Vaginal Self-Swab to Minimize Contact Contamination

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BME 301

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Client: Dr. Jean Riquelme

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Problem Statement

Current STI self-testing methods contaminate the testing environment

- 84% prefer self-swabs to gynecological exams [1]
- 67% of women received a false positive result due to contamination [2]

Contamination Methods

- Insertion into and swabbing of vaginal canal
- Transfer to the media tube

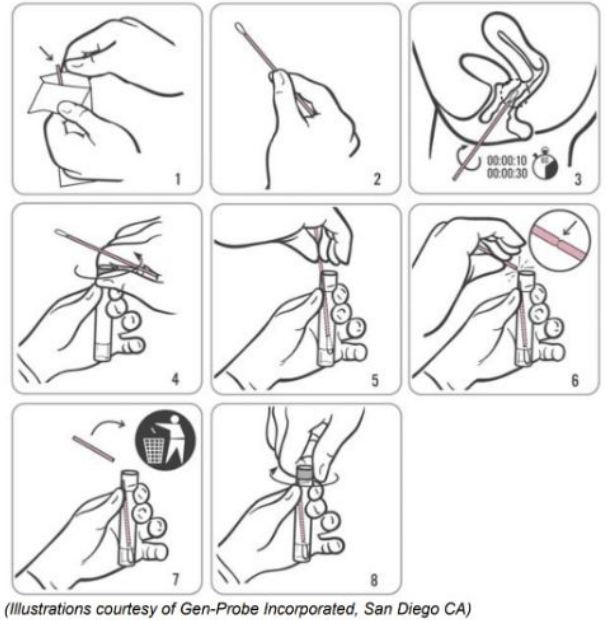


Fig.1 Current STI self-swabbing protocol [3].

Background Information

Client: Dr. Jean Riquelme

- Family medicine physician based in Madison
- Requesting a vaginal self-swab device for use in Chlamydia screening
- Promote universal STI testing

Background Information

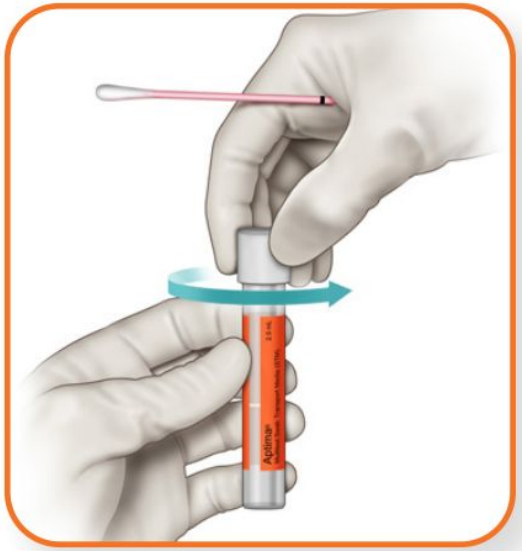


Fig. 2: Aptima Multitest swab instructional image [5]

- STIs are under-tested especially in young women
  - 1 in 4 sexually active adolescent females in US have an STI [4]
  - Asymptomatic
  - Barriers to testing [4]
  - Long term complications if untreated [1]
- Nucleic Acids Amplification Test [1]
- Existing designs
  - Aptima test by Hologic [5]
  - Patient RNA remained on testing room surfaces [2]
  - Require more thorough cleaning

Product Design Specifications

Goal: Create a vaginal self-swab device that reduces contamination of the testing room while prioritizing patient comfort in order to promote universal testing.

- User-friendly
- Housing/deployment and sealing mechanisms
  - Release of transport media [1]
- Head of swab must insert 5 cm into the vagina [3]
- Biocompatible and non-toxic materials
  - Non-cotton fiber swab (Dacron) [7]
  - Universal transport media
  - Biocompatible plastics: PLA, PP, etc.
- Overall length under ~17 cm
- Manufactured with 3D-printing
- Budget: $500

Fig. 3 Materials provided with current self-swab tests [5]

Specific Semester Goals

Leaking - Transport Media
- Class 1 medical device [8]
  - Required for sample preservation [1]
- Must be contained within the device

Sealing
- Induction-sealed thin film within media container (cap)

Ergonomics/Aesthetics
- Thin in diameter, short in length
- Threading on inside of device
- Arrows or colors incorporated for further direction

Sustainability - Single Use
- Compostable plastics: PLA, PBS, PBAT mixtures [9]

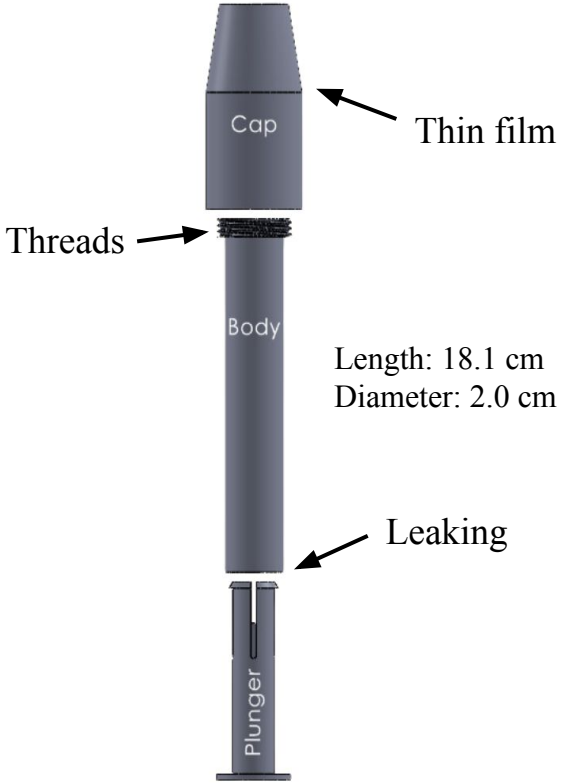


Fig.4 Previous device with areas of improvement indicated.

Design Idea 1 - Modified Plunger Design

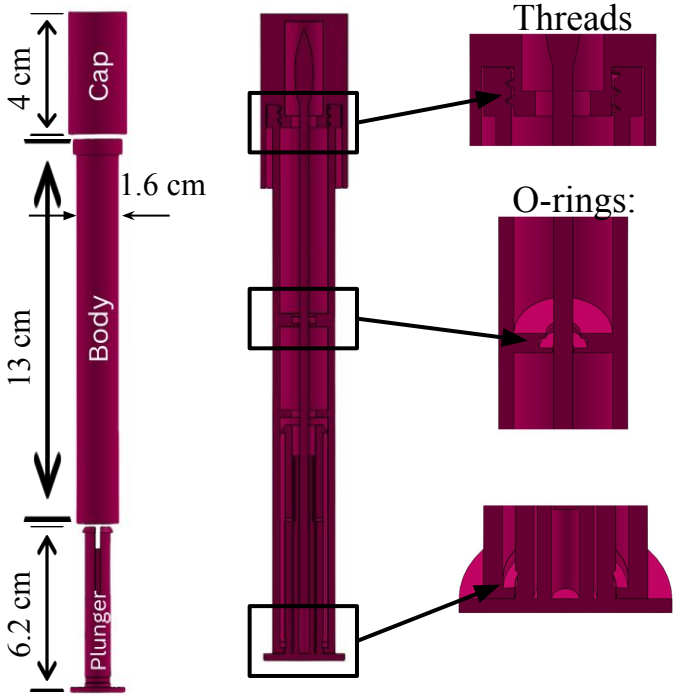


Fig.5 Modified plunger design.

- Similar to a tampon
- Plunger holds swab and provides 6 cm of vertical motion
- Body contains the swab when it is not inserted into the vagina
- Two o-rings prevent leakage of media
- Cap has location for thin film attachment
- Threads on the interior of device for aesthetics

Design Idea 2 - Snap On Design

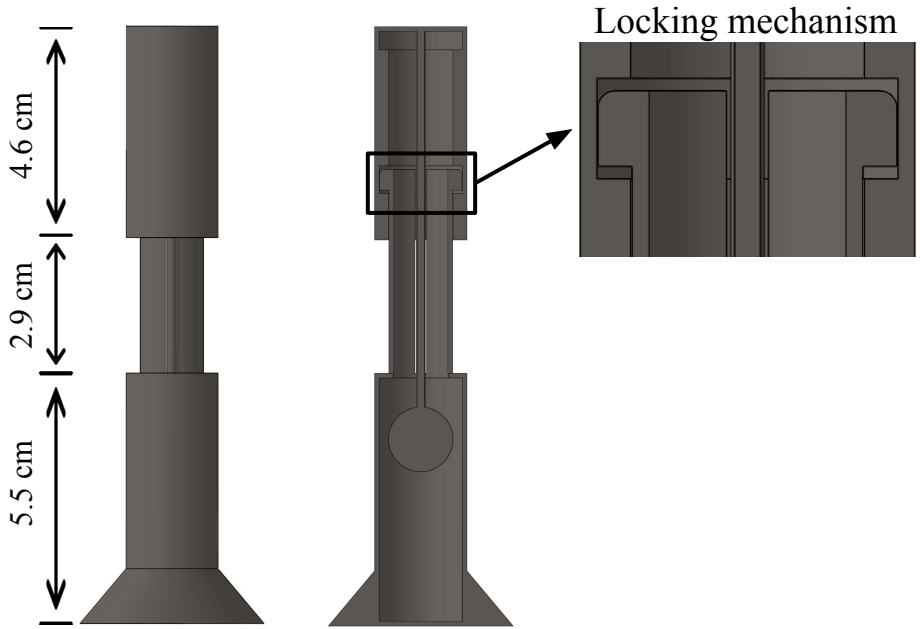


Fig.6 Full and sectional views of the snap on design

- Intuitive design that allows for swabbing with one hand
- A second locking mechanism allows the swab to be submerged in media
- Media is housed in the bottom of the base
- The device will not leak if kept upright

Design Idea 3 - Pull Back Design

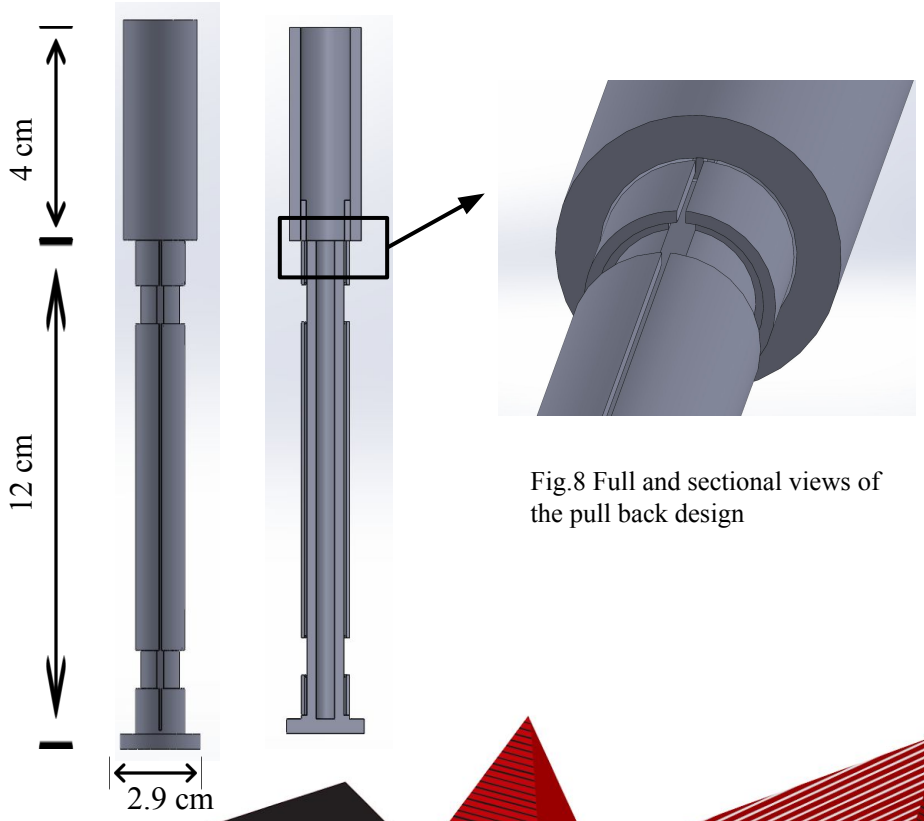
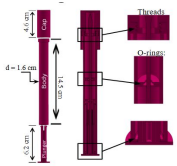
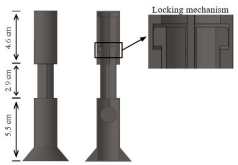
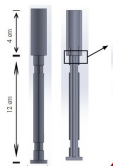


Fig.8 Full and sectional views of the pull back design

- Twisting lock mechanism allows for easy access to the swab
- The top sheath protects the swab from contamination
- Media is housed in the top of the cap (not shown)
- Room for two o-rings will help prevent leaking

Design Matrix

Criteria	Weight	Modified Plunger 		Snap On 		Pull Back 	
Limiting contamination	30	5/5	30	3/5	18	5/5	30
Leakage Prevention	25	4/5	20	5/5	25	4/5	20
Ease of use	15	4/5	12	5/5	15	3/5	9
Ease of fabrication	10	1/5	2	5/5	10	3/5	6
Patient Comfort	10	5/5	10	4/5	8	4/5	8
Safety	5	5/5	5	5/5	5	5/5	5
Cost	5	5/5	5	5/5	5	5/5	5
Total	**100**	84		**86**		83	

Future Work

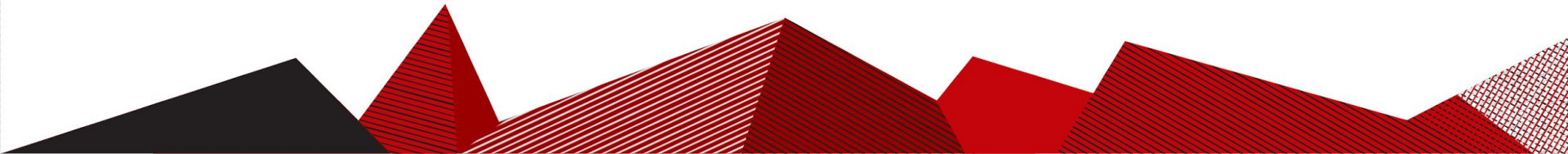
- Redesign prototypes due to limitations of testing equipment
- 3D print designs for fabrication.

Fig.9 Automated diagnostic device that will be used to test the swabs

Thank you!

Special thanks to Dr. Riquelme, Dr. McClean, and Stephen Foley for their guidance and input!

Questions?



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