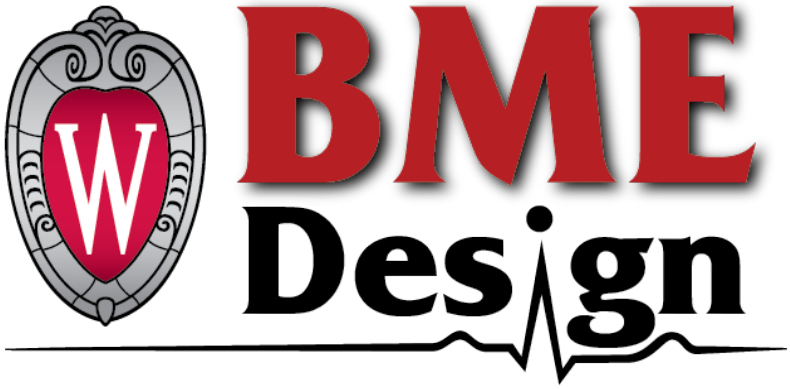

Vaginal Self-Swab Device to Minimize Contact Contamination

Preliminary Report

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Date: October 11, 2023

Abstract

Universal testing for sexually transmitted infections (STIs) is not a common practice of many sexually-active adults, as common infections such as chlamydia and gonorrhea are highly prevalent, with four million cases of chlamydia in 2018 [1]. In order to combat the rampant spread of STIs and increase universal testing, STI screening needs to promote comfort and ease. The primary way to accomplish the goal is self-swab testing, which allows women to complete an intravaginal swab in the privacy of a clinic room, without the discomfort of being swabbed by a physician [2]. However, self-swab testing presents the obstacle of contamination of the swab and of the environment the test is administered in. Currently, self-collection STI tests involve a swab that must be inserted into the body, then removed and transported to an external vial of preservative media. In this process, there are many avenues of contamination, including the swab coming in contact with surfaces and the media vial spilling [2]. The goal with this project is to create a device that limits the potential contamination of the testing environment and of the swab. To do this, a proposed final design includes a swab housed in an external casing, a cap containing the media that screws onto the device, and an intuitive structure similar to that of a tampon. Ultimately, a STI self-swab test such as this would allow for increased universal testing while limiting contamination.

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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, with 43% of those women accounting for undiagnosed cases [1]. Many cases go undiagnosed due to the commonly asymptomatic nature of the infection; between 50-70% of people diagnosed with chlamydia presented 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]. However, in recent studies considering the benefits of the self-swab method of STI testing, it was 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 [1]. If patient-collected STI tests were made more commercially available, or presented as an option for in-clinic testing, routine STI testing would become much more commonplace. One limitation of patient-collected STI samples is the potential for contamination of the testing environment and the swab itself during the collection process. 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 vagina to 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 be contaminated by the environment [4]; if false-positives are not caught, patients may be treated for STIs that they do not have.

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. For example, the Aptima Combo 2 Assay by Hologic® employs the use of a proprietary swab for sample collection, and a small media-filled tube for sample preservation [5]. Competing design Mía by XytoTest® utilizes the same design and sample collection method [6]. 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.

Background

Chlamydia results from infection with the *Chlamydia trachomatis* (CT) bacterium – a species of the *chlamydophila* genus [1] [7]. This bacteria is an anaerobic, gram-negative, obligate intracellular parasite that only naturally manifests in humans [8]. CT bacteria can be subclassified into 18 serologically variant strains (serovars), with serovars D-K leading to genital or neonatal infections [7]. 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) which is metabolically active [7]. When first coming into contact with CT bacteria, host cells take up the EB form which then differentiates into RB [7]. RB can then replicate to form additional EB and further spread the infection [7]. 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 infects the cervix but may spread to the urethra or upper reproductive tract [1]. If the bacteria spreads 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].

When testing for the CT bacteria using a swabbing technique, it is important that a non-toxic material is 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) [9]. 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 [9]. 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 the bacteria isolation during laboratory testing [10] [11]. All swab samples should be stored in a chlamydia transport media that do not contain antibiotics [10]. 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℃ [10]. A material that can withstand this wide range of temperatures must be used to store the sample and the media.

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. 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 [12]. All components of the device must be biocompatible as they will enter the vaginal canal and potentially come into contact with CT bacteria [9]. For a more detailed description of the design specifications, see Appendix A.

Preliminary Designs

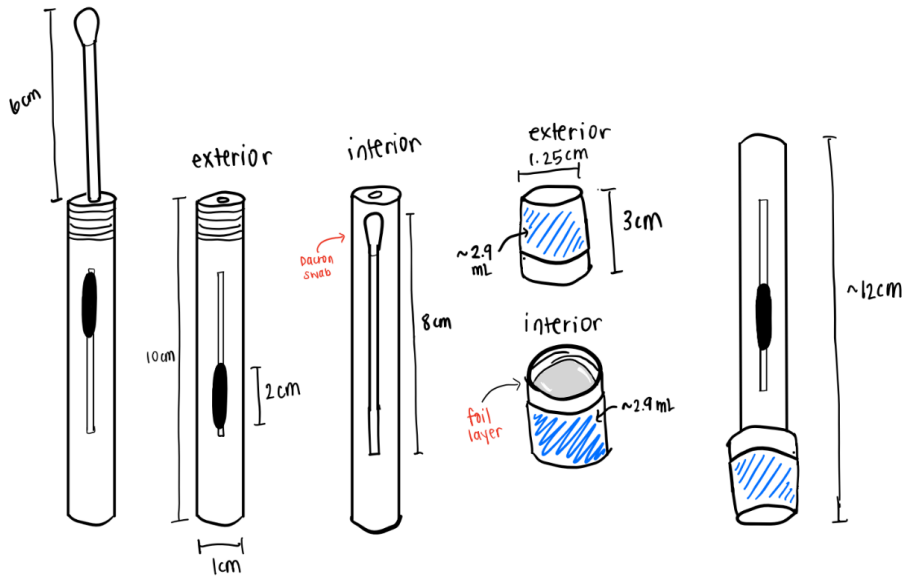


Figure 1: Screw-On Media with Slider

Design 1: Screw-On Media with Slider

The first design can be seen in Figure 1. This design idea includes a test-tube-like container made of an autoclavable material such as polypropylene or resin, that contains a proprietary swab. This design utilizes a slider mechanism to deploy and retract the swab from within the tube. Attached to the tube is a container filled with media that is able to be screwed and unscrewed from the tube by the user. The media is contained behind a foil layer that should be pierced by the swab after the sample has been collected and the container has been screwed back on. The main advantages of this design are its ease of production and processing. The design would be fairly easy to fabricate using 3D-printing, and the test-tube shape is familiar to the lab and would not require a novel processing technique. The main benefit of this design is that the unscrewable media container would limit spillage of media as it is not pierced until it is

screwed back on to the tube. However, the main drawback of this design is that it is not a single unit and is instead split into two components, increasing the opportunity for contamination when screwing and unscrewing the media container.

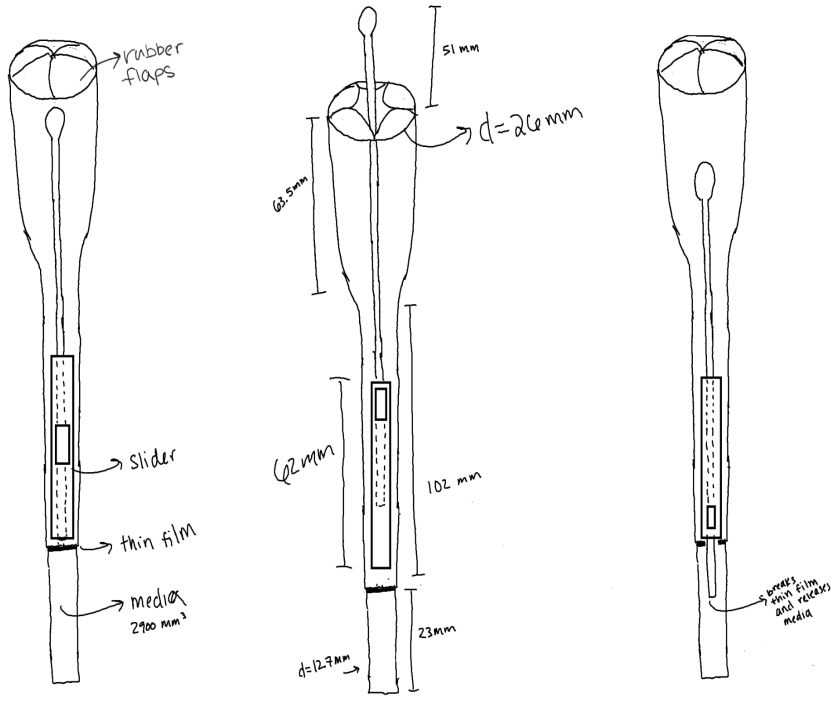


Figure 2: Slider swab design

Design 2: Slider Swab

The second design, as seen in Figure 2, utilizes a single unit design in order to limit contact contamination when self-swabbing. The design includes a slider for deployment and retraction of the testing swab, rubber flaps that will act as a sealing mechanism, and a media container that is separated by a thin film. When using the device, the patient will rest the top portion against the vaginal opening and push the slider forward to deploy the testing swab 5.1 cm into the vaginal canal. The patient will then rotate the device for 30 seconds in order to gather vaginal specimens. After collecting the specimens, the patient will pull the slider all the way down in order to break the thin film and release 2.9 mL of transport media. Some advantages of this design is that it will limit contact contamination of the testing room as the only portion of the design that must enter a potentially infected vaginal canal is to be contained in an external device. Additionally, this design's shape is similar to that of a tampon, a device that many women use on a monthly basis. This familiarity should make the testing process a bit more comfortable when compared to conventional testing methods. However, this design does introduce the risk for media spillage both before and after swabbing. If the patient were to pull the slider down

prior to taking their swab, the thin film separating the media may break and the media would then be absorbed by the testing swab. Furthermore, the rubber flaps at the top of the device may not provide an adequate seal which could cause media to leak out the top of the device.

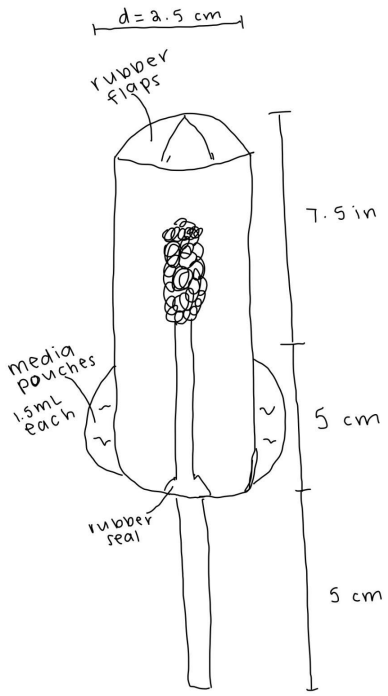


Figure 3: Plunger swab design with media pouches on the sides.

Design 3: Plunger Swab

The third design is also inspired by the structure of a tampon. Tampons are a familiar and easy-to-use device that most women are comfortable with, and this design seeks to translate that comfort into a simplistic STI test that encourages widespread testing. The upper body of this device is a shell that contains a swab, with the top portion consisting of rubber flaps that function similar to a valve. The bottom of the device is a plunger with a rubber seal and is connected to the rod of the swab. On the sides of the main body, there are two media pouches that contain 1.5 mL of transport media each and are enclosed with a thin foil or film. To use this device, the patient places the top of the device at the opening of their vagina. The plunger is pushed up, again, similar to how a tampon functions and the swab head is inserted 5 cm into the vagina. After swabbing, the patient pulls the plunger back down and the swab is retracted into the tube. The device can then be removed from the vaginal area. Next, the media pouches are squeezed and 3 mL of transport media is released into the body of the device in order to submerge the swab head. Overall, this design has the benefit of being extremely simplistic and user-friendly, making it more accessible to patients and maximizing their comfort in an uncomfortable process. However, the main drawback of this design is the potential for spillage and the close proximity

of the media to the patient's body. As the top opening must allow for the swab to go in and out through it, it is challenging to completely seal it. Additionally, there is risk of the media pouches being broken prematurely.

Preliminary Design Evaluations

Design Matrix

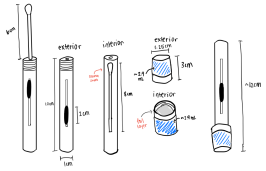
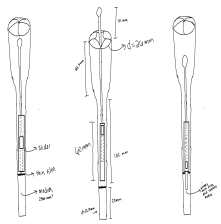
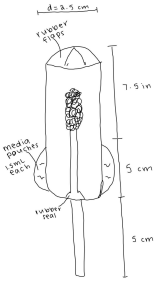
Criteria	**Weight**	**Design 1:** Screw-on media 		**Design 2:** Slider 		**Design 3:** Plunger 	
Limiting contamination	30	3/5	18	4/5	24	5/5	30
Ease of use	20	3/5	12	4/5	16	5/5	20
Ease of fabrication	15	4/5	12	3/5	9	3/5	9
Patient Comfort	15	4/5	12	4/5	12	5/5	15
Safety	15	5/5	15	3/5	9	3/5	9
Cost	5	3/5	3	4/5	4	4/5	4
Total	**100**	**72**		**74**		**87**	

Table 1: Design Matrix for Self-Swab Device

To determine with which design to proceed, six categories were evaluated for each proposed design idea. Limiting contamination refers to restricting the spreading of germs and other contaminants onto the swab or in the environment in which the test is being performed. Ease of use describes the degree of difficulty associated with performing a self-swab with the device, a metric preferred to be low. Ease of fabrication refers to the feasibility of fabrication within the constraints of ability and background of the engineer. Patient comfort details the

degree of comfortability that the patient experiences when using the device to take a swab. Lastly, safety takes into account the potential biological and physical threats that are associated with device use, and cost refers to the price of manufacturing a singular unit.

Design three scores the highest (or ties) in four out of six categories, earning it the highest total score out of the three designs. It received a 5/5 in the limiting contamination category due to the fact that the swab is never exposed to the environment and the media is contained within the device. Additionally, it scored highly in ease of use and patient comfort because the design is most similar to a tampon, which most women are familiar with and comfortable using. Design three scored a 4/5 on cost due to its sleek, one-component design, although it does have the additional side pockets of media. Ease of fabrication is a bit lower scored because of the side pouches of media, and safety also scored similarly due to the close proximity of the media pouches to the user. Normally, scoring the highest in the design matrix would imply that design three would proceed to be the final design, but all three of these designs each have components that would be useful in the final design. Therefore, a combination of the three designs will be present in the final prototype. The idea of a cap containing media from design one, the top, opening flaps from design two, and the push-stick idea from design three will all be incorporated.

Proposed Final Design

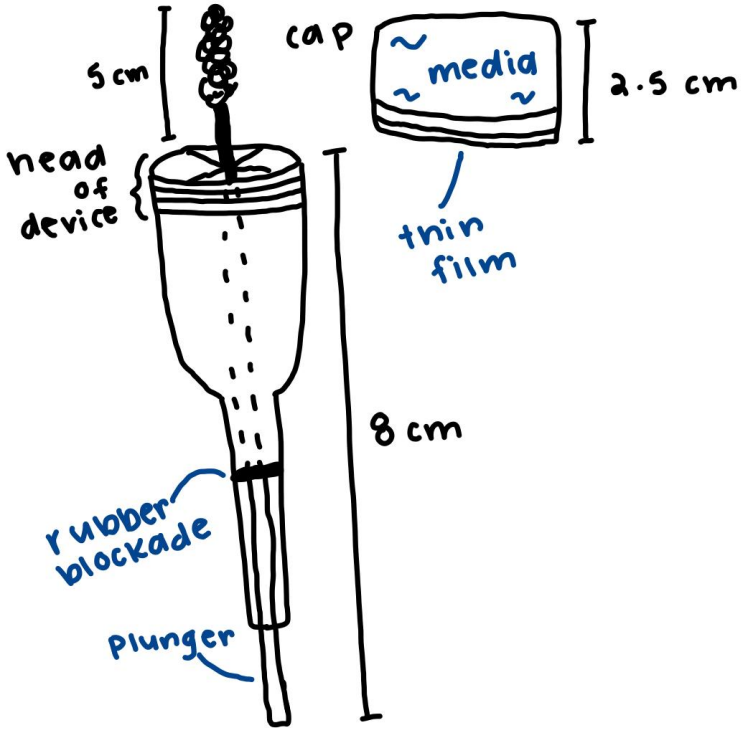


Figure 4: Proposed Final Design including device, swab and media cap

The proposed final design is inspired by the structure of a tampon, including a plunger stick that attaches to the swab. The patient rests the head of the device on the entrance to the vagina (without inserting the device inside the body) and pushes the plunger up to insert the swab into the vagina. After completing a circular swab motion five times, the patient pulls the plunger down and the swab is removed from the body. At this point, the top of the device and the swab are contaminated, but the swab is housed in the device, so it is safe from environmental contamination and will not taint any surfaces. To address the contamination of the top of the device, the user will screw on a media cap, as both the cap and the top of the device are threaded. At this point, the user will deploy the swab once more by pushing the plunger up and using the swab itself to break a thin layer of film on the bottom of the cap, releasing the media into the device. The liquid media helps to preserve the swab and promotes successful testing. Keeping the device in an upside-down orientation will limit the possibility of leaks and allow the swab to remain submerged in media, but a rubber stopper on the plunger will also prevent leaking should the device be jostled. In its final position, the swab will be resting in the media in the cap while the device is in an upside-down position, with the head of the device positioned downwards.

Fabrication/Development Process

a. Materials:

Swab: The swab will be a dacron swab. It is a non-cotton, non-toxic, hydrophilic, synthetic fiber-wrapped swab [13]. The shaft of the swab is plastic [14]. Dacron swabs are most commonly used for STI testing due to their non-toxic and hydrophilic nature. They are both safe for patients as well as most compatible with biological samples.

Transport media: A universal transport media will be used such as Vircell Transport Medium. Transport media increases the viability of the obtained specimen by keeping it in a non-dry environment and allowing the sample to be kept at room temperature [15].

Plunger: The plunger will be 3D printed using polypropylene. Polypropylene is a synthetic, autoclavable resin. It is biocompatible and often used in medical devices [16]. This material is readily available for use in the Makerspace.

Rubber Seal: The plunger will have a seal made from rubber that prevents leakage of media from the bottom of the device. This will be similar to the mechanism used in a syringe plunger [17].

Cap: The cap will also be 3D printed using polypropylene due its biocompatibility and autoclavability [16]. This material is readily available for use in the Makerspace. After

which, the universal media will be sealed inside the cap with a thin, puncturable foil [18]. Sealing the media within a thin foil keeps it from spilling or being contaminated, but also allows the media to be easily accessed when punctured by the swab. This foil will be made of aluminum foil.

Body of device: The body of the device will also be 3D printed with polypropylene since it is biocompatible and autoclavable [16]. This material is readily available for use in the Makerspace.

See Appendix B for information regarding the price of listed materials.

b. Methods:

CAD drawings of each component to be 3D printed–the plunger, cap and body of the device–will be created. After printing, media will be added to the cap and sealed beneath a thin foil. The main portion of the device will be assembled, attaching the swab to the plunger with the rubber blockade in between. The swab, blockade, and plunger being connected can then be inserted through the top of the body carefully until the plunger exits the other end of the body and the rubber blockade is firmly in the handle of the device.

Discussion

This design limits environmental contact contamination where the self-swab is used. This is beneficial because the design ensures the swab will not spill or splash when transferring the test specimen into the media. The contained design not only decreases the potential for environmental contamination, but also the likelihood of a false positive due to a contaminated room. In regards to STI testing, there is a severe lack of STI knowledge in young adults. STIs are under-tested as one in four sexually active adolescent females in the U.S. have an STI [19]. Many people will not get tested because they feel they are not at risk or because they have no symptoms. In today's society, it is clear STIs are not at the forefront of conversation, but with the proper knowledge, routine testing could become available. People aged 15 to 24 years comprise half of all new STIs in the United States, despite the fact that this age group accounts for just above a quarter of the sexually active population. The goal of this design is that it will provide comfort and make women and girls more likely to get tested, the aesthetics and the ease of use playing a large role. Another barrier to testing is that some people are not able to afford doctors visits or have health care insurance to visit a clinic creating a cost issue for testing [4]. Using quality

yet inexpensive materials could help make our device more affordable to help combat this socio-economic dilemma.

Conclusion

The goal of this project is to design a self-swab for STI testing that minimizes potential contamination. Current STI self-swab designs have issues with environmental contamination, and the testing media can easily spill creating a mess in the testing room. Currently, for our future work, we need to solidify the final design by creating CAD models and 3D printing a prototype. First, we will need to acquire the necessary materials. We researched and outlined specific materials we would like to use for our design in the PDS including a dacron (non-cotton fiber) swab, biocompatible resin for 3D printing, and commercially-available media including M4 media or Vircell Transport Medium. Then, begin the fabrication process and test the design. We need to ensure the design keeps the media contained and that nothing leaks out. Another test idea is to survey female students about whether or not they think our design would be comfortable, as we can not have someone physically use the self-swab design due to potential risks. Finally, we will analyze our results to evaluate the final prototype.

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Appendix

Appendix A: Expense Spreadsheet

Material	Cost	Price Estimate	Expected Vendor	Part Number
Polypropylene	$0.13/gram	around $33	Makerspace	-
Transport Media	Free	-	Provided by client	-
Rubber Blockade	$1.87/per	$46.40 for pack of 25	Sigma-Aldrich	Z569941
Foil	$0.09/square foot	$4.48/pack	Amazon	B00279LYL6
Dacron Swab	Free	-	Provided by client	-

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 test and screen for these common STIs in the comfort of their own home or in a clinic. 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 not only the swab itself but also 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 make a mess of the testing space in a clinic [1]. A design in which the swab is deployed and contracted back into the device while remaining inserted in the vagina would decrease the probability of contamination.

Client Requirements:

- The swab head should be contained in an external tube that is safe to enter the vagina.

- The swab head should be deployed from the external tube into the vagina and retracted back into the tube.
- The tube should seal upon retraction.
- The device should ultimately make universal STI testing more accessible and limit contamination of the testing room.
- A budget of 500 dollars should be observed.

Design Requirements:

1. Physical and Operational Characteristics

a. Performance Requirements:

i. The external tube must comfortably fit and enter the vaginal canal.

ii. The external tube must have a mechanism for deployment, retraction, and sealing of the test specimen.

1. Deployment and retraction will be accomplished via a slider mechanism or plunger mechanism.

2. Sealing will be accomplished via a simple spring mechanism.

iii. The head of the swab must be deployed 5 centimeters into the vaginal canal [2].

iv. The swab must remain connected to the external tube and allow patients to self-swab for up to 30 seconds [2].

v. The overall device must also contain a transport media in order to limit the contact contamination caused by the transfer of the specimen into the media [1].

b. Safety:

i. The swab head and shaft must be biocompatible and bioinert so as to prevent any irritation or immune response.

ii. The transport media used must be nontoxic and biocompatible in case of device malfunction or splashing that could cause it to come in contact with skin or internal vaginal tissue.

iii. The device must pass 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 needs to be reliable at detecting Chlamydia and Gonorrhea STIs for every test.

ii. To ensure accuracy, the swab must be able to be inserted about 5 centimeters into the vagina and be rotated for 10-20 seconds each time to collect the sample [1].

iii. The tip of the self-swab device should be approximately 1 cm 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 [4].

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 [5].

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 [6].

iv. Tests done at home will be transported to the lab.

v. Each test will only be used once.

e. Shelf Life:

i. The STI test should be used within 30 days of arrival [7].

ii. Swabs should be transported and/or tested within a 14 day period after the test is administered [6].

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. The swab should have no risk of outside contamination or environmental contamination when in use.
iii. The device must be able to insert into the vagina and withstand the acidic environment of the vagina (pH of 3.8-4.5) [8].

g. Ergonomics:

i. The product should insert and fit comfortably inside the vagina, submerged approximately 5 centimeters [2].

ii. All materials used in the swab and applicator should be compatible with the intravaginal environment.

iii. The fluid within the applicator should be biocompatible but contained within the device.

h. Size:

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

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

i. Weight:

i. The overall device will not exceed 250 grams. This includes the weight of the external tube, the swab shaft and head, and the cell culture media within the device.

j. Materials:

i. As the design will consist of multiple sections, a variety of materials must be used to construct the sample collector.

ii. 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 so as to withstand both the

physiological environment of the vagina as well as the chemical processing involved with experimentation [10]. The swab head material must be highly absorbent for water and proteins so as to collect many specimens, and must allow for their release and collection in medium for testing [11]. Per CDC recommendation, suggested materials include rayon, dacron, or cytobrush [12].

iii. The shaft of the swab should consist of an easily-manufactured and autoclavable material such as a biocompatible resin or plastic that can be manufactured with 3D printing [10].

iv. An appropriate transport media must be used to store the sample following insertion into the vaginal canal. Commonly used, commercially-available media includes M4 media or Vircell Transport Medium [13]. Use of a transport media will allow for improved microorganism viability when testing is performed [14].

v. The body of the sample collector should 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.

k. Aesthetics, Appearance, and Finish:

i. The finished product will be similarly shaped to a standard tampon applicator or IUD insertion device.

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

iii. The product will be long enough to insert at least 5 centimeters into the vagina for sample collection purposes [2].

2. Production Characteristics

a. Quantity:

i. One self-swab device prototype will be developed for purposes of the project.

ii. Design should be replicable for potential to be mass-produced for either at-home or in-clinic use as per client's request.

b. Target Product Cost:

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

1. $55-100 is the estimated cost for one STI swab test (including projected materials for the device, the swab itself, and the liquid media) [15].

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 [16]. The media contained within the device is a transport culture medium and Class I (general controls) device as specified in Sec. 866.2390 [17]. 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 [18].

b. Customer:

i. The customer would like to limit cross contamination of the environment with a product that is able to seal the swab, so it is no longer necessary to transfer from the vagina to the tube.

ii. The customer would like to make universal testing of Chlamydia more accessible (ideally doubling the existing 6%-8%) in order to both prevent infertility as well as the spread of disease. The customer would also like to reach younger women who are more typically under-tested [19].

c. Patient-Related Concerns:

i. This product will ideally make patients more comfortable with regular STI screening.

ii. Barriers to universal testing will still exist (socioeconomic, location, age, etc) [19].

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

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 all require the screwing/unscrewing of sample containers [20].

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. [21]

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