

Vaginal Self-Swab Device to Minimize Contact Contamination

Client: Dr. Jean Riquelme

Advisor: Prof. Randolph Ashton

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Team:

Jackie Behring	jbehring@wisc.edu (Co-Team Leader & BSAC)
Tatiana Predko	tpredko@wisc.edu (Co-Team Leader & Communicator)
Mariah Smeeding	jimenezsmeed@wisc.edu (BWIG)
Ava Fevold	fevold@wisc.edu (BPAG)

PROBLEM STATEMENT

Many cases of bacterial vaginosis, yeast infections, and sexually transmitted infections (STIs) can be asymptomatic and go undiagnosed. This can be detrimental to the well-being of an individual and cause a variety of health concerns if left untreated. It is crucial for individuals to have access to accurate and reliable screening to ensure healthy bodily function. The vaginal self-swab device offers women a noninvasive and less intimidating way for a greater population of women to get tested. By collecting and analyzing mucus samples from the vaginal canal, infections and STIs can be detected. The vaginal self swab created by Hologic, the Aptima Multitest Swab Specimen Collection Kit, has the intention of increasing effective screening accessibility; however it fails to ensure a low enough risk of contamination which jeopardizes its accuracy. This is due to excessive external contact to the swab, inaccurate breakage of the swab shaft, and the potential for transport media spillage. The goal of our project is to create a device that minimizes cross-contamination ensuring accurate test results. Our proposed final design, The Tilt-and-Break, adds a third component that would secure onto Hologic's Self Swab. By doing so, external contact to the swab is eliminated, accurate breakage is ensured, and stability is given to reduce risk of spilling.

BRIEF STATUS UPDATE

- Meeting with Dr. Accola, Lab manager at UW Madison's Hospital to discuss what is meant by contamination of the device and how TMA testing is performed in the lab. Future goals include continual 3D printing trials to ensure correct dimensions of the device.

SUMMARY OF WEEKLY TEAM MEMBER DESIGN ACCOMPLISHMENTS

- Team:
 - First prototypes of the device (media container holder and two Tilt-and-Break handle designs) 3D-printed.
 - Continual planning fabrication protocol and show-and-tell content.
 - Export SolidWorks files to UW MakerSpace and begin 3D printing process

- Print two prototypes:
 - One in PLA and one in PC
- Meet with the lab managers to discuss potential threading.
- Jackie Behring:
 - Continued to research and add to lab archives
 - Altered the measurements of the tilt and break holder on Solidworks with accurate measurements and threading
 - 3D printed two Tilt-and-break designs
 - 3D printed the medium base holder
- Tatiana Predko:
 - Facilitated team meeting with lab managers over Zoom.
 - Met with Jackie and Mariah to 3D-print the first Tilt-and-Break model in the Makerspace.
 - Prepared an elevator pitch for the show-and-tell.
 - Included additional research in LabArchives.
- Mariah Smeeding:
 - Continued research
 - Better understanding of the testing process, Transcription mediated amplification, TMA.
 - Attended the team meeting with Dr. Accola, Lab manager at UW Madison's Hospital, to speak more about the testing process and specific contamination concerns.
- Ava Fevold:
 - Researched contamination
 - Included research in LabArchives

PROJECT DIFFICULTIES

- None

UPCOMING TEAM AND INDIVIDUAL GOALS

- Team:
 - Print and finalize design
 - Meet with client to show prototypes
- Jackie Behring:
 - Alter measurements on the tilt and break so it fits on the Aptima tube
 - Continue researching and updating Lab Archives
- Tatiana Predko:

Final Lab Notebook																			
Final Report																			
Final Evaluations																			
Meetings																			
Team																			
Advisor																			
Client																			

EXPENSES

Item	Description	Manufacturer	Part Number	Date	QTY	Cost Each	Total	Link	
TOTAL:								\$0.00	

DESIGN MATRIX

Design Criteria (weight)	Design 1: Altered Bend Design	Design 2: Tilt - and - Break	Design 3: The Tunnel
Limiting Contamination (30)	4	4	4
Leakage Prevention (25)	4	5	4

Ease of Use (15)	4	12	5	15	3	9
Ease of Fabrication (10)	3	6	4	8	2	4
Patient Comfort (10)	5	10	5	10	5	10
Safety (5)	4	4	5	5	2	2
Cost (5)	5	5	5	5	5	5
Total Score (100)		81		92		74

Determination of Criteria and Weights:

- Limiting Contamination (30): Leaking contamination refers to the ability to inhibit the spread of microorganisms from biological fluids or the testing environment. This criterion was discussed in the *Accuracy and Reliability* section of the PDS, and was assigned a weight of 30/100 due to its significance of being an accurate measurement. The device must demonstrate a consistent snapping mechanism while transporting the swab into the culture media. This requires the minimization of contamination caused by the patient's own bacterium, such as their hands, or from the environmental bacterium, such as a countertop.
- Leakage Prevention (25): Leakage prevention refers to the degree to which spilling of contained culture media is prevented. This criterion was assigned a weight of 25/100 because it is of paramount importance that the culture media does not leak. Leakage of the contained culture media can lead to inaccurate testing results, due to partial loss of the sample or external contamination. Additionally, skin contact with the culture media should be avoided, as it could lead to injury of the patient.
- Ease of Use (15): This section focused on the simplicity of the process using the device. Relevant information was covered in the *Life in Service* and *Shelf Life* sections of the PDS. This criterion was given a weight of 15/100 because it is important that a patient would be able to understand and correctly use the device. A simple testing process is essential since the self-swab would be done without a doctor or physician's guidance.
- Ease of Fabrication (10): This criterion assesses the ease of fabricating the insertion and stand mechanism, including the production and assembly of its components. Ease of fabrication was given a 10/100 because it's crucial that the design is feasible within the given time frame, both for prototyping and potential commercial manufacturing. A higher score in this category reflects a design that aligns with our fabrication skills and can be more readily scaled for commercial production.
- Patient Comfort (10): Patient comfort refers to the comfort level of the patient while using the product, notably to which degree discomfort and pain are avoided. This

criterion was assigned a weight of 10/100, as it is not an essential component of device functionality, but it is vital in the marketability and convenience of the product. Due to its convenience, patients are more likely to self-swab than to obtain a physician-collected sample [1].

- Safety (5): Safety refers to risks (specifically to the user) associated with the product. This category ensures that the shaft portion of the swab can only be inserted 5 cm to prevent mechanical-induced tissue injury to the user [2]. Every material to be used is known to be biocompatible with the human body to reduce the risk of hypersensitivity [3].
- Cost (5): The cost portion of the matrix is used to determine whether the cost of the materials are justifiable and within the client's budget. Points off in this category indicate costs exceeding the budget.

Justification of Assigned Scores:

- Limiting Contamination (30): The “Altered Bend” design scored a ⅔ because although the base was extended to provide more stability, the device still has the potential of being knocked over, which could lead to contamination if the swab comes into contact with an external surface. The “Tunnel” design scored a ⅓ in limiting contamination because the mechanism is made out of malleable plastic, meaning it could tip easier without the added weight. Similarly to the other two design concepts, the “Tilt-and-Break” design received a score of ⅓. This is because although the design consists of a solid “handle” (as compared to the hollow “handles” of the other two designs) making it less prone to tipping over, there is still the possibility of the device being knocked over and becoming contaminated after unintentionally coming into contact with a surface.
- Leakage Prevention (25): The “Altered Bend” design scored a ⅓ in the leaking prevention category because of its inability to screw onto the device containing the transportation medium. The patient could accidentally knock over the tube containing the medium, leading to the potential spilling of viable bacterium through the crevices of the device. Similarly to the “Altered Bend” design, there is a possibility for tipping with the “Tunnel” design, so it is ranked a ⅓. Since there is no solid divide between the swab-holder and the tube, the culture media could spread throughout the hollow holder and escape the container. The “Tilt-and-Break” design scored full points in this category, because the “handle” component of the device is solid, and has no hollow voids for fluid to seep into if the device is not upright. Additionally, this design utilizes threads to allow for a secure, “screw-on” tightening of the two components.
- Ease of Use (15): The “Altered Bend” design was given a score of ⅓ for ease of use because the button mechanism could malfunction, leading to inconclusive results. The “Tunnel” design was ranked the lowest, with a ⅓, because of the need to apply

substantial, and variable (due to the user), pressure in order to break the swab. Finally, the “Tilt-and-Break” design scored full points in this category. This is because the device solely consists of a simple “screwing-on” mechanism, making it simple to use.

- *Ease of Fabrication (10)*: When it comes to the ease of fabrication, the “Altered Bend” design was assigned a score of 8 because, in previous semesters, the button had issues with rotating, providing an inaccurate breaking of the swab (either too long or too short). Fabricating a “button” mechanism and assembling it in a non-rotational manner would be difficult. Ranked 6, the “Tunnel” design would be difficult to fabricate due to the incorporation of sharp inserts within the holder used to stabilize the swab. Lastly, the “Tilt-and-Break” design was given a score of 10; this device would be relatively easy to fabricate due to its simplistic design, but it may be difficult to create a “handle” into which the swab can be sufficiently pressure-fit. Additionally, the “Tilt-and-Break” design utilizes threads, which is an added component of difficulty with regard to the ease of fabrication.
- *Patient Comfort (15)*: Each of the designs scored full points for patient comfort because all of the designs have a similar mechanism in terms of specimen collection by the patient. During the process, the patient must insert the swab 5 cm into the vaginal canal, which provides little-to-no discomfort to the patient if done correctly [2].
- *Safety (5)*: The “Altered Bend” design received a score of 4 for safety because the button could potentially malfunction and pinch the user if not pressed correctly. The “Tunnel” design ranked the lowest, with a 2, due to the sharp insert at the bottom of the holder. This can be dangerous to the user during the swabbing process, as well as while breaking the swab. The simplistic design of the “Tilt-and-Break” mechanism leaves little room for the user to injure themselves, which is why this design received a full score in this category.
- *Cost (5)*: Each of the designs received full points within the cost category because all of the proposed design ideas require a minimal amount of material for fabrication, leading to affordability. All of the costs required to manufacture either device are anticipated to be within the \$250 budget of the client.