

According to the CDC, Chlamydia is the most frequently diagnosed bacterial sexually transmitted infection (STI) 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. Intravaginal self-swab STI testing has been found to increase the likelihood of routine testing and diagnosis, with one study conducted at the University of Pittsburgh's School of Medicine in 2011 finding 84% of women to prefer the self-swab method and 94% feeling more willing to routinely test for STIs through a self-swab. While self-swab testing methods appear to promote universal testing, the current self-swab testing method employed by most clinics introduces great potential for contamination of the testing environment.

Conventional vaginal self-swab STI tests provide patients with a Dacron swab and a test tube filled with chlamydia transport media to collect their specimens. This process requires patients to hold the swab in their hand, insert the Dacron swab 5 cm into the vaginal canal, rotate it for 10-30 seconds, and then transfer it into the media tube for diagnostic testing. The transfer process requires patients to physically break the swab into the media tube at a perforation point which can cause media or vaginal fluids to splash onto and contaminate surfaces. The contamination of surfaces has led to false positives, with one study conducted in 2020 at the Skaraborg Hospital's Department of Clinical Microbiology in Sweden finding 67% of women to receive a false positive due to surface contamination.

A modified testing device has been developed to limit the contamination of the testing environment during STI self-testing. The proposed method utilizes a device that houses and breaks the Dacron swab while limiting contamination via the external casing. The device firmly holds the plastic shaft of the Dacron swab, leaving the upper 6.5 cm available for specimen collection. The interior of the device contains 2 points of contact with the swab, one above and one below the swab's perforation point. The exterior of the device contains a push button that aligns with the perforation point - forming a three-point bend mechanism to break the swab. To use the device for self-swabbing, a patient holds the outer housing of the device and inserts the swab 5 cm into the vagina. After rotating the swab against the vaginal walls for 10-30 seconds, the patient removes the swab and places the device on the table with the swab tip in the air, providing the patient time to collect themselves after specimen collection. The patient then unscrews the top of the provided media tube while it stands in a supportive base, picks up the device, and pushes the device over the opening of the media tube where it is firmly held in place via a friction fit such that the head of the Dacron swab is submerged in the media. To break the swab and transfer it into the tube, the patient presses the button on the exterior of the device causing the swab to break and fall into the media. They then remove the device and re-cap the media tube, which can be sent to the lab for processing. The use of the external casing should limit contamination as it allows patients to safely set the device down and prevents vaginal fluids or media from being spilled or transferred to surfaces during the swab collection process.

Validation of this device's ability to reduce contamination is to be conducted via a cervical model coated with an invisible ink. Both the conventional method and the proposed device will be used to complete a mimetic self-swab on the model, with the spreading of the invisible ink being used to quantify the contamination of each method. The force required to break the swab will also be determined in a three-point bend test on an MTS machine. This test will be used to optimize the 3-point bending configuration which should require the least amount of force. The test will also be used to provide patients with intuition on the amount of force to be applied to the button. A survey is to be sent out to students within the BME design curriculum to gather data on the aesthetics, usability, and instructions fabricated for the device. Feedback from the survey will be readily incorporated into the device and its instruction manual. Altogether, the device offers a simple modification to the current STI self-swabbing process and successfully limits contamination of the testing environment by improving the ergonomics of the process of sample collection. By doing so, this novel device holds the potential to streamline STI testing and further promote universal testing to decrease rates of STIs across the population.