Vaginal Self-Swab Device to Minimize Contact Contamination

Product Design Specification

Client: Dr. Jean Riquelme
Advisor: Professor Pamela Kreeger
Class Section: 306

Jenna Sorenson (Co-leader)
Katherine Kafkis (Co-leader)
Sara Morehouse (Communicator)
Mia LaRico (BWIG)
Kaiya Merritt (BSAC)
Morgan Kopidlansky (BPAG)

Date: September 22nd, 2023

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 2 inches 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 2 inches 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 2 inches [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 seven inches 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 3.5 inches [9].

i. Weight:

i. The overall device will not exceed 750 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 two inches 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]

References

[1] Muljadi, Michael, et al. “A Pilot Clinical Validation Study of a Self-Collected Vaginal Swab Device for the Detection of Chlamydia Trachomatis in Women.” *Frontiers in Bioengineering and Biotechnology*, Frontiers, 20 Sept. 2022, www.frontiersin.org/articles/10.3389/fbioe.2022.1008761/full.

[2] “Self-Collected Vaginal Swabs for Gonorrhea and Chlamydia.” *NCDHHS*, Gen-Probe Incorporated, Apr. 2011, epi.dph.ncdhhs.gov/cd/lhds/manuals/std/labtesting/selfcollectedswabs.pdf.

[3] ISO - International Organization for Standardization, “ISO 10993-17:2023,” ISO, 2023. https://www.iso.org/standard/75323.html.

[4] “Laboratory Bulletin.” Notification of Extended Expiry Dating for the Aptima Multitest Swab Specimen Co, www.albertahealthservices.ca/assets/wf/lab/if-lab-hp-bulletin-notification-and-collection-of-muscle-biopsy-specimens.pdf.

[5] “Aptima Specimen Transfer Kit Package Insert - Hologic.” APTIMA Specimen Transfer Kit Package Insert, stage.hologic.com/sites/default/files/package-insert/AW-11586-001_002_01.pdf.

[6] “Laboratory Test Catalog Powered by Mayo Clinic Laboratories.” Laboratory Test Catalog, Spectrum Health, 2023, spectrumhealth.testcatalog.org/show/LAB1230566#:~:text=or%20SH%20MRN)-,Laboratory%20Retention%3A%20Swab%20specimens%20will%20be%20stored%20at%20room,for%2014%20days%20from%20collection.&text=Male%20Urethral%20Specimens-,Collection%20Instructions%3A,hour%20prior%20to%20sample%20collection.

[7] "Does the STI Kit Expire? How Long Do I Have to Use It?" *Help Center*, Legacy, 2 Jan. 2023, help.givelegacy.com/s/article/Does-the-STI-Test-Kit-expire-How-long-do-I-have-to-use-it.

[8] W. E. Contributors, "What Is Vaginal pH Balance?," *WebMD*, Apr. 25, 2021. https://www.webmd.com/women/what-is-vaginal-ph-balance

[9] Cleveland Clinic, "Vagina: Anatomy, Function, Conditions & What's Normal," *Cleveland Clinic*, Mar. 08, 2022. https://my.clevelandclinic.org/health/body/22469-vagina

[10] V. Vashist, N. Banthia, S. Kumar, and P. Agrawal, "A systematic review on materials, design, and manufacturing of swabs," *Annals of 3D Printed Medicine*, vol. 9, p. 100092, Feb. 2023, doi: https://doi.org/10.1016/j.stlm.2022.100092.

[11] R. N. Kashapov and A. N. Tsibin, "Comparison of the Physical Properties and Effectiveness of Medical Swabs for Sampling Biomaterials," *Biomedical Engineering*, vol. 55, no. 4, pp. 289–293, Nov. 2021, doi: https://doi.org/10.1007/s10527-021-10120-z.

[12] "Recommendations for the Laboratory-Based Detection of Chlamydia trachomatis and Neisseria gonorrhoeae — 2014," 2019. https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm

[13] S. L. Jones et al., "Performance evaluation of two microbial transport media designed for preservation and transport of Chlamydiae, Mycoplasma and Ureaplasma," *Journal of Medical Microbiology*, vol. 64, no. 4, pp. 382–389, Apr. 2015, doi: https://doi.org/10.1099/jmm.0.000044.

[14] "TRANSPORT MEDIUM - Vircell," en.vircell.com. https://en.vircell.com/products/transport-medium/ (accessed Sep. 21, 2023).

[15] D. R. Blake et al., “Could Home Sexually Transmitted Infection Specimen Collection With e-Prescription Be a Cost-Effective Strategy for Clinical Trials and Clinical Care?,” *Sexually Transmitted Diseases*, vol. 42, no. 1, pp. 13–19, Jan. 2015, doi: https://doi.org/10.1097/olq.0000000000000221.

[16] Microbiological specimen collection and transport device, 21 C.F.R. § 866.2900 (2023).

[17] Transport culture medium, 21 C.F.R. § 866.2390 (2023).

[18] ISO - International Organization for Standardization, “ISO 20658:2023,” ISO, 2023. https://www.iso.org/obp/ui/en/#!iso:std:80035:en.

[19] Liddon, Nicole, et al. “Annual STI Testing among Sexually Active Adolescents.” American Academy of Pediatrics, American Academy of Pediatrics, 11 Apr. 2022, publications.aap.org/pediatrics/article/149/5/e2021051893/186749/Annual-STI-Testing-Among-Sexually-Active

[20] Pandya, N., & Pandya, N. (2023). Benefits Of PCR Testing For Chlamydia And Gonorrhoea. Lifecell International Pvt Ltd. https://www.lifecell.in/blog/health-check/benefits-of-pcr-testing-for-chlamydia-and-gonorrhoea#:~:text=In%20A%20Nutshell,of%20infections%20in%20your%20sample.

[21] LifeCell International Private Limited. (2022, December 13). Vaginal swab self sample collection & dispatch -Explainer video [Video]. YouTube. https://www.youtube.com/watch?v=gMpfNOQtZfg.