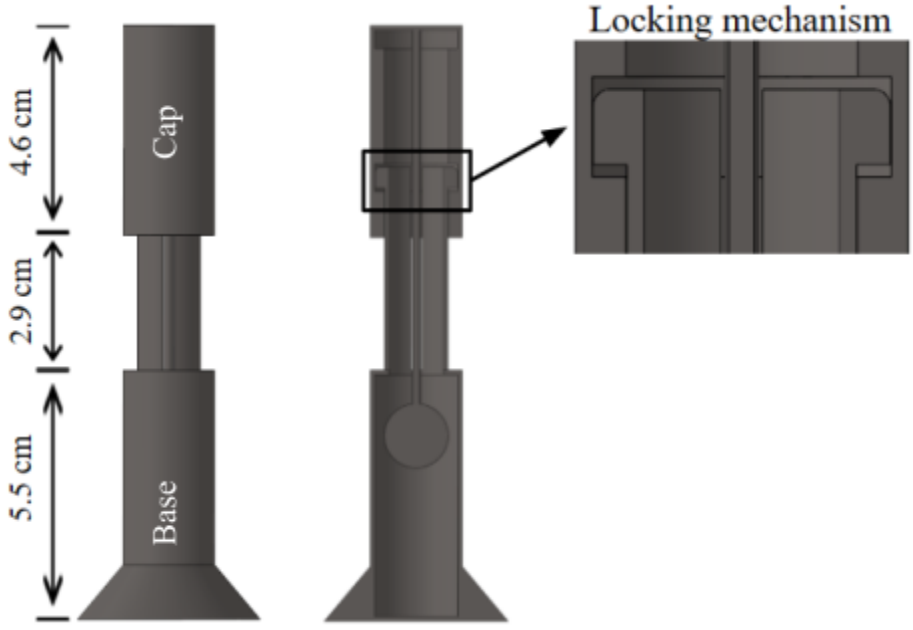


Figure 8: The Snap On was chosen as the proposed final design. The cap, base and locking mechanism of this design are all visible.

The Snap On design was chosen as the proposed final design due to its high scores in leakage prevention, ease of use, and ease of fabrication. The intuitive design and functionality will mitigate leakage since the patient is never required to move or lift the media-filled base. Additionally, this design does not require the patient to hold any extra objects while they perform the swab, resulting in a high ease of use score. Relative to the other designs, the Snap On will have the most straightforward fabrication process. There are no threads that will need to be 3D printed and there are fewer intricate components that would be difficult to print without failure. However, testing and rapid prototyping will be required to hone the tabs and locking mechanism that are attached to the base.

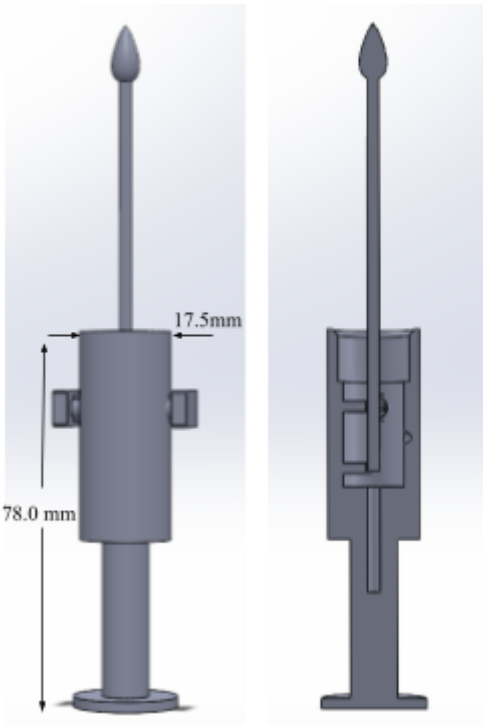
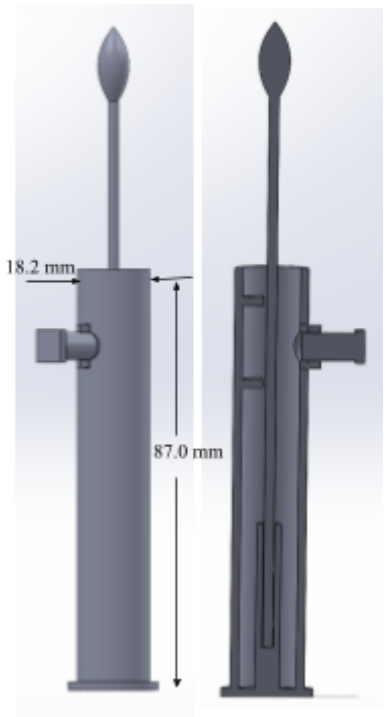
The biggest area of concern for this design is the potential for contamination. The Snap On is the only design in which the swab is exposed after insertion into the vaginal canal. This gives the potential for the patient to lay the swab on a surface, contaminating the room. This risk will be mitigated by clear instructions which detail exactly how the test is to be performed. Further precautions will be taken by creating a cap with a sturdy top so that if the patient puts it on the table, the swab does not contact the surface.

Design Challenges and Mid-Semester Shift

After evaluating the three aforementioned designs and deciding to move forward with the Snap On design, a previously-unknown design requirement for the device was discovered. During a meeting with Dr. Accola, who works in a UW Health lab that processes STI tests, it was revealed that the device must be compatible with and ultimately transfer the swab into the Aptima transport media tube. This is required as the Aptima transport media tube is directly placed into a machine used for sample processing. This machine, the Hologic® Panther, is a fully automated system designed for processing many samples at once by plunging a pipette tip directly through the foil-covered foam within the cap of the Aptima transport media tube. Therefore, in order to not disrupt this process, the Aptima media tube must be used within the device. To accommodate this new requirement, the goal of the self-swab device shifted from a fully contained device to one that integrates with the current collection kit and reduces the contamination associated with it. Streamlining the process of transferring the swab to the media tube was determined to be the main focus of the device - with the new transfer process being required to prevent the splashing or spilling of media and the contact between the contaminated swab and any surfaces in the testing environment.

To address these new requirements, two different designs of a device that attaches to the Aptima transport media tube, provides coverage of the swab shaft, and contains a mechanism for breaking the swab at its perforation point were proposed. By incorporating these key elements, the device would limit the splashing of media when transferring the swab into the transport media tube and keep the swab tip elevated from surfaces when not in use. The two designs are pictured and summarized in Table 2 below.

Table 2: Descriptions of new designs created after the mid-semester shift.

	Button Cutter Design	**Three-Point Bending Design**
Diagram		
Description	• Mechanism to cut swab via two buttons • Compression fit onto top of Aptima media tube • Internal supports to keep swab in line	• Mechanism to snap swab via 3-point bending configuration • Compression fit onto top of Aptima media tube • Internal supports to keep swab in line and create 3-point bending configuration

Both designs depicted above feature a tube-like design that can stand on its bottom surface to keep the swab tip in the air. The opening of the tube for both designs fits over the top of the Aptima transport media tube with a compression fit to prevent spillage or splashing of media. Additionally, both designs feature internal supports for the swab. The primary difference between the two lies in their respective mechanisms for breaking the swab: the button cutter design employs two buttons with sharp tips that push together to cut the swab at its perforation point, while the three-point bending design utilizes internal supports and a push-button to apply a load at the perforation point, breaking the swab in three-point bending. Both designs share many similarities and utilize identical components to minimize contamination. However, the three-point bending design was selected to be the final prototype as the mechanism to break the

swab would be more easily fabricated. Additionally, the use of one button simplifies the process of using the device when compared to two buttons. Thus, it was decided to proceed with the three-point bending design. See the Final Design section below for a more detailed description of the device.

Fabrication/Development Process

Materials

Swab: The swab was a Dacron swab. Dacron swabs are non-cotton, non-toxic, hydrophilic, synthetic fiber-wrapped swabs [15]. 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. The shaft of the swab varies depending on the Aptima Multitest Specimen Collection Kit that is used; one variation includes a swab shaft made from a proprietary plastic, whereas another variation has a swab shaft made from wood [16].

Transport media: A universal transport media was used. This media is included in the Aptima Multitest Specimen Collection Kit. Transport media increases the viability of the obtained specimen by keeping it in a wet environment [17]. It is essential that the swab head is kept in the provided transport media tube because the sample will be processed directly inside the tube using the Hologic® Panther machine.

Device body: The device prototype will be 3D-printed out of polylactic 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 [18].
See Appendix A for further descriptions of pricing and sourcing of material components.

Methods

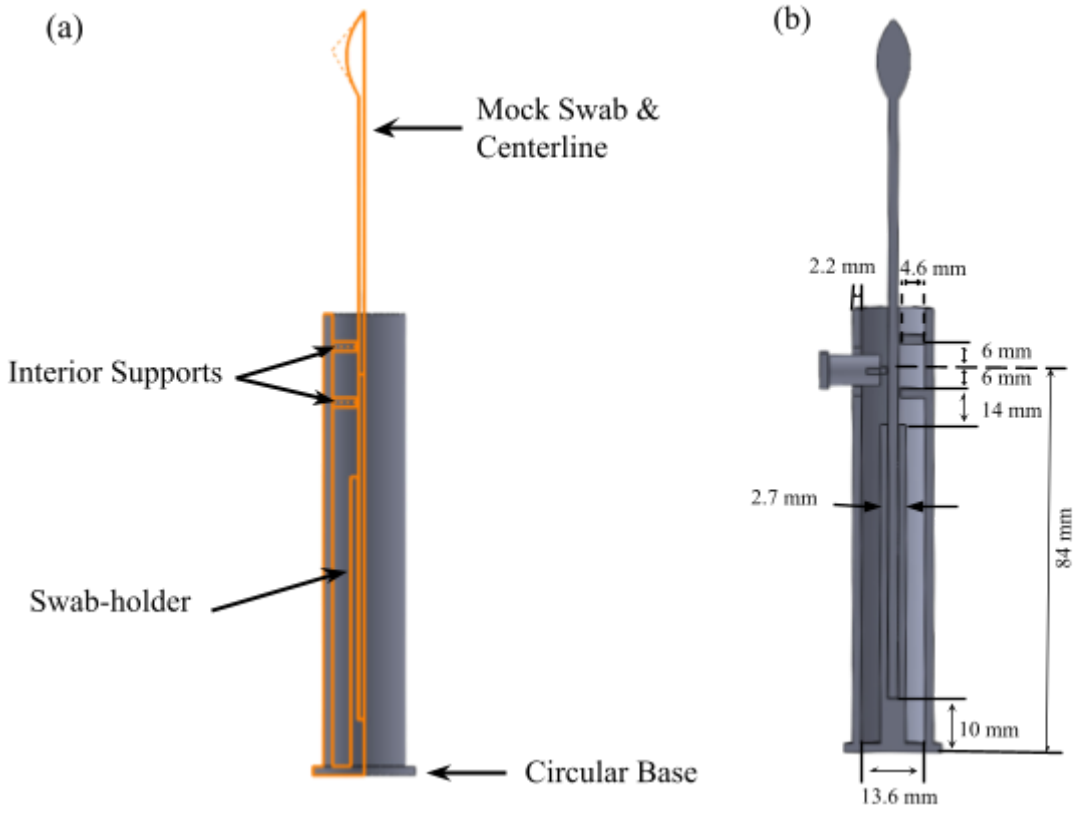


Figure 9: (a) Illustrative image of the CAD drawing utilized to fabricate the external casing with the two interior supports, swab-holder, and circular base indicated. (b) Dimensioned drawing of external casing section view.

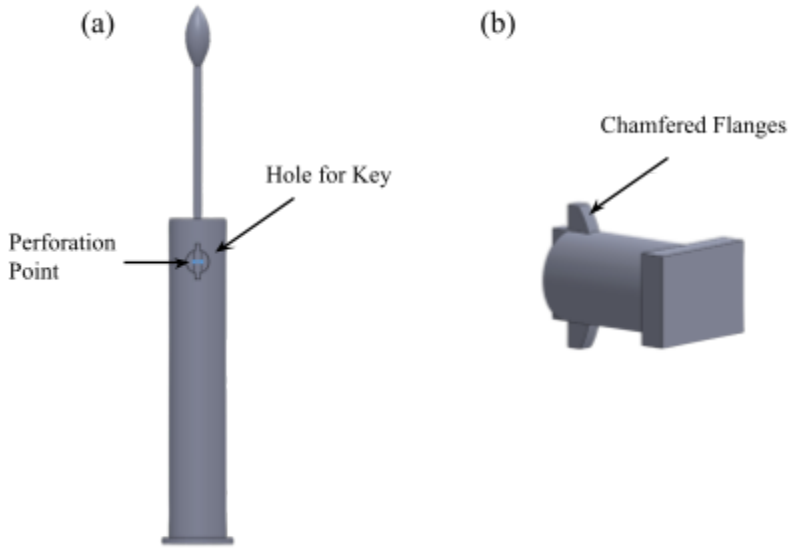


Figure 10: (a) Illustration of the hole fabricated on the exterior surface of the casing to house the push-button. (b) Keyed push-button that tightly fits into the hole of the casing and lies flush with the interior surface of the casing.

All components of the final design – consisting of an external casing, keyed push-button, and media stand – were first designed in SolidWorks. A mock swab, which can be seen in Figure 9a, was first drawn and ultimately used as a reference to generate the external casing and keyed push-button. This Dacron swab is known to have a length of 15.2 cm and a diameter of 2.4 mm, however, the location of the perforation point was not provided by the manufacturer [16]. As a result, four client-provided Dacron swabs were broken and calipers were used to determine the location of this breaking point relative to the bottom end of the swab. This distance was determined to be 74 mm ± 0.023 mm which was used to place the interior supports and keyed push-button as seen in Figures 9a and 10a. Calipers were also used to determine the diameter of the media test tube (13 mm ± 0.012 mm) which was used as a baseline for the interior diameter of the external casing.

The interior diameter of the external casing was drawn to be 13.6 mm in diameter, allowing for 0.3 mm of tolerance at the interface between the casing and the media tube. The exterior surface of the casing was then drawn to provide a wall thickness of 2.2 mm and a bottom circular surface was drawn to allow the device to stand upright (Figure 9a). A swab holder with a diameter of 2.7 mm and wall thickness of 1.5 mm was drawn to completely enclose the lower 60 cm of the swab shaft, inhibiting its removal during testing. The three-point bending supports were then drawn as two rectangles protruding from the interior surface of the casing, with one support 6 mm above the perforation point and one 6 mm below (Figure 9b). These supports were both placed 1 mm away from the outer edge of the swab to minimize the motion of the swab during three-point bending (Figure 9b). The swab and external casing were then revolved 360° about the centerline of the swab shaft while the two internal supports were extruded along the interior surface of the casing to generate the three-dimensional structure seen in Figure 8a.

A reference plane tangent to the exterior surface of the casing was then generated. This reference plane was used to draw the keyed hole of the casing and was placed such that its center point aligned with the perforation point of the swab shaft (Figure 10a). The hole was created via an extruded cut that extends through the wall of the casing. The keyed push-button was then drawn on this same reference plane, with 0.15 mm of tolerance between the cuts of the casing and the protrusions of the push-button. The flanges of the push-button were chamfered such that they lay flush with the interior surface of the casing (Figure 10b). Finally, the media stand was drawn via the extrusion of three concentric circles. The outermost circle was first drawn to have a diameter of 33 mm to maximize the base of support and thus the angle withstood before tipping. The innermost circle was drawn to have a diameter of 13 mm in order to tightly hold the media tube.

Upon completion of the SolidWorks drawings, STL files of the external casing, the keyed push-button, and the media stand were downloaded and uploaded to a flash drive. The flash drive was then plugged into the UW-Madison Makerspace computers for 3D printing on the Bambu studio printer. The Bambu studio labs software was opened and the STL files of each component were imported onto the same buildplate as separate parts of the same print. A white polylactic acid (PLA) filament with a diameter of 1.75 mm was used for all three components. Rectangular

supports were enabled with a support print speed of 150 mm/s. A layer thickness of 0.16 mm, a non-support print speed of 200 mm/s, and an infill of 20% was used. For a detailed 3D printing protocol, refer to Appendix C.

Once the print was complete, all supports were removed using picks provided by the Makerspace. A Dacron swab was then forcefully inserted into the swab holder of the casing and the keyed push-button was placed into the external casing.

Final Design

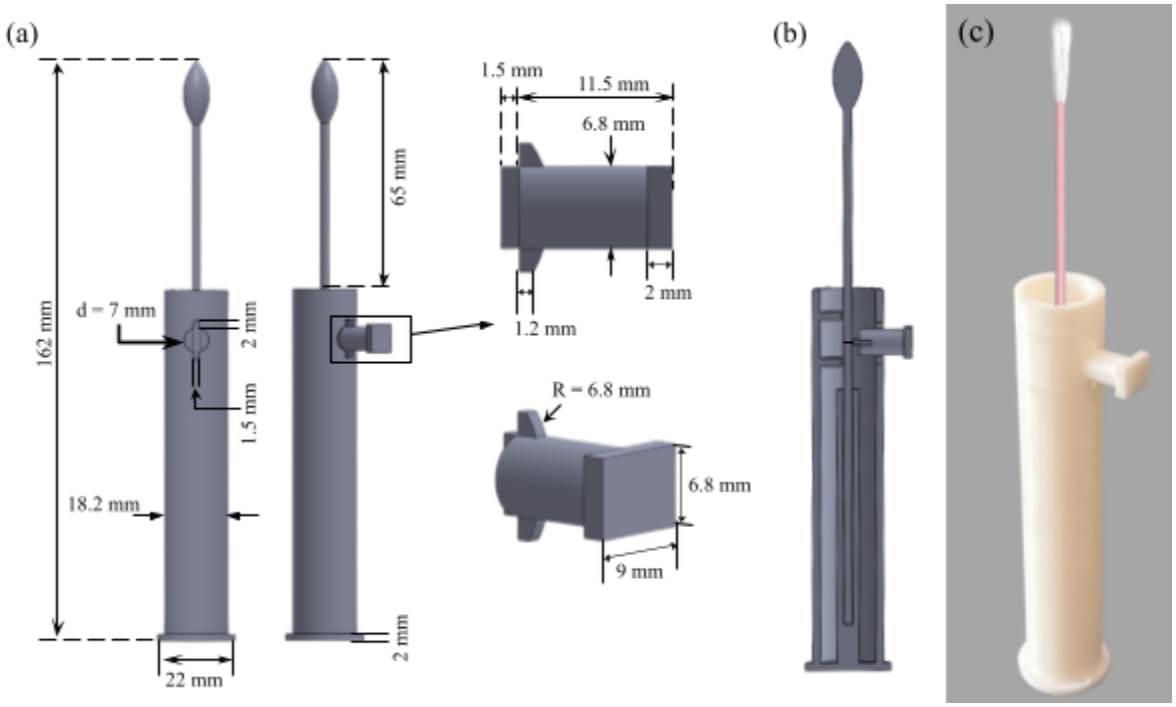


Figure 11: (a) Dimensioned images of the final specimen collection device including the external casing and keyed push-button. (b) Section view of specimen collection device illustrating the three-point bending mechanism. (c) Image of 3D printed specimen collection device housing the Dacron swab.

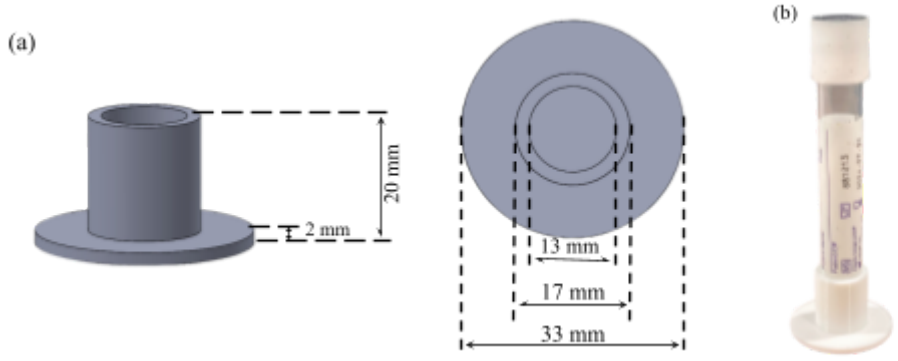


Figure 12: (a) Dimensioned image of the media test-tube stand that holds and stabilizes the Aptima media transport test-tube. (b) Image of 3D printed media stand holding the test tube.

The final design, as seen in Figures 11 and 12, consists of three main components: an external casing for specimen collection, a keyed push-button within the external casing for the transfer process, and a media stand that stabilizes the transfer process. The external casing of the specimen collection device firmly holds the lower 60 cm of the Dacron swab in place while leaving the upper 6.5 cm of the swab available for specimen collection. The external casing also allows patients to safely set the device down during the testing process as the bottom end of the device should never come into contact with the vagina and holds the swab tip upright when placed flat on its surface (Figure 11a). The three-point bending mechanism of this design is to be used when transferring the swab from the external casing to the media tube and includes the two supports on the interior surface of the casing as well as the keyed push-button (Figure 11b). The external casing has a keyed hole seen in Figure 11a that tightly fits the keyed push-button. This hole is designed such that the rectangular protrusion of the keyed push-button aligns with the perforation point of the Dacron swab shaft while the two interior supports on the casing are spaced equally above and below the perforation point. These two components come together to form the three-point bending mechanism that breaks the swab, allowing it to fall into the media test-tube. Additionally, the external casing acts as a splash guard that prevents the splashing of media during the transfer process as any expelled fluids would be contained within the device itself. The media test tube stand is the final component of the design and can be seen in Figure 12. This stand is designed to hold the Aptima media transport tube and prevent it from tipping over during the transfer process.

To use the device, a patient would receive it as shown in Figure 11c, with the Dacron swab held within the casing and the keyed-push button placed inside. The assembled device, media test tube, and media stand would all be provided in clean packaging and need to be opened by the patient before specimen collection. Upon opening the packaging, the patient would set the specimen collection device on its bottom surface and place the media tube in its stand. The patient would then grip the bottom of the external casing, insert the Dacron swab 5 cm into the vaginal canal, rotate the swab against the vaginal walls for 10-30 seconds, and remove the swab from the vagina to collect a specimen. The patient would once again place the device down on its bottom surface to open the cap to the media tube. Once the cap has been removed, the patient would flip the device upside down and firmly press it over the media tube, placing the tip of the Dacron swab in the media. At this point, the device is firmly held in place over the media test tube via a friction fit and the three-point bending mechanism is ready to be used. To use the three-point bending mechanism, the patient presses the push-button inward causing the swab to break and fall into the media tube. Any fluids that may be expelled during this process would subsequently be caught within the device, preventing contamination via the splashing of media. The patient then removes the collection device from the media tube, screws the proper cap back on, and throws the collection device away. For a detailed instruction manual with images detailing the above steps, see Appendix E.

Some shortcomings with this final design include the free rotation of the keyed push-button, the required use of an Aptima swab, and the potential misalignment between the

push-button and the perforation point of the swab. In the current final design, as seen in Figure 11, the keyed push-button is free to rotate within the casing of the device leading to the potential for the rectangular protrusion to lay parallel with the swab rather than perpendicular. This would cause the three-point bending mechanism to dysfunction and patients would likely require aid from a healthcare provider to break the swab. Additionally, there is lot-to-lot variability in the length and diameter of the Dacron swabs. This variability limits the compatibility of both the swab holder and three-point bending mechanism as the device is designed to hold a swab with a diameter of 2.4 mm, a length of 152 mm, and a perforation point 74 mm above the bottom end of the swab.

Testing

Design Survey

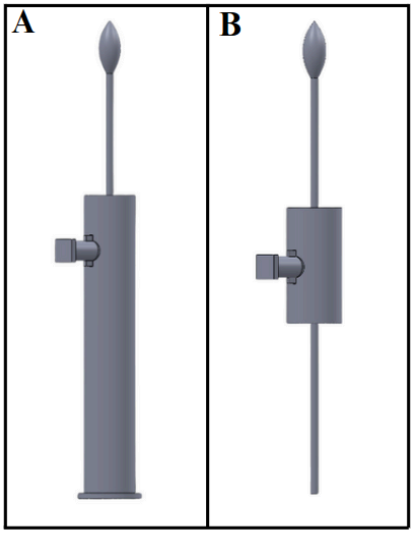


Figure 13: Prototypes A and B as presented on the survey.

A survey regarding the preferred prototype, the aesthetics of the design, the ease of use, and the efficacy of the instruction manual was conducted with fellow BME 301 students. The two prototypes seen in Figure 13 are essentially the same design, with prototype B being a shorter iteration that only incorporates the three-point bending mechanism. Survey respondents were first asked to open a document linked at the top of the survey that introduced the project and provided some background information on STI self-swab testing. This background information highlighted the contamination concerns with current self-swab testing methods and pointed out the following means of contamination: setting the swab down after specimen collection, improper holding of the swab leading to contamination of the hands, and splashing of fluids from the swab or media tube during the breaking process. This background information also briefly described how these two prototypes work and provided a section view to illustrate the three-point bending mechanism that replaces the physical breaking of the swab during the

transfer process. Respondents were then provided an instruction manual that detailed the use of prototypes A and B with visuals. To access the background information and instruction manual as provided in the survey please see Appendix F.

In short, the instruction manual was as follows:

1) *Wash hands.*
2) *Remove the media test tube from its packaging and place it in the stand.*
3) *Remove the device from its sterile packaging and hold it at its bottom end.*
4) *Holding the bottom of the outer plastic casing, carefully insert 2 inches (5 cm) of the Dacron swab into the vagina.* ***Do not insert the plastic device into the vagina.***
5) *Gently rotate the swab against the vaginal walls for 10-30 seconds.*
6) *Remove the swab from the vagina*
7) *Prototype A: Set the device down on the counter. Keeping the media test tube in the holder, remove the cap and set it down on the counter.*
   Prototype B: Hold the device in your hand. Keeping the media test tube in its holder, remove the cap and set it down on the counter.
8) *Flip the device upside down and attach it to the test tube by firmly pressing the device over the opening of the tube.*
9) *Press the button on the side of the device to break the swab.*
10) *Remove the device from the test tube by pulling up on the device. Discard the removed part of the device.*
11) *Firmly screw the original cap to the test tube back on.*
12) *Wash hands.*

Subsequently, respondents were asked the following questions and were provided with the answer choices as shown:

- Which prototype would you feel more comfortable using when conducting a vaginal self-swab in a clinic?
  (Prototype A, Prototype B, Other)
- On a scale of 1-5, how visually appealing is prototype A?
  (1 - Very Unappealing, 5 - Very Appealing)
- On a scale of 1-5, how visually appealing is prototype B?
  (1 - Very Unappealing, 5 - Very Appealing)
- Do you feel that the instructions effectively taught you how to use the device?
  (Yes, No, Other)
- After reading over the instructions, how comfortable would you be with breaking off the swab using a push-button?
  (1 - Very Uncomfortable, 5 - Very Comfortable)

- After reading over the instructions, do you think that screwing the device onto the media test tube would be more effective than just “sliding” it over with a friction fit?
  (Short Answer)
- Would you be able to use the instructions for either of the prototypes to conduct an STI swab test?
  (Yes, with the help of a healthcare provider. Yes, after a demonstration from a healthcare provider. Yes, after reading over the instructions I could use this device on my own. No)
- On a scale of 1-5, how effective do you think the device is at limiting contamination?
  (1 - Very Ineffective, 5 - Very Effective)
- Are there any aspects of either prototype that would discourage you from using the device?
  (Short Answer)
- Do you have any other feedback for our vaginal self-swab?
  (Short Answer)

These questions were chosen to evaluate specific criteria from the design specifications which required the device to be user-friendly, ensure patient comfort, and limit contamination of the testing environment. Emphasis was placed on the two prototypes in this survey due to conflicting feedback received at the BME design show and tell presentations where half of the viewers preferred prototype A and half preferred prototype B. Additionally, many questions regarding the instruction manual for the device were presented in this survey as the instructions serve as the main mode of the patient-device interface; thus they must be unambiguous to ensure the device is easy to use for any potential patient.

Mechanical Testing

Mechanical testing was performed to evaluate the ease of use of the prototype. Two of the most common types of swabs were tested into a MTS Criterion Model C43.104 in three-point bend configuration (Figure 14). The spacers were placed 12 mm apart to mimic the three point bending mechanism within the final design. The cross head was set to move at a rate of 2 mm/min while also measuring the force until the swab broke. Refer to Appendix H for the full protocol. The forces were then analyzed and are discussed in the results section of this report.

Figure 14: The pink swab placed in the MTS machine in the three point bend configuration.

Contamination Testing

To quantify the ability of the prototype to limit contamination of the testing environment compared to the current collection method, contamination testing was performed using a plastic vaginal model. The model (Figure 15) consists of a clear casing in the shape of female reproductive organs including the vagina, cervix, uterus, and ovaries. To simulate potentially infected vaginal fluids, the interior of the model was coated with washable finger paint. The vaginal model was swabbed using both the Aptima Collection Kit and the prototype for a total of 8 trials. All steps of the testing process, from the initial swab to the transfer of the swab to the media tube, were performed over a sheet of white paper that would represent the testing environment. Additionally, testing was performed while wearing nitrile gloves in order to record the contamination of the patient's hands.

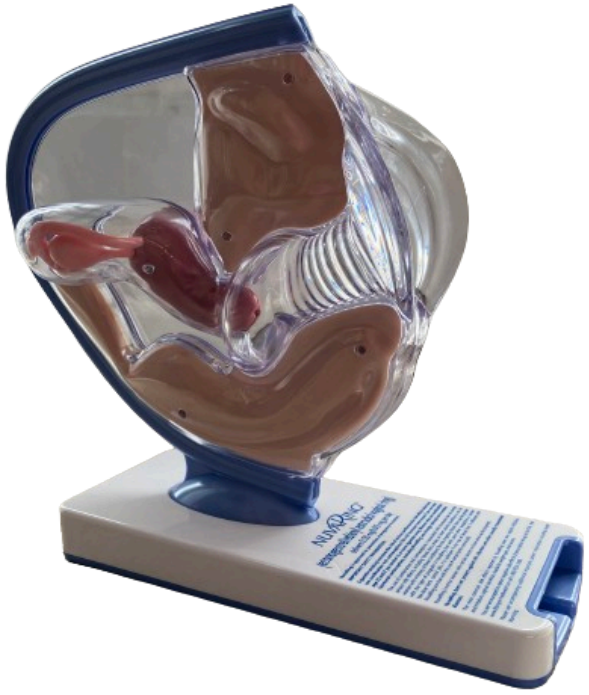


Figure 15: Plastic vaginal model used for contamination testing.

Results were obtained by imaging the piece of paper that the test was performed on. Images were uploaded into ImageJ software and converted to an 8-bit image. Next, thresholding of the images was performed to select the contaminated area, which allowed the area to then be measured and recorded. The total contaminated area was then divided by the area of the entire paper in order to measure the percentage of area contaminated during each test. Supplementary results were obtained qualitatively by imaging the media tubes and gloves used for each trial. The team recorded whether or not each test resulted in contamination of the media tube or gloves.

Statistical analysis was performed using a Wilcoxon ranked-sum test to analyze the significance between the percentage of contaminated area for the Aptima tests and the prototype tests. This test was chosen because the two sample groups were independent and not expected to be normally distributed.

Tip Testing

In order to quantify the base's ability to provide support, tip testing was performed using the 3D printed base and an Aptima tube. Twelve total trials were performed simulating four different circumstances: pushing on the cap with the base, pushing on the cap without the base, pushing on the middle of the tube with the base, and pushing on the tube without the base. To collect the data, a video recording device was used to clearly capture footage of each trial. The

footage was then reviewed to find the exact frame of the tube starting to tip over. The frame was then uploaded to ImageJ, where the angle of tipping from the cap was then measured.

Figure 16: Image of tip testing being conducted.

Statistical analysis was also performed to determine statistical significance between tests using the base and tests without the base by performing a Wilcoxon ranked-sum test. This test was chosen because the sample groups were independent and they are not expected to be normally distributed. For a detailed tip testing protocol, see Appendix I.

Results

Design Survey

Regarding the design choice of prototype A vs. prototype B, approximately 92% of respondents (n = 24) felt that they would be more comfortable using prototype A – the longer design seen in Figure 13 – during a vaginal STI self-swab test, finding it to be more visually appealing and user-friendly than prototype B. As seen in Figure 18 below, approximately 80% of respondents found prototype A to be visually appealing (4/5) or very visually appealing (5/5), while only 16% of respondents felt the same regarding prototype B. As a result, prototype A was chosen to be the final design in order to maximize patient comfort during vaginal self-swab STI testing.

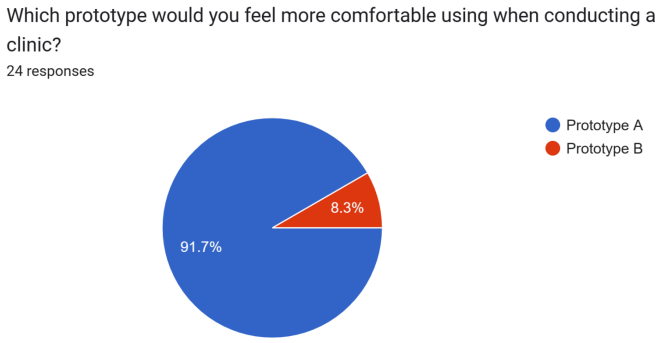


Figure 17: Pie chart indicating that approximately 92% of respondents would feel more comfortable using prototype A when conducting a vaginal self-swab.

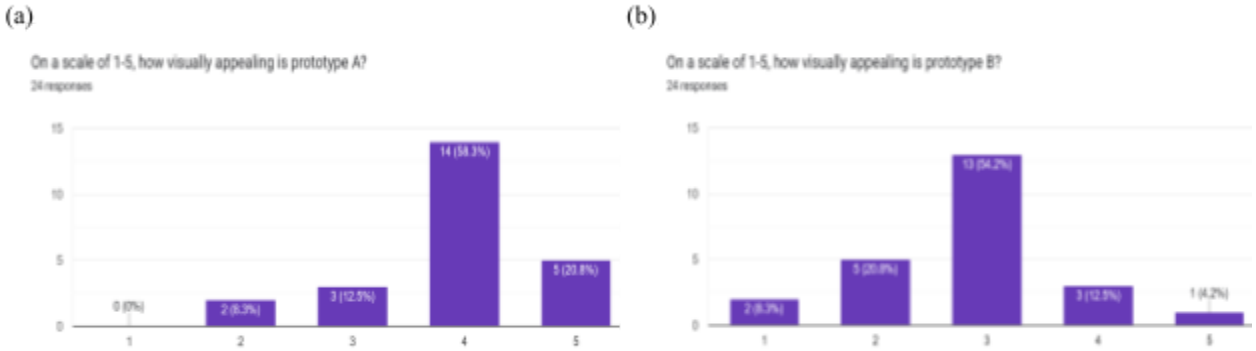


Figure 18: Bar graph results on visual appeal of (a) prototype A and (b) prototype B showcasing that a majority of respondents felt prototype A to be more visually appealing than prototype B.

The survey results concerning the instruction manual, as seen in Figure 19 below, indicated that the provided instructions would adequately teach a potential patient how to use either prototype when collecting a vaginal self-swab STI sample. As seen in Figure 19, 100% of respondents felt the instruction manual effectively taught them how to use either prototype and 96% felt that they could use the instructions to conduct a vaginal self-swab on their own or after a demonstration from a healthcare provider – indicating that the final design will provide comfort and ease of use to any potential patient. Furthermore, 92% of respondents felt they would be comfortable (4/5) or very comfortable (5/5) using the keyed-push button to break the swab, further showcasing how the design is intuitive and provides very little discomfort with the use of a three-point bending mechanism (Figure 20 below). It is also worth noting that 75% of respondents felt that either prototype would effectively limit contamination which, although subjective, shows that fellow biomedical engineers understand the need for and the effectiveness of the fabricated device (Figure 21 below).

Figure 19: (a) Pie chart indicating that 100% of respondents felt the instructions effectively taught them how to use either prototype. (b) Pie chart indicating that 87.5% of respondents could use the prototype on their own after reading over the instruction manual, 8.3% after a demonstration from a healthcare provider, and 4.2% with the help of a healthcare provider.

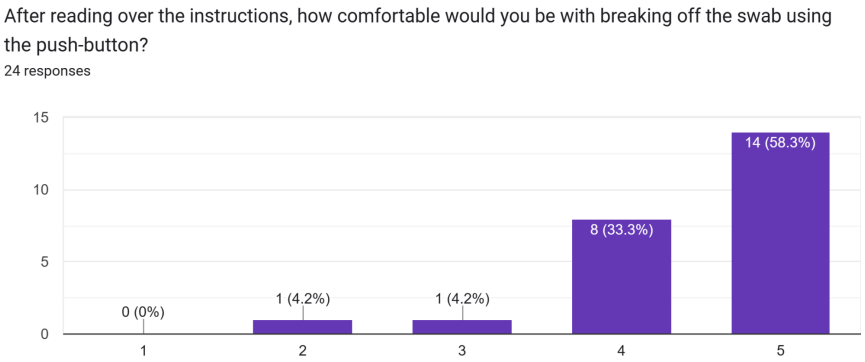


Figure 20: Bar graph results on level of comfort with using the push-button to break the swab and transfer it to the Aptima media tube.

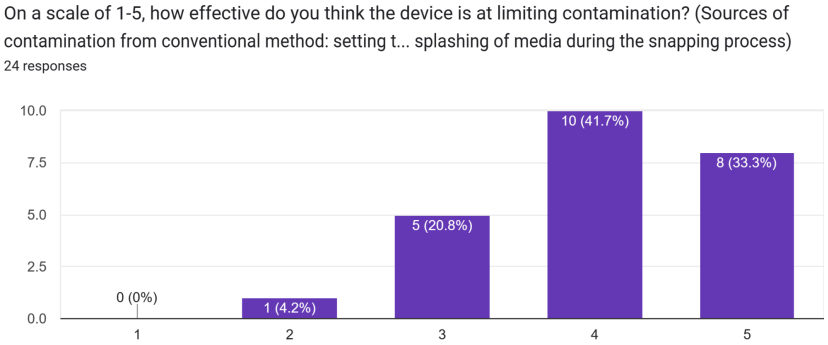


Figure 21: Bar graph results on the perceived ability for either prototype to limit contamination during vaginal self-swab STI testing.

Regarding the short answer questions, a majority of the respondents felt that screwing the device over the media tube during the transfer process would be more intuitive and more effectively prevent the spillage of media. Additionally, some respondents felt that the push-button would be confusing to use if a section view was not provided and the mechanism was not well described. As a result, a description of the device was integrated into the final prototype's instruction manual as seen in Appendix E. Some other feedback received from the survey regarded the length of the instruction manual. Given that this device is to be used by patients during STI self-swabbing, a lengthy instruction manual may deter patients from routine testing. To see each response to the short answer questions, please refer to Appendix G.

Mechanical Testing

The force required to break two of the most commonly used swabs was evaluated and compared to the average woman's grip strength to determine the ease of use of the device. After breaking three of each of the swabs, the pink swab was found to require 26.34 ± 0.65 N to break while the blue swab requires 16.62 ± 0.43 N to break. These values were then compared to the average woman's grip strength which was found to be 277.8 ± 52.8 N [19]. Given the significant gap between the force required to use the device and the force a woman is able to generate, it was determined that the device would be able to be used by the vast majority of women. A visual comparison of the force required to break the swabs and force that can be generated by women can be seen in Figure 22. It is important to note, however, that the three point bend was done under ideal conditions so the actual force to use the device will be slightly higher than measured in the MTS machine.

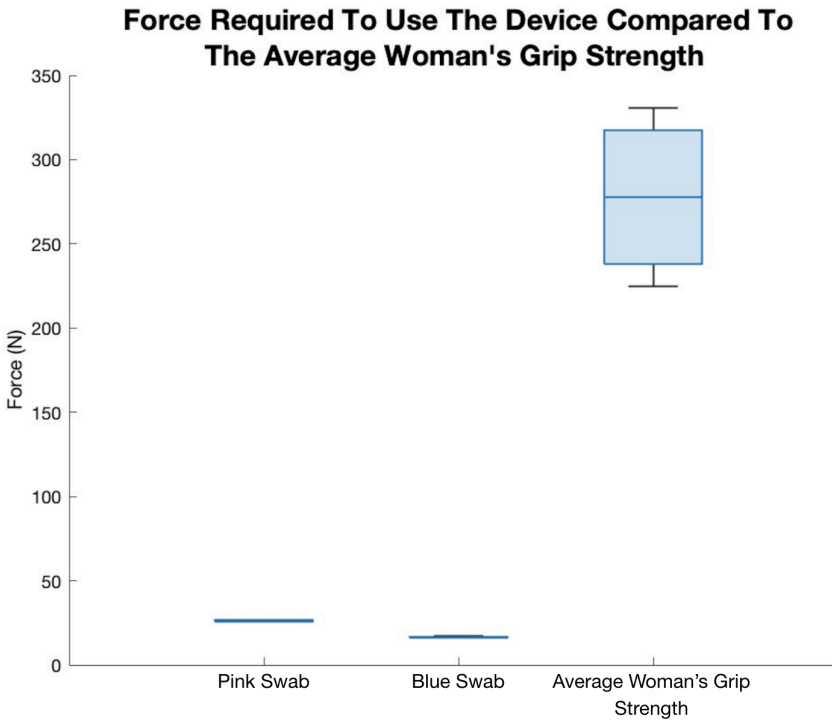


Figure 22: The force required to break the pink and blue swabs compared to the average women's grip strength.

Contamination Testing

Contamination testing revealed that the average percentage of the surface area that was contaminated by the Aptima Multitest Specimen Collection Kit was 0.75% ± 1.35%, while the average percentage of contaminated surface area for the prototype was 0% ± 0% (Figure 23). Statistical analysis with Wilcoxon Rank-Sum Test revealed a p-value of 0.14, which was not statistically significant. However, when the results are analyzed in a more qualitative manner, there was some contamination of the testing environment in almost every Aptima test, and the gloves and media tubes were contaminated in every Aptima test. Additionally, media from the tube was spilled with the Aptima testing kit. Compared to the tests run using the prototype, there was no contamination of the testing environment in any trial and there was only contamination of the media tube in 50% of trials (Figure 24).

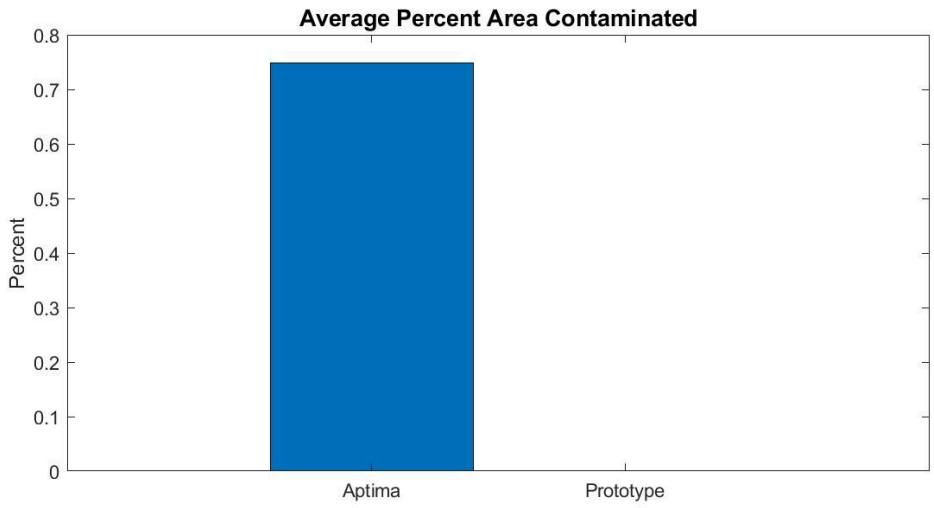


Figure 23: Average percentage of testing area contaminated by Aptima Collection Kit vs Prototype (n=4 for each group, n.s., p>0.05, Wilcoxon Rank-Sum).

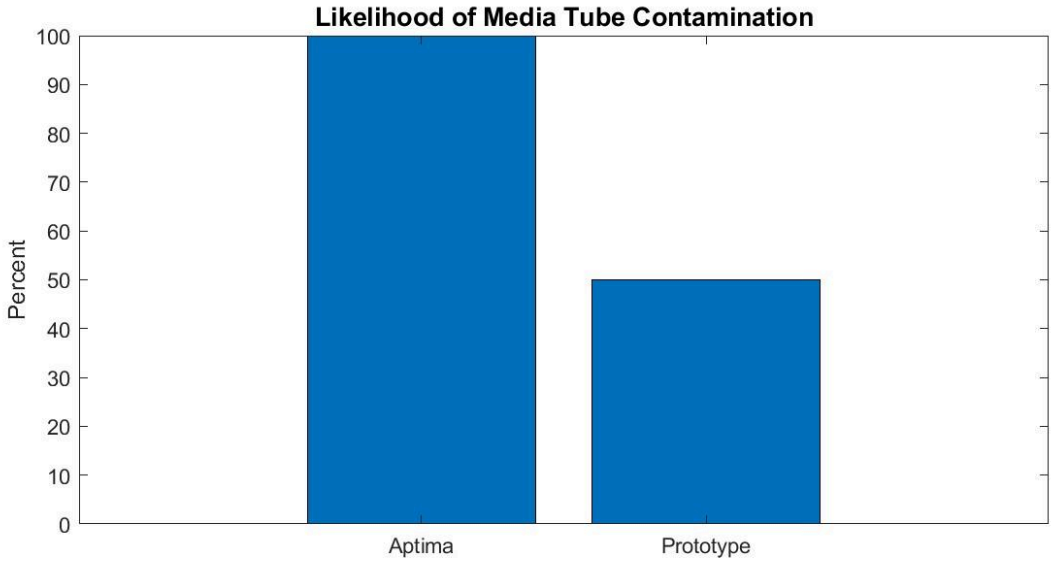


Figure 24: Likelihood of media tube contamination for Aptima Collection Kit vs Prototype (n=4 for each group).

Tip Testing

Tip testing showed that with usage of the base, it took an average of 28.9° ± 3.24° (measured from the cap) to tip the tube over with force applied to the cap and an average of 34.9° ± 3.91° (measured from the cap) to tip the tube over with force applied to the middle. In comparison, without the base it took an average of 3.22° ± 0.936° (measured from the cap) to tip the tube over with force applied to the cap and an average of 6.93° ± 1.69°(measured from the cap) to tip the tube over with force applied to the middle.

After statistical analysis using a Wilcoxon ranked-sum test, a p-value of 0.1000 was achieved when comparing base and no base tipping angles for pushing by the cap and pushing by the middle. The p-values are not statistically significant. However, the addition of the base succeeded in stabilizing the media tube and reducing the likelihood of media spillage, which was one of the main goals of the design.

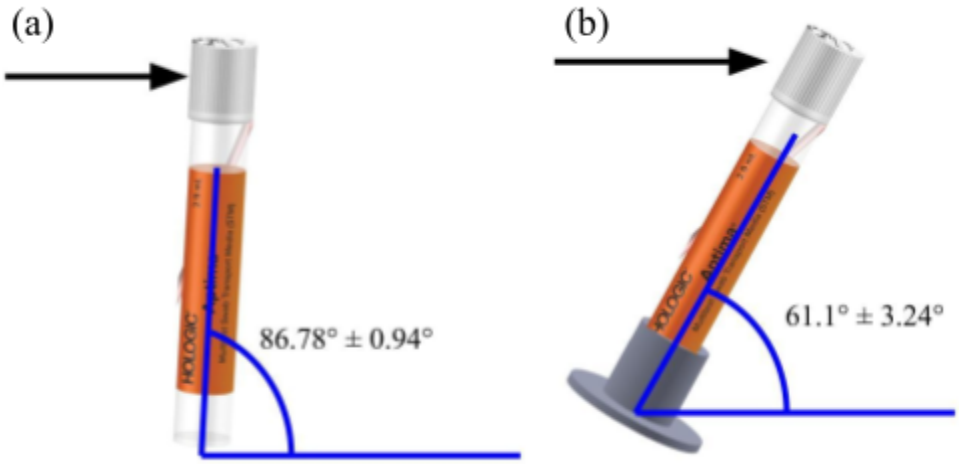


Figure 25: Figures showing required tipping angle measured from the tube base with our prototyped base (a) and without (b).

Discussion

Based on the first iteration of the Design Matrix, the Snap On Design would be the best design to go forward with, however, the design was not compatible with a Hologic® Panther machine which processes the STI tests. With the new requirement of being compatible with a Hologic® Panther machine in mind, the Three-Point Bending Design was chosen as the final design.

The primary goal of this project is to provide greater accessibility and safety for STI testing. By making STI tests more accessible, more people will be able to get tested and protect their health. Adequate healthcare is a universal right, so the device needs to maintain a low budget in order to still be easily accessible. With the testing done so far, the prototype is shown to be easily accessible and limit contamination.

The design survey results show that, overall, the final design is well received and the average female patient could use the design. The survey also showed that the drafted instructions for the prototype were clear and effectively taught potential users how to use the device. However, the population of the survey were fellow biomedical engineering students, which could have potentially skewed the data. Biomedical engineering students are more likely to have previous knowledge with three point bending and contamination-limiting techniques. Therefore,

it is likely that patients will require more thorough explanation and instructions when using the device.

The MTS testing results clearly showed that the required force needed to break the swabs in three point bending is significantly less than the average grip strength of a woman. However, the group only tested two types of swabs. There are many other types of swabs available in the clinical setting, which would require further testing to ensure that all swabs can be broken by the device. Additionally, further MTS testing is required to show how much force the average woman can produce using the three point mechanism, not just the grip strength.

With the contamination testing conducted, the results show that contact contamination was limited with use of the device as it helps prevent the patient's hands from coming into contact with vaginal fluid. The population used to conduct this portion testing was fairly limited, with group members conducting testing and only one person in the testing population who had no previous knowledge of the device. In order to achieve more accurate results, the group would need to conduct further testing on a population of people who are only given the device, instruction manual, and model to conduct the contamination testing. Another way to increase accuracy of the contamination simulation would be to use some sort of invisible ink or fluid. By using red finger paint in the test, the person taking the test could very clearly see the spread of the finger paint. By using invisible ink, it would better mirror the spread of clear contaminated vaginal fluid, which would more accurately mimic the conditions of self-swabbing.

With the base tipping test, the results clearly showed that the base helped to prevent contamination by lowering the chance for the media to spill out of the tube. Further testing is required to see how the base's stability withstands the entire process of using the device and using the three point mechanism to cut the swab into the media tube.

Some ethical considerations of the design included accessibility of both the device and the instructions. The device requires dexterity in both hands in order to use it properly, which could bar patients with limited mobility from using it. The current instructions are lengthy and wordy, which could cause confusion and can be cumbersome for patients to read especially if they have visual processing issues. Modification should be done in future work to condense the instruction manual and add more visual instructions for ease of processing the instructions.

Conclusion

Contamination of STI self-swab testing environments with chlamydia or gonorrhea is prevalent, with one study finding 13% of testing rooms to have at least one of these bacteria on their surfaces [4]. Although the threat of transmitting infection to other patients is low, this contamination of surfaces has led to false positives, with another study finding that 67% of women who tested in the clinic received a false positive due to surface contamination [5]. As a result, there is a need for extensive cleaning of the testing room between every patient, which requires both time and resources.

The goal of this project was to limit the contamination of the testing environment during vaginal self-swab STI tests. To do this, a design that provides coverage of the swab and containment of the media during transfer to the Aptima tube has been fabricated. The final design, as seen in Figure 11, utilizes an external casing that firmly holds the swab to prevent motion during specimen collection while also providing patients with a handle-like part to grip and safely set down. This external casing limits contamination as it keeps the swab pointing upward when it is set down on its bottom circular surface, maximizes the distance between the patient's hand and the vaginal opening during specimen collection, and prevents the splashing of media during the transfer process by tightly fitting over the opening of the media tube. The use of the three-point bending mechanism provides an alternative method to breaking the swab, reducing the risk of contamination via the splashing of media or expulsion of vaginal fluids from the shaft of the swab. Additionally, the fabricated test-tube stand (Figure 12) further limits contamination as it stabilizes the media tube during the transfer process, increasing the base of support and the angle withstood before media spillage.

All three components of the final design – the external casing, the three-point bending mechanism, and the media stand – serve to reduce contamination of the testing environment while maintaining ease of use, patient comfort, and compatibility with the Hologic® Panther processing machine. By minimizing surface contamination, the final design is expected to lower the rate of false positives associated with vaginal STI self-swab tests. Moreover, its simplicity in fabrication through 3D printing makes it a potentially marketable product that could be easily integrated with the current testing methods used by clinics worldwide

Future Work

Moving forward, additional research into mass production methods and an analysis of the supplemental costs due to the final design should be conducted as their findings will help refine the potential for marketing the design and integrating it with Hologic's Aptima Multitest Specimen Collection Kit. Additionally, design components of the final prototype such as the use of a friction fit, the freely rotating keyed push-button, and the limited potential to accommodate other swab types should be modified in the future to increase ease of use, patient comfort, and the universality of the design. According to results from the design survey (Appendix G), many respondents felt that attaching the device to the Aptima media tube via threading would be more intuitive and more effective at limiting contamination than the current friction fit. As a result, the thread type used on the Aptima media tube should be determined and integrated with the current design. To limit the potential dysfunction of the three-point bending mechanism due to the rotation of the keyed push-button, the following mechanisms should be designed and tested: the use of a track that extends through the interior of the casing to guide the push-button up to the swab shaft or the redesigning of the tip of the push-button such that it can break the swab in any orientation. Additionally, investigations into modular swab holders should be conducted to address the limited potential for the use of swab types other than the Aptima swab. One potential mechanism that addresses this limited compatibility is the use of a tapered, cone-like design;

however, further consideration of this component should be carried out in the future. Similar redesigning should be done to the keyed push-button such that it can move up or down the exterior surface of the casing. A modular push-button may be accomplished via the use of a track on the interior surface of the casing – similar to the design of a retractable box-cutter – allowing the push-button to slide up and down the casing, locking into place at the perforation point of that particular swab. The use of a modular push-button would also require the redesigning of the three-point bending supports within the casing, which may simply require the placement of additional supports along the interior wall.

Overall, refinement of the final design should be prioritized in the future to enhance patient comfort, universality, and marketability of the device. Following these adjustments, further prototypes should be 3D printed according to the procedure outlined in Appendix C and subjected to testing for aesthetics, contamination reduction, and ease of use with various swab types. Subsequently, a commercially viable prototype should be presented to Hologic to explore the possibility of integrating the device with the existing STI self-collection kit. Given that the Hologic® self-collection kit is distributed in over 15 countries, the incorporation of the final design has the potential to mitigate contamination, lower the incidence of false positives, and promote universal STI testing globally [20].

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Appendix

Appendix A: Materials and Expenses Spreadsheet

Table 2: The expense spreadsheet for the design project

Item	Description	Manuf-acturer	Mft Pt#	Vendor	Vendor Cat#	Date	#	Cost Each	Total	Link
Aptima Multitest Swab Specimen Collection Kit	Dacron Swabs and Universal Transport Media	Hologic	n/a	Client Provided	n/a	2/27	50	Free	Free	n/a
Preliminary prototype print	Material: PLA	n/a	n/a	Makerspace	n/a	2/27	n/a	$0.05/gram	$3.34	n/a
Prototype prints	Material: PLA	n/a	n/a	Makerspace	n/a	3/20	n/a	$0.05/gram	$4.92	n/a
Prototype print	Material: PLA	n/a	n/a	Makerspace	n/a	4/9	n/a	$0.05/gram	$1.00	n/a
Bag of Lemons	n/a	n/a	n/a	Target	n/a	4/15	1	$5.39	$5.39	n/a
Washable paint	n/a	Crayola	081-04-1137	Target	n/a	4/15	1	$5.99	$5.99	link
Prototype print	Material: PLA	n/a	n/a	Makerspace	n/a	4/18	n/a	$0.05/gram	$0.95	n/a
Prototype print	Material: PLA	n/a	n/a	Makerspace	n/a	4/19	n/a	$0.05/gram	$1.76	n/a
Prototype print	Material: PLA	n/a	n/a	Makerspace	n/a	4/22	n/a	$0.05/gram	$3.73	n/a
Poster print	Material: Satin Paper	n/a	n/a	Steenbock Library	n/a	4/25	1	$4/square-foot	$48	link
-	-	-	-	-	-	-	-	**TOTAL:**	**$75.08**	-

Appendix B: Product Design Specifications

Function:

This device should be a vaginal self- swab used for STI testing in the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*. A swab such as this would allow women to comfortably test and screen for these common STIs in a clinical setting. Current self-swab studies have found that 84% of women prefer this self-swab method of testing to getting swabbed by a clinician [1]. However, the current methods provide many avenues for contamination of the swab and of the environment. If the swab touches any exterior surfaces, such as the leg or table, it is considered contaminated and results can be faulty [2]. Furthermore, liquid in the testing kit can easily spill and contaminate the testing space in a clinic [1]. A design in which the swab is secured in a holder that also facilitates the breaking of the swab into the media tube will limit contamination.

Client Requirements:

- The device will limit contamination of the testing environment.
- The device will make universal STI testing more accessible.
- The swab shaft will be contained in an external tube that is safe to come in contact with the vagina.
- The swab head must be exposed to allow for insertion in the vagina.
- The device will be used for specimen collection only.
- The device must be integrated with the Hologic® transport media tube.
- A budget of 500 dollars will be observed.

Design Requirements:

1. **Physical and Operational Characteristics**
    a. Performance Requirements:
        i. The external casing must comfortably rest against the vaginal opening.
        ii. The external casing must firmly contain the swab shaft to ensure it does not dislodge during specimen collection, allowing patients to self-swab for up to 30 seconds [2].
        iii. At least 5 centimeters of the head of the swab will be available for specimen collection [2].
        iv. The device must contain a mechanism or method for transferring the swab head and shaft into the Aptima transport media tube.
    b. Safety:
        i. All components of the device including the swab head, shaft, and any external casing must be biocompatible and bioinert to prevent any irritation or immune response.
        ii. The swab shaft must not dislodge from the external casing throughout use to mitigate contamination concerns and patient discomfort.
        iii. The transport media used must be nontoxic and biocompatible to prevent patient harm in the case that the media stand is knocked over.
        iv. The device must pass a toxicological risk assessment as defined by ISO-10993-17 to ensure that the device will not have any harmful chemical or biochemical interactions with the vaginal or bodily components that it comes in contact with [3].

c. Accuracy and Reliability:

   i. The swab device must be reliable at detecting Chlamydia and Gonorrhea STIs for every test with a sensitivity of 95% [4].

   ii. To ensure accuracy, the swab must be able to be inserted 5 cm into the vagina and be rotated for 10-30 seconds each time to collect the sample [1].

   iii. The head of the swab contained in the device should be approximately 1 cm in length for optimal collection of vaginal discharge samples [1].

d. Life in Service:

   i. Fully assembled STI tests should have a shelf life ranging from 12-18 months. The exact standard cellular media used will further dictate the precise storage longevity of the test as a whole [5].

   ii. Tests should not be stored in direct sunlight and should be kept between 2 – 8 °C (36 – 46 °F) for maximum shelf life before use [6].

   iii. After samples have been collected, the test will be in service until the lab has gathered cells from the swab. Swabs can be stored at room temperature in the lab for a maximum of 14 days [7].

   iv. Each test will only be used once.

e. Shelf Life:

   i. The STI test should be used within 30 days of arrival [8].

ii. Swabs should be transported and/or tested within 14 days after the test is administered [7].

f. Operating Environment:

i. The STI swab must be user-friendly and able to withstand room temperature (20-22°C) for several hours before and after use.

ii. Tests are to be conducted in the testing room of a clinic and kept in clinic-provided storage until lab processing.

iii. The swab should have no risk of outside contamination or environmental contamination when in use.

iv. The device must be able to insert into the vagina and withstand the acidic environment of the vagina (pH of 3.8-4.5) [9].

g. Ergonomics:

i. The device should be easily and comfortably hand-held and self-insertable.

ii. The swab head should be comfortably inserted five centimeters inside the vagina [2].

iii. All materials used within the swab and external casing should be compatible with the intravaginal environment.

iv. Even though the media will always be contained in a separate media tube, it will still be biocompatible.

h. Size:

i. The device will not exceed 17 cm in length. This provides the patient with enough length to comfortably swab the vaginal canal.

1. The average depth of an unaroused vaginal canal is 9 cm [10].

i. Weight:

   i. The device will not exceed 7 grams to ensure the device is not cumbersome in the hands of patients. This includes the weight of the external casing, keyed push-button, and Dacron swab.

j. Materials:

   i. The head of the swab must be made of a non-cotton fiber that will not shed in the process of sample collection or analysis. The material must have chemical resistance and biocompatibility to withstand both the physiological environment of the vagina as well as the chemical processing involved with experimentation [11]. The swab head material must be highly absorbent for water and proteins to collect many specimens and must allow for their release and collection in a medium for testing [12]. Per CDC recommendation, suggested materials include rayon, Dacron, or cytobrush [13].

      1. Dacron swabs have been provided by the client and will be used in all future prototype iterations. These swabs are inert and can be purchased with a wooden or plastic shaft [14].

   ii. The Aptima Multitest Specimen Collection Kit transport media must be used to store the sample following insertion into the vaginal canal. Use of a transport media will allow for improved microorganism viability when testing is performed [15].

iii. The sample collection device will be manufactured from an autoclavable, single-use plastic. The material must not irritate the vaginal canal or induce an immune response. Possible materials include polyethylene or polypropylene, similar to the composition of a plastic tampon applicator.

1. Additionally, viable biopolymers that will minimize the device's contribution to single-use medical waste include blends of Polylactic Acid (PLA) with Polybutylene Succinate (PBS) or Polybutylene Adipate Terephthalate (PBAT) [16].

k. Aesthetics, Appearance, and Finish:

i. The finished product will be relatively similar in shape to a standard tampon applicator or IUD insertion device.

ii. The exterior finish of the product will be smooth and sleek to prevent damage to tissue during insertion into the vagina.

1. The external casing is not meant for insertion, however, the casing will be biocompatible, inert to the body, and of appropriate size to not harm the patient.

iii. The device will be long enough to allow swab insertion of at least 5 cm into the vagina for sample collection purposes [2].

iv. The device will be made of a colored material that appeals to patients.

2. Production Characteristics

a. Quantity:

i. Multiple self-swab device prototypes will be developed for testing and quality assessments.

ii. The design should be replicable for the potential to be mass-produced for clinical-use settings.

1. Potential methods of large-scale production include injection molding.
2. Production of the device has the potential to be used globally in clinics, impacting millions.
    a. 1.65 million cases of chlamydia and 648,056 cases of gonorrhea occurred in 2022 [17].

b. Target Product Cost:

i. The end cost of the design process should not exceed the client's budget request of $500.

1. 3D printing of the device costs an average of $0.93 with additional costs to be expected from the Dacron swab and cell culture media. Dacron swabs are available for purchase at most medical manufacturing companies with an expected price of $0.57 per swab [14].

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 [18]. 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 [19]. 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 [20].

b. Customer:

i. The customer would like to limit contact contamination of the testing environment with a product that prevents the swab tip from contacting surfaces and the transport media from splashing or spilling onto surfaces.

ii. The customer would like to make universal testing of Chlamydia more accessible (ideally doubling the existing 6%-8%) to prevent both infertility and the spread of the infection. The customer would also like to reach younger, typically under-tested women [21].

c. Patient-Related Concerns:

i. This product will make patients more comfortable with regular STI screening by providing a safe, reliable, and user-friendly option.

ii. Barriers to universal testing will still exist (socioeconomic, location, age, etc) [21].

1. The device should aim to be relatively inexpensive to dismantle the socioeconomic barrier to STI testing

iii. Proficient self-swabbing is important in collecting vaginal samples to be tested.

1. The patient must be provided with clear instructions that include a visual component to model the actions the patient will perform.

d. Competition:

i. There exist similar products to a self-swab for *Chlamydia Trachomatis*, none of which address the client's concern for contamination as they only provide patients with a Dacron swab and require the physical breaking of the swab into the media test tube [22].

1. The current standard test used by the client is the Aptima Multitest Swab Specimen Collection Kit. This test consists of a Dacron swab and a media tube with a screw-on cap. After collecting a sample with the swab, the patient unscrews the cap of the tube, inserts the head of the swab, breaks off the end of the swab shaft, and screws the cap of the tube back on [6].

ii. A design for a swab with a detachable head exists, yet the collection process still involves a separate entity, the collection tube, being unscrewed to place the head into. [23]

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Appendix C: 3D-Printing Protocol

Project title: Vaginal Self-Swab To Limit Contact Contamination
Team members: Sara Morehouse, Adam Berdusco, Katherine Kafkis, Cherry Qiu
Materials and costs table:

Date	**Material**	**Quantity (g)**	**Cost Each**	**Total Cost**
2/26	Ultimaker PLA	66.8	$0.05 per gram	$3.34
3/18	Ultimaker PLA	19.2	$0.05 per gram	$0.96
4/8	Ultimaker PLA	17.4	$0.05 per gram	$0.87
4/18	Ultimaker PLA	19	$0.05 per gram	$0.95
4/19	Ultimaker PLA	35.2	$0.05 per gram	$1.76
4/22	Ultimaker PLA	74.6	$0.05 per gram	$3.73
			Total Cost:	$11.61

Equipment used: Bambu Lab X1 Carbon printer, Ultimaker PLA Filament

Fabrication Protocol

- ☐ Open the SolidWorks file of each design component
- ☐ Download STL files of each design component (ie. Casing, Key, Stand etc.)
- ☐ Save STL files to a flash drive with an easily identifiable name
- ☐ Plug the flash drive into MakerSpace computers
- ☐ Open the Bambu studio software to conduct printing on a Bambu printer.
- ☐ Import the STL files into a new project to populate the build plate.
- ☐ Click the lay-on face button and select the face with the largest diameter. This will place the selected face on the build plate and must be repeated for each component.
    - ☐ Ensure all components are 2-3 squares apart
- ☐ Select the printer to be used by opening the devices tab
    - ☐ Note that printer names can be found on the printer itself. Choose a printer that is available or nearly completing a print.
    - ☐ Additionally, make note of the filament types and colors loaded onto the printer being used.
- ☐ Highlight all components of the print. Right-click on the mouse and select filament type. Select the PLA filament in an available color.
    - ☐ PLA filament should be 1.75 mm in diameter
- ☐ Click the enable supports button.
    - ☐ Select rectangular supports.

- ☐ Select a layer thickness of 0.16 mm
- ☐ Set layer speed to be 200 mm/s and support speed to be 150 mm/s
- ☐ Set infill to be 20%
- ☐ Click the slice all button. Make a note of the grams of material used and the print time.
- ☐ Download a 3MF file
- ☐ Navigate to Google Chrome and fill out the 3D print form
    - ☐ Note that the form should already be open; if not, consult a staff member.
- ☐ Consult a MakerSpace employee for loading the print onto the printer and for billing purposes.

Appendix D: Contamination Testing Protocol

Project Title: Vaginal Self-Swab To Limit Contact Contamination
Team members: Sara Morehouse, Adam Berdusco, Katherine Kafkis, Cherry Qiu
Timeline:

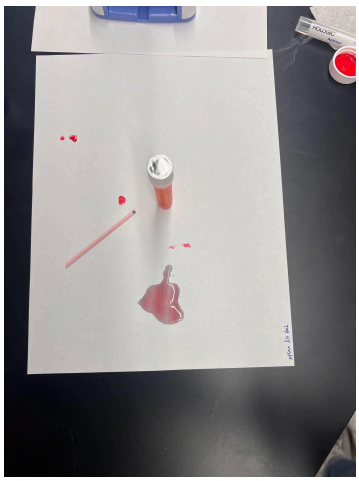
- Perform test on 4/17/2024

Materials and Costs Table:

Material	**Quantity**	**Purpose**	**Manufacturer**	**Part #**	**Cost**	**Link**
Washable paint	1	To simulate vaginal fluids.	Crayola	081-04-1137	$5.99	Crayola 10ct 2oz Washable Kids Paint Classic Colors : Target
Aptima Multitest Swab Specimen Collection Kit	8	Swabs to use for simulation of STI collection test.	Hologic		n/a (provided by client)	n/a
Plastic Vaginal Model	1	To act as the "patient's" vagina for STI test.	n/a (provided by client)	n/a	n/a	n/a
ImageJ software	1	To use for measuring surface area contaminated by self-swab.	NIH	n/a	$0	Download (imagej.net)
White paper 8.5inx11in	6	To act as the testing environment in order to measure contaminat	Any (provided by University of Wisconsin Computer Lab)	n/a	$0	n/a

		ed area while swabbing				
Nitrile gloves	9 pairs	For use with applying paint to the vaginal model and during tests.	Any (provided by BME Teaching Lab)	n/a	$0	n/a
Prototype	1	To be used to test contaminati on of the surface while swabbing.	n/a	n/a		n/a

Contamination Testing Protocol
Date to be Completed: 4/17/24
Images of Testing Setup:



Steps:

1. Lay 2 pieces of white paper flat on a bench top or countertop.
2. Put on one pair of nitrile gloves.
3. In a separate area, open the paint bottle and separate the vaginal model in half.

4. Dip fingers into the paint bottle and scoop a liberal amount (2-4 tablespoons) and apply to the interior of the vaginal model and on the exterior of the opening. Ensure the model is sufficiently coated on the interior and at the opening.
5. Dispose of gloves and re-cap the paint bottle.
6. Carefully put the vaginal model back together and place it in the center of one of the pieces of white paper.
7. Put on a new pair of nitrile gloves.
8. Open an Aptima Multitest Swab Specimen Collection Kit.
9. Perform the test with the vaginal model using the dominant hand following the Aptima Multitest Swab Specimen Collection Kit instructions. Ensure that all transfer of swab and media uncapping and swab breakage occurs over a single piece of the white paper.
10. Remove gloves and media tube and place in a designated area to be photographed in order to record contamination.
11. Take a picture of the entire white sheet of paper with the paint stains visible.
12. Save the contaminated paper for records and replace it with a new clean sheet of paper.
13. Repeat the test once more using the dominant hand, and then repeat twice using the non-dominant hand.
14. Obtain the prototype and open an Aptima Multitest Swab Specimen Collection Kit. Remove the swab from the package and insert the shaft of the swab into the central hole inside the prototype device. Place the media tube from the package on the white paper for use in testing.
15. Perform two tests with the prototype using the dominant hand and two tests using the non-dominant hand following the instructions. Be sure to keep slight pressure on the button of the device while swabbing to ensure the swab does not fall out of the device.
16. Take a picture of the contaminated paper, gloves, and media tube in the same way as done for the Aptima tests.
17. After testing, dispose of any extra paper or waste produced during the tests. Take apart the vaginal model and clean with soap and water.
18. Using iPhone image editing, ensure that all of the images of the contaminated papers are cropped to size and not distorted. Fix any distortion using the Straighten, Vertical, and Horizontal tools under the “Crop” button.
19. Upload photos to a computer and open ImageJ software.
20. Click “File” > “Open…” and select the image you wish to analyze first.
21. When the image is open, click “Image” > “Type” > “8-bit” to first convert the image to binary.
22. Next, click “Image” > “Adjust” > “Threshold…” and unclick the “Dark Background” button on the pop-up. Use the bottom sliding bar to adjust the threshold value as needed. Visually inspect the image to ensure that only the contaminated areas are highlighted in red. Click “Apply” when the desired threshold is achieved.

23. Select the “Wand (tracing) tool” from the toolbar. Move the cursor to the left of the first contaminated spot and click. When the area is successfully surrounded with a yellow perimeter, click the keys “Ctrl” + “M” to measure the highlighted area. Repeat with each individual contaminated object on the image. When finished, navigate to the “Results” pop-up window and click “File” > “Save As…” and save the file as a .csv file in the desired file location.
24. Use a preferred spreadsheet viewer to sum up the contaminated areas. Record the summed value.
25. Navigate back to the imageJ program. At the top of the image currently opened, record to the total pixel area of the image.
26. Calculate the percent area contaminated by dividing the contaminated area by the total pixel area and multiplying by 100.
27. Upload data to MATLAB and save each the Aptima test results and the Prototype test results as separate variables. Perform a Wilcoxon Rank-Sum Test using the ranksum() command. Record p-value.
28. Create desired graphs to display results. See attached code for exact MATLAB commands used.

Results:

Test #	**Test**	**Hand used**	**Total Area (pixels)**	**Contaminated Area (pixels)**	**Percentage Contaminated**	**Gloves Contaminated?**	**Tube Contaminated?**
1	Aptima	Dominant	1676x2156	7690	0.2128156535	yes	yes
2	Aptima	non-dominant	2174x2808	169140	2.770701138	yes	yes
3	Aptima	Non-dominant	1897x2462	391	0.008371848834	yes	yes
4	Aptima	dominant	2038x2654	0	0	yes	yes
5	Prototype	non-dominant	2062x2687	0	0	yes	no
6	Prototype	dominant	2192x2835	0	0	yes	no

7	Prototype	dominant	2308x2997	0	0	yes	yes
8	Prototype	Non-dominant	2393x3074	0	0	yes	yes

Test	**Average % Area Contaminated**
Aptima	0.74797216
Prototype	0

Aptima Test Notes:

- Media spilled
- Gloves were very contaminated
- Media tube was very contaminated

Prototype Test Notes:

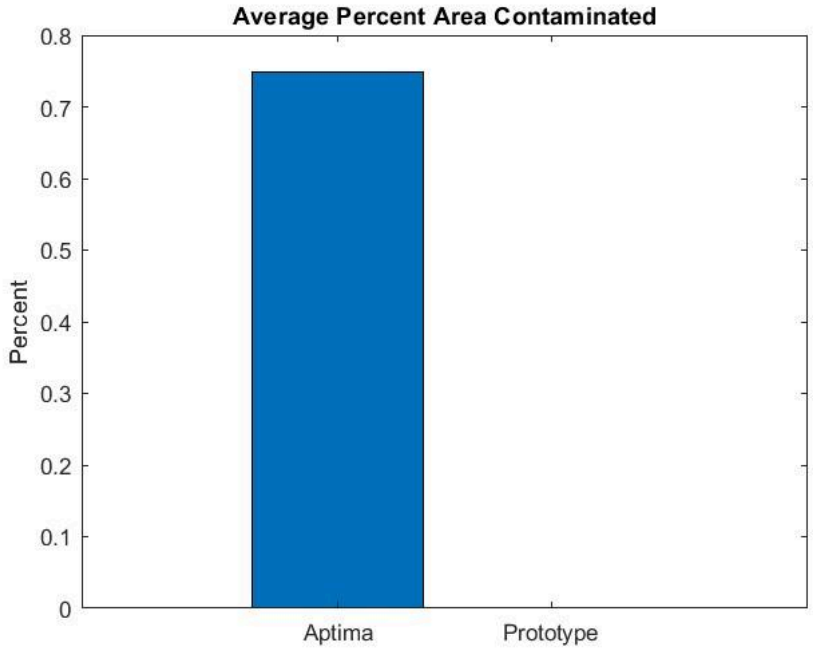
- No media spillage
- Gloves were minimally contaminated
- Media tube contamination, if present, was minimal

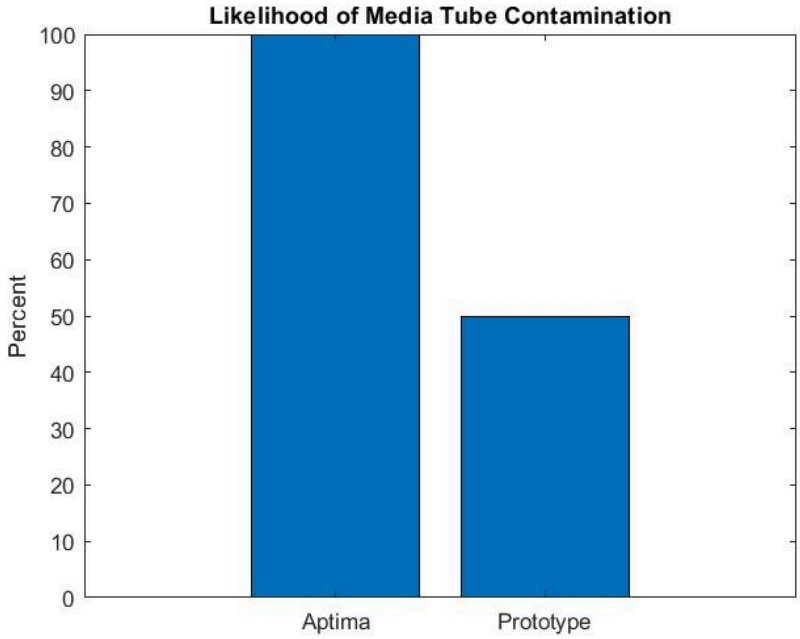
Using Wilcoxon Rank-Sum test to analyze significance between groups:

- Calculated a p-value of 0.1429

Results summary:

- While there was no statistically significant difference between percent area contaminated, it is important to note that in ¾ of the Aptima Multitest samples, the testing area was contaminated with splashing of simulated vaginal fluids and media spillage. However, in all Prototype samples, there was no contamination of the testing area.
- For the Aptima tests, both gloves and media tubes were very contaminated with simulated vaginal fluids.
- For the Prototype tests, gloves were minimally contaminated and media tube contamination, if present, was minimal.
- With the Aptima tests, there was a 50% greater chance of contaminating the media tube, which is then used inside the sample processing machine. This increases the likelihood of false positives due to cross-contamination during sample handling.



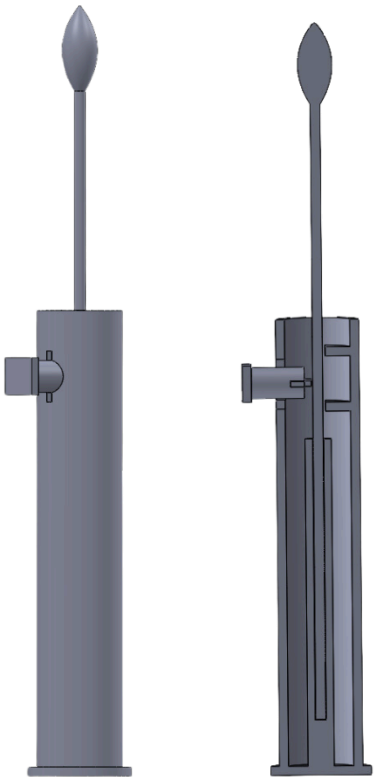


MATLAB Code:

```
aptima = data(:,1)
prototype = data(:,2)
[p,h,stats]=ranksum(prototype, aptima)
a_mean = mean(aptima)
p_mean = mean(prototype)
means = [a_mean p_mean]
```

```
figure(1)
bar(means)
title 'Average Percent Area Contaminated'
ylabel 'Percent'
tubes = [100 50]
figure(2)
bar(tubes)
title 'Likelihood of Media Tube Contamination'
ylabel 'Percent'
```

Appendix E: Final Prototype Instruction Manual

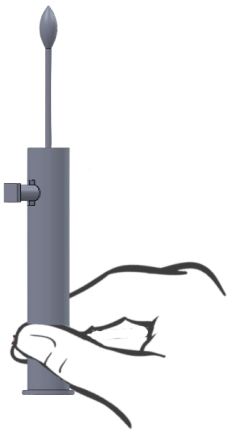


Description: The above prototype is designed to limit contamination when collecting vaginal self-swabs for STI testing. The prototype houses the Dacron swab that is to be inserted into the vaginal canal, rotated for 10-30 seconds, and then transferred into a media-containing tube for diagnostic testing. The transfer process for this design uses bending to break the swab, with the top of the device tightly fitting over the top of the media tube. As seen in the above figure, there is a push-button that aligns with a perforated point on the Dacron swab. When this push-button is pressed inward, the swab is forced to bend and will ultimately break.

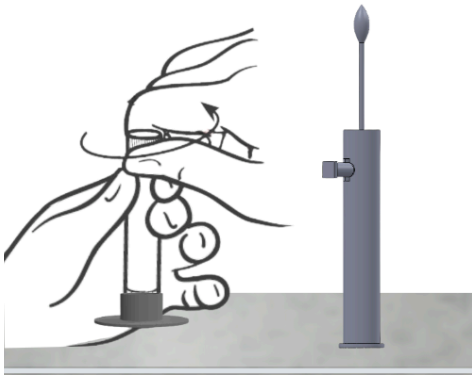
Instructions:

1) Wash hands.
2) Remove the media test tube from its packaging and place it in the stand as shown:

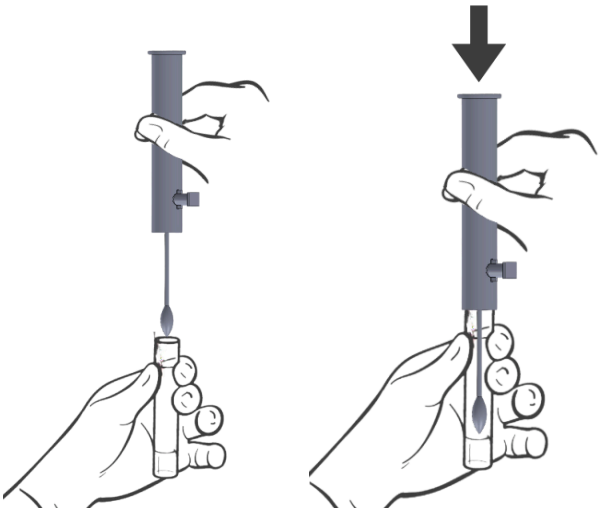
3) Remove the device from its sterile packaging and hold it as shown



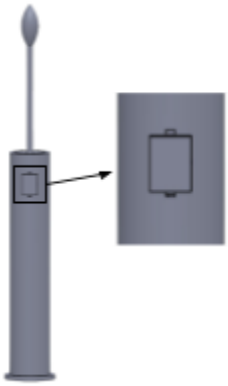
4) Holding the bottom of the outer plastic casing, carefully insert 2 inches of the Dacron swab into the vagina - marked by the black line.
5) Gently rotate the swab against the vaginal walls for 10-30 seconds.
6) Remove the swab from the vagina
7) Set the device down on the counter. Keeping the media test tube in the holder, remove the cap and set it down on the counter.



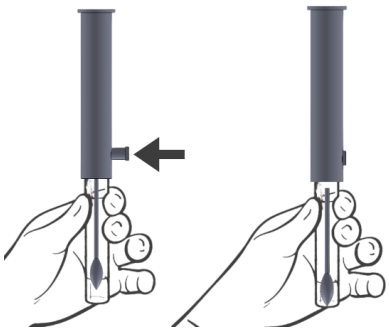
8) Flip the device upside down and attach it to the test tube by firmly pressing the device over the opening of the tube.



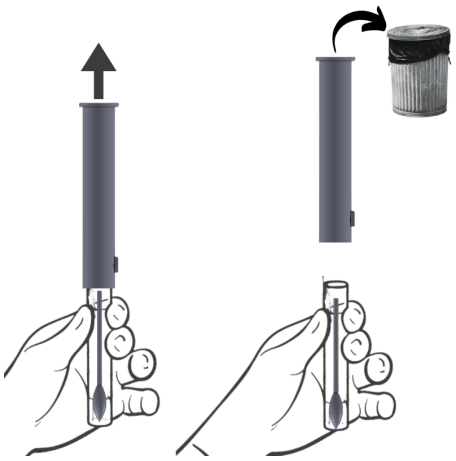
9) Rotate the button on the side of the device such that its long edge is facing up as shown:



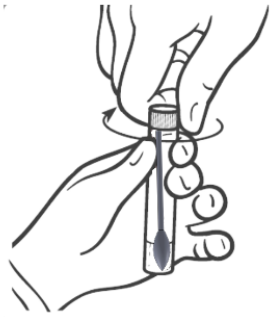
10) Press the button on the side of the device to break the swab.



11) Remove the device from the test tube by pulling up on the device. Discard the removed part of the device.



12) Firmly screw the original cap to the test tube back on.

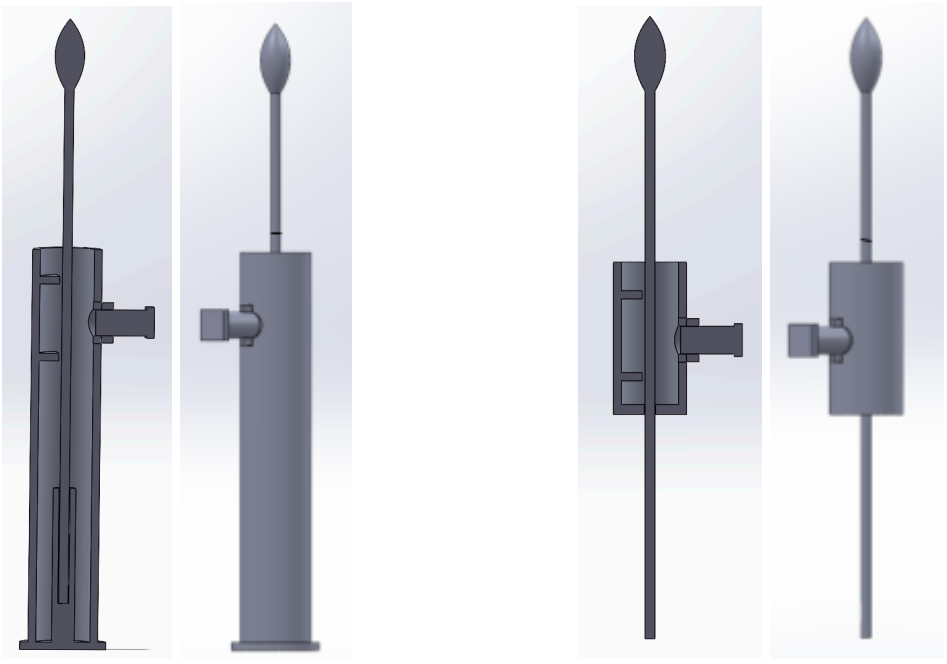


13) Wash hands.

Appendix F: Survey Background Information & Instruction Manual

Background: Conventional Vaginal Self-Swab STI tests provide patients with a Dacron swab and media tube to collect their specimens. This process requires patients to insert the Dacron swab 5 cm into the vaginal canal, rotate it for 10-30 seconds, and then transfer it into a media tube for diagnostic testing. The transfer process requires patients to physically break the swab into the media tube at a perforation point which can cause media or other vaginal fluids to splash onto surfaces. Some sources of contamination include: setting the swab down after specimen collection, improper holding of the swab leading to contamination of the hands, and splashing of fluids from the swab during the breaking process.

(A) (B)

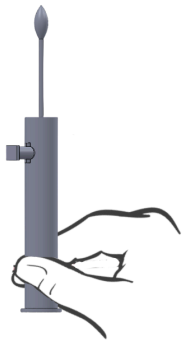


Background: The above two prototypes are designed to limit contamination when collecting vaginal self-swabs for STI self-testing. Both prototypes house the Dacron swab that is to be inserted into the vaginal canal, rotated for 10-30 seconds, and then transferred into a media-containing tube for diagnostic testing. The transfer process for these designs uses 3-point bending to break the swab, with the top of the device tightly fitting over the top of the media tube. Prototypes A and B are essentially the same design, with prototype A being a full-length iteration and prototype B a shorter version.

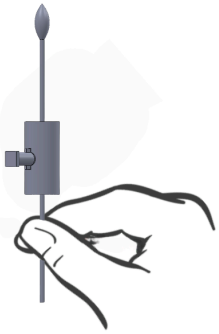
Instructions:

1) Wash hands.
2) Remove the media test tube from its packaging and place it in the stand as shown:

3) Remove the device from its sterile packaging and hold it as shown (for respective prototypes)

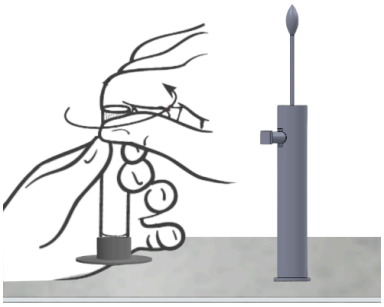


(A)

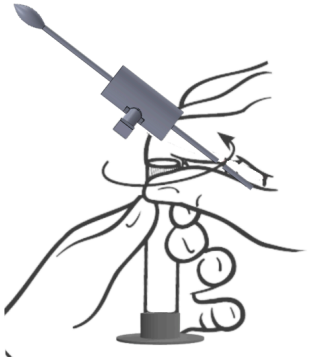


(B)

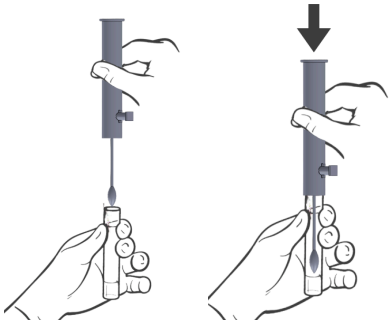
4) Holding the bottom of the outer plastic casing, carefully insert 2 inches (5 cm) of the Dacron swab into the vagina. **Do not insert the plastic device into the vagina.**
5) Gently rotate the swab against the vaginal walls for 10-30 seconds.
6) Remove the swab from the vagina
7) Prototype A: Set the device down on the counter. Keeping the media test tube in the holder, remove the cap and set it down on the counter.



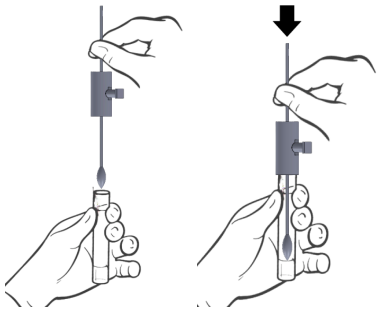
Prototype B: Hold the device in your hand. Keeping the media test tube in its holder, remove the cap and set it down on the counter.



8) Flip the device upside down and attach it to the test tube by firmly pressing the device over the opening of the tube.

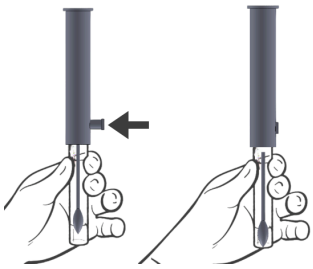


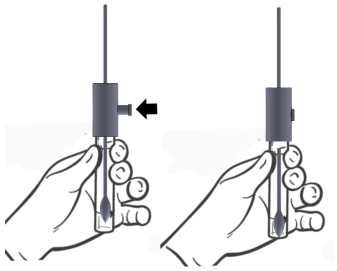
(A)



(B)

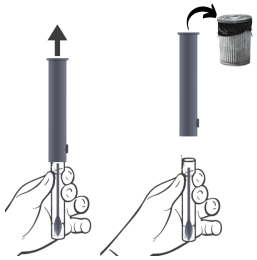
9) Press the button on the side of the device to break the swab.

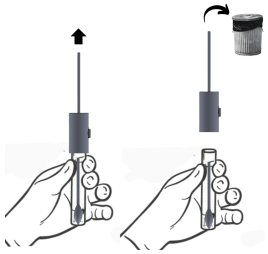




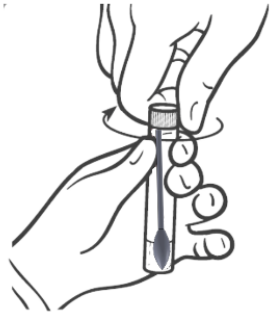
(A) (B)

10) Remove the device from the test tube by pulling up on the device. Discard the removed part of the device.





11) Firmly screw the original cap to the test tube back on.



12) Wash hands.

Appendix G: Survey Short Answer Responses

After reading over the instructions, do you think that screwing the device onto the media test tube would be more effective than just “sliding” it over with a friction fit?

Yes

7 responses

yes

3 responses

Screwing the device may help people feel more comfortable that its securely in there.

1 response

No, only concern is trying to hold prototype b while unscrewing cap

1 response

Ya

1 response

Yes.

1 response

Less room for contamination

1 response

Possibly more effective at limiting contamination once in the test tube, but less effective at being easy/ergonomic for the user

1 response

I think this is referring to step 8? I would think that sliding something would be easier for the user than having to screw something on.

1 response

No not necessarily

1 response

Screwing it would feel more secure.

1 response

Unsure

1 response

Maybe. If there was a click that indicated when the device was secure, that would be effective, but otherwise screwing it on would make more sense.

1 response

I think so

1 response

Yes I think screwing the device is going to be easier for people and more effective

1 response

no

1 response

Are there any aspects of either prototype that would discourage you from using the device?

No

6 responses

no

3 responses

I don't like the narrow stick that you hold and would have to open the media at the same time. I feel like that can be difficult especially if a patient has arthritis in their hands. The prototype where you stand the swab up makes more sense.

1 response

Both prototypes are kind of long, and I may want to use the device when I am sitting on the toilet (like a pregnancy test), so if the length could be shortened that would be cool (not sure if that has implications for the 3-point bend).

1 response

The lengthiness of instructions would be the only barrier but still I think they are clear and easy to follow especially if a provided also verbally pointed out the relatively more nuanced parts of the procedure of use.

1 response

Nothing comes to mind, I thought that the directions and the images were very well done. It looks so much less intimidating than the prototypes y'all had at the preliminary presentation!

1 response

Question: will the people easily be able to see the black line for the 2 inch marker or is there an easier way to know when the device is inserted 2 inches?

1 response

Prototype B is likely more difficult to hold/ uncap the collection tube while holding. In prototype A, allowing it to stand on a counter is useful

1 response

A is more visually appealing but at the same time that makes it more intimidating to use, if that makes any sense...

1 response

A is better bc you don't have to hold the sample when you are opening the test tube to put the swab in.

1 response

(B) looks very easy to snap and inconvenient to hold while opening the media test tube.

1 response

Prototype B seems more fragile and potentially more user error prone

1 response

Prototype B seems too thin on the bottom to get a good grip.

1 response

I do not have a vagina, so this is not really my expertise

1 response

No - maybe make the directions more basic and less words

1 response

The button

1 response

Nope

1 response

Do you have any other feedback for our vaginal self-swab?

14 responses

1) You may want to also include appropriate warning labels. (Marketability standpoint) 2) The 12 step process is very thorough, but people may not want to read that many steps. (Marketability standpoint) 3) The fist image in the linked google docs seems like a good summary photo 4) I would include both inches and cm in the instructions to increase user friendliness.

1 response

Maybe have the person unscrew the media top before doing the test so they can directly insert the swab into the media when the test is complete.

1 response

I like prototype A because it visually and tactilely seems more pleasant and less probey/ sticky/pokey.

1 response

you could implement design elements of covid 19 tests maybe if you haven't already

1 response

Design looks sleek and well thought out. Great job!

1 response

No additional feedback

1 response

Maybe like a tampon?

1 response

no it looks great!

1 response

None. Looks great!

1 response

No

1 response

Appendix H: Three-Point Bend Testing Protocol

Project Title: Vaginal Self-Swab To Limit Contact Contamination
Team members: Sara Morehouse, Adam Berdusco, Katherine Kafkis, Cherry Qiu
Date performed: 4/12/24
Pictures of testing setup:

Materials and Costs Table:

Material	**Quantity**	**Purpose**	**Manufacturer**	**Part #**	**Cost**	**Link**
Swab	6	A three point bend test will be done on the swab to determine ins	Hologic	PRD-03546	n/a	https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab

Protocol Instructions:

1. Log into the computer using the person's CAE account
2. Turn the MTS machine on using the power switch on the back right corner of the machine
3. Ensure the MTS machine is set up of three point bending

   a. Attach load cell
   b. Attach 3-point bending fixture
   c. Change the distance between supports to 16mm, each 8mm from center location of applied load
4. Open the TW Elite software
5. File→ New “Test From Template”
6. Click “Templates”
7. Choose “BME 315 3 Point Bend To Failure”
8. Ensure the control is connected to the program
9. Change the test rate to 2 mm/min
10. Move cross head up using the minute changer
11. Hit kill switch
12. Load the sample into the MTS Machine
13. Position the gripper so that it lightly touches the sample
14. Zero the force load by right clicking on the box and hitting “clear signal”
15. Undo kill switch (the yellow light should turn on)
16. Unlock the Machine again to gain control with the controller (hit lock button twice)
17. Record the gauge length
18. Press the lock button on the controller again to control the machine with the computer
19. Zero both the meters for load and for cross-head displacement with “clear signal”
20. Press the green play button and enter the diameter of sample
21. Hit OK
22. Watch graph and data collection until sample fails and graph beings to fall
23. Hit the red stop button
24. Press Return to Zero
25. Right-click on the Test Run and export raw data
26. Choose what path to export the data
27. Hit Export
28. Hit kill switch
29. Unload sample
30. Take a picture of graph
31. Repeat with the remaining samples starting at step 2
32. Clean up machine and station after all samples have been tested

Test #	Swab	Notes	Force Required to Break (N)
1	Pink		25.45
2	pink		26.96
3	pink		26.62
4	blue	when it failed, it bent and started to press down on the fixture and an increased load was recorded	15.94
5	blue	when it failed, it bent and started to press down on the fixture and an increased load was recorded	16.97
6	blue	when it failed, it bent and started to press down on the fixture and an increased load was recorded	16.67

Mean hand-grip force of healthy young adult females: 277.8 ± 52.8 N
Maximal hand-grip force of healthy young adult females: 329.4 ± 57.7 N
Source: https://doi.org/10.1007/s00421-006-0351-1
[1] D. Leyk et al., “Hand-grip strength of young men, women and highly trained female athletes,” *European Journal of Applied Physiology*, vol. 99, no. 4, pp. 415–421, Dec. 2006, doi: https://doi.org/10.1007/s00421-006-0351-1. [Accessed: Apr. 21, 2024]

MATLAB Code:

```
% Load your data file
dataPink1 = readmatrix('BlueSwab3.txt');
%import your data
dispPink1 = dataPink1(:,1);
forcePink1 = dataPink1(:,2);
% Plot your raw data and inspect it to make sure it looks as you expect
figure;
plot(dispPink1,forcePink1);
hold on
maxForce = max(forcePink1)
```

```
% Plots the gathered data
pinkData = [25.45,26.96,26.62];
blueData = [15.94,16.97,16.67];
gripStrength = [225,277.8,330.6];
xLableNames = ["Pink Swab", "Blue Swab", "Average Woman Grip Strength"];
%%namedLables = categorical(xLableNames,1:3,xLableNames);
allData = [pinkData;blueData;gripStrength];
figure(1);
boxchart(allData');
ylabel("Force (N)");
title({"Force Required To Use The Device Compared To", ...
   "The Average Woman's Grip Strength "});
```

Appendix I: Tipping Test Protocol

Project Title: Vaginal Self-Swab To Limit Contact Contamination
Team members: Sara Morehouse, Adam Berdusco, Katherine Kafkis, Cherry Qiu
Date performed: 4/22/24

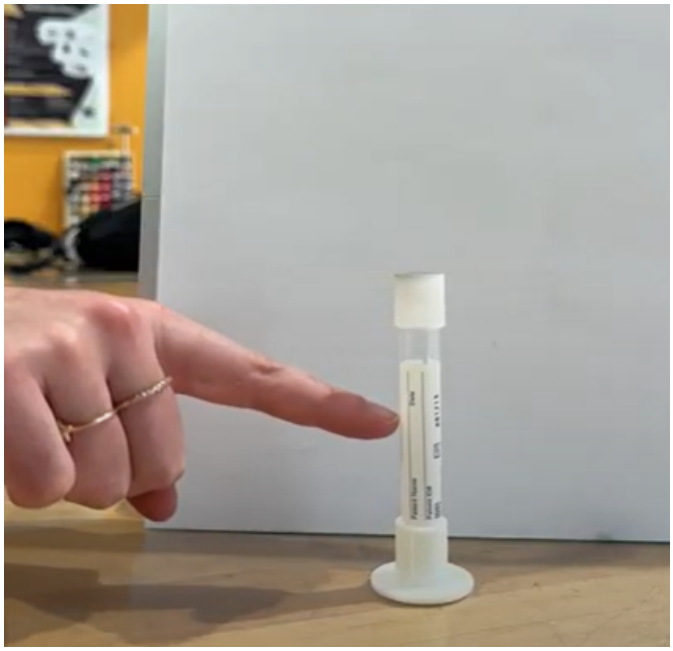
Materials and Cost Table:

Material	**Quantity**	**Purpose**	**Manufacturer**	**Part #**	**Cost**	**Link**
Aptima Hologic Tube filled with Media	1	Used to determine stability of Prototyped Base	Hologic	PRD-03546	n/a	https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab
Prototype Base	1	Testing the base stability	Makerspace	n/a		n/a

Steps:

1. Place the Hologic tube in the 3D printed base
2. Set up the camera to clearly show the tube and base level in frame.
3. Start recording.
4. Push the tube by the cap until the tube completely tips over.
5. Stop Recording.
6. Repeat steps 2-5 for remaining pushing by the cap tests.
7. Repeat steps 2-6 for pushing the middle of the tube tests.
8. Repeat for the tube without the base.
9. Upload images to ImageJ.
10. Draw a line following the angle of the tube at the tipping point.
11. Measure the angle of the line and record value.

Images of Testing Setup:



Results

Test	Point of Contact	Tipping Angle Measured from the Horizon (Degrees)	Notes
1	Cap	56.78	
2	Cap	64.58	
3	Cap	61.99	
4	Middle	49.61	Tube stayed upright with applied force for a couple of seconds before beginning to tip.
5	Middle	57.01	Tube stayed upright with applied force for a couple of seconds before beginning to tip.

6	Middle	58.56	Tube stayed upright with applied force for a couple of seconds before beginning to tip.
7	Middle	83.7	No base
8	Middle	84.35	No base
9	Middle	81.16	No base
10	Cap	85.96	No base
11	Cap	86.58	No base
12	Cap	87.8	No base

Test	**Mean (degrees)**	**Standard Deviation (degrees)**
Cap with base	61.10	3.24
Middle with base	55.06	3.91
Cap without base	86.78	0.936
Middle without base	83.07	1.69