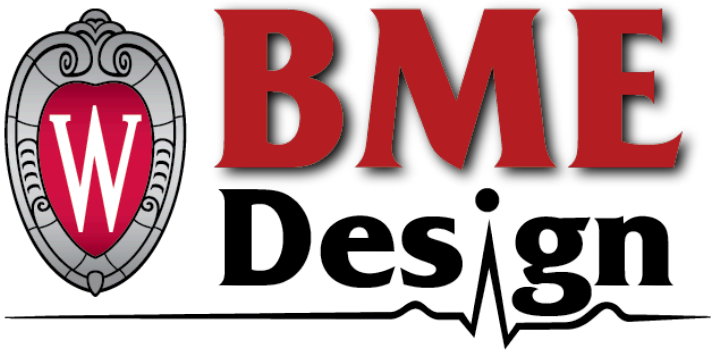

Vaginal Self-Swab Device to Minimize Contact Contamination

Product Design Specification

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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].

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 tip of the self-swab 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. 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 [15]. Use of a transport media will allow for improved microorganism viability when testing is performed [16].

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) [17].

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 Gonnorhea occurred in 2022 [18].

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 [19]. 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 [20]. 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 [21].

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 [22].

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) [22].

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 [23].

    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. [24]

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