Vaginal Self Swab - BME 300/200

Design Matrix

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Section 312

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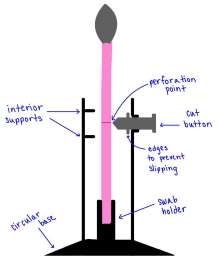
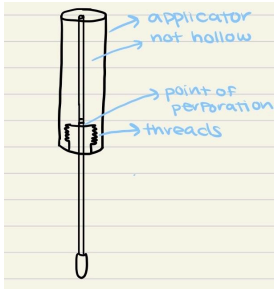
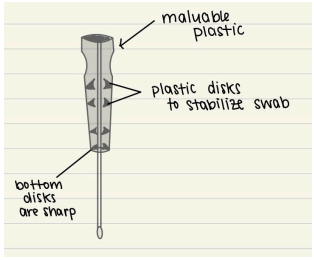
Table 1. Design matrix

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

Cost (5)	5	5	5	5	5	5
Total Score (100)	81		92		74	

Determination of Criteria and Weights:

- *Limiting Contamination (30):* Leaking contamination refers to the ability to inhibit the spread of microorganisms from biological fluids or the testing environment. This criterion was discussed in the *Accuracy and Reliability* section of the PDS, and was assigned a weight of 30/100 due to its significance of being an accurate measurement. The device must demonstrate a consistent snapping mechanism while transporting the swab into the culture media. This requires the minimization of contamination caused by the patient's own bacterium, such as their hands, or from the environmental bacterium, such as a countertop.
- *Leakage Prevention (25):* Leakage prevention refers to the degree to which spilling of contained culture media is prevented. This criterion was assigned a weight of 25/100 because it is of paramount importance that the culture media does not leak. Leakage of the contained culture media can lead to inaccurate testing results, due to partial loss of the sample or external contamination. Additionally, skin contact with the culture media should be avoided, as it could lead to injury of the patient.
- *Ease of Use (15):* This section focused on the simplicity of the process using the device. Relevant information was covered in the *Life in Service* and *Shelf Life* sections of the PDS. This criterion was given a weight of 15/100 because it is important that a patient would be able to understand and correctly use the device. A simple testing process is essential since the self-swab would be done without a doctor or physician's guidance.
- *Ease of Fabrication (10):* This criterion assesses the ease of fabricating the insertion and stand mechanism, including the production and assembly of its components. Ease of fabrication was given a 10/100 because it's crucial that the design is feasible within the given time frame, both for prototyping and potential commercial manufacturing. A higher score in this category reflects a design that aligns with our fabrication skills and can be more readily scaled for commercial production.
- *Patient Comfort (10):* Patient comfort refers to the comfort level of the patient while using the product, notably to which degree discomfort and pain are avoided. This criterion was assigned a weight of 10/100, as it is not an essential component of device functionality, but it is vital in the marketability and convenience of the product. Due to its convenience, patients are more likely to self-swab than to obtain a physician-collected sample [1].
- *Safety (5):* Safety refers to risks (specifically to the user) associated with the product. This category ensures that the shaft portion of the swab can only be inserted 5 cm to prevent mechanical-induced tissue injury to the user [2]. Every material to be used is

known to be biocompatible with the human body to reduce the risk of hypersensitivity [3].

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

Justification of Assigned Scores:

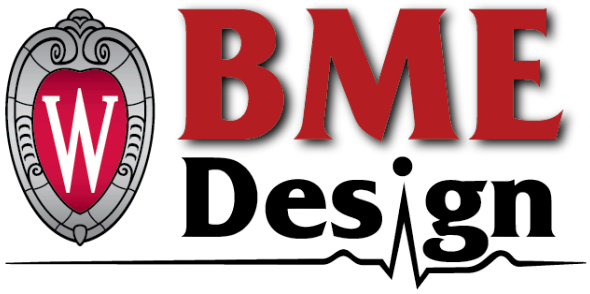
- *Limiting Contamination (30):* The "Altered Bend" design scored a ⅘ because although the base was extended to provide more stability, the device still has the potential of being knocked over, which could lead to contamination if the swab comes into contact with an external surface. The "Tunnel" design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

- *Leakage Prevention (25):* The "Altered Bend" design scored a ⅘ in the leaking prevention category because of its inability to screw onto the device containing the transportation medium. The patient could accidentally knock over the tube containing the medium, leading to the potential spilling of viable bacterium through the crevices of the device. Similarly to the "Altered Bend" design, there is a possibility for tipping with the "Tunnel" design, so it is ranked a ⅘. Since there is no solid divide between the swab-holder and the tube, the culture media could spread throughout the hollow holder and escape the container. The "Tilt-and-Break" design scored full points in this category, because the "handle" component of the device is solid, and has no hollow voids for fluid to seep into if the device is not upright. Additionally, this design utilizes threads to allow for a secure, "screw-on" tightening of the two components.
- *Ease of Use (15):* The "Altered Bend" design was given a score of ⅘ for ease of use because the button mechanism could malfunction, leading to inconclusive results. The "Tunnel" design was ranked the lowest, with a ⅗, because of the need to apply substantial, and variable (due to the user), pressure in order to break the swab. Finally, the "Tilt-and-Break" design scored full points in this category. This is because the device solely consists of a simple "screwing-on" mechanism, making it simple to use.
- *Ease of Fabrication (10):* When it comes to the ease of fabrication, the "Altered Bend" design was assigned a score of ⅗ because, in previous semesters, the button had issues with rotating, providing an inaccurate breaking of the swab (either too long or too short). Fabricating a "button" mechanism and assembling it in a non-rotational manner would be

difficult. Ranked ⅖, the "Tunnel" design would be difficult to fabricate due to the incorporation of sharp inserts within the holder used to stabilize the swab. Lastly, the "Tilt-and-Break" design was given a score of ⅕; this device would be relatively easy to fabricate due to its simplistic design, but it may be difficult to create a "handle" into which the swab can be sufficiently pressure-fit. Additionally, the "Tilt-and-Break" design utilizes threads, which is an added component of difficulty with regard to the ease of fabrication.

- *Patient Comfort (15):* Each of the designs scored full points for patient comfort because all of the designs have a similar mechanism in terms of specimen collection by the patient. During the process, the patient must insert the swab 5 cm into the vaginal canal, which provides little-to-no discomfort to the patient if done correctly [2].
- *Safety (5):* The "Altered Bend" design received a score of ⅘ for safety because the button could potentially malfunction and pinch the user if not pressed correctly. The "Tunnel" design ranked the lowest, with a ⅖, due to the sharp insert at the bottom of the holder. This can be dangerous to the user during the swabbing process, as well as while breaking the swab. The simplistic design of the "Tilt-and-Break" mechanism leaves little room for the user to injure themselves, which is why this design received a full score in this category.
- *Cost (5):* Each of the designs received full points within the cost category because all of the proposed design ideas require a minimal amount of material for fabrication, leading to affordability. All of the costs required to manufacture either device are anticipated to be within the $250 budget of the client.

I. Appendix I : PDS



Vaginal Self-Swab Device

BME 200/300 PDS

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Function:

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

Client Requirements:

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

Design Requirements:

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

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

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

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

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

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

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

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

b. *Safety*:

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

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

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

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

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

c. *Accuracy and Reliability*:

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

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

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

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

d. *Life in Service*:

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

   ii. Distance traveled is undefined.

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

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

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

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

e. *Shelf Life:*

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

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

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

f. *Operating Environment*:

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

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

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

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

g. *Ergonomics*:

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

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

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

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

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

h. *Size*:

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

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

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

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

iii. Device size should accommodate easy transportation.

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

i. *Weight*:

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

a. The device will have a weight of approximately 15-45 grams, including the casing and swab.

j. *Materials*:

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

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

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

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

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

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

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

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

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

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

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

2. Production Characteristics

a. *Quantity*:

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

b. *Target Product Cost*:

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

3. Miscellaneous

a. *Standards and Specifications*:

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

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

b. *Customer*:

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

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

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

c. *Patient-related concerns*:

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

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

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

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

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

d. *Competition*:

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

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

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

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