BME Design-Fall 2024
Complete Notebook

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Team Contact Information

Tatiana Predko - Dec 10, 2024, 7:54 PM CST

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Project Description

Tatiana Predko - Dec 10, 2024, 7:55 PM CST

Course Name: Biomedical Engineering Design 200/300

AVA FEVOLD - Oct 06, 2024, 12:33 PM CDT

Course Number: 312

Project Name: Vaginal self-swab device to minimize contact contamination

Short Name: Vaginal Self-Swab

Project description/problem statement:

Bacterial Vaginosis, yeast infections, and sexually transmitted infections (STIs) can be detrimental to the well-being of an individual and cause a variety of health concerns if left untreated. The vaginal self-swab device is to be utilized by patients to easily collect cervicovaginal mucus samples from the vaginal canal to diagnose vaginal infections and STIs. This device design aims to provide a convenient, accessible method of breaking the swab into the transfer tube while minimizing cross-contamination of the self-collected sample. Cross-contamination, with the surface and environment, typically occurs while 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 break into the culture media solution directly, and to prevent media leakage.

About the client:

Dr. Jean Riquelme

- Family medicine doctor based in Madison
  - UW Health, Department of Family Medicine and Community Health
- Requests a vaginal self-swabbing device that can screen for bacterial vaginosis, yeast infections, and sexually transmitted infections (STIs)
- Goal is to promote safer, more accurate vaginal self-testing

09/12/2024-Client Meeting #1

Tatiana Predko - Sep 12, 2024, 1:22 PM CDT

Title: Client Meeting #1

Date: 09/12/2024

Content by: Tatiana Predko

Present: All team members

Goals: Meet with the client, determine problem statement of the project (background info and why the device is needed), discuss design criteria, etc.

Content:

- Sexual transmitted diseases responsible for infertility and decreased quality of life.
- Need vaginal specimen for women, more accurate than urinary.
- Self-swab more convenient for the patient. Additionally, it is more accurate than clinically-collected samples.
- Self-swabs have been providing false positives; possibly due to cross-contamination in the process of transporting the specimen to the medium.
- Want to eliminate/simplify the transfer step in transferring the swab to the medium.
- Last prototype had fitting issues (fitting swab into device), but breaking off swab works great from previous design; fitting swab into device needs improvement. Having the device stand needs improvement.
- No sealing issues on the last model; liquid does not leak.
- For seating tests of the device, must use the orange swabs. Clinician test swabs currently available.
- Might need to repeat contamination testing; can use the pelvis model (plastic vaginal model) located at the clinic.
- Work on seating; make sure to use orange color swabs
- Proprietary product; for product development, need to reach out to Hologic.
- Reach out to the lab director once the device is easier to use; see how they like it; Can potentially be used at the clinic.
- Hologic is the manufacturer of self-swab; device name is Aptima.
- Client is gone 22-30th of September (clinical project in Ukraine).
- School of Medicine can't transfer money to the College of Engineering. Pay out of pocket, client pays back on venmo. Can use her Wiscard to pay.
- Poster presentations in March; academic presentation requirement.
- No testing on real patients; in the past, teams did surveys through friends. Need permission to survey patients.
- Long-term if considering patent; need IRB. Very marketable device.
- Price range: approximately $50.
- Budget: approximately $250.

Conclusions/action items:

- Add presentation date and schedule/availability in email to client. (Tanya Predko)
- Pick up test swabs tomorrow from 1102 South Park Street (Wingra Clinic- open 8-5PM). Front desk if on the first floor, ask about engineering project. (Ava Fevold)
- Schedule team meeting, assign PDS sections, and begin working on PDS. (All team members)
- Upload Progress Report to website by 5PM today. (Mariah Smeeding)

09/20/2024-Client Meeting 2

JACKIE BEHRING - Sep 20, 2024, 12:23 PM CDT

Title: Client Meeting 2

Date: 9/20/2024

Content by: Jackie

Present: Team

Goals: Meet with the client to discuss the PDS as well as any uncertainties we have about the project.

Content:

- Snapping mechanism was too high so the breaking point was not hit
- device should consistently cut at the breaking point
- Biodegradable
- cone shaped base
- next week shipment of more swabs

Conclusions/action items:

2024/10/17-Client Meeting 3

JACKIE BEHRING - Oct 17, 2024, 12:18 PM CDT

Title: Client Meeting 3

Date: 10/17/2024

Content by: Jackie

Present: Tanya, Ava, Mariah, Jackie, Jean

Goals: Meet with the client and ask questions we have from advisor meeting.

Content:

- What is the level of contamination that the lab sees?
  - 10-25%
  - not sure if that is the specific lab stat
  - that is the general lab stat
- Is this an at home test?
  - collected in the lab bathroom
  - if test was more reliable then to send it home with people
  - mail to people, mail back to lab to increase universal screening
- Can we secure the handle onto the media container?
  - ask the lab
- make a stand
- more accurate breaking point
- pitch to lab threading on the cap
- Ava going to pick up more swabs 10/18/2024

Conclusions/action items: Use these answers to determine the next steps of the design process. Meet with the lab managers.

2024/10/25-Lab Meeting 1

Tatiana Predko - Oct 25, 2024, 3:44 PM CDT

Title: Lab Meeting 1

Date: 10/25/2024

Content by: Jackie and Tanya

Present: Jackie, Tanya, Mariah, Ava

Goals: Meet with the lab to discuss what contamination means and determine goal of project.

Content:

- fear in lab of self collection
  - foil caps perforated by tips during laboratory protocol
  - any contamination on top of foil will ruin the sample (whether during specimen collection or in the laboratory).
  - some touches foil cap with hand/glove with some HPV could cause false positive
  - Lab workers NEVER touch foil cap
  - patient themselves can contaminate top
  - nurse who handled some else's sample could contaminate top
  - PANTHER fusion
- temporarily cover with parafilm
- how often are you seeing HPV contamination on sample?
  - she does not know
- Transcription mediated amplification - panther fusion
  - very sensitive, more than PCR
  - technology is so sensitive it amplifies part of viral genome so well
  - if someone is sloppy while changing the waste, then all the little virus fragments will be amplified
  - if instruments touched, gloves not changed, door handle touch
- Very intense bleach smell in lab area because constantly cleaning lab.
- 15,000 - 20,000 tests per year; so, could be tedious for the laboratory staff to replace each cap if the media tube does not come with the foil cap.
- if considering the threaded handle design, the lab would have to open and dispose of the handle in a biosafety cabinet
- if the handle is broken at the perforation line, no need to dispose of the swab, reduces contamination in laboratory; only thing that the laboratory would have to do is to replace the cap.
- opportunity for contamination in the lab, if at home tests
- goal of self collection: as many women get tested as possible
- perfect swab height, so when cap screw on the end of the swab gets pulled off to the side
- what is the level of contamination that the lab sees?

Conclusions/action items:

- Schedule appointment to visit lab next week, learn more about TMA testing.

- Send Molly team availability to get in lab and watch procedure.

9/20/2024-Advisor Meeting 1

JACKIE BEHRING - Sep 20, 2024, 1:34 PM CDT

Title: Advisor Meeting 1

Date: 9/20/2024

Content by: Jackie

Present: Team

Goals: Clarify the goals of the project and go over progress report and PDS.

Content:

- Team picture by next week!
- Get client meetings regularly scheduled
- lab notebooks
  - Put in entries per articles
  - IEEE citation format
  - Summary of information learned
  - Bullet points are ok
  - Designs can be hand sketched, have to be well labeled
- PDS
  - what does contamination mean?
  - what is altering the data?
  - outside world? the person taking the test (their hands?)
  - is the concern when you remove the swab to clip it off with fingers?
  - is the concern when the device is being transported?
- is there anyone else we can work with while Jean is gone?
- testing
  - tubes with sugar containing nutrients that bacteria like to grow in
  - if becomes cloudy then it has been contaminated
- research microbiome of the vaginal canal
- what contaminates vaginal swab tests
- MAKE EVERYTHING MORE QUANTIFIABLE
- DIMENSIONS
- how do they run the test?
  - swabbing on a plate?
  - analysis of DNA?

Conclusions/action items: Talk to Jean and lab to confirm how testing is done afterward.

2024/09/27-Advisor Meeting 2

JACKIE BEHRING - Sep 27, 2024, 1:32 PM CDT

Title: Advisor Meeting 2

Date: 9/27/2024

Content by: Jackie

Present: Jackie, Ava, Mariah

Goals: Talk through the design matrix with the advisor, address any concerns or confusions.

Content:

- Update Progress Report with advisor comments
- Design Matrix looks good
- Include why the sample needs to break off in the report
- Run a MTS test
    - hold the top of the swab in fixed place and test the bending on the opposite side
    - run the test in the tube and out of the tube

Conclusions/action items: Meet with team this upcoming week to discuss Preliminary Report and Presentation.

2024/10/11-Advisor Meeting 3

JACKIE BEHRING - Oct 11, 2024, 1:54 PM CDT

Title: Advisor Meeting 3

Date: 10/11/2024

Content by: Jackie

Present: Jackie, Tanya, Mariah, Ava

Goals: Meet with advisor to discuss Preliminary Report.

Content:

- $50 from BME design in MakerSpace
    - Use first, then use client budget
- threading may not be necessary
- Only testing PC?
- Why did past semesters use PLA
- add bottom base
- testing
    - focus on quantitative values
        - skip survey
    - bacterial plates to test if sample has been contaminated
        - ask someone who is not involved or familiar with the project
        - 10-20 people
    - measure swab to find ideal length
        - measure how well device snaps and where device snapped using device and not using device
        - note any spillage of solution
        - break 10-20 swabs and measure the length
    - lack of spillage, lack of contamination, snapping consistency
    - Lack of Spilling
        - have someone else come in and load swab into device, see how many times it falls over
        - assess on rubric
    - lack of contamination
        - open package, open device, snap off swab,

Questions to ask Jean

- what is the level of contamination that the lab sees?
- is this an at home test?

Conclusions/action items: Continue to work on the project and change the testing protocols.

10/18/24 advisor meeting

MARIAH SMEEDING - Oct 18, 2024, 1:55 PM CDT

Title: Advisor Meeting Oct. 18

Date: 10/18/2024

Content by: Mariah

Present: Mariah, Jackie, Ava

Goals: Discuss this week's accomplishments and what direction we should be headed in for the upcoming week with Professor Randolph.

Content:

- **Top Priority**: Figure out what contamination means exactly.
Current plan is to speak with the lab manager and/or lab technicians to understand what they consider to be contamination in the tests to produce inaccurate testing.

- We watched a video PCR: https://www.bing.com/videos/riverview/relatedvideo?&q=hologic+aptima+testing&&mid=DA01B0F2C92D813125C7DA01B0F2C92D813125C7&&FORM=VRDGAR
Video includes how the testing works to translate DNA to RNA and replicate it many times so it can be assessed with a fluorescent probe and a quencher to detect the unwanted bacteria (such as chlamydia, gonorrhea, etc..)

- Discussed our meeting with Dr. Riquelme.
Jean was able to tell us there is about 15-20% contamination in the testing. This is a general statistic not a specific one to the lab at UW hospital. She was not able to tell us what the contamination itself was and so it is clear we must speak to the lab to understand exactly what contamination we will be preventing in our design.

- Professor Randolph believes we should 3D print our prototypes and begin testing even though we are still unclear about the contamination for now.
We do know that Jean would like certain changes to be made to the device to ensure easier swab breakage and reduced spillage and this is something we know how to solve, so focus should be placed here as well as the contamination mystery.

Conclusions/action items:

- Set up meeting with the lab, send out when2meet.

- 3D print prototypes and begin swab breakage testing.

2024/10/25-Advisor Meeting 5

JACKIE BEHRING - Oct 25, 2024, 1:10 PM CDT

Title: Advisor Meeting 5

Date: 10/25/2024

Content by: Jackie

Present: Tanya, Jackie, Ava

Goals: Update advisor on the project.

Content:

- Meet with lab and discover what contamination means
- Understand PANTHER system
- Understand PCR testing
- What problem are we trying to solve?

Conclusions/action items: Meet with the lab to define the problem of the project.

11/08/2024-Advisor Meeting 6

Tatiana Predko - Nov 08, 2024, 1:22 PM CST

Title: Advisor Meeting 5

Date: 11/08/2024

Content by: Tatiana Predko

Present: Tanya and Mariah

Goals: Meet with advisor to determine next steps for testing.

Content:

- can order agar plates for testing.

- positive and negative controls for testing.

- can also ask client if she can provide us with agar plates for testing.

- might need to determine the type of bacteria; pseudomonas is common.

- bacteria can grow at room temperature, but faster at higher temperature.

- don't need IRB if no personal data or specimens associated with assay.

- positive control: worst case scenario, swab something to ensure bacterial growth.

- negative control: no swabbing, careful handling.

- one of the controls should be plate to which nothing is done, not even opened.

- while testing, one person should do each test to prevent variability between users. but, if can afford it, have each person do each of the trails, can compare results between people.

Conclusions/action items:

- order agar plates right away, double what we need.

- can do testing ourselves, don't need more participants.

11/20/2024-Meeting with Jesse (Design Advisor)

Tatiana Predko - Nov 20, 2024, 11:29 AM CST

Title: Meeting with Jesse (Design Advisor)

Date: 11/20/2024

Content by: Tatiana Predko

Present: Jackie, Mariah, and Tanya

Goals: Have a meeting with Jesse the design advisor to get his opinion on how to create the threads on the handle portion of the design.

Content:

- For prototype, can create a 3D-printed version because of the low volume of fabrication.

- For final product, have to do injection molding (because of high volume of fabrication); will be more affordable.

- For the threads, use calipers to measure threading dimensions, and create custom threads on SolidWorks.

- Threads used for media container are raised (not extruded), two raised components interlock; measure pitch of the threads.

- Starts: how many threads there are; 2 starts in our media container (2 components of a helix- 180 degree difference). On SolidWorks rotate 180 degrees for second start.

Conclusions/action items: Using measurements collected during the meeting, can create custom threads on SolidWorks.

2024/11/22-Advisor Meeting 7

JACKIE BEHRING - Nov 22, 2024, 1:27 PM CST

Title: Advisor Meeting 7

Date: 11/22/2024

Content by: Jackie

Present: Ava, Mariah, Jackie

Goals: Meet with advisor and talk through testing protocols.

Content:

- Email Jean and lab manager asking if there is a purpose for breaking the swab into the medium
- Print multiple Tilt-and-Break devices
- Autoclave - testing the threads and measurements after and before autoclave
- Ask Jean and lab manager if they can run tests using the actual tests they have provided and the Panther
- Testing protocol looks good, use as many plates as possible
    - testing with and without device
    - wet the swab before swabbing
    - Criss cross swabbing technique
- Poster:
    - orient audience with current procedure
    - show analysis of what happens after swabbing - what happens in the lab
- Reduction in the number of colonies

Conclusions/action items: Finish printing the devices and begin testing.

Final Expense Sheet

Tatiana Predko - Dec 10, 2024, 8:15 PM CST

Title: Final Expense Sheet

Date: 12/10/2024

Content by: Tatiana Predko and Ava Fevold

Present: N/A

Goals: Add and record final materials and expenses in a spreadsheet.

Content:

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat #	Date	QTY	Cost Each	Total	Link
Base	3D print - PLA	n/a	n/a	Makerspace	n/a	10/29	1	$0.33	$0.33	n/a
Base	3D print - PC	n/a	n/a	Makerspace	n/a	10/29	1	$0.33	$0.33	n/a
Tilt-and-Break	3D print - clear	n/a	n/a	Makerspace	n/a	11/25	1	$4.96	$4.96	n/a
Tilt-and-Break	3D print - PLA	n/a	n/a	Makerspace	n/a	10/29, 10/30	4	$0.45	$1.80	n/a
Tilt-and-Break	3D print - PC	n/a	n/a	Makerspace	n/a	10/29	1	$0.45	$0.45	n/a
Dacron Swab	n/a	Hologic	n/a	Provided by client	n/a	n/a	n/a	Free	Free	n/a
Transport Media	n/a	Hologic	n/a	Provided by client	n/a	n/a	n/a	Free	Free	n/a
Agar Plates	testing agar plates	EZ BioResearch	n/a	Amazon	n/a	11/20	3	$22.10	$66.30	Amazon
Total Cost: $74.17										

Fig. 1. Spreadsheet depicting final materials and expenses for the final project; spreadsheet made by Ava Fevold.

Conclusions/action items: Include the final expense spreadsheet in the final report.

Initial Designs

AVA FEVOLD - Dec 11, 2024, 11:37 AM CST

Title: Initial Designs

Date: 9/26/24

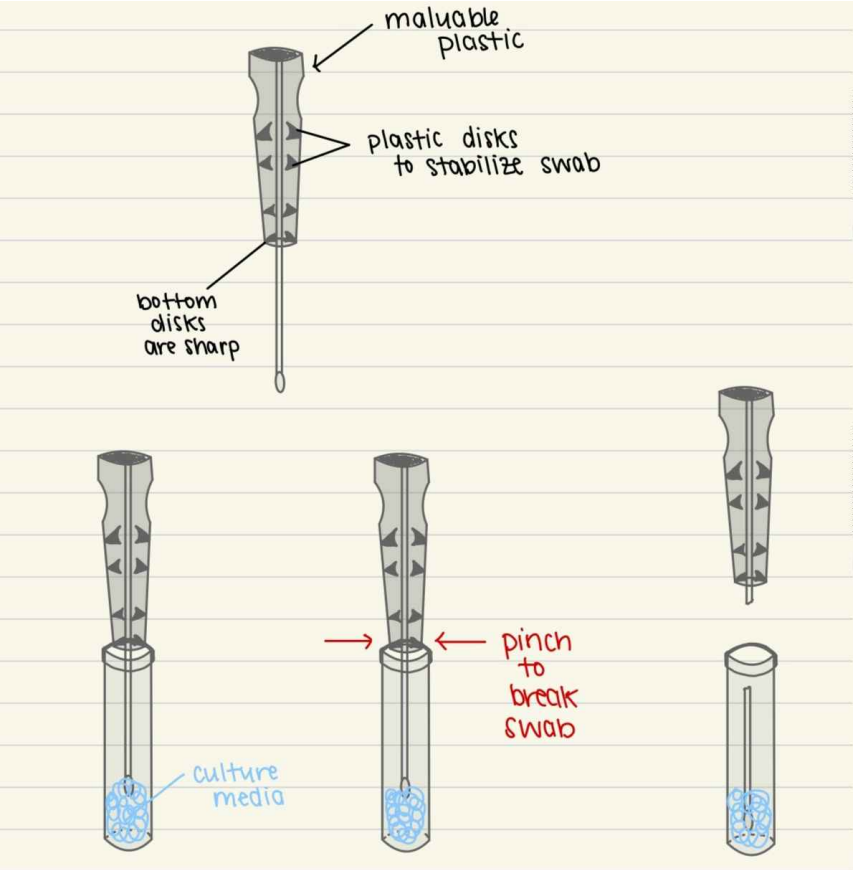
Content by: Ava, Tanya, and Jackie

Present: n/a

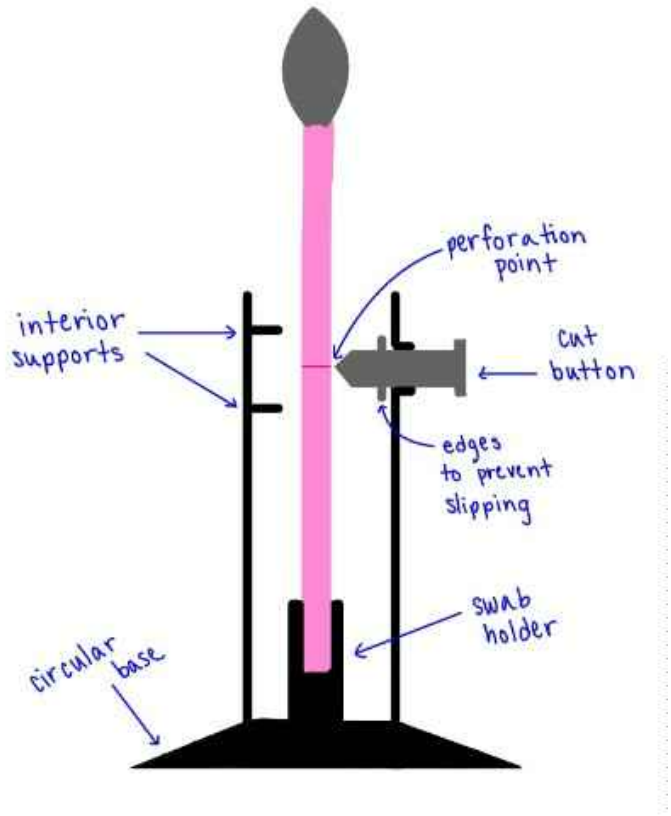
Goals: begin the initial design process by creating preliminary designs

Content:

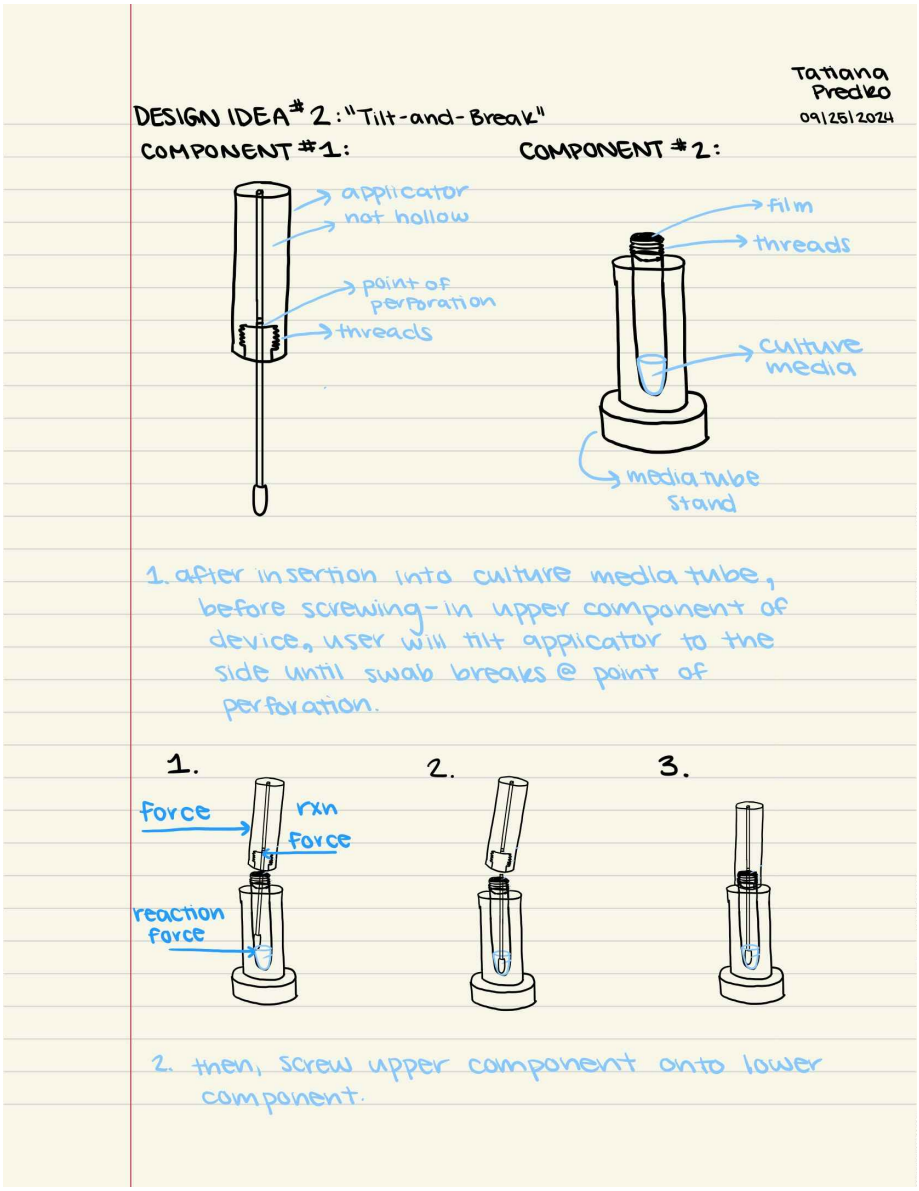
The Tunnel Design:



Three Point Bend:



Tilt-and-Break:



Conclusions/action items:

According to the design matrix, we have decided to go forward with the Tilt-and-Break design.

2024/12/11-STM Base SolidWorks Protocol

JACKIE BEHRING - Dec 11, 2024, 11:44 AM CST

Title: STM Base SolidWorks Protocol

Date: 12/11/2024

Content by: Jackie

Present: n/a

Goals: Create a protocol designing a 3D model of the STM Base in SolidWorks.

Content:

Objective: Create a 3D model of the STM Base in SolidWorks.

Steps:

1. In SolidWorks, begin a new part file.
2. In the bottom right corner of the screen, change the units to MMGS.
3. Begin a new sketch on the top plane.
4. Use the circle feature to draw a circle centered at the origin.
5. Dimension the sketch to have a diameter of 49.5 mm.
6. Exit the sketch.
7. Use the Extruded Boss/Base feature to extrude 2 mm down.
8. Start a new sketch on the top of the cylinder.
9. Use the circle feature to draw two circles centered at the origin.
10. Dimension one of the sketches to have a diameter of 17 mm.
11. Dimension the other sketch to have a diameter of 13 mm.
12. Exit the sketch.
13. Use the Extruded Boss/Base feature to extrude the feature 18 mm up.

Conclusions/action items: Use this protocol in future designs.

2024/12/11-Tilt-and-Break SolidWorks Protocol

JACKIE BEHRING - Dec 11, 2024, 11:46 AM CST

Title: Tilt-and-Break SolidWorks Protocol

Date: 12/11/2024

Content by: Jackie

Present: n/a

Goals: Create a protocol of the 3D model of Tilt-and-Break in SolidWorks.

Content:

Objective: Create a 3D model of the Tilt-and-Break in SolidWorks.

Steps:

1. In SolidWorks, begin a new part file.
2. In the bottom right corner of the screen, change the units to MMGS.

Shaft:

3. Begin a new sketch on the top plane.
4. Use the circle feature to draw a circle centered at the origin.
5. Dimension the sketch to have a diameter of 16.5 mm.
6. Exit the sketch.
7. Use the Extrude Boss/Base feature to extrude 84 mm down.

Cap:

8. Start a new sketch on the top of the cylinder.
9. Use the circle feature to draw a circle centered at the origin.
10. Dimension the circle to have a diameter of 14.5 mm.
11. Exit the sketch.
12. Use the Extruded Cut feature to cut 10 mm of material out of the shaft.

Internal Tube:

13. Start a new sketch on the 14.5 mm circle.
14. Use the circle feature to draw a circle centered at the origin.
15. Dimension the circle to have a 2.8 mm diameter.
16. Exit the sketch.
17. Use the Extruded Cut feature to cut 70 mm of material out of the shaft.

Threading:

18. Click on the Helix/Spiral feature and the inner cap.
19. Defined by Height and Pitch with Constant Pitch parameters.
20. Make the height 10 mm.
21. Make the pitch 4 mm.

22. Check the reverse direction box.
23. Make the start angle clockwise 0 degrees.
24. Check the green arrow.
25. Start a new sketch on the right plane.
    1. The plane chosen should align with the top of the shaft, tip of the cap, and beginning of the spiral.
26. Click on the line feature and draw a line from the tip of the spiral in a downward diagonal direction toward the center of the cap. Click to end the line.
27. Click to begin another line from the ending of the first straight down toward the bottom of the cap. Click to end the line.
28. Click to begin another line from the ending of the second line toward the side of the cap. Click to end the line.
29. Click to begin a fourth line from the ending of the third line straight up and click on the beginning of the first line. This will connect the first and third lines.
30. Add a centerline from the midpoint of the fourth line to the midpoint of the second line.
31. Add a relation to the centerline to make it horizontal.
32. Add a relation to the second and fourth lines to make them vertical.
33. Dimension the fourth line and make it 1 mm.
34. Dimension the centerline and make it 0.6 mm.
35. Dimension the first line and the centerline to create a 10 degree angle.
36. Exit the sketch.
37. Use the Sweep feature to extrude the threading.
38. Make the Profile and Path a Sketch Profile.
39. Click on the trapezoid made in the previous sketch as the profile.
40. Click on the Helix/Spiral made previously in steps 18-24 as the path.
41. The profile orientation should follow the path and the profile twist should have minimum twist.
42. The boxes should be checked for the following: Merge tangent faces, Show preview, and Merge result.
43. Click on the green check mark.
44. Click on the Chamfer feature.
45. The items to chamfer should be the Edges 1 and 2, these were the first and third lines drawn in the trapezoid.
46. The chamfer parameters should have a distance of 2 mm with a 10 degree angle.
47. Click the green check mark.
48. Click on the chamfer feature to start another chamfer.
49. The item to chamfer should be Edge 1, or the second line drawn in the trapezoid.
50. The chamfer parameters should have a distance of 2 mm with a 25 degree angle.
51. Click on the green check mark.
52. Click on the circular pattern feature.
53. Under the Direction tab the face chosen should be the inner tube in the cap. The equal spacing should be checked. The angle should be 360 degrees. The amount should be 2.

54. Under the Features and Faces tab click on both chamfers and the sweep feature.
55. Click on the green check mark. There should now be a total of 2 starting threads.

Conclusions/action items: Use this protocol to design any future Tilt-and-Break models.

2024/12/11-STM Base Fabrication Process

JACKIE BEHRING - Dec 11, 2024, 2:01 PM CST

Title: STM Base Fabrication Process

Date: 12/11/2024

Content by: Jackie

Present: N/a

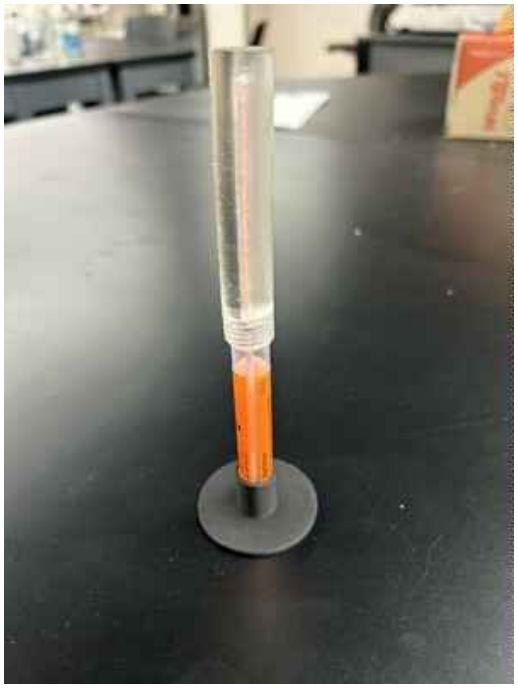
Goals: 3D print STM Base in PLA.

Content:

- Follow the steps of the STM Base SolidWorks protocol.
- Save the part as an STL file.
- At the UW Makerspace, share the files with the computers in the 3D lab.
- Makerspace staff will then help to complete the printing process.
- Pick up finished part after printing completion.

Conclusions/action items: Use created part to test in final prototype.

JACKIE BEHRING - Dec 11, 2024, 2:16 PM CST



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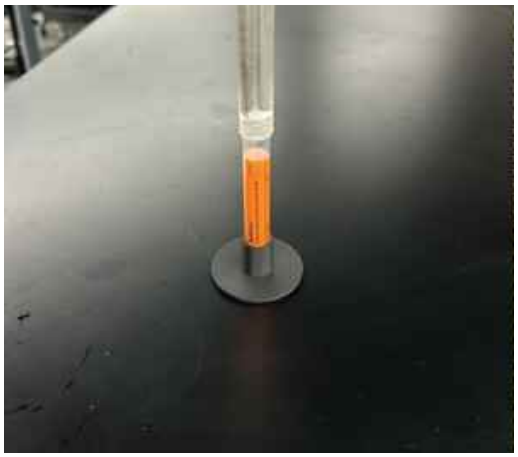
thumbnail_IMG_0543.jpg (332 kB)

JACKIE BEHRING - Dec 11, 2024, 2:16 PM CST



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thumbnail_IMG_0539.jpg (298 kB)

2024/12/11-Tilt-and-Break Fabrication Process

JACKIE BEHRING - Dec 11, 2024, 2:02 PM CST

Title: Tilt-and-Break Fabrication Process

Date: 12/11/2024

Content by: Jackie

Present: N/a

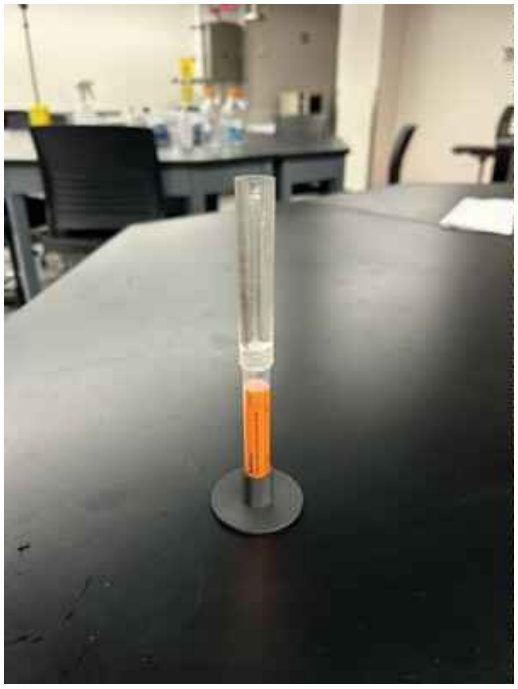
Goals: 3D print Tilt-and-Break in clear resin.

Content:

- Follow the steps of the STM Base SolidWorks protocol.
- Save the part as an STL file.
- At the UW Makerspace, share the files with the computers in the 3D lab.
- Makerspace staff will then help to complete the printing process.
- Pick up finished part after printing completion.

Conclusions/action items: Use created part to test in final prototype.

JACKIE BEHRING - Dec 11, 2024, 2:15 PM CST



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JACKIE BEHRING - Dec 11, 2024, 2:15 PM CST

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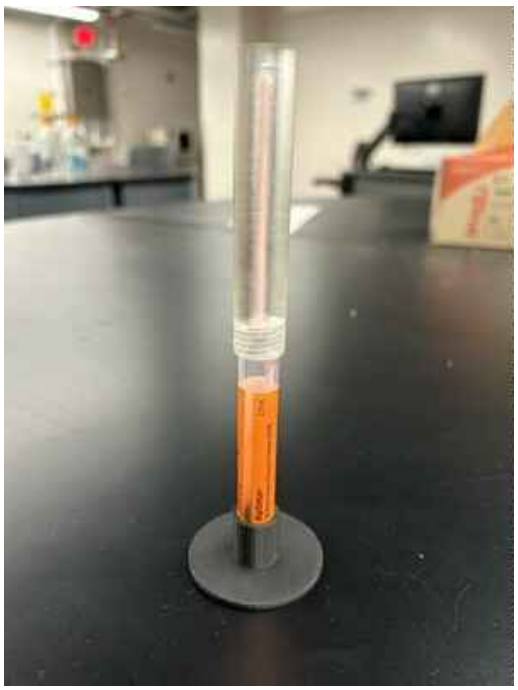
JACKIE BEHRING - Dec 11, 2024, 2:15 PM CST



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Agar Plate Testing Protocol

Tatiana Predko - Nov 20, 2024, 11:49 AM CST

Title: Agar Plate Testing Protocol

Date: 11/20/2024

Content by: Tatiana Predko

Present: N/A

Goals: Determine testing protocol for contamination testing of the different conditions.

Content:

1. Without swabbing anything, go through the motions of using the Tilt-and-Break. Then, streak the sample contained on the swab onto an agar plate. Repeat three times with three separate agar plates.
2. Without swabbing anything, go through the motions of using the Hologic Aptima device. Then, streak the sample onto an agar plate. Repeat three times with three separate agar plates.
3. For the positive control, swab a countertop and then streak the sample onto an agar plate. Repeat three times with three separate agar plates.
4. For the negative control, keep three agar containers closed and sterile for the entirety of the testing period.
5. To speed up the bacterial proliferation process, for each testing condition, place petri dishes into a heated orbital shaker for 60 rpm at 37℃; leave samples in orbital shaker for 24 hours.
6. Following the 24-hour incubation period, count the number of colonies on the agar plate with the help of a colony-counting app.

Conclusions/action items: Follow testing protocol for testing of the limiting contamination parameter of the device.

Tatiana Predko - Dec 04, 2024, 6:47 PM CST

Title: Agar Plate Testing Protocol Revised

Date: 12/01/2024

Content by: Tatiana Predko

Present: N/A

Goals: Alter the current testing protocol for the bacterial to be able to more rapidly and abundantly proliferate.

Content:

1. Without swabbing anything, go through the motions of using the Tilt-and-Break.

2. Streak the sample contained on the swab onto the surface of an agar plate; rotate the swab while streaking to ensure even distribution of bacteria along the agar surface.

3. Repeat this process for a total of three trials, using a new agar plate and swab for each trial.

4. Repeat steps 1-3 for the Hologic Aptima device.

5. For the positive control, swab the surface of a phone screen.

6. Streak the sample contained on the swab onto the surface of an agar plate; rotate the swab while streaking to ensure even distribution of bacteria along the agar surface.

7. Repeat this process for a total of three trials, using a new agar plate and swab for each trial.

8. For the negative control, place three unopened agar plates into the incubator.

9. Place all of the agar plates upside-down in the incubator to prevent condensation build-up; make sure that the agar plates are positioned near the center of the incubator to prevent potential over-heating of the agar plates.

10. Set the incubator to 32°C for a duration of 48 hours.

11. Following the 48-hour incubation period, use the colony-counting app called "ColonyCount" to quantify the colonies present on each agar plate.

12. Record the data in a data table.

Conclusions/action items: Use the revised agar plate testing protocol to test for cross-contamination differences between each of the four conditions. Use statistical analysis to interpret the findings of the data obtained from this experiment.

Swab-Breaking Accuracy Testing Protocol

Tatiana Predko - Nov 25, 2024, 9:46 AM CST

Title: Swab-Breaking Accuracy Testing Protocol

Date: 11/23/2024

Content by: Tatiana Predko

Present: N/A

Goals: Determine testing protocol for swab-breaking accuracy of the Tilt-and-Break compared to the Hologic Aptima.

Content:

1. Go through the motions of using the Tilt-and-Break device.

2. After breaking the swab into the media tube, remove the swab from the media tube.

3. Lay the swab onto a flat, dry surface and measure the distance between the breaking point and the line of perforation using calipers; record the value in a data table.

4. Repeat this process for a total of ten times for the Tilt-and-Break device.

5. Repeat the same procedure for the Hologic Aptima device (for a total of ten times).

Conclusions/action items: Follow testing protocol for testing of the swab-breaking accuracy parameter of the device.

Testing Experimentation

Tatiana Predko - Nov 25, 2024, 10:10 AM CST

Title: Testing Experimentation

Date: 11/25/2024

Content by: Tatiana Predko

Present: Mariah, Ava, and Tanya

Goals: Complete swab-breaking accuracy testing for the Hologic Aptima device, and streaking protocol for the positive control, negative control, Hologic Aptima, and Tilt-and-Break device.

Content:

hologic aptima distance from line of perforation (in mm)
14.27
8.42
20.51
15.59
16.72
16.32
15.81
17.71
14.71
15.96

Table 1. Table depicting data obtained from swab-breaking accuracy testing of the Hologic Aptima device.

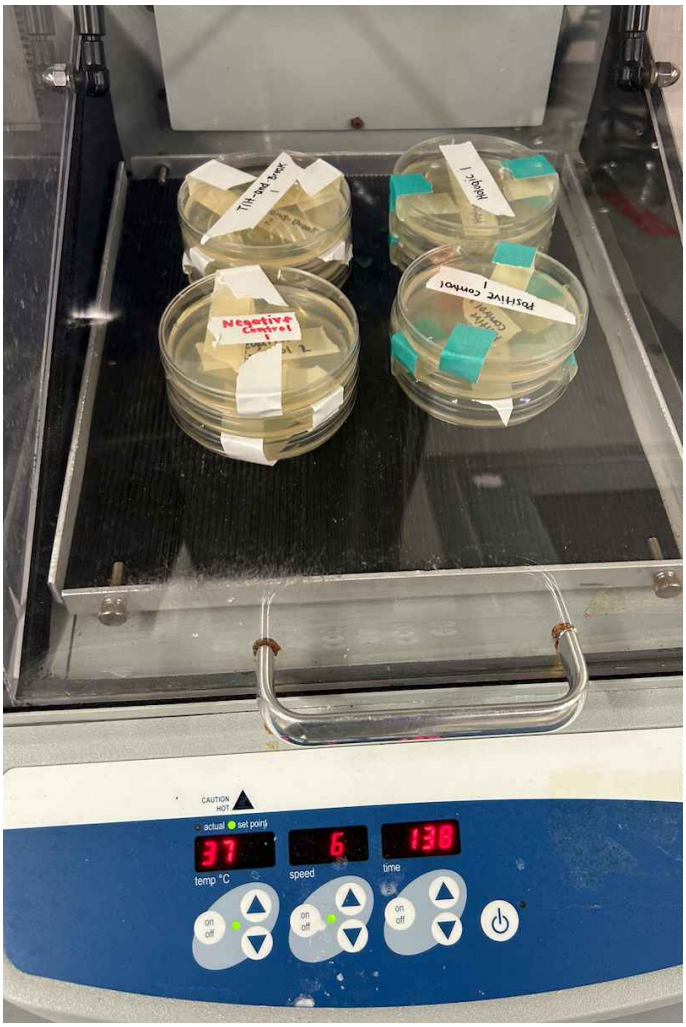


Figure 1. All four conditions of agar plate testing contained in the orbital shaker set to 37 degrees Celsius at 60 rpm.

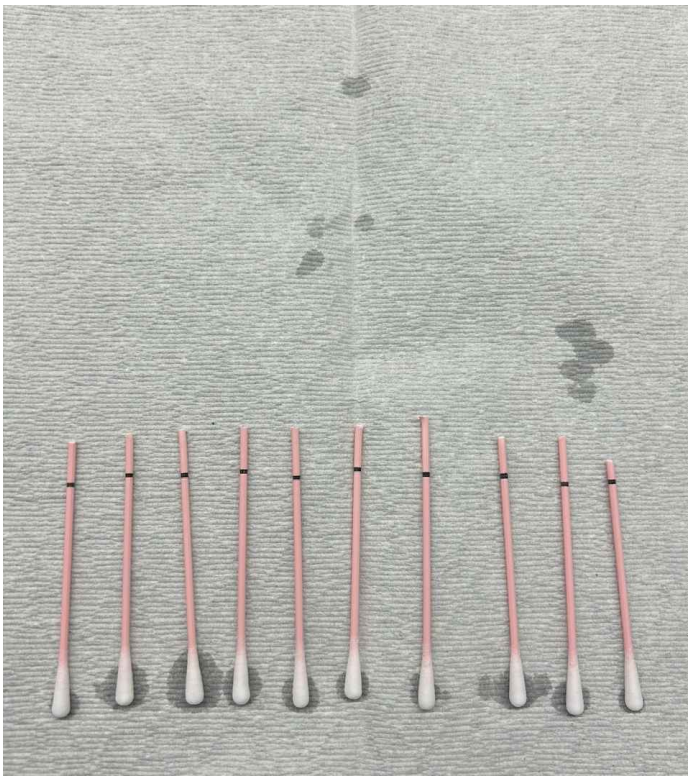


Figure 2. Swab-breaking results from the Hologic Aptima.

Conclusions/action items:

Following the 24-hour incubation period, remove the agar plates from the orbital shaker and use a colony-counting app to quantify the bacterial colonies for each sample; record the data in a spreadsheet and create a graph comparing the different conditions.

After Jackie prints the final Tilt-and-Break model, use the final model to complete 10 trials of swab-breaking accuracy testing using the Tilt-and-Break model.

JACKIE BEHRING - Dec 11, 2024, 2:21 PM CST

Title: Additional Pictures of Results

Date: 12/11/2024

Content By: Jackie

Present: N/a

Content:

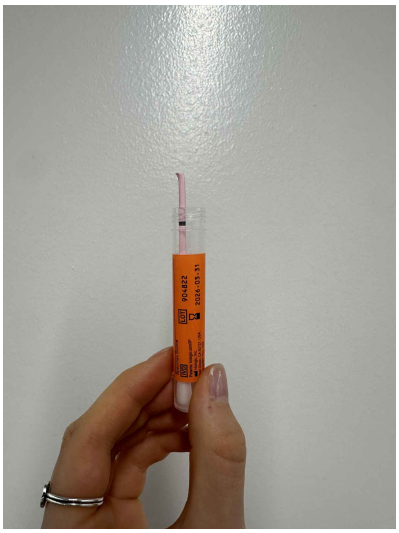


Figure 3: Picture of Hologic Aptima Results in the STM tube.

Conclusion/Action Items: Use these pictures in presentation/report.

Testing Experimentation Day 2

Tatiana Predko - Nov 26, 2024, 10:01 AM CST

Title: Testing Experimentation Day 2

Date: 11/26/2024

Content by: Tatiana Predko

Present: Jackie, Mariah, and Tanya

Goals: Finish swab-breaking accuracy for the Tilt-and-Break model, and begin colony-counting protocol.

Content:

- Following 24-hour incubation period, no colonies were present on the agar plates. Due to this, the agar plates were incubated for an additional 24 hours at the same settings.

tilt-and-break distance from line of perforation (in mm)	hologic aptima distance from line of perforation (in mm)
-0.64	14.27
-2.43	8.42
-0.47	20.51
-0.57	15.59
-0.45	16.72
-0.95	16.32
-0.67	15.81
-0.62	17.71
-0.77	14.71
-0.59	15.96
-0.816	15.602

Table 1. Table depicting values obtained during swab-breaking accuracy testing of both the Tilt-and-Break and Hologic Aptima device. Mean of both data sets is present on the bottom.

Conclusions/action items:

Following the swab-breaking accuracy protocol it is evident that the Tilt-and-Break improves swab-breaking accuracy. Use statistical analysis to create plots of data and analysis.

Due to lack of colonies, no data was obtained for contamination testing.

JACKIE BEHRING - Dec 11, 2024, 2:25 PM CST

Title: Additional Pictures of Tilt-and-Break Results

Date: 12/11/2024

Content By: Jackie

Present: N/a

Content:

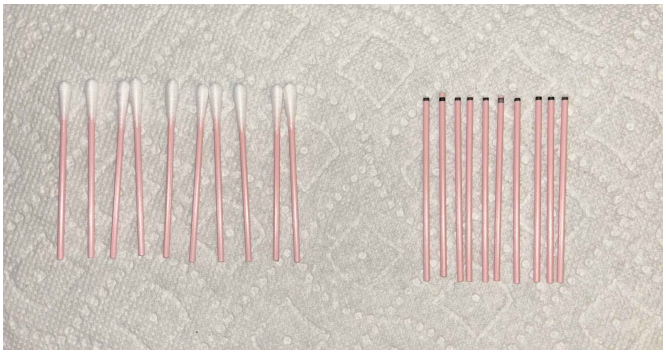


Figure 1: Picture of the Tilt-and-Break results.

Figure 2: Picture of Tilt-and-Break mechanism.

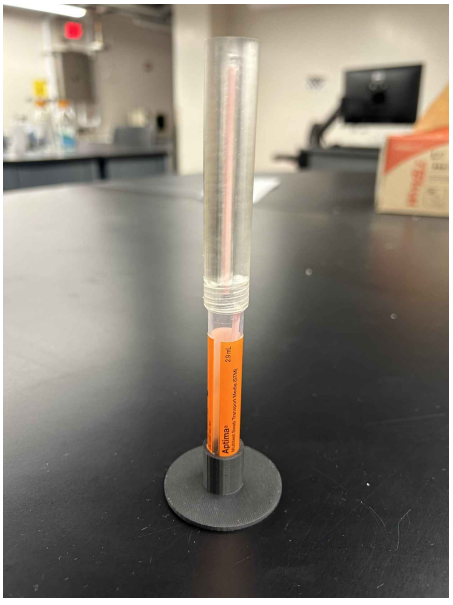


Figure 3: Picture of Tilt-and-Break after swab is broken in tube and Tilt-and-Break is screwed on the tube acting as a cap.

Conclusion/Action Items: Use these pictures and results in final report/presentation.

Testing Experimentation Day 3

Tatiana Predko - Dec 10, 2024, 8:08 PM CST

Title: Testing Experimentation Day 3

Date: 12/04/2024

Content by: Tatiana Predko

Present: All group members

Goals: Finish the colony-counting protocol, analyze data, and finish final poster.

Content:

- After 48-hours of incubation (with the revised colony-counting protocol), found colony growth on the LB agar plates.

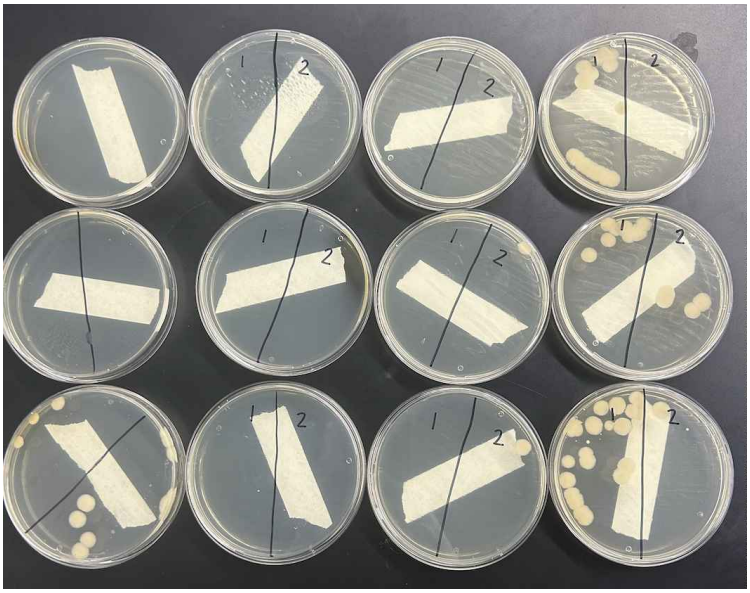


Fig. 1. Photo depicting bacterial growth on agar plates following the 48-hour incubation period.

	positive control	tilt-and-break	hologic	negative control
trial 1	30	0	0	13
trial 2	9	0	0	0
trial 3	20	0	1	0
	19.66666667	0	0.3333333333	4.333333333

Table 1. Table depicting number of colonies for each of the four testing conditions for three trials; mean number of colonies in the bottom row.

Conclusions/action items: Conduct a two-sided t-test to obtain p-value and create graphs of cross-contamination data to be used for the final poster.

Bacterial Colony Test Results

MARIAH SMEEDING - Dec 10, 2024, 8:57 PM CST

Title: Bacterial Colony Test Results

Date: 12/10/2024

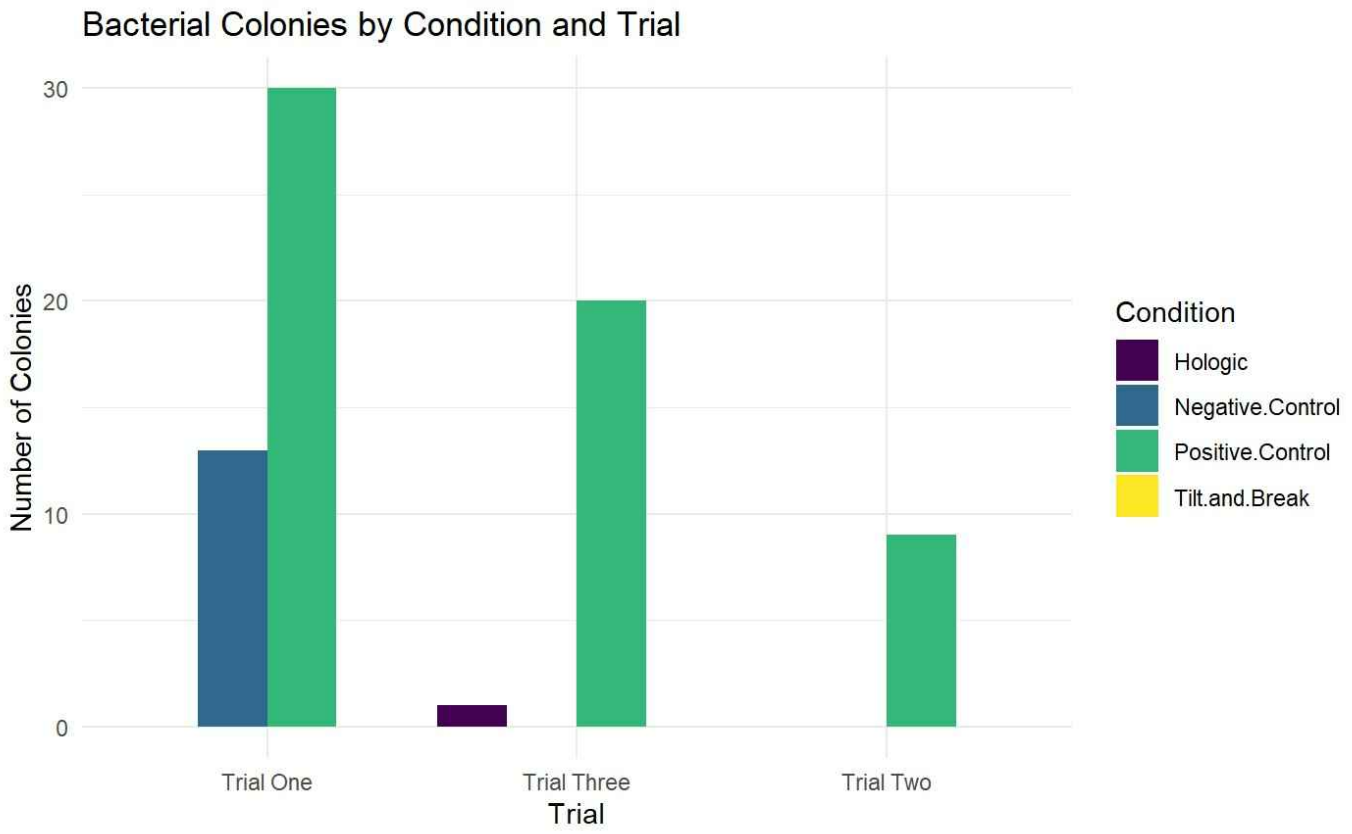
Content by: Mariah Smeeding

Present: Everyone for the testing, Mariah for analysis

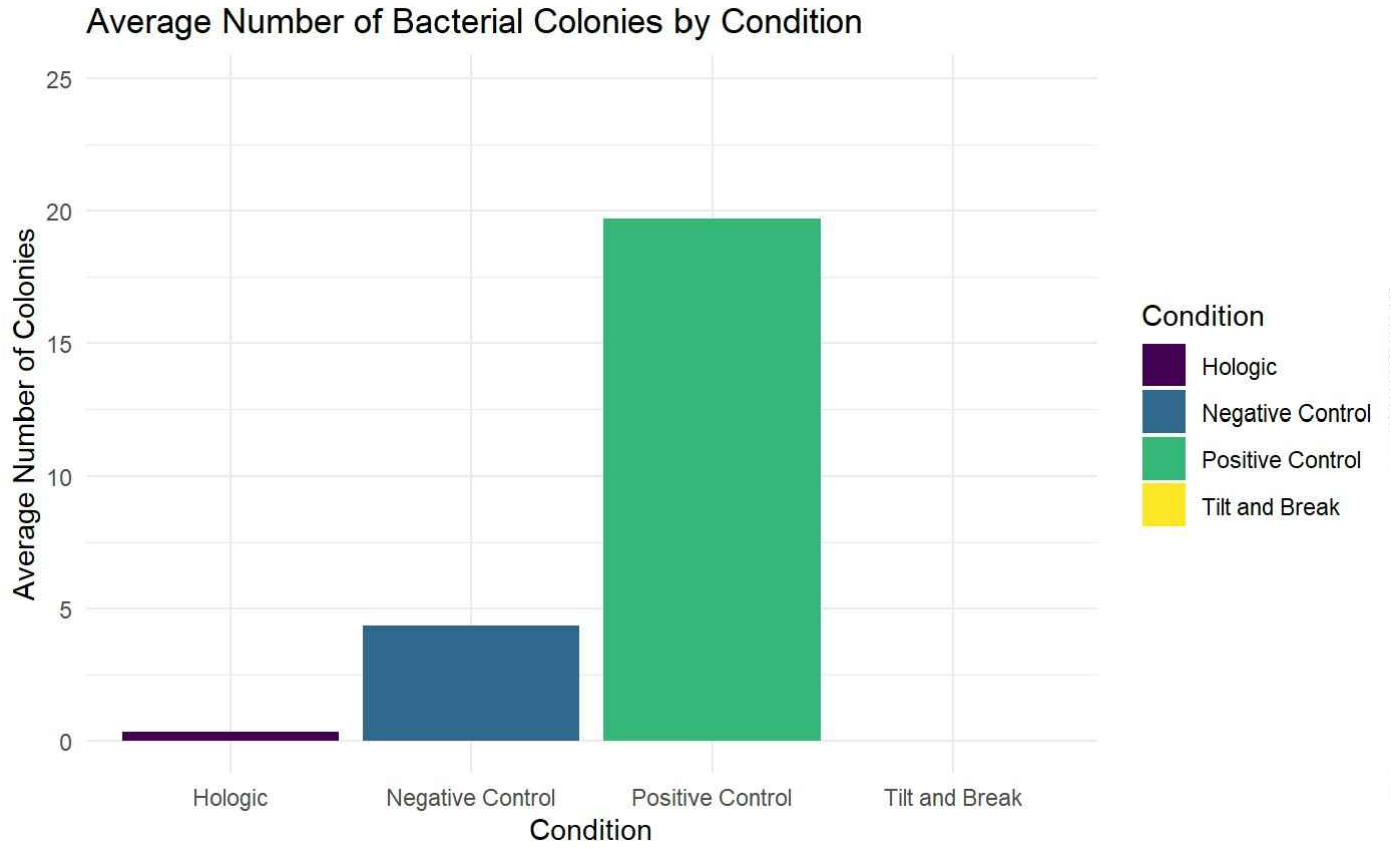
Goals: To identify whether the Tilt-and-Break design reduced cross-contamination more than the Hologic Aptima during the sampling process.

Content:

Raw Data graph:



Averages Graph:



Conclusions/action items:

A two-sided t-test provided a p-value of 0.423, which is greater than the significance threshold of 0.05. These results indicate that the observed differences among the groups are statistically insignificant, leading to a failure to reject the null hypothesis that there will be no difference between the Hologic Aptima and Tilt-and-Break conditions.

Swab Breaking Test Results

MARIAH SMEEDING - Dec 10, 2024, 8:59 PM CST

Title: Swab Breaking Test Results

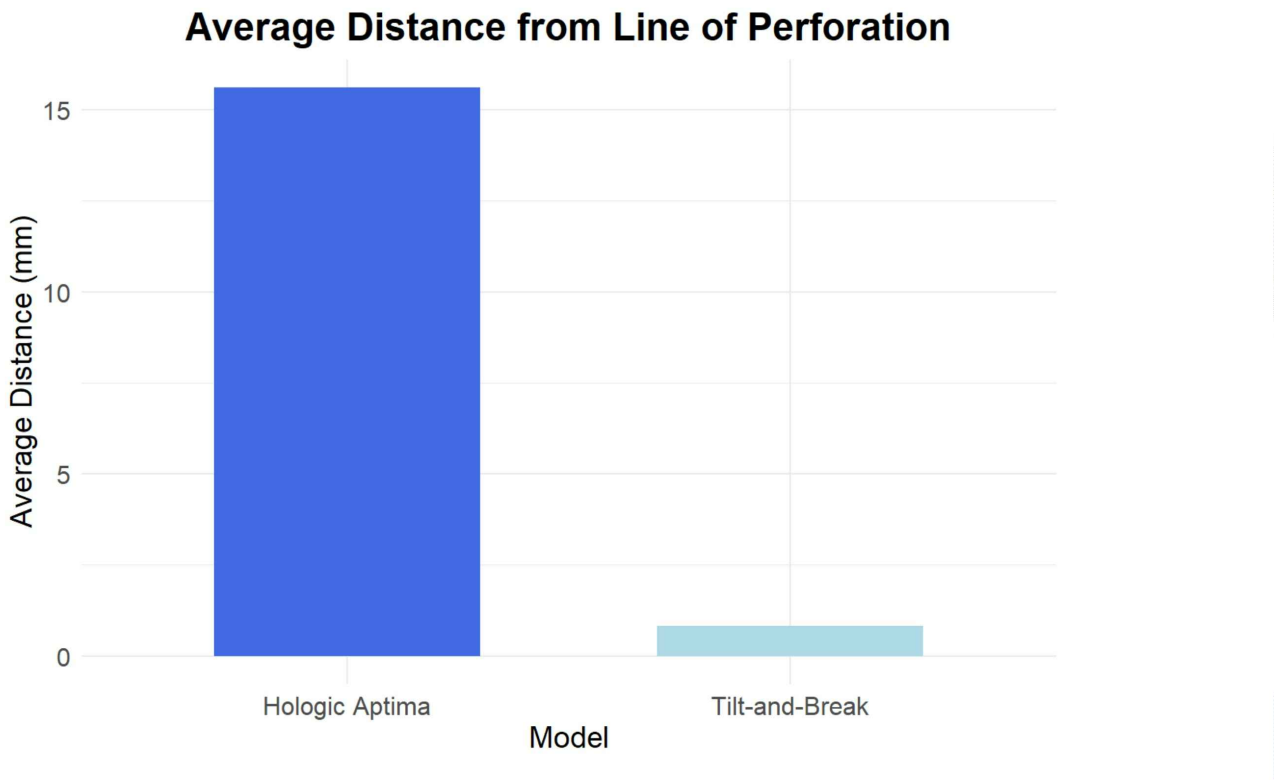
Date: 12/10/2024

Content by: Mariah Smeeding

Present: Everyone for testing, Mariah for analysis

Goals: The objective of the swab-breakage accuracy test was to assess whether the Tilt-and-Break model achieved closer mean distance from the breakage point to the line of perforation than the Hologic Aptima test, which would indicate higher precision.

Content:



Conclusions/action items:

The null hypothesis states that the mean distance from the perforation point for the Tilt-and-Break model is equal to or greater than the mean distance for the Hologic Aptima model. The alternative hypothesis states that the mean distance from the perforation point for the Tilt-and-Break model is less than the mean distance for the Hologic Aptima model. The test yielded a p-value of 2.776e-09, which is significantly below the 0.05 threshold, concluding that there is sufficient evidence to reject the null hypothesis. This result strongly indicates that the Tilt-and-Break model achieves a significantly smaller mean distance from the perforation point compared to the Hologic Aptima model, suggesting that the Tilt-and-Break model is more reliable and precise than the Hologic Aptima model

2024/12/11-PDS

JACKIE BEHRING - Dec 11, 2024, 3:02 PM CST

Title: PDS

Date: 12/11/2024

Content by: Jackie

Present: n/a

Goals: Upload the PDS to Lab Archives

Content:

-See PDF attached

Conclusions/action items: Reference the PDS throughout the design process.

JACKIE BEHRING - Dec 11, 2024, 3:03 PM CST


BME Design

Vaginal Self-Swab Device

BME 200/300 PDS

Client: Dr. Jess Rigdon

Adviser: Prof. Randolph Ashton

Team:

Jackie Behring (Co-Leader and BSAC)

Tehara Pradhe (Co-Leader and Communicator)

Mariah Standing (BWIG)

Ava Parvid (BBAG)

Section: 312

Date: 09/13/2024

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PDS_Vaginal_Self-Swab_-_USE_2_.pdf (266 kB)

2024/12/11-Design Matrix

JACKIE BEHRING - Dec 11, 2024, 3:24 PM CST

Title: Design Matrix

Date: 12/11/2024

Content by: Jackie

Present: n/a

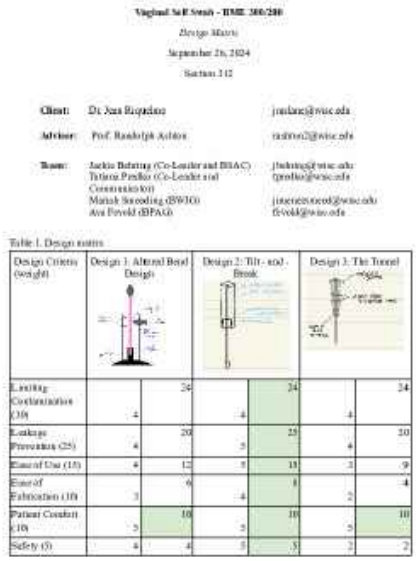
Goals: Upload the Design Matrix to Lab Archives

Content:

-See PDF attached

Conclusions/action items: Reference the Design Matrix throughout the design process.

JACKIE BEHRING - Dec 11, 2024, 3:24 PM CST



Vaginal Self Swab - BME 300/200

Design Matrix

September 26, 2024

Section 242

Client:	Dr. Jean Ristenbatt	jristenbatt@wisc.edu
Advisor:	Prof. Randolph Ashton	rashton2@wisc.edu
Team:	Jackie Behring (Co-Leader and BSAC)	jbehring@wisc.edu
	Tatiana Pinilla (Co-Leader and Communication)	tpinilla@wisc.edu
	Mariah Swoboda (BWIG)	jmswoboda@wisc.edu
	Ava Fewell (BPAG)	fewell@wisc.edu

Table 1. Design matrix

Design Criteria (weight)	Design 1: Altered Bend Design		Design 2: Tilt - and - Break		Design 3: The Tunnel	
Limiting Contamination (20)	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	3	2

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Vaginal_Self_Swab_Design_Matrix_9_26_2024.docx_2_.pdf (481 kB)

2024/12/11-Preliminary Presentation

JACKIE BEHRING - Dec 11, 2024, 3:26 PM CST

Title: Preliminary Presentation

Date: 12/11/2024

Content by: Jackie

Present: n/a

Goals: Upload the Preliminary Presentation to Lab Archives

Content:

-See PDF attached

Conclusions/action items: Reference the Preliminary Presentation throughout the design process.

JACKIE BEHRING - Dec 11, 2024, 3:28 PM CST

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Vaginal_Self_Swab_Preliminary_Presentation_10_4_2024_1_.pdf (960 kB)

2024/12/11-Preliminary Report

JACKIE BEHRING - Dec 11, 2024, 3:30 PM CST

Title: Preliminary Report

Date: 12/11/2024

Content by: Jackie

Present: n/a

Goals: Upload the Preliminary Report to Lab Archives

Content:

-See PDF attached

Conclusions/action items: Reference the Preliminary Report throughout the design process.

JACKIE BEHRING - Dec 11, 2024, 3:30 PM CST


Biomedical Engineering
UNIVERSITY OF WISCONSIN-MADISON
Vaginal Self-Swab
Preliminary Report
Date: 10/09/2024
BME 200/300: Biomedical Engineering Design
Team Members
Tatiana Prokko (Team Co-Leader & Communicator)
Jackie Behring (Team Co-Leader & BSAC)
Mariah Stoessling (BWIG)
Ava Fewell (BPAG)
Client
Dr. Jean Riquelme, UW Health, Department of Family Medicine and Community Health
Advisor
Professor Randolph Ashton, UW-Madison, Department of Biomedical Engineering

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Vaginal_Self_Swab_Preliminary_Report_10_9_2024.pdf (1.26 MB)

2024/12/11-Final Poster

JACKIE BEHRING - Dec 11, 2024, 3:35 PM CST

Title: Final Poster

Date: 12/11/2024

Content by: Jackie

Present: n/a

Goals: Upload the Final Poster to Lab Archives

Content:

-See PDF attached

Conclusions/action items: Present Final Poster at poster presentation!

JACKIE BEHRING - Dec 11, 2024, 3:35 PM CST

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Final_Poster_Self_Swab_USE_.pdf (1.3 MB)

2024/12/11-Final Report

JACKIE BEHRING - Dec 11, 2024, 3:38 PM CST

Title: Final Report

Date: 12/11/2024

Content by: Jackie

Present: n/a

Goals: Upload the Final Report to Lab Archives.

Content:

-See PDF attached

Conclusions/action items: Upload Final Report to Canvas. Begin patenting process!!

JACKIE BEHRING - Dec 11, 2024, 3:38 PM CST


Biomedical Engineering
UNIVERSITY OF WISCONSIN-MADISON
Vaginal Self-Swab
Final Report
Date: 12/11/2024
BME 301/302: Biomedical Engineering Design
Team Members
Client
Advisor

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Self-Swab_Final_Report.pdf (1.82 MB)

2024/09/13-Team Meeting 1

JACKIE BEHRING - Sep 13, 2024, 12:33 PM CDT

Title: Team Meeting 1

Date: 9/13/2024

Content by: Jackie Behring

Present: All team members

Goals: Meet with team to discuss any questions regarding the PDS and assign sections to team members.

Content:

- Assign roles to PDS
- Complete assigned section by Tuesday, September 17
- Plan to submit PDS to advisor on Tuesday in order to be reviewed

Conclusions/action items: Begin working on PDS and set up second meeting with client.

2024/09/17-Team Meeting 2

JACKIE BEHRING - Sep 17, 2024, 4:55 PM CDT

Title: Team Meeting 2

Date: 9/17/2024

Content by: Jackie

Present: All Team Members

Goals: Discuss and give clarification to any questions about the PDS and the upcoming weeks.

Content:

- Discuss any questions about the PDS
- Include the standards from the hologic source in standards
- Meet with advisor on Friday, September 20 at 1:05-1:35
- Begin working on second Progress Report II
- No first person in the PDS
- Fix the PDS format and layout
- Meet the following week to take team picture
- Tanya will email advisor with where the meeting location is

Conclusions/action items: Continue working on the PDS and meet with advisor on Friday 9/20.

2024/09/25-Team Meeting 3

JACKIE BEHRING - Sep 26, 2024, 9:57 PM CDT

Title: Team Meeting 3

Date: 9/25/2024

Content by: Jackie

Present: Jackie, Tanya, Ava

Goals: Assign roles to each of the determination of criteria and weights sections and come up with design ideas.

Content:

-Chose the design criteria for the design matrix

-Assigned each criteria with a certain weight

- Assigned sections for the Determination of Criteria and Weights

- Jackie: Limiting Contamination, Ease of Use
- Tanya: Leakage Prevention, Patient Comfort
- Ava: Ease of Fabrication
- Mariah: Safety, Cost

Conclusions/action items: Begin working on sections and meet on 9/26 to discuss design ideas.

2024/09/26-Team Meeting 4

JACKIE BEHRING - Sep 26, 2024, 10:02 PM CDT

Title: Team Meeting 4

Date: 9/26/2024

Content by: Jackie

Present: Jackie, Ava, Mariah

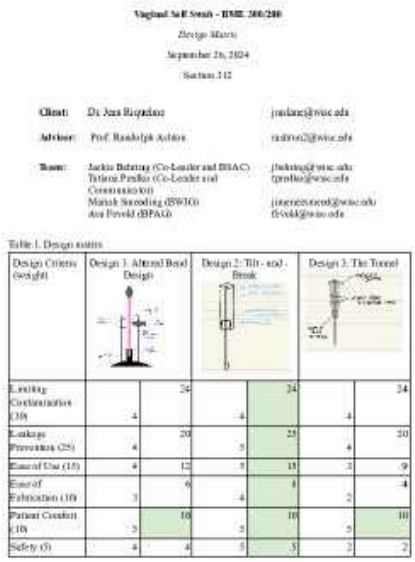
Goals: Go over individual designs and decide on three final designs. Finish the design matrix.

Content:

- Discussed each design idea
- Talked through each design and gave feedback where necessary
- Decide on three best designs
- Weighed all three designs in the matrix
- Chose a final design to continue the project with
    - talked about making further altercations to the chosen final design
- Assigned sections to the rest of the design matrix
- Completed the Justification of Assigned scores

Conclusions/action items: Upload the Design Matrix and begin working on the Preliminary Report.

JACKIE BEHRING - Sep 27, 2024, 12:06 PM CDT



Vaginal Self Swab - BME 300/200

Design Matrix

September 26, 2024

Section 312

Client: Dr. Jean Ringstrom — jringstrom@wisc.edu

Advisor: Prof. Randolph Ashton — rashton2@wisc.edu

Team: Jackie Behring (Co-Leader and BSAC) — jbehring@wisc.edu
Tatiana Perdue (Co-Leader and Communication) — tperdue@wisc.edu
Mariah Sneeding (BWIG) — jmariesneed@wisc.edu
Ava Fewell (BPAG) — fewell@wisc.edu

Table 1. Design matrix

Design Criteria (weight)	Design 1: Altered Bead Design		Design 2: Tilt - and - Break		Design 3: The Tunnel	
Limiting Contamination (10)	4	36	4	34	4	34
Leakage Prevention (25)	4	20	5	25	4	20
Ease of Use (10)	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

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Vaginal_Self_Swab_Design_Matrix_9_26_2024.docx.pdf (421 kB)

2024/11/20-Team Meeting 5

JACKIE BEHRING - Nov 20, 2024, 11:51 AM CST

Title: Team Meeting 5 - Testing Protocol

Date: 11/20/2024

Content by: Jackie

Present: Tanya, Mariah, Jackie

Goals: Discuss and create a testing protocol.

Content:

- Jackie: order more agar plates

- Ava: pick up more testing tubes?

-Tanya: upload testing protocol

-Team: begin progress report 11

Conclusions/action items: Brainstorm swab breaking testing protocol.

2024/11/23-Team Meeting 6

JACKIE BEHRING - Nov 23, 2024, 4:35 PM CST

Title: Team Meeting 6

Date: 11/23/2024

Content by: Jackie

Present: Tanya, Ava, Mariah

Goals: Assign roles for the final report and the presentation.

Content:

- Email Prof. John P and Prof. Randolph Ashton about ECB Lab 1002 time period.
- Keep same roles as assigned for the Preliminary Report
    - Added new roles to the Final Report

Conclusions/action items: Begin working on assigned roles for final report and presentation.

2024/09/26-Past Semester Review

JACKIE BEHRING - Sep 26, 2024, 9:44 PM CDT

Title: Past Semester Review

Date: 9/26/2024

Content by: Jackie

Present: N/A

Goals: Research what the past semesters have done for the project to gain an understanding of what aspects need to be improved with the new semester.

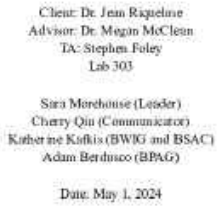
Content:

Team Spring 2024:

- Design Challenges:
  - Dr. Accola: works at UW Health Lab and processes STI tests
  - the device must be compatible and transfer the swab into the Aptima transport media tube
  - Aptima media tube is directly placed into a machine for sample processing
  - The machine is called the Hologic Panther
    - processes many samples at once by plunging a pipette tip directly through the foil-covered foam withing the cap of the Aptima transport media tube
    - if any other tube besides the Aptima tube was used the process would be disrupted
  - New goal of the project: create transfer process to prevent splashing or spilling of the media
    - no contact between the contaminated swab and any surfaces in the testing environment
  - Team went with Three Point Bending Design
    - Three Main Components: external casing for the transfer process, keyed push-button, and a media stand that stabilizes the transfer process
    - External casing: hold the lower 60 cm of the Dacron swab while exposing 6.5 cm of the swab for specimen collection
      - allows patients to set casing down, since the bottom end of the device would never make contact with the vagina
    - Key push button aligns with the Dacron swab shaft perforation point
      - two interior supports inside the casing
      - when button is pushed the swab makes three points of contact, two with the interior and one with the button push
      - external casing is shaped to that when swab is being dispensed into media there is no splashing
  - Problems with the design:
    - free rotation of the key push button which caused a misalignment of the perforation point
    - base was not large enough causing instability to device leading to possible contamination if the device was set on a counter

Conclusions/action items: Reach out to old team member to get SolidWorks model and update with changes to improve base and push button. Continue to reference the old semesters if needed for clarification purposes.

JACKIE BEHRING - Sep 26, 2024, 9:44 PM CDT


Client: Dr. Jean Riquelme
Advisor: Dr. Megan McClean
TA: Stephen Foley
Lab 303

Sara Morehouse (Leader)
Cherry Qin (Communicator)
Katherine Kafkis (BWIG and BSAC)
Adam Berdusco (BPAG)

Date: May 1, 2024

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Spring_2024_BME_Final_Report_1_.pdf (7.03 MB)

2024/09/27-STI Hologic Self Swab Instructions

JACKIE BEHRING - Sep 27, 2024, 12:34 PM CDT

Title: STI Hologic Self Swab Instructions

Date: 9/27/2024

Content by: Jackie

Present: N/a

Goals: Understand the STI self swab procedure.

Content:

- 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.
- 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

IEEE citation:

Hologic, “APTIMA® Instructions for obtaining patient-collected ... - hologic,” Aptima, https://www.hologic.com/sites/default/files/package-insert/IN0146-IFU-PI_004_01.pdf?msclkid=9e992e29ba8511eca52a9bfa2c519604 (accessed Sep. 19, 2024).

Conclusions/action items: Use this information and gain more on what happens after the swab is taken. How is the test run in the lab to check for STIs?

JACKIE BEHRING - Sep 27, 2024, 12:34 PM CDT

Download

Hologic_STI_instructions.pdf (264 kB)

2024/09/27-Swab Insertion Guidelines

JACKIE BEHRING - Nov 14, 2024, 12:43 PM CST

Title: Swab Insertion Guidelines

Date: 9/27/2024

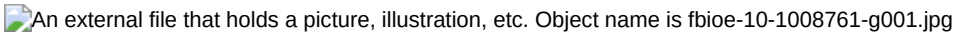
Content by: Jackie

Present: n/a

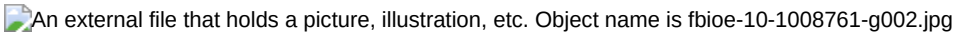
Goals: Research to determine how far the swab should be inserted in order to gain a viable test.

Content:

- The tip of the self-swab devices should be approximately 1 cm in length for optimal collection of vaginal discharge samples
- Average grip is 3 cm, while the entire toll is approximately 10 cm with a diameter of 1 cm


An external file that holds a picture, illustration, etc. Object name is fbioe-10-1008761-g001.jpg

- Sample Processing:
  - self collected and doctor collected swabs were transported to the lab
  - no special refrigeration was arranged during specimen transport
  - Nucleic Acid Amplification Tests (NAATs) do not depend on viable pathogens
  - using a traditional plate culture method DOES depend on viable pathogens


An external file that holds a picture, illustration, etc. Object name is fbioe-10-1008761-g002.jpg

URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9576940/

IEEE Citation: M. Muljadi, C.-M. Cheng, C.-Y. Yang, T.-C. Chang, and C.-J. Shen, “A pilot clinical validation study of a self-collected vaginal swab device for the detection of chlamydia trachomatis in women,” *Front. Bioeng. Biotechnol.*, vol. 10, Oct. 2022, doi: 10.3389/fbioe.2022.1008761.

Conclusions/action items: Use this research in the PDS and while asking the lab assistant about testing.

2024/09/27-Vaginal Microbiota

JACKIE BEHRING - Sep 27, 2024, 2:01 PM CDT

Title: Vaginal Microbiota

Date: 9/27/2024

Content by: Jackie

Present: n/a

Goals: Learn about common vaginal microbiota and how it is affected by infection.

Content:

- Healthy vaginal microflora: mainly Gram-positive bacilli of the genus Lactobacillus
- vaginal microbiota and pH varies according to ethnic groups
    - most common species: Lactobacillus crispatus, L. iners, L. gasseri, and L, jensenii
- Lactobacillus are essential to maintain vaginal health because of the production of antimicrobial compounds
    - ex: hydrogen peroxide, lactic acid, bascteriocinlike substances,
- essential bc of the capability to adhere to the vaginal epithelium
- vaginal pH is acidic (3.5 - 4.5)
- bacterial vaginosis caused a pH>4.5

URL: https://www.sciencedirect.com/science/article/pii/S0378517320306438?via%3Dihub#s0005

IEEE citation:

Tomás, M., Palmeira-de-Oliveira, A., Simões, S., Martinez-de-Oliveira, J., & Palmeira-de-Oliveira, R. (2020). Bacterial vaginosis: Standard treatments and alternative strategies. International journal of pharmaceutics, 587, 119659. https://doi.org/10.1016/j.ijpharm.2020.119659

Conclusions/action items: Continue to research about healthy vs infected vaginal microbiota.

2024/10/05-FDA Medical Device Regulations

JACKIE BEHRING - Oct 05, 2024, 2:46 PM CDT

Title: FDA Medical Device Regulations

Date: 10/5/2024

Content by: Jackie

Present: N/a

Goals: Learn about the regulations for microbiological specimen collection and transport devices.

Content:

- Code of Federal Regulations Title 21
- Microbiological specimen collection and transport devices
    - specimen collecting chamber intended for medical purposes to preserve the viability or integrity of microorganisms during storage of specimens after their collection and during the transport process from collecting area to the laboratory
    - medium solution that the swab is placed into and shipped to the laboratory
    - device may be labeled or represented as sterile
    - aids in the diagnosis of disease caused by pathogenic microorganism
- Classification. Class I

URL: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm?fr=866.2900

IEEE Citation:

“CFR - Code of Federal Regulations Title 21,” *www.accessdata.fda.gov*.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=866.2900

Conclusion/ Action Items: Use these FDA regulations in reports relating to the sample medium.

2024/10/09-Hologic Liquid Media Solution

JACKIE BEHRING - Oct 09, 2024, 6:54 PM CDT

Title: Hologic Liquid Media Solution

Date: 10/9/2024

Content by: Jackie

Present: n/a

Goals: Research about the liquid media and what it is.

Content:

- After collection, the transport tube containing the liquid media should be stored at 2-30 degrees C until tested
- should be tested within 30 days of taking the sample
- PreservCyt Solution liquid Pap specimens
    - intended for CT and GC testing
- methanol based reagent
    - serves as a transport preservative
    - antibacterial medium for gynecologic samples
- enables the transport and preservation of cells
    - preserves DNA
- Methanol based
- buffered preservative solution
- 35-55% Methanol

URL: file:///C:/Users/jbehr/Downloads/AW-19089-002_001_02.pdf

Conclusions/action items: Use this information to understand how the sample media preserves the sample cells.

2024/10/11-Aptima Diagnosis of STIs

JACKIE BEHRING - Oct 11, 2024, 3:01 PM CDT

Title: Aptima Assays (Hologic) for the diagnosis of STIs

Date: 10/11/2024

Content by: Jackie

Present: N/a

Goals: Learn about the typical contamination throughout swabs.

Content:

- Measure the detection of *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, *Trichomonas vaginalis* and *Mycoplasma genitalium* in clinical practice
- Aptima is based on a transcription-medicated amplification (TMA) method
- Comparing Aptima (TMA testing) against Allplex (multiplex Real-Time PCR (RT-PCR) method)
- 622 clinical samples were tested using both methods
- Aptima showed a slightly higher rate of positive results for all pathogens except *T. vaginalis*
- Most commonly detected pathogen: *C. trachomatis*
    - 37 samples
    - 5.9% using TMA assays
- Aptima test consist of 3 main steps
    - target capture
    - TMA of the species-specific targets in the rRNA
    - target detection by hybridization with complementary probes linked to chemiluminescent labels
- TMA step consists of a target nucleic acid amplification method using RNA transcription (RNA polymerase) and DNA synthesis (reverse transcriptase) to produce a RNA amplicon from target nucleic acid
- TMA can target both DNA and RNA
- The sensitivity of TMA was higher for most pathogens compared to RT-PCR
- recently, false-negative Chlamydia trachomatis have been reported using Aptima in Finland and Sweden due to a 23S rRNA C1515T mutation

URL: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6742210/

IEEE Citation:

A. de Salazar *et al.*, “Comparison between Aptima Assays (Hologic) and the Allplex STI Essential Assay (Seegene) for the diagnosis of Sexually transmitted infections,” *PLOS ONE*, vol. 14, no. 9, p. e0222439, Sep. 2019, doi: https://doi.org/10.1371/journal.pone.0222439.

Conclusions/action items: Continue to use this information while consulting with Jean and the UW lab about acceptable contamination.

2024/10/11-Sensitivity vs Specificity

JACKIE BEHRING - Oct 11, 2024, 3:00 PM CDT

Title: Sensitivity vs Specificity

Date: 10/11/2024

Content by: Jackie

Present: N/a

Goals: Learn about what sensitivity within a swab test really means.

Content:

- Sensitivity: percentage of people who are actually infected with an ST that will correctly identify as positive
- higher sensitivity is better, because it is more likely to correctly identify someone who has an STI
- lower sensitivity means that there is a higher chance that a patient will receive a false negative result
    - test indicated that patient is not infected when they actually are
- Specificity: the ability of a test to correctly identify someone who does not have an STI
    - avoiding false positives
- Ability to designate an individual who does not have a disease as negative
- High specificity: few false positives results
- Suitable screening test:
    - adequate sensitivity and specificity
    - low cost
    - ease of administration
    - safe
    - imposes minimal discomfort upon administration
    - acceptable to both patients and practitioners

URL: https://www.health.ny.gov/diseases/chronic/discreen.htm#:~:text=Sensitivity%20refers%20to%20a%20test's,have%20a%20disease%20as%20negative.

IEEE Citation:

New York State Department of Health, “Disease Screening - Statistics Teaching Tools - New York State Department of Health,” *Ny.gov*, 2019. https://www.health.ny.gov/diseases/chronic/discreen.htm

Conclusions/action items: Continue to use this knowledge in further research and reports.

2024/10/28-Hologic Panther TMA

JACKIE BEHRING - Oct 28, 2024, 12:34 PM CDT

Title: High-Throughput Transcription-mediated amplification on the Hologic Panther is a highly sensitive method of detection for SARS-CoV-2

Date: 10/28/2024

Content by: Jackie

Present: n/a

Goals: Research about the Panther TMA testing system for detection.

Content:

- Test conducted to compare the sensitivity and specificity of PCR and TMA.
- collecting nasopharyngeal swabs using 116 human specimens
- TMA showed higher sensitivity than PCR
- PCR
  - doubling of a target nucleic acid in each of 40 cycles
- TMA -
  - generation of potentially thousands of transcribed copies o target which can be turned into transcriptional templates
  - very easy to use compared to PCR

URL: https://pmc.ncbi.nlm.nih.gov/articles/PMC7286273/

IEEE:

A. J. Gorzalski *et al.*, “High-Throughput Transcription-mediated amplification on the Hologic Panther is a highly sensitive method of detection for SARS-CoV-2,” *Journal of Clinical Virology*, vol. 129, p. 104501, Aug. 2020, doi: https://doi.org/10.1016/j.jcv.2020.104501.

Conclusions/action items: Continue to research about TMA testing.

2024/10/28-Aptima Assays (TMA) Video

JACKIE BEHRING - Oct 28, 2024, 12:54 PM CDT

Title: Inside Aptima assays: An overview of TMA and Real-Time TMA 2022

Date: 10/28/2024

Content by: Jackie

Present: N/a

Goals: Watch video to understand how TMA testing works inside the Panther.

Content:

- Transcription-Mediated Amplification (TMA)
  - isothermal nucleic acid technology
  - used to amplify RNA and DNA sequences
- entire reaction occurs in single tube

1. Pathogens in clinical specimens are lysed to release nucleic acid molecules
2. During the target capture step, capture oligonucleotides hybridize to target genetic material of the pathogen
3. Capture oligonucleotides are attached to magnetic beads, to separate the target sequences from non-target debris and inhibitors
4. Amplification phase - reverse transcriptase extends to T7 promoter primer to synthesize a DNA copy of the target nucleic acid
5. Chemiluminescent labels confirm the pathogen genetic material

URL: https://www.youtube.com/watch?v=RPuGrg3cBOE

IEEE:

“Inside Aptima assays: An overview of TMA and Real-Time TMA 2022,” *www.youtube.com*. https://www.youtube.com/watch?v=RPuGrg3cBOE

Conclusions/action items: Use this video to understand the process of TMA and Hologic Panther system.

2024/10/09-At Home STI Tests

JACKIE BEHRING - Oct 09, 2024, 6:36 PM CDT

Title: Issues with At Home STI Tests

Date: 10/9/2024

Content by: Jackie

Present: n/a

Goals: Research about issues with at home STI tests to learn about what needs to be improved.

Content:

- Centers for Disease Control and Prevention (CDC) says that approximately 20 million estimated new STD infections occur each year
  - half of them are in young people, ages 15-24
- large surge of cases involving: gonorrhea, chlamydia, primary and secondary syphilis, and congenital syphilis
- some STDs do not cause symptoms
- if left untreated, STDs can lead to severe health complications
  - pelvic inflammatory disease, increased risk for HIV, some cancers, and infertility
- People avoid going to a physician because of inconvenience or limited access to a provider
- STD kits can be purchased online or at a pharmacy
- results are returned by phone, email, or published securely online
- Prices range from $40-$100
- Physicians are concerned that people at home are not collecting good, reliable sample results
- tests may get false positives
- false negatives are more serious, because the infection would be left untreated

URL: https://www.uabmedicine.org/news/home-std-tests-are-convenient-but-there-are-drawbacks/#

IEEE Citation:

“Home STD Tests are Convenient, but There are Drawbacks,” *UAB Medicine*, Jul. 03, 2023. https://www.uabmedicine.org/news/home-std-tests-are-convenient-but-there-are-drawbacks/# (accessed Oct. 09, 2024).

Conclusions/action items: Use this information to move forward with further research about current self swab STI methods.

2024/09/27-Swab Materials

JACKIE BEHRING - Sep 27, 2024, 2:45 PM CDT

Title: Swab Materials

Date: 9/27/2024

Content by: Jackie

Present: N/a

Goals: Research about different materials that current self swabs use.

Content:

- Swab Head
  - natural fibers
    - cotton
  - inorganic and inert fibers
    - viscose
    - polyester
    - flocked fibers
  - Flocked fiber head swabs are used for conjunction with liquid transport media
    - they offer the best sample absorption and elution capacity in the liquid transport media
    - tiny nylon fibers sticking up, like a soft brush
    - fibers help to absorb sample very well
    - when the swab enters a liquid transport tube, they release the sample very easily
- Swab Shaft
  - wood
  - polystyrene
  - aluminum
- Material for swab shaft chosen based on what is being swabbed
  - nasopharyngeal, urethral, paediatric, and standard

URL: https://www.deltalab.es/en/productes/do-you-know-all-the-types-of-swabs/#:~:text=The%20swab%20head%20can%20be,depending%20on%20the%20intended%20use.

IEEE citation:

deltalab, “SWABS: do you know all the types of swabs?,” *Deltalab*, Apr. 14, 2021. https://www.deltalab.es/en/productes/do-you-know-all-the-types-of-swabs/#:~:text=The%20swab%20head%20can%20be (accessed Sep. 27, 2024).

Conclusions/action items: Research was swab shaft material is most common for urethral procedures.

2024/09/27-Biodegradable Polymers in Medical Devices

JACKIE BEHRING - Sep 27, 2024, 4:56 PM CDT

Title: Synthetic Biodegradable Polymers as Medical Devices

Date: 9/27/2024

Content by: Jackie

Present: N/a

Goals: Research other biodegradable materials to get an idea of what to use while 3D printing

Content:

- PGA
  - Melting point (degrees C): 225-230
  - Modulus (GPA): 7.0
  - Degradation Time (months): 6-12
- LPLA
  - Melting point: 173-178
  - Modulus: 2.7
  - Degradation Time (months): >24
- DLPLA
  - Melting point: Amorphous
  - Modulus: 1.9
  - Degradation Time (months): 12-16
- PCL
  - Melting point: 58-63
  - Modulus: 0.4
  - Degradation Time (months): >24

PLA

- high tensile strength and low elongation
- more suitable for load bearing applications
  - ex: orthopedic fixation and sutures

URL: https://www.mddionline.com/orthopedic/synthetic-biodegradable-polymers-as-medical-devices

IEEE citation:

J. Middleton and A. Tipton, “Synthetic Biodegradable Polymers as Medical Devices,” *Medical Device and Diagnostic Industry*, Mar. 01, 1998. https://www.mddionline.com/orthopedic/synthetic-biodegradable-polymers-as-medical-devices (accessed Sep. 27, 2024).

Conclusions/action items: Keep these materials in mind and possibly use to 3D print.

2024/10/05-Polycarbonate

JACKIE BEHRING - Oct 05, 2024, 2:35 PM CDT

Title: Polycarbonate (PC)

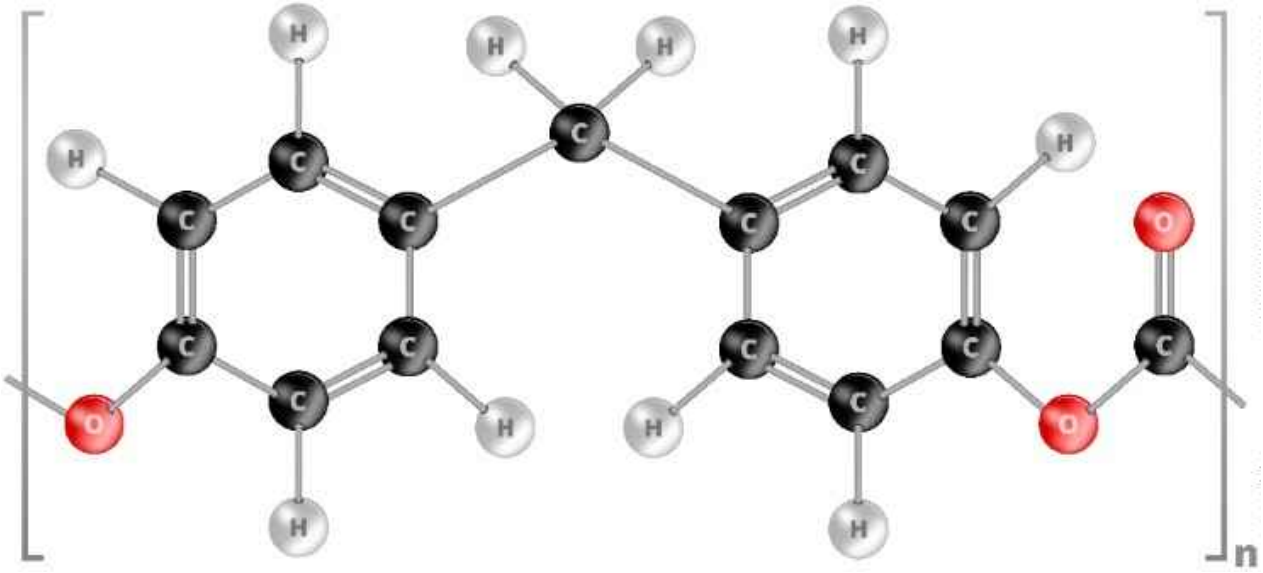
Date: 10/5/2024

Content by: Jackie

Present: N/A

Goals: Research other autoclavable, biodegradable 3D printing materials.

Content:

- Polycarbonate (PC) is transparent thermoplastic
- high strength
  - resistant to impact and fracture
- lightweight
- PC is melted and forced into a mold with high pressure to give desired shape
- eco-friendly processing
  - recyclability
- maintains strength over time, even in stressful conditions
- High impact strength
- high dimensional stability
- good electrical properties
- 
- melting point of 155 degrees C
- Toughness: PC has toughness value between -20 to 140 degrees C
  - virtually unbreakable
- High impact strength
  - density of 1.2 - 1.22
- PC designed to block UV radiation
- PC has good chemical resistance against:
  - diluted acids
  - aliphatic hydrocarbons
  - alcohols
  - moderate resistance against oils and greases
  - sensitive to abrasive alkaline cleaners
- Heat resistance:
  - thermally stable up to 135 degrees C
- PC is 100% recyclable

URL: https://omnexus.specialchem.com/selection-guide/polycarbonate-pc-plastic

IEEE Citation:

Omnexus, “Polycarbonate (PC) Plastic: Properties, Uses, & Structure - Guide,” *Specialchem.com*, 2018. https://omnexus.specialchem.com/selection-guide/polycarbonate-pc-plastic

Conclusions/action items: Consider using PC as an alternative material instead of PLA for 3D printing.

2024/10/05-Autoclavable Materials

AVA FEVOLD - Oct 07, 2024, 12:22 PM CDT

Title: Autoclavable Materials

Date: 10/5/2024

Content by: Jackie

Present: N/a

Goals: Research different autoclavable materials for the swab holder.

Content:

- Polycarbonate Plastics (PC)
  - can be safely autoclaved, BUT only for a certain number of cycles
  - with each autoclave cycle, the strength of the material is lowered
  - can be autoclaved for 30-50 cycles
- Polypropylene and Polypropylene Copolymer
  - polypropylene is a plastic resin known for durability and low cost
  - can be autoclaved without losing strength

URL: https://bluethundertechnologies.com/what-materials-are-autoclavable/

IEEE Citation:

B. T. Technologies, “What Materials Are Autoclavable? What are the Different Types of Autoclaves?,” *Blue Thunder Technologies*, Oct. 31, 2022. https://bluethundertechnologies.com/what-materials-are-autoclavable/

Conclusions/action items: Continue to research different materials that can be autoclaved and used for the swab holder.

2024/10/05-Autoclaving PLA

JACKIE BEHRING - Oct 05, 2024, 2:54 PM CDT

Title: Autoclaving PLA

Date: 10/5/2024

Content by: Jackie

Present: n/a

Goals: Research about PLA and autoclaving.

Content:

- Autoclaving
  - used to kill bacteria and germs by heat, pressure, and saturated steam
- Common Autoclaving Process
  - 121 degrees C for 20 min at 100 kPa
- PLA
  - Melting temperature is greater than 184 degrees C
- partial degradation and destruction after autoclaving 3D printing polymers
  - formation of holes
- Researcher Boursier found minor changes in the accuracy of the larger 3D polymer models
  - considered autoclaving sterilization a viable method

URL: https://www.mdpi.com/2073-4360/15/2/369#:~:text=One%20of%20the%20most%20frequently,a%20viable%20method%20%5B24%5D.

IEEE Citation:

J. Neijhoft, D. Henrich, A. Kammerer, M. Janko, J. Frank, and I. Marzi, “Sterilization of PLA after Fused Filament Fabrication 3D Printing: Evaluation on Inherent Sterility and the Impossibility of Autoclavation,” *Polymers*, vol. 15, no. 2, p. 369, Jan. 2023, doi: https://doi.org/10.3390/polym15020369.

Conclusions/action items: Consider using PLA as a material for the swab holder.

2024/11/23-Carbon Fiber Injection Molding

JACKIE BEHRING - Nov 23, 2024, 9:20 PM CST

Title: Carbon Fiber Injection Molding

Date: 11/23/2024

Content by: Jackie

Present: n/a

Goals: Research materials that would be used in the manufacturing process if UW had no material limitations.

Content:

- While PLA has satisfactory qualities, improvements should be made for future work.
- Carbon fiber injection molding should be used in manufacturing due to its mechanical properties: lightweight, durable, easily sterilized, and resistance to heat and chemicals.
- It is currently used in hospital equipment and tools while remaining an inexpensive material
-

URL: https://masterplastics.com/carbon-fiber-injection-molding-an-innovative-alternative-to-metal/

IEEE citation:

SMITeam, “How Is Carbon Fiber Used for Medical Equipment?,” *SMI Composites*, Mar. 24, 2023. https://www.smicomposites.com/how-is-carbon-fiber-used-for-medical-equipment/

Conclusions/action items:

2024/12/05-Clear Resin

JACKIE BEHRING - Dec 07, 2024, 4:19 PM CST

Title: Clear resin (3D Printed)

Date: 12/5/2024

Content by: Jackie

Present: n/a

Goals: Research different materials that will be more precise while 3D printing in order to ensure accurate threading.

Content:

- Fast print speed
- high accuracy
- transparency
    - easier to show internal features
    - high clarity
- stiff and strong
- strong mechanical properties
- Ultimate tensile strength: 60 MPa
- Flexural Strength: 105 MPa
- high dimensional accuracy
    - precise tolerances and fine features
- Limitation: more expensive than PLA or PC
    - use as last/final prototype

URL: https://formlabs.com/store/materials/clear-resin/

IEEE:

“Clear Resin,” *Formlabs*. https://formlabs.com/store/materials/clear-resin/

Conclusions/action items: After SolidWorks model measurements are perfected, use this material for final prototype.

2024/09/26-The Altered Three Point Bending Design

JACKIE BEHRING - Sep 26, 2024, 8:54 PM CDT

Title: The Altered Three Point Bending Design

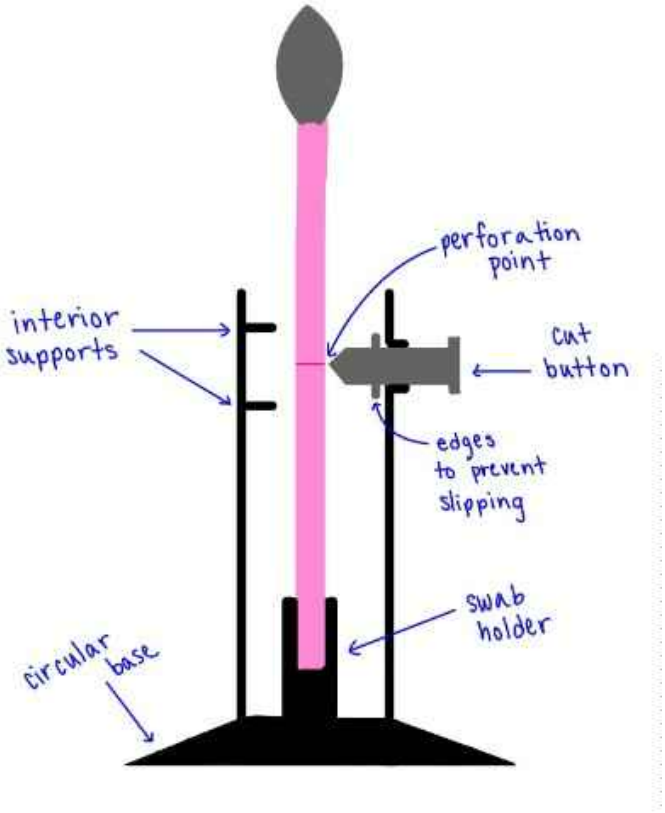
Date: 9/26/2024

Content by: Jackie

Present: N/A

Goals: Use the design from the past semester and make altercations to improve the design.

Content:



Additions:

- added larger base in order to provide more stability to the device

- changed the cutting mechanism to provide more accurate cut

Conclusions/action items: Weigh this design in the design matrix to see if the group should continue with the altered design.

2024/09/27- Altered Three Point Bending Design from Spring 2024

JACKIE BEHRING - Sep 27, 2024, 2:22 PM CDT

Title: Altered Three Point Bending Design from Spring 2024

Date: 9/27/2024

Content by: Jackie Behring, Sara Morehouse, Cherry Qiu, Katherine Kafkis, Adam Berdusco

Present: Jackie

Goals: Email the spring 2024 team and get the SolidWorks file of the final prototype to make altercations and fix the design.

Content:

- Final Prototype from Spring 2024

Conclusions/action items: Make altercations to the SolidWorks to get new design printed and tested.

JACKIE BEHRING - Sep 27, 2024, 2:22 PM CDT

Download

Final_Prototype_-_PRINT.SLDPRT (241 kB)

2024/10/09-Tilt and Break SolidWorks

JACKIE BEHRING - Nov 14, 2024, 1:20 PM CST

Title: Tilt and Break SolidWorks

Date: 10/9/2024

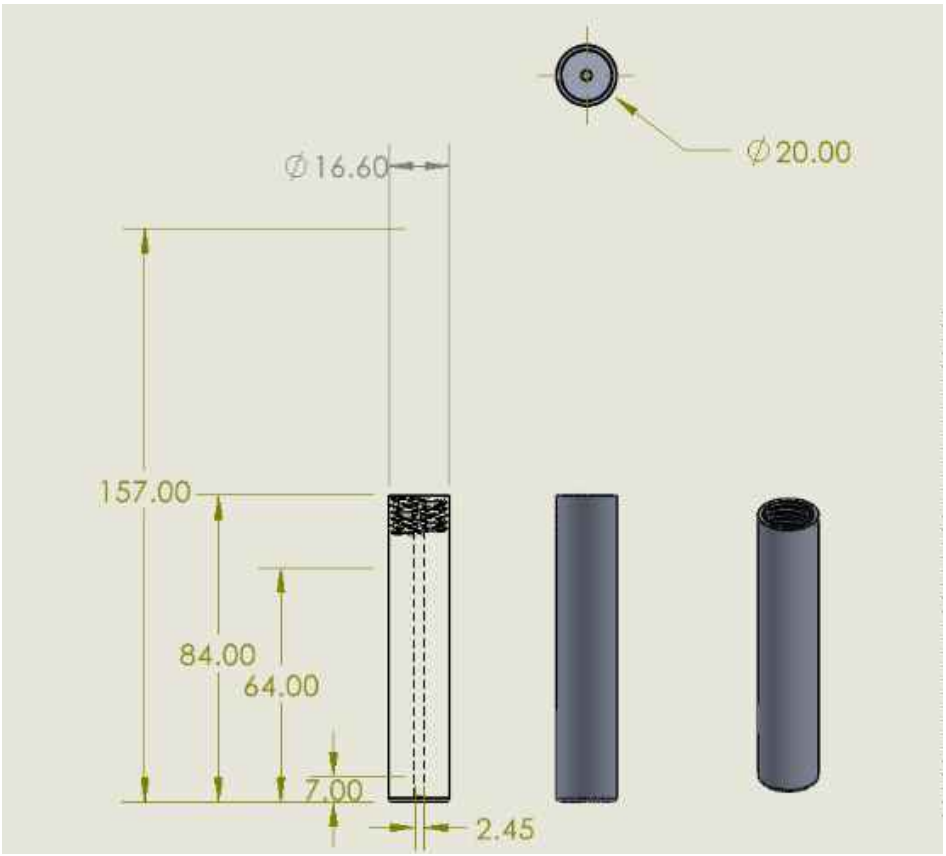
Content by: Jackie

Present: n/a

Goals: Create a part and drawing in SolidWorks of the Tilt and Break design.

Content:

The goal of this project is to design a new cap system to screw onto the medium solution tube. The Tilt and Break design is solid throughout the bottom 64 mm of the tube in order to hold the bottom of the swab in place. It has an opening of 2.45 mm in order to hold the swab with a pressure effect. The top 20 mm of the holder open right below the perforation point so that when the user breaks the swab into the solution, there is a constant snapping point. The threading was measured in the TeamLab and would need 9/16" inch tap. SolidWorks lacked the needed measurement so it was converted from inch holes to metric M8x1.0.



Conclusions/action items: Convert SolidWorks part file to STL file and work with the MakerSpace staff to 3D print first prototype using PLA.

Download

Drawing_Tilt_Break_Model_1.SLDDRW (342 kB)

JACKIE BEHRING - Oct 09, 2024, 6:19 PM CDT

Download

Tilt_Break_Model_1.SLDPRT (264 kB)

2024/10/28-Swab Holder Stand Base

JACKIE BEHRING - Oct 28, 2024, 12:13 PM CDT

Title: Swab Holder Stand Base

Date: 10/28/2024

Content by: Jackie

Present: n/a

Goals: Design the swab holder base in order to stand up the medium solution. Add a larger base for extra balance.

Content:

-See attached SolidWorks file

Conclusions/action items: 3D print this base holder and the tilt and break model.

JACKIE BEHRING - Oct 28, 2024, 12:15 PM CDT

Download

Swab_Holder_base.SLDPRT (71 kB)

2024/12/05-Final Tilt and Break Prototype

JACKIE BEHRING - Dec 05, 2024, 5:40 PM CST

Title: Final Tilt and Break Prototype

Date: 12/5/2024

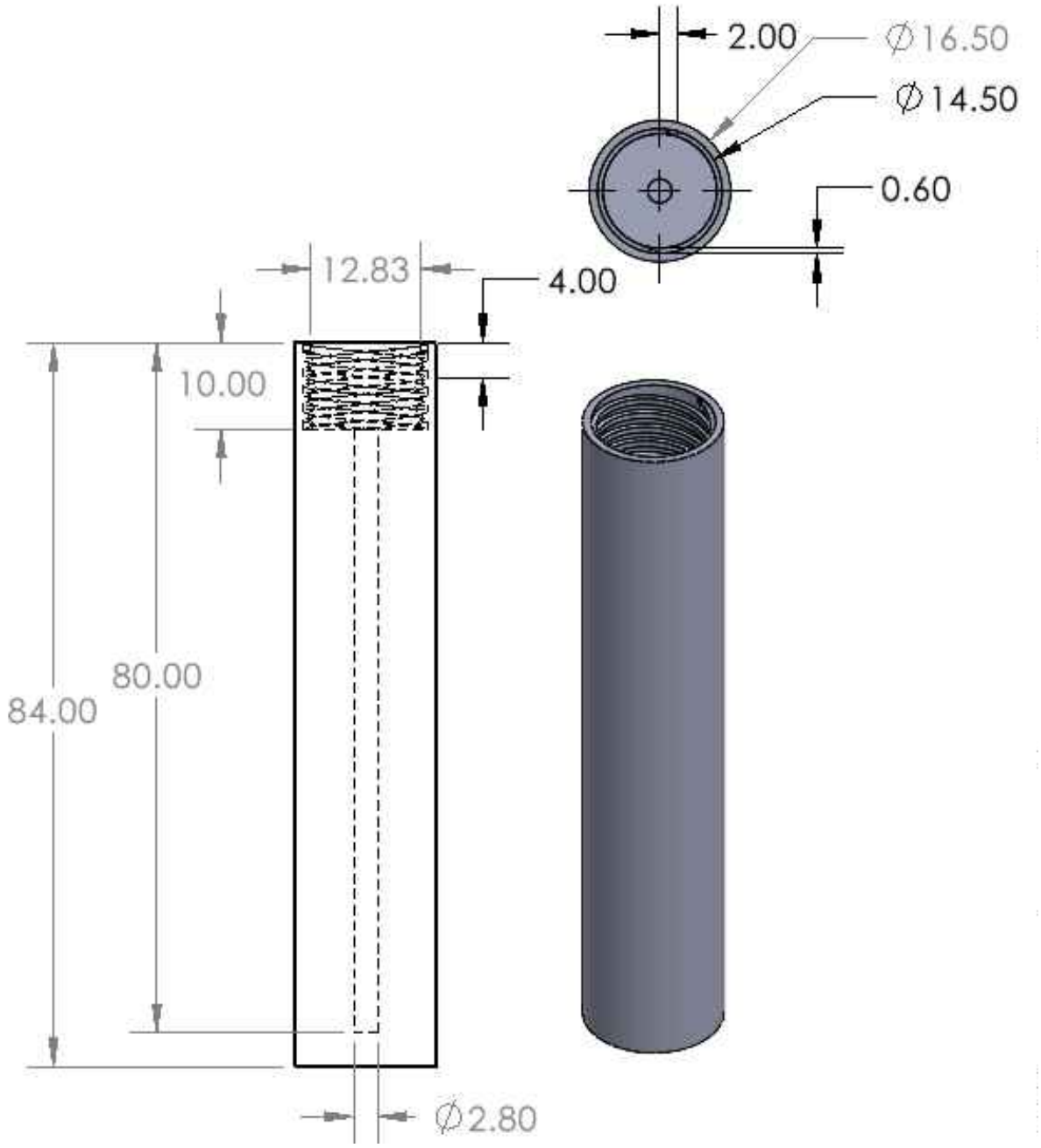
Content by: Jackie

Present: n/a

Goals: Use Jesse's advice from Team Lab to complete the final model of the Tilt and Break in Solidworks.

Content:

The final design was completed after consulting with Jesse Darley in the UW Madison Team Lab in order to determine the threading. After discovering the threading was not standard, our team had to work with Jesse in order to manually design the threading. A SolidWorks part file and an image including the dimensions is uploaded below. The team used Clear resin to print the final prototype in the UW Makerspace using the Formlabs printer. The total cost for one prototype was $4.96 for 20.67mL of material used.



Conclusions/action items: Begin testing with the final prototype!

JACKIE BEHRING - Dec 05, 2024, 5:40 PM CST

Download

STL_Tilt_Break_Model_11-23.SLDPRT (262 kB)

2024/12/11-Design Innovation Lab Memberships

JACKIE BEHRING - Dec 11, 2024, 3:51 PM CST

Title: Design Innovation Lab Memberships

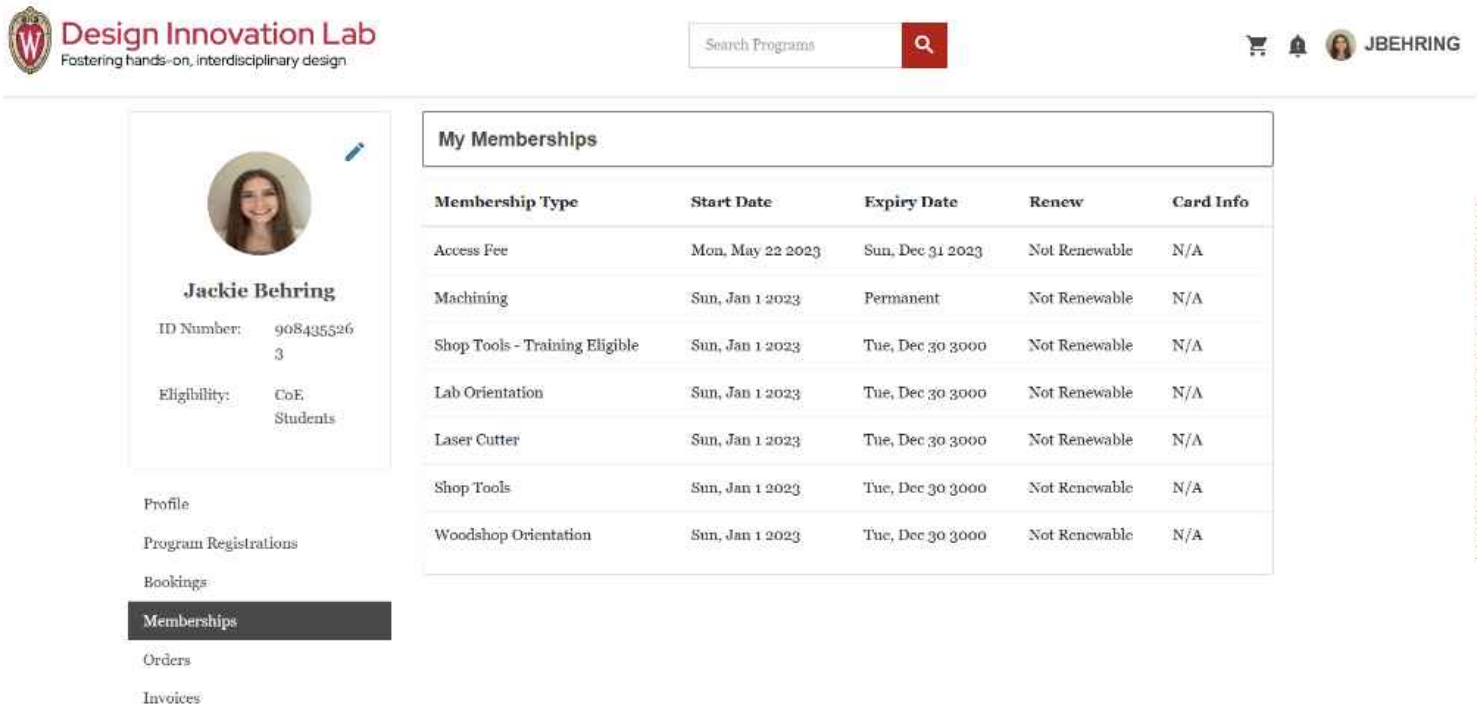
Date: 12/11/2024

Content by: Jackie

Present: n/a

Goals: Upload documentation of machine training.

Content:



Conclusions/action items: Use access to machines for different aspects of the project.

2024/12/05-Testing

JACKIE BEHRING - Dec 05, 2024, 5:31 PM CST

Title: Testing

Date: 12/5/2024

Content by: Jackie

Present: n/a

Goals: Complete the swab breaking accuracy and the agar plate testing as a team.

Content:

-All testing was done as a team and the results and protocols are found in the team folder.

Conclusions/action items: Convert raw data to data for the presentation and report.

2024/12/11-STM Base SolidWorks Protocol

JACKIE BEHRING - Dec 11, 2024, 11:21 AM CST

Title: STM Base SolidWorks Protocol

Date: 12/11/2024

Content by: Jackie

Present: n/a

Goals: Create a protocol designing a 3D model of the STM Base in SolidWorks.

Content:

Objective: Create a 3D model of the STM Base in SolidWorks.

Steps:

1. In SolidWorks, begin a new part file.
2. In the bottom right corner of the screen, change the units to MMGS.
3. Begin a new sketch on the top plane.
4. Use the circle feature to draw a circle centered at the origin.
5. Dimension the sketch to have a diameter of 49.5 mm.
6. Exit the sketch.
7. Use the Extruded Boss/Base feature to extrude 2 mm down.
8. Start a new sketch on the top of the cylinder.
9. Use the circle feature to draw two circles centered at the origin.
10. Dimension one of the sketches to have a diameter of 17 mm.
11. Dimension the other sketch to have a diameter of 13 mm.
12. Exit the sketch.
13. Use the Extruded Boss/Base feature to extrude the feature 18 mm up.

Conclusions/action items: Use this protocol in future designs.

2024/12/11-Tilt-and-Break SolidWorks Protocol

JACKIE BEHRING - Dec 11, 2024, 11:28 AM CST

Title: Tilt-and-Break SolidWorks Protocol

Date: 12/11/2024

Content by: Jackie

Present: n/a

Goals: Create a protocol of the 3D model of Tilt-and-Break in SolidWorks.

Content:

Objective: Create a 3D model of the Tilt-and-Break in SolidWorks.

Steps:

1. In SolidWorks, begin a new part file.
2. In the bottom right corner of the screen, change the units to MMGS.

Shaft:

3. Begin a new sketch on the top plane.
4. Use the circle feature to draw a circle centered at the origin.
5. Dimension the sketch to have a diameter of 16.5 mm.
6. Exit the sketch.
7. Use the Extrude Boss/Base feature to extrude 84 mm down.

Cap:

8. Start a new sketch on the top of the cylinder.
9. Use the circle feature to draw a circle centered at the origin.
10. Dimension the circle to have a diameter of 14.5 mm.
11. Exit the sketch.
12. Use the Extruded Cut feature to cut 10 mm of material out of the shaft.

Internal Tube:

13. Start a new sketch on the 14.5 mm circle.
14. Use the circle feature to draw a circle centered at the origin.
15. Dimension the circle to have a 2.8 mm diameter.
16. Exit the sketch.
17. Use the Extruded Cut feature to cut 70 mm of material out of the shaft.

Threading:

18. Click on the Helix/Spiral feature and the inner cap.
19. Defined by Height and Pitch with Constant Pitch parameters.
20. Make the height 10 mm.
21. Make the pitch 4 mm.

22. Check the reverse direction box.
23. Make the start angle clockwise 0 degrees.
24. Check the green arrow.
25. Start a new sketch on the right plane.
    1. The plane chosen should align with the top of the shaft, tip of the cap, and beginning of the spiral.
26. Click on the line feature and draw a line from the tip of the spiral in a downward diagonal direction toward the center of the cap. Click to end the line.
27. Click to begin another line from the ending of the first straight down toward the bottom of the cap. Click to end the line.
28. Click to begin another line from the ending of the second line toward the side of the cap. Click to end the line.
29. Click to begin a fourth line from the ending of the third line straight up and click on the beginning of the first line. This will connect the first and third lines.
30. Add a centerline from the midpoint of the fourth line to the midpoint of the second line.
31. Add a relation to the centerline to make it horizontal.
32. Add a relation to the second and fourth lines to make them vertical.
33. Dimension the fourth line and make it 1 mm.
34. Dimension the centerline and make it 0.6 mm.
35. Dimension the first line and the centerline to create a 10 degree angle.
36. Exit the sketch.
37. Use the Sweep feature to extrude the threading.
38. Make the Profile and Path a Sketch Profile.
39. Click on the trapezoid made in the previous sketch as the profile.
40. Click on the Helix/Spiral made previously in steps 18-24 as the path.
41. The profile orientation should follow the path and the profile twist should have minimum twist.
42. The boxes should be checked for the following: Merge tangent faces, Show preview, and Merge result.
43. Click on the green check mark.
44. Click on the Chamfer feature.
45. The items to chamfer should be the Edges 1 and 2, these were the first and third lines drawn in the trapezoid.
46. The chamfer parameters should have a distance of 2 mm with a 10 degree angle.
47. Click the green check mark.
48. Click on the chamfer feature to start another chamfer.
49. The item to chamfer should be Edge 1, or the second line drawn in the trapezoid.
50. The chamfer parameters should have a distance of 2 mm with a 25 degree angle.
51. Click on the green check mark.
52. Click on the circular pattern feature.
53. Under the Direction tab the face chosen should be the inner tube in the cap. The equal spacing should be checked. The angle should be 360 degrees. The amount should be 2.

54. Under the Features and Faces tab click on both chamfers and the sweep feature.
55. Click on the green check mark. There should now be a total of 2 starting threads.

Conclusions/action items: Use this protocol to design any future Tilt-and-Break models.

2024/09/13-BSAC Meeting 1

JACKIE BEHRING - Sep 13, 2024, 11:50 AM CDT

Title: BSAC Meeting 1

Date: 9/13/2024

Content by: Jackie

Present: Jackie

Goals: Complete and attend first BSAC meeting

Content:

Advice from 400:

- Meet in person
- Get documents done early submit them to advisor to be reviewed by Monday because they are usually due by Wednesday

problems and how they were fixed:

- Assign tasks to each section, so people have to take accountability
- Ensure that people meet at the same time

Conclusions/action items: Take this advice from the 400s and apply to this semester project.

2024/09/11-Lecture 1

JACKIE BEHRING - Sep 11, 2024, 2:01 PM CDT

Title: Lecture 1

Date: 9/11/2024

Content by: Jackie Behring

Present: Jackie

Goals: Listen and take notes on the first lecture.

Content:

- BME Career Prep
  - Keep track of what you apply to - ECS tracking sheet
  - Use resources - Handshake, LinkedIn, Indeed
  - Connect with people BEFORE you are a candidate
  - Applying is step 1
    - following up is crucial!! (2-3 weeks after)
- Resume Tips
  - Tailor your resume to the position - quick changes
  - Create good balance - full picture of your experience
    - Design projects WITHOUT years or semesters - what did you do?
    - Technical skills and coursework
- For career fair - do not need cover letters
- Career fair advice for BME
  - Identify your purpose - more than just an internship
  - Looking beyond the obvious - overlap with other disciplines
  - Research the employer - feedback from out partners
  - Develop your "value added" statement - why you?
- Industries in Handshake
  - exact sciences
  - do not get caught up in the job title
  - expand viewpoint
  - get experience to get better experience later
    - Healthcare
    - Internet and Software
    - Manufacturing
    - Biotech and Life Sciences
    - Pharmaceuticals
- career fair: September 16-19
  - 11 am - 5 pm
- Look into BME, ME, healthcare

Conclusions/action items: Attend the career fair after preparing and researching the companies that I show interest in.

2024/09/18-Lecture 2

JACKIE BEHRING - Sep 18, 2024, 1:56 PM CDT

Title: Lecture 2

Date: 9/18/2024

Content by: Jackie

Present: N/A

Goals: The goal of the lecture is to discuss leadership and dive into the meaning of being a leader.

Content:

- I am a leader
- Important qualities of a leader
  - inclusiveness
  - confidence
  - respectful
  - guidance
  - bravery
  - responsibility
- Power model
  - "Someone has to take control and it should be me"
  - Hierarchy, authority, command
- Servant Leadership
  - Empathetic, empowering, shared decision making
- Authentic Leadership
  - Transparency, genuineness, honesty
- Team Goal: relationship building, adaptability
- Self Goal: Patience, Problem-solving, coaching and mentoring

Conclusions/action items:

2024/09/25-Lecture 3

JACKIE BEHRING - Sep 25, 2024, 2:07 PM CDT

Title: Lecture 3

Date: 9/25/2024

Content by: Jackie

Present: N/A

Goals: Learn about different post graduate plans.

Content:

Fall Post Graduate Plans

- General Pointers
  - Use undergraduate experience to "build a story"
  - Letters of recommendation - 3 strong ones
  - Gain experience while you can while still in school
  - Connect with Alums on LinkedIn
  - Research helps with most post-degree plans
- Writing your story
  - General: start with what you want to do - thesis statement
    - cancer stem cells, role, etc
    - narrow experience and how it applies to your broad interest
    - specific to each position of place to which you apply
  - Personal statement: show a reasonable idea of what
    - you will achieve at Company X
- Grad School Options
  - Masters, MS
  - Doctoral, PhD
- MS - 24 credits
  - make you more desirable
  - fill gaps in resume
  - higher level of skills
  - more experiences and skills
  - powerful if add in industry experience
  - higher starting salary
  - can co-op during MS
  - time to find dream job
- Research MS
  - 1.5-2 years
- Accelerated program MS
  - accelerated 1 yr
- Biomedical Innovation, Design, and Entrepreneurship
  - accelerated - 1 yr
  - project based - project required
  - partnership with business school
- If you have over a 3.0 you will be admitted into the program automatically
- Explore opportunities and interests:
  - MEng
  - MS in Global Health
  - MS in other Engineering Dept.
  - MBA - generally industry pays for credits or evening options
- classwork
- experience
- leadership / extracurricular activities

Conclusions/action items: Continue to get involved with different experiences in order to grow my resume. Start applying to industry jobs.

2024/10/02-Lecture 4

JACKIE BEHRING - Oct 02, 2024, 6:44 PM CDT

Title: Lecture 4

Date: 10/2/2024

Content by: Jackie

Present: N/a

Goals: Learn about the importance and soft skill development BME 300 has to offer.

Content:

- why are 300s mentoring 200s?

  - teaching helps us learn as well

  - allows growth of relationship within group

  - emotional support

  - instructional support

  -peer mentors are more approachable

  - increases belonging

  transferable skills

  - leadership

  -communication

  -active listening

  - study practices

  - self awareness

  - interpersonal skills

  benefits of mentoring

  - increased self esteem

  - increased patience

  - build positive habits

  - foster personal growth

  - help identify gaps in your own knowledge

  - sense of accomplishment

  listen effectively

  - get rid of distractions

  - stop talking

Conclusions/action items: Take this advice and make a plan for after graduation.

2024/10/09-Lecture 5

JACKIE BEHRING - Oct 09, 2024, 2:01 PM CDT

Title: Sustainability Engineering

Date: 10/5/2024

Content by: Jackie

Present: n/a

Goals: Learn more about environmental engineering and how important it is for the atmosphere.

Content:

- Life cycle assessment: constant process
  - resources
  - processing
  - manufacturing
  - distribution
  - use
  - end of life
- First life cycle assessment was in 1969 by the Coca-Cola
- How does sustainability fit into Vaginal Self Swab project?
  - creating a biodegradable, recyclable swab holder for one time use
  - can be recycled to be reused

Conclusions/action items: Use biodegradable equipment and materials while fabricating a product. This will lead to easier and better manufacturing.

2024/10/16-Lecture 6

JACKIE BEHRING - Oct 16, 2024, 2:04 PM CDT

Title: Introduction to WARF, IP, Disclosing and Licensing

Date: 10/16/2024

Content by: Jackie

Present: N/a

Goals: The goal of todays lecture is to understand the fundamentals of patents and the process in order to protect intellectual property.

Content:

- Vision
  - support UW by patenting and licensing
- Mission
  - support scientific research within UW community by providing financial support
  - actively managing assets
  - moving innovation to the marketplace for a financial return and global impact
- Independent
  - Nonprofit supporting organization
  - board of UW alumni
- Technology Transfer
  - moving research results from campus out into market
  - WARF works to facilitate securing IP rights and commercial licenses
- Intellectual Property Overview
  - Four common types of IP
    - Patents
    - Copyrights
    - Trademarks
    - Trade Secrets
  - Other WARF IP
    - biomaterials
    - Technique and know how (akin in some ways to Trade Secrets
    - Data
- Overview of Non-Patent IP
  - Copyrights
    - protection for creative works that are expressed in a tangible medium
    - wide range of subject matter, including software code
  - Trademarks
    - protection for names, marks, logos, dress, etc
    - requires use in commerce
    - source-identifying function
  - Trade Secrets
    - can be used to protect anything of value
    - protection is good so long as the concept is not generally known
    - ex: CocaCola recipe
- Patents Generally
  - Patent is a property right, granted by governmental agency
    - US Patents and Trademark Office
    - No global patent
  - Patent holder has a right to exclude others from making, using, selling, or importing the claimed invention
  - Three different US patent types:
    - Design
    - Plant
    - Utility
- Requirements for Patenting
  - Statutory requirements for patenting:
    - 101 - Eligible; cannot be a product of nature, abstract idea, or natural phenomenon
    - 102 - Novel; it must be new

        - 103 - Non-obvious; it cannot be simple modification or combination of existing products
        - 112 - Enabled and Described; must provide enough detail to teach others how to make or use the invention
- Disclosing an innovation to WARF
    - WARF receives about 400 new innovation disclosures each year
    - Disclosing
        - describe innovation
        - identify its advantages and potential applications
        - name contributors (inventors, authors)
        - provide funding and public disclosure details
    - Meeting with WARF
        - Discuss the innovation in more detail
        - Ask questions about WARF and patenting processes
        - Discuss next steps
- Marketing and Licensing
    - Licensing the IP is the next step in transferring the technology
        - Market Analysis
            - Market Status - established, emerging, new
            - Size and Type - large and growing, medium and contracting
            - Potential Licenses - companies in the market
        - License Negotiation
            - Type and Terms - exclusive and field limited, sublicensing
            - Consideration - upfront payment, royalties, reimbursement
        - Ongoing
            - Technology development, enforcement, amendment, termination
- Value of Licensing
    - Benefits to the company:
        - reduced R&D costs
        - improved time to market
        - opportunity to enter new markers and expand company quickly
- AI and Patents
    - Can AI invent? (no)
        - "Inventor" = natural person, conception
    - Limited to US only? (no)
        - South Africa is the exception
    - Can AI assist in inventing?
        - Evolving, but likely yes under Pannu Factors

Conclusions/action items: In the next couple months, review the patent process and hopefully file a disclosing request and schedule a meeting with WARF.

2024/10/23-Lecture 7

JACKIE BEHRING - Oct 23, 2024, 2:29 PM CDT

Title: Institutional Review Board Notes

Date: 10/23/2024

Content by: Jackie Behring

Present: n/a

Goals: Learn the basics of IRBs and the review process. **Content:**

- IRBs began because of unethical research involving human subjects
  - Mostly studies in world war II, nazi experiments
  - Tuskegee Syphilis Study also prompted the creation of IRBs
- IRBs must consist of a variety of people
  - At least one scientist
  - One not involved with the research
- MRR IRBs involve biomedical, education, and social / behavioral research
- Health Sciences IRBs involve any risk level of health-related research
  - All FDA and VA regulated research
- **What projects need IRBs?**
  - Research by definition is a systematic investigation into R&D, testing, evaluation - designed to develop or contribute to a generalizable knowledge
  - Human subjects involve a living individual about whom a researcher is conducting an investigation
    - Information or biospecimens through interactions
    - Generates identifiable private information / biospecimens
  - Determining if research falls under human research by the FDA or DHHS is important
  - For researchers, they need to complete required trainings to meet with IRBs and conduct human research
    - Finding a PI to take charge of the project is necessary
  - Consider research participants

Conclusions/action items: Continue to use this information for my current BME 300 project, since it is about STI testing for women.

2024/10/30-Lecture 8

JACKIE BEHRING - Oct 30, 2024, 2:04 PM CDT

Title: Navigating FDA Device Requirements

Date: 10/30/2024

Content by: Jackie

Present: n/a

Goals: Define a medical device and how FDA regulates devices, understand the different categories of medical devices, and apply regulations to medical devices.

Content:

- Defining a medical device
  - an instrument, apparatus, implement, machine, contrivance, in vitro reagent
  - intended to affect the structure or any function of the body of man or other animals, and does not achieve its primary purposes through chemical reactions
- Traditional medical devices:
  - MRI
  - Syringes
  - oscilloscope
- Non-traditional medical devices
  - Software, AI, virtual reality
    - analyzes data and imaging
  - medical mobile apps
    - apple watch
  - mouth wash
    - coats your teeth
- Software as a Medical Device (SaMD)
  - software IN a medical device
  - software AS a medical device
- Device classification overview
  - Class I
    - Low Risk - minimal potential for harm
    - Regulatory requirements
      - Exempt from premarket approval and Quality System (QS) Requirements
      - must follow certain general controls: labeling, record retention, and complaint files
    - Band-Aids, floss, tongue depressor
  - Class II
    - Moderate risk
    - Regulatory requirements
      - must follow general and special controls which can include performance standards, post marker surveillance, and specific labeling requirements
    - Approval process:
      - 510(k) application showing substantial equivalence
  - Class III
    - high risk
      - sustain or support life, implanted, or potential for unreasonable risk
    - Regulatory requirements
      - must follow general controls and additional stringent requirements, such as clinical trials to demonstrate safety and efficacy
    - Approval process
      - PMA submission, which involves a comprehensive FDA review of safety and effectiveness data before marketing
- General controls
  - registration and listing
  - adverse event reporting
  - general labeling
  - good manufacturing practice

        - document management
        - production and process controls
        - management responsibility
- Special controls
    - performance standards
    - special labeling requirements
    - post-market surveillance
    - potential data requirements
- premarket approval
    - data to show safety and effectiveness

Conclusions/action items: Use this information in the future if development of medical device leads to receiving FDA approval.

2024/11/06-Lecture 9

JACKIE BEHRING - Nov 06, 2024, 2:00 PM CST

Title: Regulatory Strategy: The Framework Guiding Advanced Therapeutic Product Development

Date: 11/6/2024

Content by: Jackie

Present: n/a

Goals: Understand the overall structure of the FDA, including the framework of laws, regulations, and guidance for advanced therapeutics.

Content:

- FDA Structure and Advanced Therapeutics
  - Device (CDRH)
    - PMA
    - 510(k)
    - IDE
  - Drug (CDER)
    - NDA - New Drug Application
    - IND - Investigational New Drug
  - Biologic (CBER)
    - BLA - Biologics Licence Agreement
    - IND - Investigational New Drug
  - Genome editing
    - target a precise genome locus and delete, insert, or change existing sequences
  - Gene delivery
    - transfer molecular tools and assembled gene systems into the cell
  - Cell therapy
    - use expanded cells to transfer medical bio-activity to regenerate damages tissue or restore health
- Product Development Life Cycle
  - The things done in academic laboratories is adding important information to scientific literature
  - Each stage of the product development life cycle faces its own risks and challenges and proper management of these risks is vital for successful commercialization
- A target product profile (TPP)
  - when to use the product, why to use the product, how to use the product?
  - Patient identification: indication
  - Patient benefits: efficacy profile
  - Patient risks: safety profile
  - is it medically and commercially compelling?

Conclusions/action items: Keep the FDA requirements in mind while designing, fabricating, and testing a prototype.

2024/11/13-Lecture 10

JACKIE BEHRING - Nov 13, 2024, 1:59 PM CST

Title: Medical Device Innovation From Prototype to Commercial Clinical Use

Date: 11/13/2024

Content by: Jackie

Present: N/a

Goals: Learn about the process of bringing a medical device into clinical use.

Content:

- Medical Device Process at a Glance
  - Innovation Idea Development
  - Human Testing Data Acquisition with IRB Oversight
  - FDA Regulatory Process
  - Reimbursement or Financial Incentive
  - Sales
- Breakthrough Devices Program
  - Formerly Expedited Access Program
  - Timely access to medical devices for life-threatening or irreversibly debilitating diseases/conditions
  - program to expedite development, assessment and review
  - enables early interaction with FDA experts in the review phase and prioritized review
- General Steps from Approval to Adoption
  - Clinical Studies
  - FDA Approval
  - CPT Codes
  - CMS National Insurance Decisions
  - Standards of Practices
  - National Regional Buying Groups
  - Regional/Local IDNs, Hospitals
  - Hospital/IDN Value Analytics Groups
  - Product Evaluations
  - Regional/Just in Time Distribution
  - Product Implementation
- Value Drivers to Discover
  - Economic
    - Money
    - Staff Time
    - Resources
    - Waste
    - Metrics
  - Clinical
    - Improve Outcomes
    - Reduce Risk
    - Reduce Complications
    - Shorten Length of Stay
    - Solve "Issues"
  - Mission Impact
    - Patient Satisfaction
    - Academic Leadership
    - Innovation in Care
  - Evidence more compelling than "hand-waving" benefit assumptions
- Who Buys, Pays, and gets Reimbursed
  - CMS - Centers for Medicare and Medicaid Services
  - DRG - Diagnostic Related Groups
  - CPT - Current Procedural Code
  - ICD 10 - International Categorization of Diseases
  - GPO - Group Purchasing Organization

- IDN - Integrated Delivery Networks
- Payer Mix (% private, Capitated, Medicare)

Conclusions/action items: Use this information going into a summer medical sales internship.

2024/11/015-Tong Lecture

JACKIE BEHRING - Nov 15, 2024, 12:53 PM CST

Title: Starting from scratch: how we built Tasso

Date: 11/15/2024

Content by: Jackie

Present: n/a

Goals: Learn about the design process leading into entrepreneurship.

Content:

- Tasso: at home diagnostic access for blood draws
- Blood draws are time consuming, annoying, painful process
- Design idea: create easier blood draw process
    - everything sent to home (amazon, door dash, etc)
- they know nothing about business side
    - started talking to Law and Entrepreneurship Clinic
- Got scrappy with funding opportunities
    - SBIR grants
    - Funding from DARPA and NIH
- Finding a key customer
    - USADA was looking to switch anti-dropping to blood but everyone hates needles and lancets
    - Tasso developed tamper proof security case to solved the chain-of-custody problem
    - Tasso does blood testing for MLB, Olympics, and Conor McGregor
- Scaling up - lessons in quality, culture, and HR
    - Covid hit, everything shut down
    - Big pharma companies reached back out
    - Began manufacturing
- FDA
    - Class I medical device - super easy clearance
        - month process, $100,000

Conclusions/action items: Anything is attainable with a good mindset and effort. Finding a good team and developing trust is important in success.

2024/11/20-Lecture 11

JACKIE BEHRING - Nov 20, 2024, 2:13 PM CST

Title: How New Product Development Works in the Medical Device Industry

Date: 11/20/2024

Content by: Jackie

Present: n/a

Goals: Learn more about how new medical device development works.

Content:

Speaker: Russ Johnson

Types

Key Points on New Product Development (NPD):

- How New Products Are Selected and Prioritized:
  - Evaluate ideas based on company goals, market needs, and resources.
  - Focus on projects that align with strategy and offer the best value.

NPD in the Medical Device Industry:

- Highly Regulated**: Strict requirements from the FDA and other authorities shape the process.
- Expensive**: Extensive testing (verification and validation) significantly increases costs.
- Resource-Intensive**: Large teams and significant effort are required to complete projects.

How Projects Are Selected and Prioritized:

1. Corporate Business Strategy**: Align projects with the company’s overall goals.
2. Product Portfolio Review**: Analyze current and potential products to fill gaps or expand offerings.
3. Project Review**: Assess feasibility, risks, and potential returns of each idea.
4. Budgeting and Resource Allocation**: Assign money and teams to the highest-priority projects.

of NPD Projects (New Product Development):

- Line Extensions: Expanding an existing product line with minimal risk, cost, and time.
- Product Improvements: Making changes to enhance existing products.
- New-to-Company: Products that are new for the company but exist in the market.
- New-to-World: Completely new products with the highest risk, cost, and time to market.

Managing NPD: Stage-Gate Process

- Stage 0: Ideation ("The Cloud")
  - Brainstorm and generate new ideas.

- Stage 1: Exploration ("The Funnel")
  - Identify the problem.
  - Review, refine, and narrow down ideas.

- Stage 2: Concept Development
  - Develop ideas based on feedback from customers.

- Stage 3: Design Development
  - Create a working prototype.

- Stage 4: Design Confirmation ("The Tunnel")
  - Perform thorough testing to ensure quality.
  - Finalize the design and specifications.

- Stage 5: Design Transfer and Commercialization
  - Complete remaining tests and prepare for production.

- Ongoing: Post-Market Monitoring
  - Continuously track and improve the product after launch.

Conclusions/action items: Apply this to the Vaginal Self Swab project.

2024/10/05-Polycarbonate - Copy

JACKIE BEHRING - Nov 14, 2024, 12:49 PM CST

Title: Polycarbonate (PC)

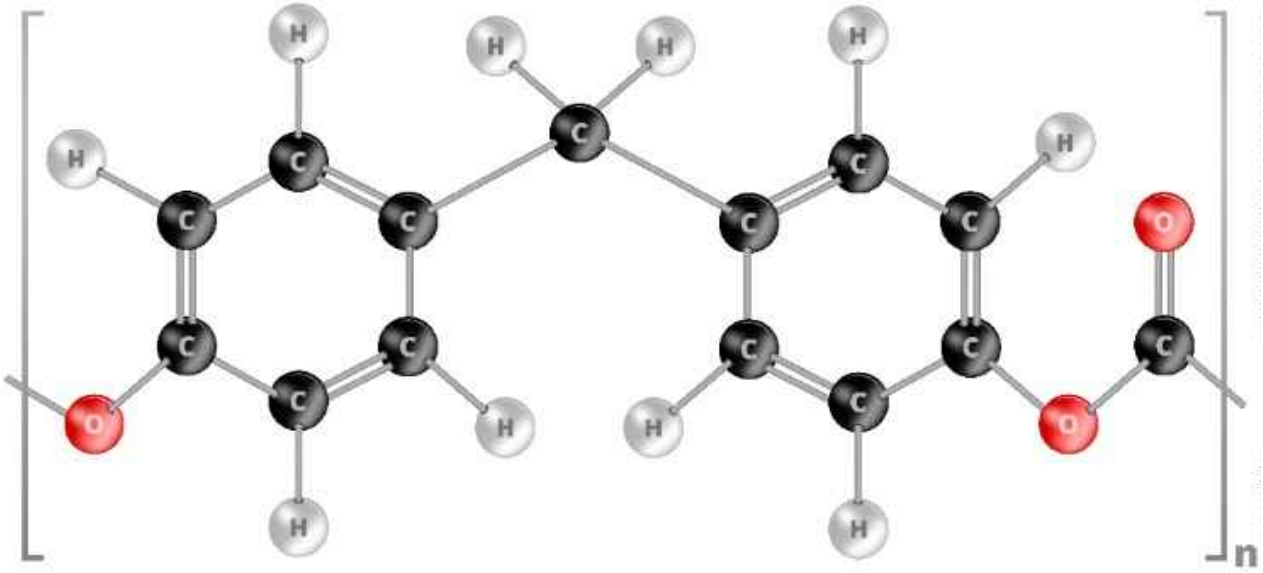
Date: 10/5/2024

Content by: Jackie

Present: N/A

Goals: Research other autoclavable, biodegradable 3D printing materials.

Content:

- Polycarbonate (PC) is transparent thermoplastic
- high strength
  - resistant to impact and fracture
- lightweight
- PC is melted and forced into a mold with high pressure to give desired shape
- eco-friendly processing
  - recyclability
- maintains strength over time, even in stressful conditions
- High impact strength
- high dimensional stability
- good electrical properties
- 
- melting point of 155 degrees C
- Toughness: PC has toughness value between -20 to 140 degrees C
  - virtually unbreakable
- High impact strength
  - density of 1.2 - 1.22
- PC designed to block UV radiation
- PC has good chemical resistance against:
  - diluted acids
  - aliphatic hydrocarbons
  - alcohols
  - moderate resistance against oils and greases
  - sensitive to abrasive alkaline cleaners
- Heat resistance:
  - thermally stable up to 135 degrees C
- PC is 100% recyclable

URL: https://omnexus.specialchem.com/selection-guide/polycarbonate-pc-plastic

IEEE Citation:

Omnexus, “Polycarbonate (PC) Plastic: Properties, Uses, & Structure - Guide,” *Specialchem.com*, 2018. https://omnexus.specialchem.com/selection-guide/polycarbonate-pc-plastic

Conclusions/action items: Consider using PC as an alternative material instead of PLA for 3D printing.

2024/10/09-Tilt and Break SolidWorks - Copy

JACKIE BEHRING - Nov 14, 2024, 1:21 PM CST

Title: Tilt and Break SolidWorks

Date: 10/9/2024

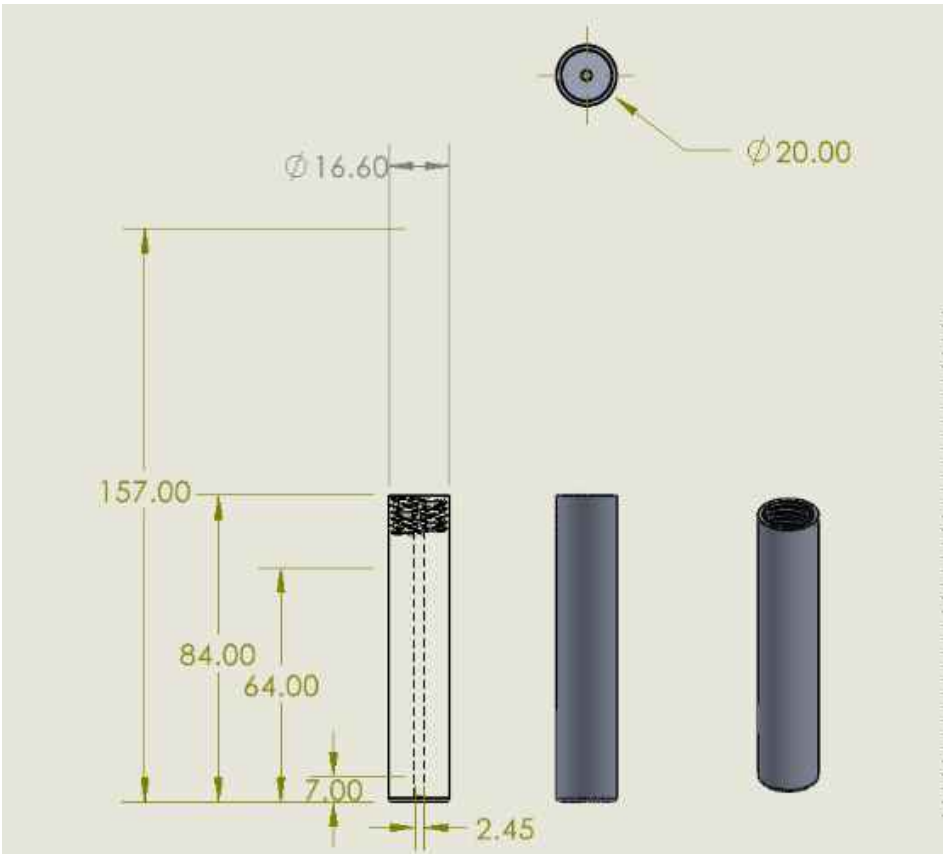
Content by: Jackie

Present: n/a

Goals: Create a part and drawing in SolidWorks of the Tilt and Break design.

Content:

The goal of this project is to design a new cap system to screw onto the medium solution tube. The Tilt and Break design is solid throughout the bottom 64 mm of the tube in order to hold the bottom of the swab in place. It has an opening of 2.45 mm in order to hold the swab with a pressure effect. The top 20 mm of the holder open right below the perforation point so that when the user breaks the swab into the solution, there is a constant snapping point. The threading was measured in the TeamLab and would need 9/16" inch tap. SolidWorks lacked the needed measurement so it was converted from inch holes to metric M8x1.0.



Conclusions/action items: Convert SolidWorks part file to STL file and work with the MakerSpace staff to 3D print first prototype using PLA.

Download

Drawing_Tilt_Break_Model_1.SLDDRW (342 kB)

JACKIE BEHRING - Nov 14, 2024, 1:21 PM CST

Download

Tilt_Break_Model_1.SLDPRT (264 kB)

09/11/2024-Vaginal Self-Swab Background

Tatiana Predko - Sep 11, 2024, 10:17 PM CDT

Title: Vaginal Self-Swab Background Research

Date: 09/11/2024

Content by: Tatiana Predko

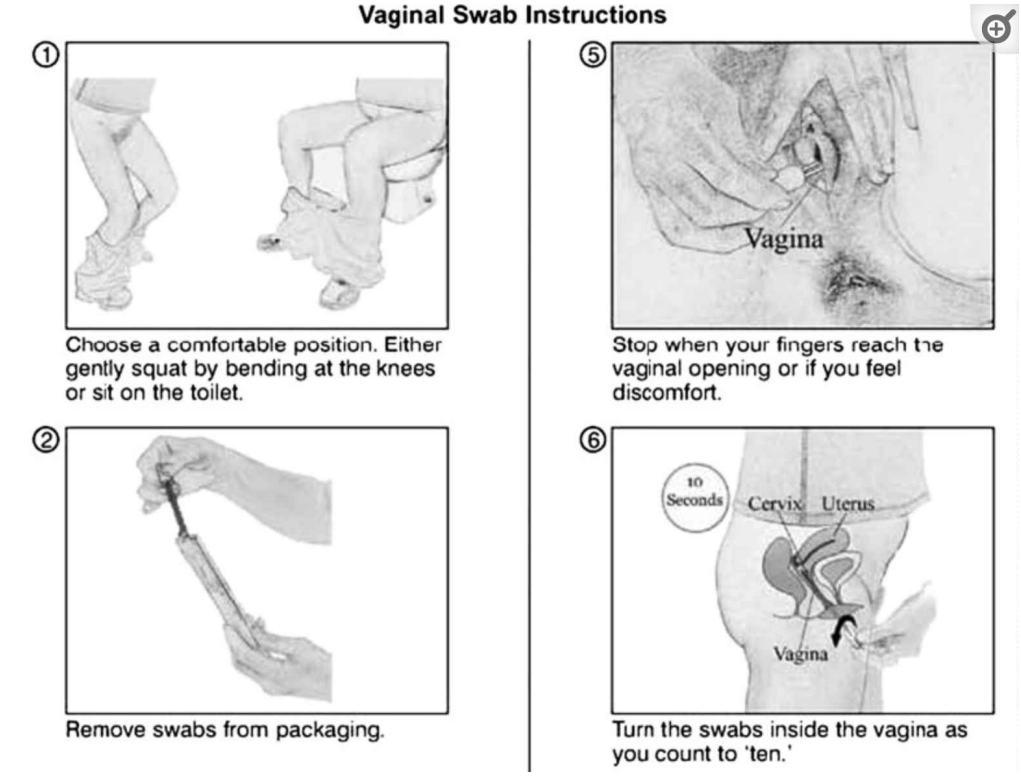
Present: Tatiana Predko

Goals: Research vaginal self-swab techniques to gauge purpose, benefits, and disadvantages of the vaginal self-swab process.

Content:

In a study analyzing the efficacy of vaginal self-swabs in the detection of GBS colonization in cases of late pregnancy, it was found that the accuracy of vaginal self-swabbing was relatively similar to swabs collected by medical professionals. This particular study included 2578 female participants, with the pooled sensitivity of self-swabs being 0.9, and a pooled specificity being 0.98 [1].

One study analyzed the efficacy of at-home vaginal self-swabbing for the detection of bacterial vaginosis (BV), vaginal candidiasis (VC), high-risk human papilloma virus (HR-HPV), and cytological characteristics [2]. The demographic of this study were older women, aged 60 and older. It was found that using the vaginal self-swab method for each of the four factors studied yielded high specimen adequacy rates (they had useable samples) [2]. Another similar study proved self-swabbing to be as effective as provider-collected swabs in the diagnosis of BV, by having strong validity for morphotype-specific scores, as well as good reliability [5].



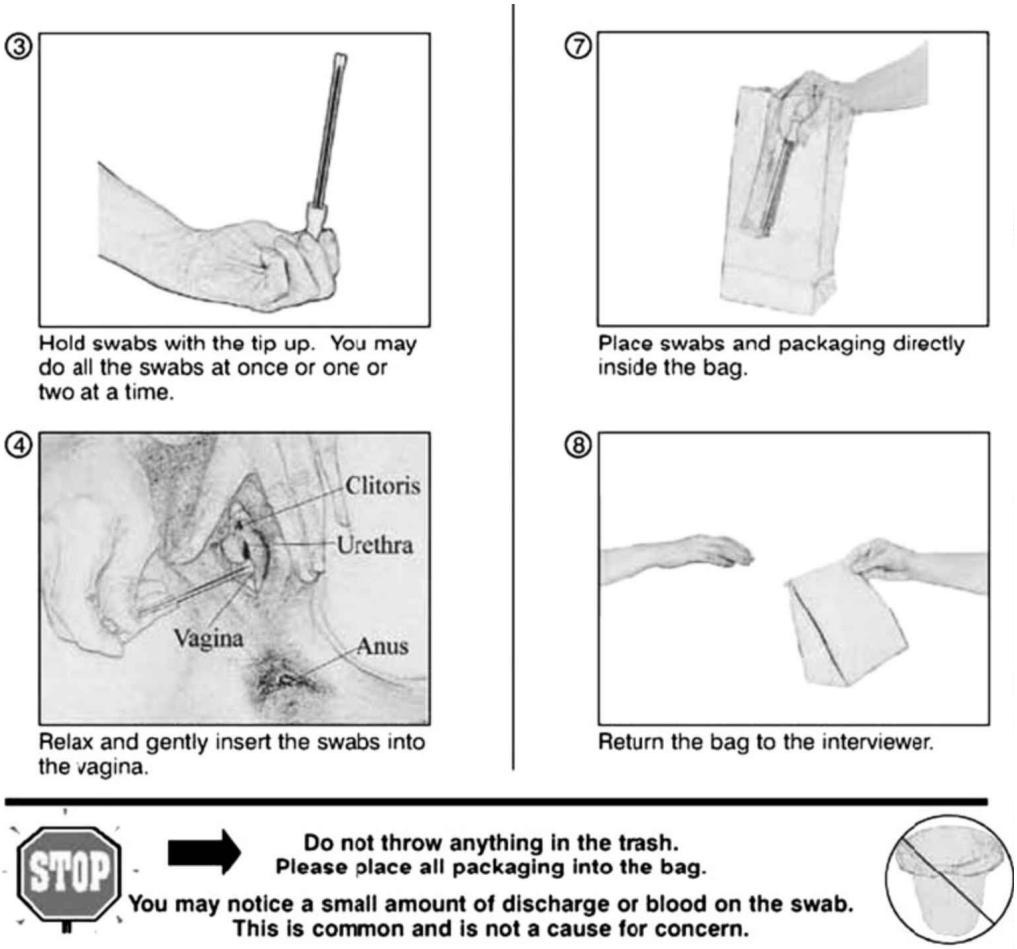


Fig. 1. Instructions for vaginal self-swab [2].

After following the vaginal self-swab instructions (Figure 1), the sample is then transferred to a tube containing transport medium [2]. Transportation of the samples requires cold-packs to preserve samples [2].

In another study, 20 women between the ages of 18-40 were selected as participants to determine whether self- or physician-collected vaginal swabs were more effective. It was found that both self- and physician-collected vaginal swabs had the same microbial diversity, making them equally as effective [4].

Depending on the transport medium used for a swab sample, the swab can either be stored at room temperature or frozen [4].

Resources:

[1] Odubamowo, K., Garcia, M., Muriithi, F., Ogollah, R., Daniels, J. P., & Walker, K. F. (2023). Self-collected versus health-care professional taken swab for identification of vaginal-rectal colonisation with group B streptococcus in late pregnancy: a systematic review. *European journal of obstetrics, gynecology, and reproductive biology*, *286*, 95–101. https://doi.org/10.1016/j.ejogrb.2023.05.027

[2] Lindau, S. T., Hoffmann, J. N., Lundeen, K., Jaszczak, A., McClintock, M. K., & Jordan, J. A. (2009). Vaginal self-swab specimen collection in a home-based survey of older women: methods and applications. *The journals of gerontology. Series B, Psychological sciences and social sciences*, *64 Suppl 1*(Suppl 1), i106–i118. https://doi.org/10.1093/geronb/gbn021

[4] Forney, L. J., Gajer, P., Williams, C. J., Schneider, G. M., Koenig, S. S., McCulle, S. L., Karlebach, S., Brotman, R. M., Davis, C. C., Ault, K., & Ravel, J. (2010). Comparison of self-collected and physician-collected vaginal swabs for microbiome analysis. *Journal of clinical microbiology*, *48*(5), 1741–1748. https://doi.org/10.1128/JCM.01710-09

[5] Nelson, D. B., Bellamy, S., Gray, T. S., & Nachamkin, I. (2003). Self-collected versus provider-collected vaginal swabs for the diagnosis of bacterial vaginosis: an assessment of validity and reliability. *Journal of clinical epidemiology*, *56*(9), 862–866. https://doi.org/10.1016/s0895-4356(03)00073-8

Conclusions/action items:

Following the analysis of four separate studies, it can be concluded that vaginal self-swabbing provides samples of similar quality to those obtained by a medical professional. This could be beneficial as self-swabs are typically more available and convenient than a professional swab, and could be implemented in point-of-care scenarios. Additionally, the medium used for the swab can be highly influential in the efficacy of the sample.

09/11/2024-Swabbing for Bacterial Vaginosis

Tatiana Predko - Sep 11, 2024, 10:02 PM CDT

Title: Bacterial Vaginosis

Date: 09/11/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Learn more about bacterial vaginosis: what it is, the affected demographic, and how it is treated.

Content:

- Bacterial vaginosis (BV) is a poly-microbial condition of the vaginal canal which is caused by an increase in the vaginal pH, alongside a disturbance in the vaginal microbiome (microbial disbiosis). BV is characterized by a thin, watery vaginal discharge which possesses a foul odor [2].

- BV is a common condition, affecting roughly 29% of women aged 14-19 within the United States [2]. In a particular study, it was found that those aged 20 and above had a BV prevalence of 28-31% [3].

- Among the younger population, BV is more likely to be prevalent in patients who douche, participate in sexual intercourse, and smoke cigarettes [2]. Additionally, studies have found that the risk of developing BV increases with the use of an IUD, as well as with antibiotic usage [3].

- BV is closely associated with other genital conditions and infections, such as: uterine lining infections, upper genital tract infections, urinary tract infections, infections due to gynecologic procedures, and sexually-obtained HIV [2].

- BV has been reported in 1/3 of women worldwide; it is extremely common [3].

- BV is typically treated via topical or oral antibiotics [3].

- The bacteria responsible for BV can be detected via vaginal swab contained within culture media [3].

- Molecular tools (such as vaginal swabbing) typically offer higher sensitivity and accuracy for the diagnosis of BV than microscopy methods; this is due to the poly-microbial nature of Bacterial vaginosis [3].

[2] Lindau, S. T., Hoffmann, J. N., Lundeen, K., Jaszczak, A., McClintock, M. K., & Jordan, J. A. (2009). Vaginal self-swab specimen collection in a home-based survey of older women: methods and applications. *The journals of gerontology. Series B, Psychological sciences and social sciences*, *64 Suppl 1*(Suppl 1), i106–i118. https://doi.org/10.1093/geronb/gbn021

[3] Joseph, R. J., Ser, H. L., Kuai, Y. H., Tan, L. T., Arasoo, V. J. T., Letchumanan, V., Wang, L., Pusparajah, P., Goh, B. H., Ab Mutalib, N. S., Chan, K. G., & Lee, L. H. (2021). Finding a Balance in the Vaginal Microbiome: How Do We Treat and Prevent the Occurrence of Bacterial Vaginosis?. *Antibiotics (Basel, Switzerland)*, *10*(6), 719. https://doi.org/10.3390/antibiotics10060719

Conclusions/action items:

Bacterial vaginosis (BV) is a common condition affecting 1/3 of women worldwide [3]. This condition can cause discomfort to the person suffering from it, as it is closely associated with conditions such as other genital and urinary infections. Vaginal self-swabbing can be an effective tool in the detection of BV. This is mainly due to the poly-microbial nature of BV, which makes molecular detection methods more accurate than traditional microscopy methods [3].

10/09/2024-Materials

Tatiana Predko - Oct 09, 2024, 10:06 PM CDT

Title: Materials to be Used for the Self-Swab

Date: 10/09/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Determine possible materials to be used for the handle portion of the self-swab with regard to the design criteria.

Content:

Polylactic Acid (PLA):

- PLA is a biodegradable polyester, often used in circumstances that require eco-friendly materials [7].

- One downside of PLA is that it does not degrade to a sufficient extent under natural circumstances. To mitigate this issue, could potentially utilize enzymes (produced by enzyme-secreting microorganisms) to accelerate the degradation process [7].

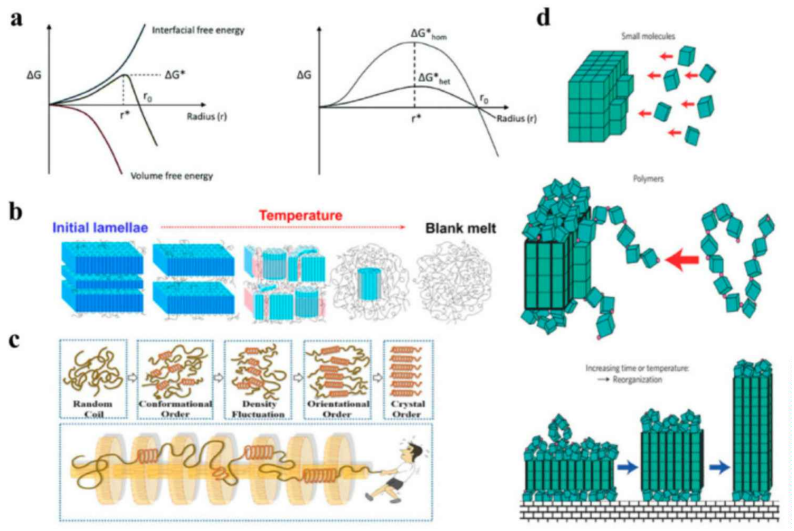


Fig. 2. Image of PLA properties in response to different variables [8].

- PLA is a good material to be used for 3D printing, due to its low Tg and shape-memory [8].

- According to one study, it was found that PLA is highly temperature-sensitive, making it unsuitable for autoclave-based sterilization processes [9]. Too high of temperatures (induced via autoclave) could lead to deformation of the device [9].

Polycarbonate (PC):

- According to one study on the use of PC for intraocular lenses, PC is able to withstand autoclave-based sterilization [10].

- PC has low toxicity and is biodegradable [11].

References:

[7] Shalem, A., Yehezkeli, O., & Fishman, A. (2024). Enzymatic degradation of polylactic acid (PLA). *Applied microbiology and biotechnology*, *108*(1), 413. https://doi.org/10.1007/s00253-024-13212-4

[8] Zhou, Y., Chen, J., Liu, X., & Xu, J. (2023). Three/Four-Dimensional Printed PLA Nano/Microstructures: Crystallization Principles and Practical Applications. *International journal of molecular sciences*, *24*(18), 13691. https://doi.org/10.3390/ijms241813691

[9] Ferràs-Tarragó, J., Sabalza-Baztán, O., Sahuquillo-Arce, J. M., Angulo-Sánchez, M. Á., De-La-Calva Ceinos, C., Amaya-Valero, J. V., & Baixauli-García, F. (2022). Autoclave sterilization of an in-house 3D-printed polylactic acid piece: biological safety and heat-induced deformation. *European journal of trauma and emergency surgery : official publication of the European Trauma Society*, *48*(5), 3901–3910. https://doi.org/10.1007/s00068-021-01672-6

[10] Yalon, M., Goldberg, E. P., Osborn, D., Stacholy, J., & Sheets, J. W. (1988). Polycarbonate intraocular lenses. *Journal of cataract and refractive surgery*, *14*(4), 393–395. https://doi.org/10.1016/s0886-3350(88)80145-7

[11] Y Yuen, A., Porcarelli, L., H Aguirresarobe, R., Sanchez-Sanchez, A., Del Agua, I., Ismailov, U., G Malliaras, G., Mecerreyes, D., Ismailova, E., & Sardon, H. (2018). Biodegradable Polycarbonate Iongels for Electrophysiology Measurements. *Polymers*, *10*(9), 989. https://doi.org/10.3390/polym10090989

Conclusions/action items:

- PLA is a potential material to be used in the production of the "handle" component of the device, as the client requested for the material to be biodegradable, which is a property of PLA. Depending on the intended shelf-life of the device, could incorporate enzymes to accelerate degradation process [7].

- Although PLA has good mechanical and biodegradable properties, as requested by the client, the material is highly temperature-sensitive, making it unsuitable for autoclaving [9]. This is possibly a major downside, as it is necessary for the device used in this project to be sterile.

- PC is a great contender when it comes to materials to be used for the fabrication of the handle component of the device. This is due to the fact that PC is biodegradable, which meets the client's request [11]. It is also resistant to autoclave temperatures, making it easily-sterilizable for use in a clinical setting [10]. Additionally, due to its high temperature resistance, it has low risk of deformity following 3D printing.

11/08/2024-Testing for Bacterial Contamination

Tatiana Predko - Nov 08, 2024, 12:24 PM CST

Title: Research on Bacterial Contamination Testing

Date: 11/08/2024

Content by: Tatiana Predko

Present: N/A

Goals: Identify methods of testing for bacterial contamination of samples obtained via self-swab.

Content:

- One study found that smartphone apps are an effective method for quantifying bacterial colonies on agar plate; especially the app called 'CFU.Ai' [1].

- Can possibly use quantitative PCR (qPCR) to quantify bacteria, due to affordability, ease of use, and accuracy [2].

	CFU.Ai	Promega Colony Counter	APD Colony Counter App Pro	@BactLAB
Tested version	Version 1.4 on iOS	Version 1.5 on iOS	on iOS (august 2021)	Version 1.1.1 on Android
Available on	iOS	iOS, Android	iOS, Android	iOS, Android
Costs	free	free	2.99$	free
Time expenditure (1 = low, 3 = high)	1	1	3	2
User-friendliness (1 = simple, 3 = complex)	1	1	2	2
Import already captured images	yes	yes	yes	yes
Save analyzed images	no	yes	no	yes
Erase false-positive CFU manually, mark extra colonies as required	no	yes	yes	no
Accuracy	+app with overall best performance, particularly good on blood agar and LB	+overall, second best app, strength chrome and blood agar	- showed poor performance, often did not detect CFU correctly	- showed poor performance

Fig. 1. Table showing study results in analysis of colony-counting apps [1].

References:

[1] Moucka, M., Muigg, V., Schlotterbeck, A. K., Stöger, L., Gensch, A., Heller, S., & Egli, A. (2022). Performance of four bacterial cell counting apps for smartphones. *Journal of microbiological methods*, *199*, 106508. https://doi.org/10.1016/j.mimet.2022.106508

[2] Lima, A., França, A., Muzny, C. A., Taylor, C. M., & Cerca, N. (2022). DNA extraction leads to bias in bacterial quantification by qPCR. *Applied microbiology and biotechnology*, *106*(24), 7993–8006. https://doi.org/10.1007/s00253-022-12276-4

Conclusions/action items:

- For testing of vaginal self-swab efficacy in reducing exogenous cross-contamination, subjects can go through steps of using the device (without vaginal swabbing), using both Hologic Aptima and Tilt-and-Break. Then, swab the sample onto agar plate and allow bacteria to proliferate. Finally, a colony-counting app (possibly CFU.Ai or Promega Colony Counter) can be used to count colonies present on agar plate. If there are less bacterial colonies from samples obtained using Tilt-and-Break, then it can be concluded that it is effective at reducing cross-contamination.

12/01/2024-Agar Streaking

Tatiana Predko - Dec 01, 2024, 9:25 PM CST

Title: Agar Streaking Protocol Research

Date: 12/01/2024

Content by: Tatiana Predko

Present: N/A

Goals: Collect research through literature to identify proper agar streaking and storage techniques, along with optimal temperatures necessary for evident bacterial proliferation.

Content:

- According to an article on basic bacteriological routines, streaking onto agar plates is a technique used to isolate individual colonies; typically, each individual colony present on an agar plate is resultant of one specific bacterial strain, and can be an effective indicator of bacterial contaminants [1].

- In one study, it was found that, when rich LB medium was used, a colony consisting of *Salmonella* contained approximately 5 x 10^8 cells following a 24-hour incubation period of 37°C [1].

- Another study found *Paenibacillus piri* bacterium to proliferate the most in conditions of 28°C [3].

- One study looked at bacteria present on a variety of kitchen surfaces, and found that kitchen countertops commonly had the following phyla of bacteria: *Actinobacteria, Bacteriodetes, Firmicutes,* and *Proteobacteria* [2].

- In order to prevent condensation within the agar plates, they must be incubated upside-down [4]. Condensation can result in dehydration of the agar, as well as cross-contamination from other microbes [4].

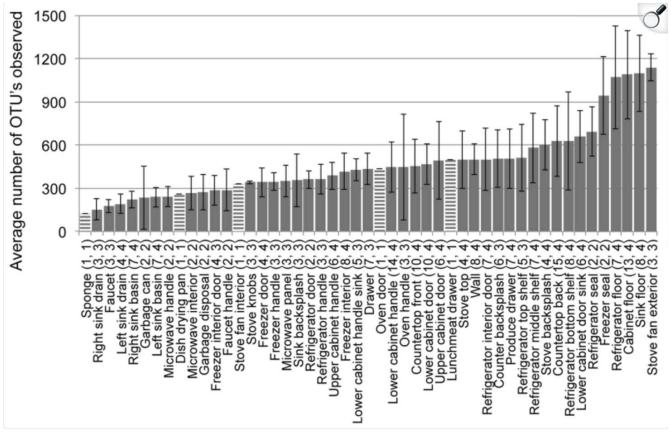


Fig. 1. Figure depicting average number of OTUs observed for a variety of kitchen surfaces [2].

References:

[1] N. Figueroa-Bossi, R. Balbontín, and L. Bossi, “Basic Bacteriological Routines,” *Cold Spring Harbor Protocols*, vol. 2022, no. 10, p. pdb.prot107849, Aug. 2022, doi: https://doi.org/10.1101/pdb.prot107849.

[2] G. E. Flores *et al.*, “Diversity, distribution and sources of bacteria in residential kitchens,” *Environmental Microbiology*, vol. 15, no. 2, pp. 588–596, Nov. 2012, doi: https://doi.org/10.1111/1462-2920.12036.

[3] Ngoc Hoang Trinh and J. Kim, “Paenibacillus piri sp. nov., isolated from urban soil,” *International journal of systematic and evolutionary microbiology*, vol. 70, no. 1, pp. 656–661, Jan. 2020, doi: https://doi.org/10.1099/ijsem.0.003811.

[4] “Why Petri dishes Inverted During Incubation? : Pharmaguideline,” *www.pharmaguideline.com*. https://www.pharmaguideline.com/2015/09/incubation-of-petri-dishes-in-inverted-position.html#google_vignette

Conclusions/action items:

Alter the agar streaking protocol to be set to 32°C; additionally, store the agar plates upside-down in the incubator to prevent dehydration and cross-contamination.

09/16/2024-Hologic Aptima

Tatiana Predko - Oct 09, 2024, 9:37 PM CDT

Title: 'Aptima Multitest Swab' by Hologic

Date: 09/16/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Determine current competing designs to the vaginal self-swab.

Content:

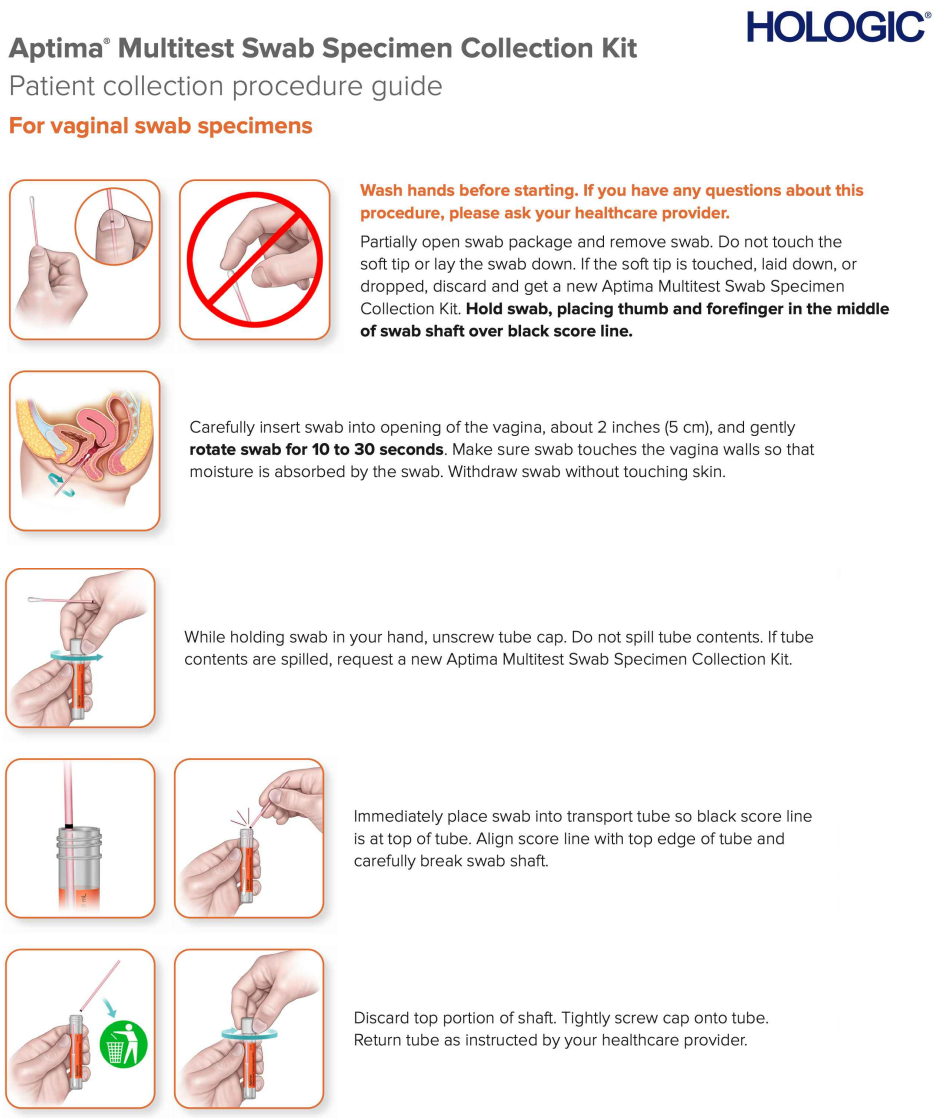


Fig. 1. 'Aptima Multitest Swab' by Hologic instructions for use.

The 'Aptima Multitest Swab' by Hologic consists of two components: the swab and the media-containing tube [6]. To use the device, the user must swab their vaginal canal, then open the media tube, break the swab into the media tube, and seal the tube (Figure 1).

[6] “Aptima® Multitest Swab | Hologic,” *www.hologic.com*. https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab

Conclusions/action items:

- This device poses a risk for exogenous contamination of the bacterial sample, possibly during the time period in which the patient has to open the container while holding the swab.

- Designing a device which can either conceal the swab immediately after swabbing, or one in which the swab can be "stood" on its end while the user handles the media container could be more efficient and reduce the risk of exogenous contamination.

09/11/2024-Lecture 1

Tatiana Predko - Oct 09, 2024, 10:11 PM CDT

Title: Lecture 1

Date: 09/11/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Determine methods to prepare for a career within biomedical engineering.

Content:

Prior to career fair:

- Use Handshake, LinkedIn, and Indeed.

- Connect with people prior to attendance.

- Apply and make sure to follow-up; use proper communication etiquette.

Resume:

- Adjust the resume to "fit" the position more.

- Well-rounded experiences

- Include design projects (do not include the year or semester in which the project was complete), technical skills, and coursework.

Conclusions/action items:

- Prepare/refine resume and attend career fair.

09/18/2024-Lecture 2

Tatiana Predko - Sep 18, 2024, 2:02 PM CDT

Title: Lecture 2 (Exploring Leadership Style)

Date: 09/18/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Determine how to develop own leadership style.

Content:

Important qualities of a leader:

a) self-awareness

b) vision

c) transparency

d) communication

e) decision-making

f) empathy

Leadership styles:

1. Power Model:

- "someone has to take control, and it should be me"

- "great man theory"

- being in control is the most important thing

- hierarchy, authority, command

2. Servant:

- "it's not about me and my needs, the needs of my followers is most important"

- being of service to others

- sharing power

- listening and understanding

- empathetic, empowering, shared decision-making

3. Authentic:

- "by being my genuine self, I will gain and build trust"

- building self esteem and self-awareness

- emotional intelligence

- transparency, genuineness, honesty

People-oriented leader: holds team together; build relationships. Build trust and inclusivity.

Process-oriented: Sets pace for the team; get work done.

Thought-oriented: anticipate future; open to new ideas.

Impact-oriented: set bar high and push for excellent performance.

Leadership doesn't require a particular job title; leading others starts with leading yourself.

- Self-asses: determine motivations, strengths, and values.

- Observe and reflect: what tasks and experiences give you a sense of accomplishment? how do you get in your own way? where do you show up well?

- Seek feedback: others may be able to identify strengths and areas for growth you're not actively aware of.

Self goal:

This semester I aspire to stay organized and be reliable when it comes to schoolwork. Being organized and reliable is crucial for optimal productivity and a key element in leadership positions. Organization and time management will allow me to become a better leader. I will practice this skill by planning tasks ahead in my planner, and staying accountable by completing them as planned. Success looks like not procrastinating, and getting things done well before they are due.

Conclusions/action items:

Reflect on myself as a leader, asses my strengths and weaknesses, try to be a leader.

Set a goal for myself (self or team).

09/25/2024-Lecture 3

Tatiana Predko - Sep 25, 2024, 2:00 PM CDT

Title: BME 300 Lecture 3

Date: 09/25/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Cover post-graduation possibilities and advice for pursuing a career in the BME field.

Content:

- Have a diverse experience during your undergraduate years.

- Recommended to get 3 letter of recommendation

- Research is helpful for employment and pursuit of higher education

- Network via LinkedIn and other opportunities

- Higher education such as a master's or doctorate degree can qualify you for more positions; looks better on resume, more experience and skills.

- UW offers accelerated 1 year MS.

- Automatic admission into biomedical innovation, design, and entrepreneurship program if you have a GPA of 3.0 and above; project-based program, takes 1 year to complete.

- Can get a master's in other areas (e.g. MBA, engineering management, other engineering, etc.).

Conclusions/action items:

Look into research and co-op opportunities and update LinkedIn profile.

10/02/2024-Lecture 4

Tatiana Predko - Oct 02, 2024, 2:09 PM CDT

Title: Lecture 4

Date: 10/02/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Discuss BME mentoring purpose and methods.

Content:

Mentoring of BME 200 students provides:

- additional instructional and emotional support

- peer mentors are more approachable, more willing to ask questions

- share experiences

- increases belonging

- mutual benefits (transferable skills: leadership, communication, active listening, study practices, self-awareness, interpersonal skills).

*talk about mentoring experiences at interviews.

- increased self-esteem and confidence

- increased patience

- build positive habits

- foster personal growth identify gaps in own knowledge

- identify gaps in own knowledge

- sense of accomplishment

"Good" mentor traits:

- building trust

- psychological safety (share w/o fear)

- reliability

- support/enthusiasm

- availability

- transparency

- humanizing their challenges; be their coach

- good listening (get rid of distractions, stop talking, act like you're interested, look at the other person, get the main idea, ask questions, check for understanding, react to ideas, not to the person, avoid hasty judgements)

What do you wish you knew in BME 200?:

- You can check the schedule for due dates, and an outline of the project timeline.

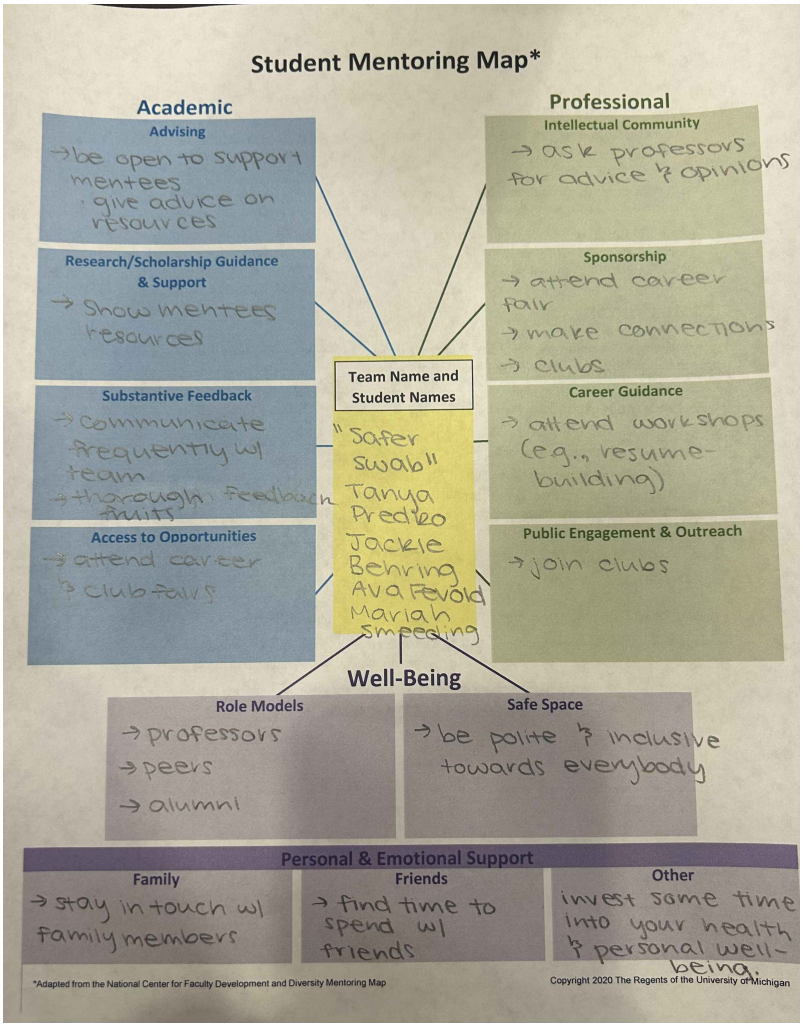
- Try to have things done ahead of time, and meet with the group to go over everything well before the deadline to avoid unexpected conflicts.

- Communicate with the group multiple times per week to ensure everybody is on the same page.

- If you have a conflict or cannot attend to your responsibilities, let your group know in advance.

- Frequently update LabArchives.

Mentor Map:



Conclusions/action items:

1. Integrate good mentoring practices into BME 300 project.

2. Next week, choose a few things from action plan and focus on working on it.

10/09/2024-Lecture 5

Tatiana Predko - Oct 09, 2024, 2:08 PM CDT

Title: Lecture 5

Date: 10/09/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Learn more about the field of environmental engineering.

Content:

components include:

- resources

- processing

- manufacturing

- distribution

- use

- end of life: discarding of product/material.

Conclusions/action items:

Consider the role of environmental engineering within BME 300 project. How does the vaginal self-swab affect the environment? which materials can be used to promote a healthy environment (environmentally-friendly)?

10/16/2024-Lecture 6

Tatiana Predko - Oct 16, 2024, 2:02 PM CDT

Title: Lecture 6

Date: 10/16/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Listen to and take notes on lecture about WARF, IP, disclosing, and licensing.

Content:

WARF:

- enable UW-Madison research

- provide financial support, manage assets, move innovations to marketplace for financial return and global impact (patenting).

- non-profit

Technology Transfer:

- moving research from campus out into market

- WARF works at this interface to facilitate and secure IP rights and commercial licenses

- ex. intellectual property licenses, industry sponsored research, consulting arrangements, fee for service.

4 Common Types of IP:

1. patents: property right, granted by a governmental agency (varies by country, no global patent)

- patent holder has right to exclude others from making, using, selling, or importing the claimed invention.

- detailed description of invention, can be easily replicated by others, but others cannot replicate it for a particular period.

- 3 types of US patents: design (15-year term, limited to ornamental features), plant (20-years, asexually-reproducing, non-tuber), utility (issued for invention of new and useful process, machine, manufacture, or composition of matter).

- utility patents often take 2-5 years to issue after filing; costs $30K on average (mostly attorney fees).

2. copyrights (protection for creative works expressed in a tangible medium; includes software code)

3. trademarks (protection for names, marks, logos, dress, etc; required use in commerce, source-identifying function)

4. trade secrets (can be used to protect anything of value; protection is good so long as the concept is not generally known)

Other, WARF IP:

- biomaterials

- technique and know how (similar to trade secrets)

- data

Patent Requirements:

- eligible: cannot be a product of nature, abstract idea, or natural phenomenon

- novel: must be new

- non-obvious: cannot be simple modification or combination of existing concepts

- enabled and described: must provide enough detail to teach others how to make or use invention

Disclosing an Innovation to WARF:

a) disclosing

- describe innovation

- identify advantages and potential applications

- name contributors

- provide funding and public disclosure details

b) meeting with WARF

- discuss the innovation in more detail

- ask questions about WARF and patenting process

- discuss next steps

c) IP considerations

- type of IP protection - potential breadth and strength of IP protection

- public disclosure

- stage of development

d) licensing considerations

- applications

- likelihood of identifying a commercial partner

- likely return from licensing

Marketing and Licesing:

a) market analysis

- market status: established, emerging, new.

- size and type: large and growing, medium and contracting, etc.

- potential licenses: companies in the market

b) license negotiation

- type and terms: exclusive and field limited, sub licensing, etc.

- consideration: upfront payment, royalties, reimbursement

c) ongoing

- technology development, enforcement, amendment, termination

Conclusions/action items:

- Schedule a meeting with the laboratory managers and look into patenting process for this semester's project.

- Possibly fill out WARF form on website (only takes 15 minutes, on average).

10/23/2024-Lecture 7

Tatiana Predko - Oct 23, 2024, 2:03 PM CDT

Title: Lecture 7

Date: 10/23/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Learn more about human research subjects and IRB (institutional review board).

Content:

IRB:

- conducts ethical and regulatory review of research involving human participants.

- formed due to unethical research and unethical principles (e.g., Nazi prisoner experiments, hepatitis studies, shock experiments, syphilis studies).

- instituted by Common Rule and FDA regulations

- review research studies to ensure they meet regulatory and ethical standards.

Regulations for protection of human subjects:

- Department of Health and Human Services (DHHS), aka 'Common Rule'

- FDA

Belmont Principles: respect for persons, beneficence, and justice.

UW-Madison IRBs:

1. Minimal Risk Research IRB (MRR IRB):

- biomedical, education, and social.behavioral sciences research

- secondary data analysis, survey research, behavioral health interventions, and evaluations of educational practice.

2. Health Sciences IRB (HS IRB)

- biomedical, interventional, any risk level.

- all FDA regulated and VA regulated research.

* serve UW-Madison, UW-Health affiliates, and Madison VA Hospital.

* may 'cede' oversight to other institutions or independent IRBs.

Does my project need an IRB?:

- *Is it research under the Common Rule?* research means a **systematic** investigation, including research development, testing, and evaluation; **designed** to develop or contribute to **generalizable** knowledge.

- *Does it involve human subjects (Common Rule)?* human subject means a living individual about whom an investigator is conducting research; obtains information or bio specimens through intervention or interaction, or obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

- *Is it human research under FDA device regulations?*

device: intended for use in diagnosis, treatment, or prevention of disease; or that affects structure or function of the body.

research/clinical investigation: involves one or more subjects to determine device safety or effectiveness.

subject: individual on whom or on whose specimen an investigational device is used or as a control in an investigation.

Preparing for IRB review:

- Complete required training for researchers through CITI.

- Complete annual Outside Activities Reports.

- Identify appropriate principal investigator and study team

- collect preliminary (non-human) data and background info

- develop research question and steps to answer it

- if evaluating efficacy or safety, consult UW's FDA Regulated Research Oversight Program

- consider research participants

What IRB application type will you need?

- all use UW-Madison's electronic submission system: **ARROW**

a) PBA:

- protocol document

- informed consent forms

- recruitment tools, screening scripts

- written assessments

b) nPBA:

Conclusions/action items:

- For testing of the self-swab, might need an IRB, since interacting with people (asking them to perform tasks to quantify usability and swab-breaking accuracy).

- Ask Professor Randolph Ashton whether or not our testing is subject to an IRB.

10/30/2024-Lecture 8

Tatiana Predko - Oct 30, 2024, 2:09 PM CDT

Title: Lecture 8

Date: 10/30/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Learn more about FDA device requirements.

Content:

Defining a Medical Device

- anything that is intended to improve health or that affects structure/function of the body that is NOT a drug or biologic.

- e.g., MRI, drug infusers, monitoring systems, bandages, syringes, stethoscope, etc.

- non-traditional medical devices examples: laboratory-developed tests, health-related applications and software, medical mobile apps (ECG), mouthwash, etc.

Software as a Medical Device (SaMD): has its own status, regulation, and product code. Software intended for one or more uses that may run on different iterating systems or in virtual environments.

Device Classification

1. Class 1

- low risk, mostly exempt from pre-market approval and Quality System (QS) requirements.

- must follow certain general controls: labeling, record retention, and complaint files.

- approval process is self-registration and listing with the FDA.

- ex. band-aids, floss, tongue depressor, etc.

2. Class 2

- moderate risk, 510(k) showing substantial equivalence.

- must follow general and specific controls, which can include performance standards, post-marker surveillance, and specific labelling requirements.

- approval process is submission of 510(k) application to show substantial equivalence; may be exempt.

- ex. blood pressure cuffs, sutures, catheters, etc.

3. Class 3

- highest risk (sustain or support life, implanted, or potential for unreasonable risk), pre-market approval.

- must follow general controls and additional stringent requirements, such as clinical trials to demonstrate safety and efficacy.

- approval process is PMA submission, which involves comprehensive FDA review of safety and effectiveness data before marketing.

- ex. hip joint, replacement heart valve, implantable pacemaker, etc.

Regulatory Controls Key Elements

- Pre-market approval: data to show safety and effectiveness.

- General controls: automatically apply to every device; registration and listing, adverse event reporting, general labeling, and good manufacturing practice.

- Special controls: performance standards, special labeling requirements, post-market surveillance, and potential data requirements. Typically applied to Class 2 devices.

Market Submission Types

- 510(k) Exempt: registration and listing only.

- 510(k)-Premarket Notification: substantial evidence.

- PMA-Premarket Approval: full safety and effectiveness submission, manufacturing details.

- De Novo Classification: novel medical devices, no legally marketed predicate.

Conclusions/action items: Determine which classification our self-swab device falls under, and if FDA approval is needed for marketing purposes.

11/06/2024-Lecture 9

Tatiana Predko - Nov 06, 2024, 1:58 PM CST

Title: Lecture 9

Date: 11/06/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Learn more about FDA regulations for therapeutic product development.

Content:

FDA components - therapeutics:

- device (CDRH)

- drug (CDER)

- biologic (CBER)

genome editing: targeting a precise genome to delete, insert, or alter existing sequence

gene delivery: transfer of molecular tools and gene systems into cell

cell therapy: using expanded cells to regenerate damaged tissue

Target Product Profile (TPP): when, why, and how to use a product.

- patient identification

- patient benefits

- patient risks

- marketability (medical and commercial)

Conclusions/action items: Determine whether the self-swab device is compatible with FDA regulations.

11/13/2024-Lecture 10

Tatiana Predko - Nov 13, 2024, 2:07 PM CST

Title: Lecture 10

Date: 11/13/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Learn more about medical device development.

Content:

Development of Medical Device Components and Considerations:

- innovation and development of idea

- human testing and data acquisition - with IRB oversight (depending on circumstances)

- FDA regulation

- reimbursement or financial incentive

- sales and marketing

Breakthrough Devices Program:

- aka "expedited access program"

- purpose is to speed up development, assessment, and review of medical device; provide quick access to medical devices for life-threatening or irreversibly-debilitating diseases and conditions.

Steps of Medical Device Development:

1. clinical studies

2. FDA approval

3. CPT codes

4. CMS National Insurance decisions

5. standards of practices

6. national and regional buying groups

7. regional or local IDNs and hospitals

8. hospital or IDN value analytics groups

9. product evaluations

10. regional distribution (or "just-in-time")

11. product implementation

Economic Factors:

- money, staff time, resources, waste, and metrics.

Clinical Factors:

- improve outcomes, reduce risk, reduce complications, shorten length of hospital stay, resolve issues.

Mission Impact: patient satisfaction, academic leadership, and innovation in care.

Who buys, pays, and gets reimbursed?

- CMS (centers for medicare and Medicaid services), DRG (diagnostic-related groups), CPT (current procedural code), ICD 10 (international categorization of diseases), GPO (group-purchasing organization), IDN (integrated delivery networks), and Payer Mix (private, captivated, and Medicare).

Conclusions/action items:

- Apply medical device development steps in self-swab development, use as a general outline for next steps to be taken; especially if considering patent.

11/15/2024-Tong Lecture

Tatiana Predko - Nov 15, 2024, 1:11 PM CST

Title: Tong Lecture

Date: 11/15/2024

Content by: Tatiana Predko

Present: N/A

Goals: Learn more about entrepreneurship.

Content:

- Created a blood drawing device which is more convenient; can draw blood from home. However, don't have business knowledge to turn this into reality.

- Focused on affordable methods to market their product.

Timeline of business:

1. prototypes, grants, and innovation ideas.

2. growing the business; networking, marketing product.

3. FDA regulation.

Conclusions/action items:

- As long as you put in the effort, it is possible to achieve most goals.

09/25/2024-"Tilt-and-Break"

Tatiana Predko - Sep 26, 2024, 12:18 AM CDT

Title: Design Concept-"Tilt-and-Break"

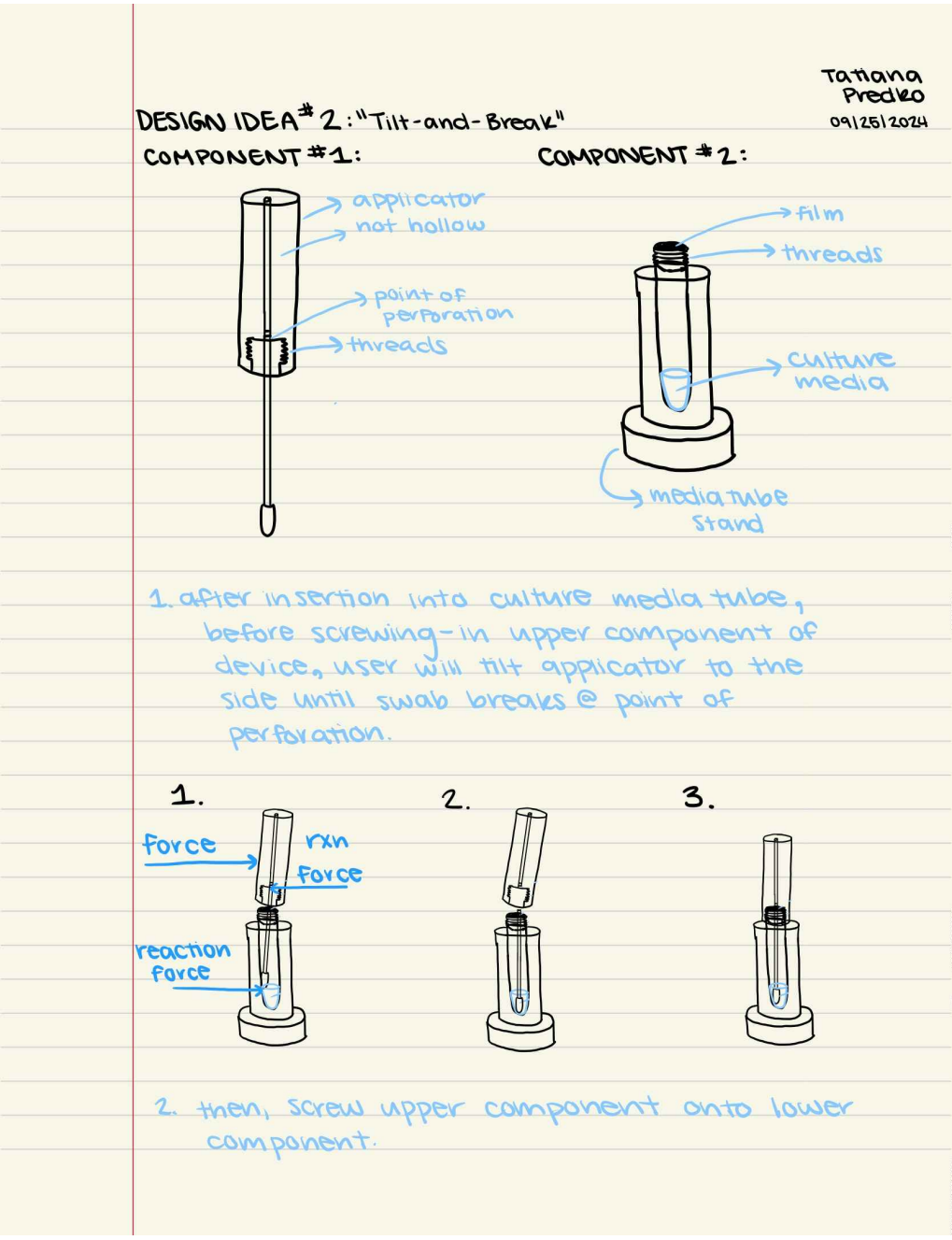
Date: 09/25/2024

Content by: Tatiana Predko

Present: Tatiana Predko

Goals: Determine a possible design to be used in the design matrix.

Content:



Conclusions/action items:

- The "Tilt-and-Break" design consists of two primary components: the applicator and the media tube stand.

- To use the device, following collection of a specimen and prior to screwing the applicator component onto the stand component, the patient must insert the swab into the tube. Then, while keeping the end of the swab in the tube, the patient must tilt the applicator to either side, until the swab breaks at the point of perforation. Finally, the user can screw the top component to the bottom component and the sample can be collected by a clinician.

09/22/24 - Efficacy of Vaginal Self Swabs

MARIAH SMEEDING - Oct 09, 2024, 12:28 PM CDT

Title: Effectiveness of Vaginal Self-sampling for Infection and Bacterial Vaginosis.

Date: 09/22/2024

Content by: Mariah Smeeding

Present: Mariah Smeeding

Goals: Research how effective self-sampling is versus going to a clinician. Understand the disadvantages of the vaginal self-swab process.

Content:

- *"Self-collected vaginal swabs (SCVS) appear to be more sensitive for diagnosing chlamydia and gonorrhea than health-professional–collected endocervical swabs and first-catch urine (FCU) are. Endocervical swabs and FCU testing might miss up to 10% of sexually transmitted infections in women. When pelvic examination is not required, SCVS is recommended in women."*

- **"**Vaginal swab specimens allowed sensitive and specific detection of Chlamydia trachomatis and Neisseria gonorrhoeae in the APTIMA assays. Vaginal swabs identified as many infected patients as endocervical swabs and more than FCUs, and may well be the specimen of choice for screening" [3].

- *Women are more likely to get screened if they have a choice of a vaginal self-swab because it is a quicker and non-invasive process compared to a clinician collected sample [2]. "[...]*offering self-collection of specimens at home or in other non-clinical settings could be used as an additional strategy to increase sexually transmitted infection testing in countries that have not yet widely adopted this collection method" [2].

- Vaginal self-swabs and clinician collected vaginal swabs were collected by a group of women to see if either test was inferior.
  - Both swabs were treated the same way: routine microbiology analysis was performed: BV was defined by a Nugent score equal or superior to 7, and yeast infection was defined by yeast growth on nutrient agar media
  - The test results showed excellent agreement between both tests.

Resources:

[1] claire camus, sabine camiade, and melissa lebsir, “Acceptability and efficacy of vaginal self-sampling for genital infection and bacterial vaginosis: A cross-sectional study,” *November 18, 2021*, doi: 10.1371/journal.pone.0260021. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8601421/

[2] L. Fajardo-Bernal, P. Vigil, E. Angel-Muller, C. Rincon, and N. Low, “Home-based versus clinic-based specimen collection in the management of Chlamydia trachomatis and Neisseria gonorrhoeae infections,” Sep. 2015, doi: 10.1002/14651858.CD011317.pub2. Available: https://pubmed.ncbi.nlm.nih.gov/26418128/

[2] J. Schachter, D. Willis E., P. Fine M., D. Fuller, W. Janda, and J. Jordan A., “Vaginal swabs are the specimens of choice when screening for Chlamydia trachomatis and Neisseria gonorrhoeae: results from a multicenter evaluation of the APTIMA assays for both infections,” Dec. 2005, doi: 10.1097/01.olq.0000190092.59482.96. Available: https://pubmed.ncbi.nlm.nih.gov/16314767/

Conclusions/action items:

Vaginal self-swabs are reported to be just as effective as clinician collected vaginal samples. They also reach a wider population.

09/22/24 - Tables of Efficacy of Vaginal Self Swab

MARIAH SMEEDING - Oct 09, 2024, 12:28 PM CDT

Title: Effectiveness of Vaginal Self-sampling for Infection and Bacterial Vaginosis.

Date: 09/22/2024

Content by: Mariah Smeeding

Present: Mariah Smeeding

Goals: Provide a visual aid of the comparison between Vaginal Self collected samples and clinician collected vaginal samples.

Contents: two tables depicting the process of collecting and testing the accuracy of Vaginal Self collected samples versus clinician collected samples.

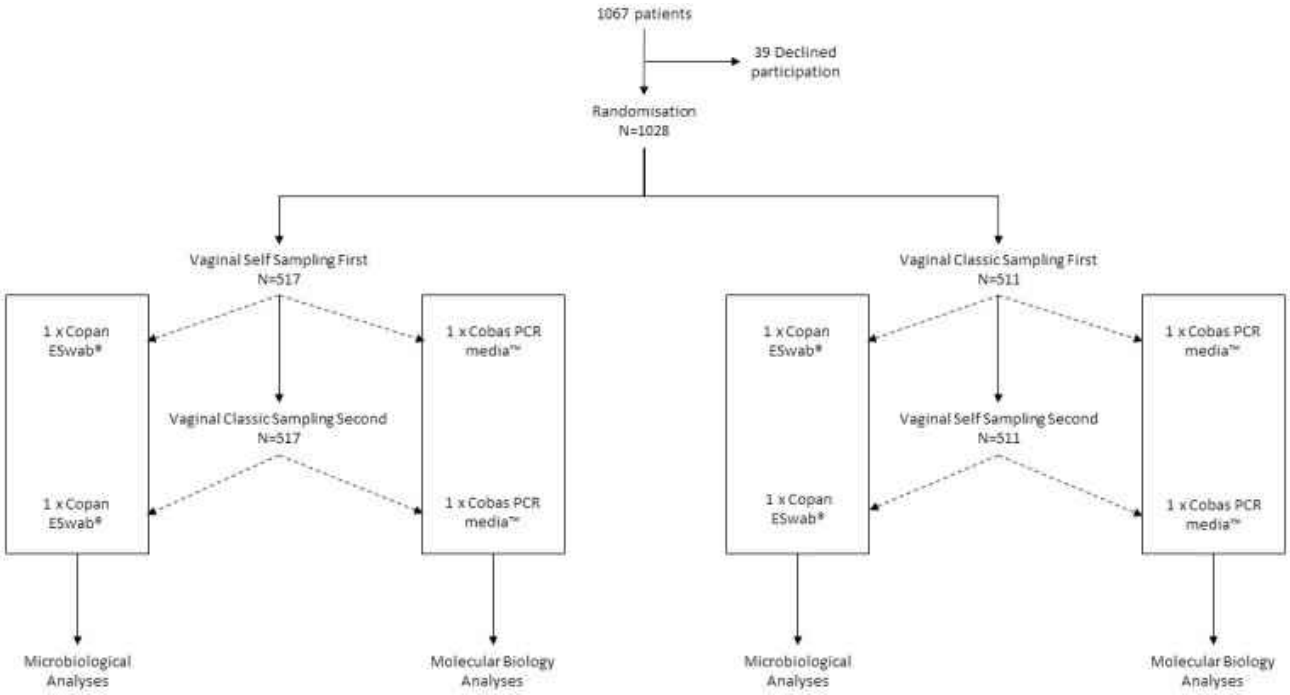


Table 2

Detection rates of GI, STI infection and GBS asymptomatic carriage, and non-inferiority test.

Sample type	Vaginal classic-sampling		Vaginal self-sampling		P-value (for non-inferiority of vaginal self-sampling)
	Positive N	% (95% CI)	Positive N	% (95% CI)	
GI	392	38.1 (35.2–41.1)	408	39.7 (36.7–42.7)	0.0016
Bacterial vaginosis	*105*	*10.7 (8.8–12.7)*	*104*	*10.6 (8.7–12.5)*	*0.0348*
Yeast infection	*304*	*29.6 (26.8–32.4)*	*322*	*31.3 (28.5–34.2)*	*0.0009*
STI	83	8.1 (6.4–9.7)	87	8.5 (6.8–10.2)	0.0087
Trichomonas vaginalis	*18*	*1.8 (1.0–2.6)*	*19*	*1.9 (1.0–2.7)*	*0.0217*
Chlamydia trachomatis	*33*	*3.2 (2.1–4.3)*	*34*	*3.3 (2.2–4.4)*	*0.0354*
Neisseria gonorrhoeae	*9*	*0.9 (0.3–1.4)*	*10*	*1.0 (0.4–1.6)*	*0.0140*
Mycoplasma genitalium	*14*	*1.4 (0.7–2.1)*	*14*	*1.4 (0.7–2.1)*	*0.0336*
Herpes simplex virus	*17*	*1.7 (0.9–2.4)*	*19*	*1.9 (1.0–2.7)*	*0.0120*
Group B streptococcus	118	11.5 (9.5–13.2)	138	13.4 (11.3–15.5)	0.0001
Group B streptococcus in pregnant women	*18*	*8.0 (4.5–11.6)*	*20*	*8.9 (5.2–12.7)*	*0.0010*

Resources:

[1] claire camus, sabine camiade, and melissa lebsir, “Acceptability and efficacy of vaginal self-sampling for genital infection and bacterial vaginosis: A cross-sectional study,” *November 18, 2021*, doi: 10.1371/journal.pone.0260021.
Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8601421/

Conclusions/action items:

Vaginal self-swabs are reported to be favorable and just as effective as clinician collected vaginal samples.

10/08/24 - preferred sampling method

MARIAH SMEEDING - Oct 09, 2024, 12:28 PM CDT

Title: The preferred sampling method for detecting chlamydia and Gonorrhea

Date: 10/08/2024

Content by: Mariah Smeeding

Present: Mariah Smeeding

Goals: Understand why Self Testing is preferred/ more accurate

Content:

Self-swabbing has been concluded to be more accurate than physician collected sampling.
"Self-collection of vulvovaginal swabs with nucleic acid amplification testing (NAAT) has excellent sensitivity in women with and without symptoms"[1].

The only reason sample collection from a physician may be preferrable is due to risk of contamination by the patient. It may be easier for a physican to be in the position to be more precise and sterile when taking the collection.
"Swabbing by health-care professionals could be expected to have easier access to the vagina and anus, be able to collect a sufficient sample of mucosal fluid from both vagina and lower rectum and be less prone to accidental contamination" [2]
However, many observational studies, such as the one sources below [1], have shown that taking self-samples is more accurate and acceptable by a wider population of women.

Citations:

[1] J. Schachter, D. Willis E., P. Fine M., D. Fuller, W. Janda, and J. Jordan A., “Vaginal swabs are the specimens of choice when screening for Chlamydia trachomatis and Neisseria gonorrhoeae: results from a multicenter evaluation of the APTIMA assays for both infections,” Dec. 2005, doi: 10.1097/01.olq.0000190092.59482.96. Available: https://pubmed.ncbi.nlm.nih.gov/16314767/

[2] K. Odubamowo, M. Garcia, F. Muriithi, R. Ogollah, J. P. Daniels, and K. F. Walker, “Self-collected versus health-care professional taken swab for identification of vaginal-rectal colonisation with group B streptococcus in late pregnancy: a systematic review,” *European Journal of Obstetrics & Gynecology and Reproductive Biology*, vol. 286, pp. 95–101, Jul. 2023, doi: 10.1016/j.ejogrb.2023.05.027. Available: https://www.sciencedirect.com/science/article/pii/S0301211523002178. [Accessed: Oct. 08, 2024]

[3] C. Page, A. Mounsey, and K. Rowland, “PURLs: Is self-swabbing for STIs a good idea?,” *J Fam Pract*, vol. 62, no. 11, pp. 651–653, Nov. 2013, Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3948498/. [Accessed: Oct. 08, 2024]

Conclusions/action items:

Self-Sampling is preferred due to increased accuracy and more appealing to a wider population of women [3].

10/31 - Contamination/TMA

MARIAH SMEEDING - Oct 31, 2024, 12:20 PM CDT

Title: The Contamination in question to prevent with TMA testing procedures.

Date: 10/31/24

Content by: Mariah Smeeding

Present: Mariah Smeeding

Goals: To identify the contaminants causing false positive test results from vaginal self-swabbing.

Content:

It is helpful to understand how the pathogens in the samples are detected because of how sensitive the process is. Transcription mediated amplification, TMA, is what is used instead of PCR, what we initially thought.

The process of TMA:
Three main steps include: target capture, transcription, and amplification.
- step one : target RNA or DNA is captured by a specific capture probe that is complementary to the target sequence.

-step two : captured target is converted into multiple copies of RNA by transereve transcriptase enzyme. The reverse transcriptase synthesizes a complementary DNA (cDNA) strand using the captured target as a template. The cDNA strand is then used as a template for RNA synthesis by RNA polymerase enzyme.

-step three : Amplified RNA is detected using a labeled probe that is specific to the RNA product.

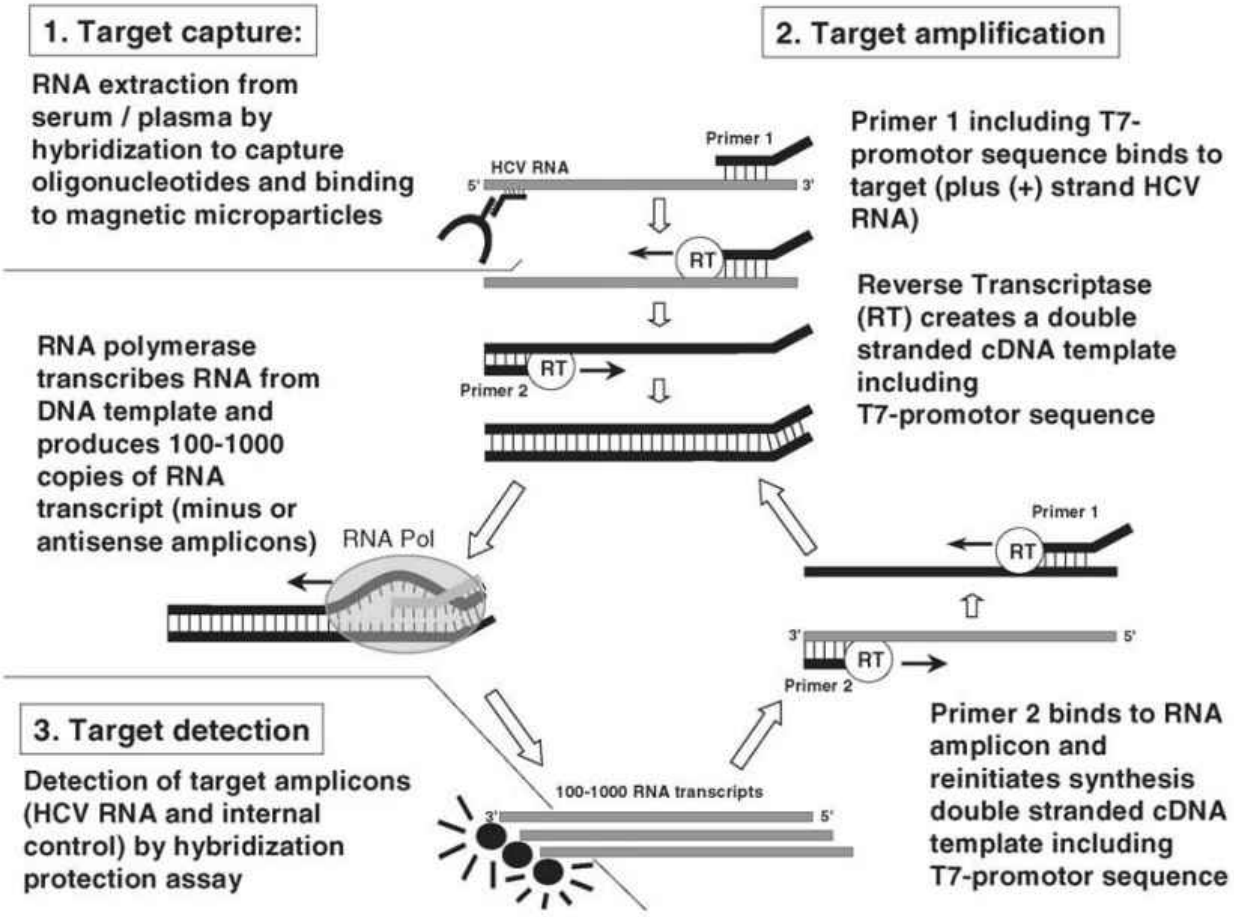


Fig. 1. Schematic illustration of TMA.

How it differs from PCR:

- Amplification method: TMA amplifies RNA via a transcription step followed by amplification using reverse transcriptase and RNA polymerase, while PCR amplifies DNA using DNA polymerase.

- Reaction conditions: TMA amplifies RNA under isothermal conditions (i.e., constant temperature), while PCR requires a thermal cycler to cycle through different temperatures.

- Detection: TMA products can be detected visually by turbidity, colorimetry, or fluorescent dyes, while PCR products are typically detected using gel electrophoresis or by hybridization with probes.

- Sensitivity: TMA is more sensitive than PCR due to the high amplification efficiency and use of multiple primers and probes.

- Specificity: TMA is highly specific to the target RNA sequence, with a reduced risk of nonspecific amplification compared to PCR.

Citations:

[1] Notomi, T., Mori, Y., Tomita, N., & Kanda, H., “Comparison of PCR with Other Nucleic Acid Amplification Techniques,” *MyBioSource Learning Center*. Available: https://www.mybiosource.com/learn/comparison-of-pcr-with-other-nucleic-acid-amplification-techniques/. [Accessed: Oct. 31, 2024]

Conclusions/action items:

Due to TMA being so much more sensitive than PCR, contamination is much more likely. If a sample were to come in contact with other viral genomes present in the lab, than it is very possible it will detect it, and the result will be a positive test result sent to the patient who should have received a negative result. The spread of misinformation is concerning, as expected, and this is why self-swabbing of the vaginal canal must be done in office to limit the amount the patient has to handle the sampling device itself.

the contamination in question: viral genomes present in the external environment of the swab. Although it may sound unlikely for random viral genomes to come in contact with a sample, in a lab that tests for viral genomes in it not uncommon for surfaces to contain them.

10/03/2024 - Hologic Aptima

MARIAH SMEEDING - Oct 03, 2024, 12:44 PM CDT

Title: Hologic Aptima Self Swab Information

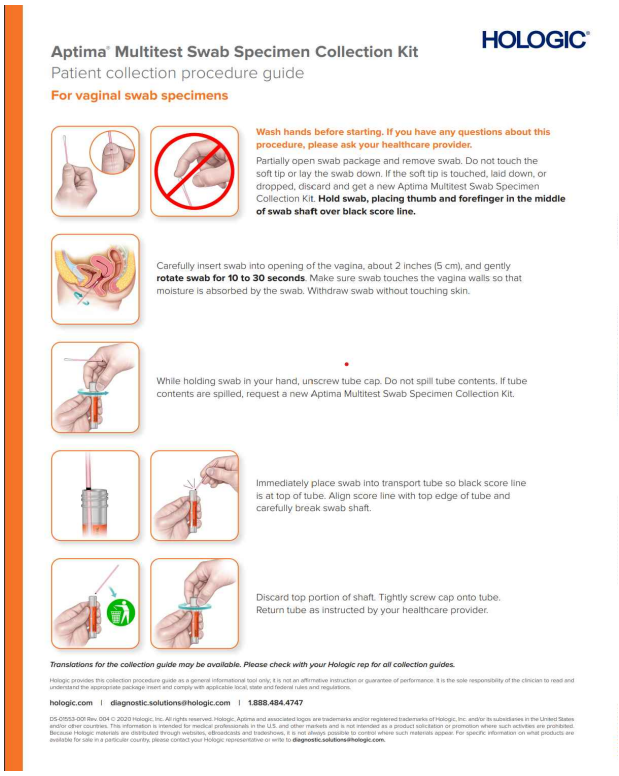
Date: 10/03/24

Content by: Mariah Smeeding

Present: Mariah Smeeding

Goals: Research the current device being used for Vaginal Self Swabs and understand why it is not working sufficiently.

Content:



Aptima® Multitest Swab Specimen Collection Kit

Patient collection procedure guide

For vaginal swab specimens

HOLOGIC®

Wash hands before starting. If you have any questions about this procedure, please ask your healthcare provider.

Partially open swab package and remove swab. Do not touch the soft tip or lay the swab down. If the soft tip is touched, laid down, or dropped, discard and get a new Aptima Multitest Swab Specimen Collection Kit. **Hold swab, placing thumb and forefinger in the middle of swab shaft over black score line.**

Carefully insert swab into opening of the vagina, about 2 inches (5 cm), and gently **rotate swab for 10 to 30 seconds**. Make sure swab touches the vagina walls so that moisture is absorbed by the swab. Withdraw swab without touching skin.

While holding swab in your hand, unscrew tube cap. Do not spill tube contents. If tube contents are spilled, request a new Aptima Multitest Swab Specimen Collection Kit.

Immediately place swab into transport tube so black score line is at top of tube. Align score line with top edge of tube and carefully break swab shaft.

Discard top portion of shaft. Tightly screw cap onto tube. Return tube as instructed by your healthcare provider.

Translations for the collection guide may be available. Please check with your Hologic rep for all collection guides.

Hologic provides this collection procedure guide as a general informational tool only; it is not an affirmative instruction or guarantee of performance. It is the sole responsibility of the clinician to read and understand the appropriate package insert and comply with applicable local, state and federal rules and regulations.

hologic.com | diagnostic.solutions@hologic.com | 1.888.484.4747

The Hologic Aptima Self Swab contains two portions of the device: the swab and the container with the transport media. The way it works is that after collecting a sample from the vaginal canal, the patient will break the swab into the transport media by hand. They will then promptly screw a lid back onto the container with the media and swab and then send it off to the lab.

This process is reported to lead to increased risk of contamination due to the patient directly touching the swab and the transport media possibly spilling/splashing. There have also been issues with the swab not breaking where it is supposed to break.

Our contribution to this device will be adding a third element. This third element will be essentially and handle for the swab. This is so any external contact can be avoided to the swab and ensure the swab to break at the specific marked region every time.

Sources:

[1] “Aptima-Multitest Patient Vaginal Collection Guide,” *HOLOGIC*. Available: https://www.hologic.com/hologic-products/collection-devices/aptima-multitest-swab#4257225834-3862873779

Conclusions/action items:

It is essential to know exactly how the current hologic aptima test functions and understand which part of the device are problematic.
It is clear the device we design must break the swab at the same point every time and reduce external contact to eliminate contamination.

By ensuring these two components get completed in our design, the new product will be more accurate and reliable.

09/27/24 - material of the swab

MARIAH SMEEDING - Sep 27, 2024, 11:58 AM CDT

MARIAH SMEEDING - Nov 16, 2024, 6:05 PM CST

Title: Importance of Correct Materials of Nasal Swab

Date: 09/27/24

Content by: Mariah Smeeding

Present: Mariah Smeeding

Goals: Understand the importance of why it is crucial to use specific material for nasal swabs. Understand which materials inactivate certain viruses, which would alter molecular tests, and why. Determine whether there is a strong enough correlation between the nasal mucosa and vaginal mucosa to see if similar materials should be used for vaginal swabs.

Content:

Due to covid-19, nasal self-swabs have been heavily researched to determine the most effective way to self-test for the virus via the nasal mucosa.
It has been undertstood that certain materials are to be avoided when creating the swab because it inhibits some viruses.

"Use only synthetic fiber swabs with thin plastic or wire shafts that have been designed for sampling the nasopharyngeal mucosa. Do not use calcium alginate swabs or swabs with wooden shafts, as they may contain substances that inactivate some viruses and may inhibit molecular tests" [1].

The reason as to why substances like calcium alginate and wood may inactivate some viruses is due to their antiviral properties. In short, calcium alginate is a crosslinked biopolymer that is compacted negative charges that may bind to viral envelopes inactivating membrane receptors [2].

On the other hand, wood has antibacterial components. Antimicrobial research has worked to develop products and materials that specifically affect certain pathogens. It has been found that wood has structural and chemical components that make it antibacterial. "The porous and hygroscopic wood absorbs the water contained in the inoculum, which draws the bacteria into wood and causes desiccation and loss of viability while chemical constituents of wood also contribute to antibacterial activity" [3].

Sources:

[1] “Interim Guidelines for Collecting and Handling of Clinical Specimens for COVID-19 Testing.” Jun. 04, 2024. https://www.cdc.gov/covid/hcp/clinical-care/clinical-specimen-guidelines.html#:~:text=Use%20only%20synthetic%20fiber%20swabs%20with%20thin%20plastic,inactivate%20some%20viruses%20and%20may%20inhibit%20molecular%20tests.

[2] K. Takayama, A. Serrano-Aroca, and R. Hashimoto, “Biocompatible Films of Calcium Alginate Inactivate Enveloped Viruses Such as SARS-CoV-2,” Apr. 2022, Biocompatible Films of Calcium Alginate Inactivate Enveloped Viruses Such as SARS-CoV-2 - PubMed (nih.gov)doi: 10.3390/polym14071483.

[3] E. Kettunen, M. kurkilahti, T. Belt, A. Harju, K. Kuroda, and T. Jyske, “Touch the wood: Antimicrobial properties of wooden and other solid material surfaces differ between dry and moist contamination in public and laboratory exposure,” Oct. 2023, Touch the wood: Antimicrobial properties of wooden and other solid material surfaces differ between dry and moist contamination in public and laboratory exposure - ScienceDirect, doi: https://doi.org/10.1016/j.envadv.2023.100416.

Conclusions/action items:

The question here is not whether there is a correlation between the vaginal mucosa and nasal mucosa because that is irrelevant. Viruses and bacteria react similarlly so we can conclude bacteria and viruses in the vagina would also be inactivated by antibacterial and antiviral materials.

We must use a material for our swabs that do not contain antiviral or antibacterial properties, such as PC or PLA.

10/08/24 - NAAT

MARIAH SMEEDING - Oct 08, 2024, 10:24 AM CDT

MARIAH SMEEDING - Oct 08, 2024, 10:39 AM CDT

Title: How NAAT's work

Date: 10/08/2024

Content by: Mariah Smeeding

Present: Mariah Smeeding

Goals: understand NAAT's better so it is clearer why the swab must break at the correct spot each time.

Content:

NAAT (Nucleic-Acid Amplification Tests) work because they identify very small amounts of DNA and RNA by amplifying it with PCR or LCR [2]. Another step is used to detect and diagnose an infection. These tests usually involve some form of nucleic acid hybridization. In those tests, the sample is probed with an artificially produced complementary strand of DNA or RNA labeled in some way that makes it easy to detect. By "highlighting" the pathogens, scientists are able to identify viruses and bacteria.

The reason the swab must be a specific length is so the machine can work properly. It is purely a mechanical requirement so the NAAT testing can ensue accurately.

Citations:

[1] E. Boskey, “What Do I Need to Know About Nucleic-Acid Amplification Tests?,” *Verywell Health*, Jun. 19, 2024. Available: https://www.verywellhealth.com/nucleic-acid-amplification-tests-3132631. [Accessed: Oct. 08, 2024]

Conclusions/action items:

The swab must be a specific length every time due to the process of NAAT's.

MARIAH SMEEDING - Oct 08, 2024, 10:24 AM CDT

10/15 - Aseptic Laboratory Techniques: Plating Methods

MARIAH SMEEDING - Oct 31, 2024, 11:57 AM CDT

Title: Plating Methods for testing for Contamination

Date: 10/15/2024

Content by: Mariah Smeeding

Present: Mariah Smeeding

Goals: To understand how our team will test for contamination in our new device using plating methods. This research is intended to set a baseline expectation for how the testing will ensue.

Content:

Five step procedure (for biosafety level one, BSL-1, as our team will not be preforming tests on samples from the vaginal canal):

(1) streak-plating bacterial cultures to isolate single colonies.

(2) pour-plating.

(3) spread plating to enumerate viable bacterial colonies.

(4) soft agar overlays to isolate phage and enumerate plaques.

(5) replica-plating to transfer cells from one plate to another in an identical spatial pattern.

Outlined is a general plating method routinely used in the laboratory to isolate, propagate, or enumerate microorganisms such as bacteria and phage.

As stated to our team by Dr. Accola, Lab manager at UW Madison's Hospital, keeping a clean and sterile environment is crucial. Our device must not interfere with the necessary procedure of sampling and testing protocols.
We have come to the conclusion that adding threads to the cap of our swabbing device will do the best job at limiting contamination of the sample while maintaining a similar procedure for lab technicians to complete. It will just be needed for the cap to be manually unscrewed instead of piercing the sampling capsule itself.

Citations:

[1] E. R. Sanders, “Aseptic Laboratory Techniques: Plating Methods,” *J Vis Exp*, no. 63, p. 3064, May 2012, doi: 10.3791/3064. Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4846335/. [Accessed: Oct. 15, 2024]

Conclusions/action items:

Our Tilt and Swab device will include threading as it does not interfere with the necessary lab procedures, and it can do a better job at preventing possible contamination from the lab environment and/or lab technician. This is because any contamination on top of the foil will ruin the sample.

More on contamination in a different note.

11/20 - Agar Plate Testing Precautions

MARIAH SMEEDING - Nov 20, 2024, 8:49 PM CST

Title: Agar Plate Testing Precautions

Date: 11/18

Content by: Mariah Smeeding

Present: Mariah Smeeding

Goals: Understand Agar Plate Testing protocols to prepare for testing.

Content:

Agar plate testing should be a s

Potential risks/protocals our team should be aware of:

- Contamination.
    - While handling the plates, we should always wash our hands before and wear gloves and tie our hair back. It is important that we sterilize all equipment and work surfaces before and after use.
    - Signs of potential contamination include unexpected fungal colonies. This could be classified as growth with different colors, shapes, textures, or smells compared to common bacteria such as:
        1. Bacillus spp: rod-shaped, they typically form large, rough, irregular colonies that are usually dry and can be slightly white or yellow.
        2. Corynebacterium spp: club shaped; they form small white/gray and slightly opaque colonies.
        3. Lactobacillus spp: rod-shaped; small, smooth, and shiny colonies that are usually white to off white.
        4. E.coli: (could be seen if we test near a toilet) Forms large, moist, round colonies that are usually cream or yellow in color.
        5. Pseudomonas spp: Forms greenish colonies with a metallic sheen.
        6. Staphylococcus spp: produced small, round, white to golden colonies that usually have a dry and matte finish.
- Methodology
    - Aseptic Technique: good hygiene and sterilizing measures to reduce contamination
    - sampling technique: This will need to be consistent so we must plan as a team an exact procedure. It may be preferred to have one person preform the testing. We will also need to make clear where our samples will be collected.
    - Controls: We will include positive controls, such as swabbing a door handle or a bathroom stall to ensure bacteria is able to grow, and negative controls, where will not tough a plate so nothing grows to ensure they are sterile.
    - Documentation: it will be essential we take throughout notes and records of our procedure, observations, and results. We will also need to clearly label all of the plates with sample location and date.
    - Be prepared for incubation time however long that may take. So, the sooner we can start testing the better.

Citations:

[1] C. Giuliano, C. R. Patel, and P. B. Kale-Pradhan, “A Guide to Bacterial Culture Identification And Results Interpretation,” *P T*, vol. 44, no. 4, pp. 192–200, Apr. 2019, Available: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6428495/. [Accessed: Nov. 20, 2024]

Conclusions/action items:

Our team should be testing no later than 11/ 25 to ensure we can get results before thanksgiving. This way we can have time to analyze the data we collect and go from there.

11/15 Tong Lecture

MARIAH SMEEDING - Nov 15, 2024, 12:46 PM CST

Title: Tong Lecture

Date: 11/15/24

Content by: Mariah Smeeding

Present: Mariah Smeeding

Goals: Learn About Tasso

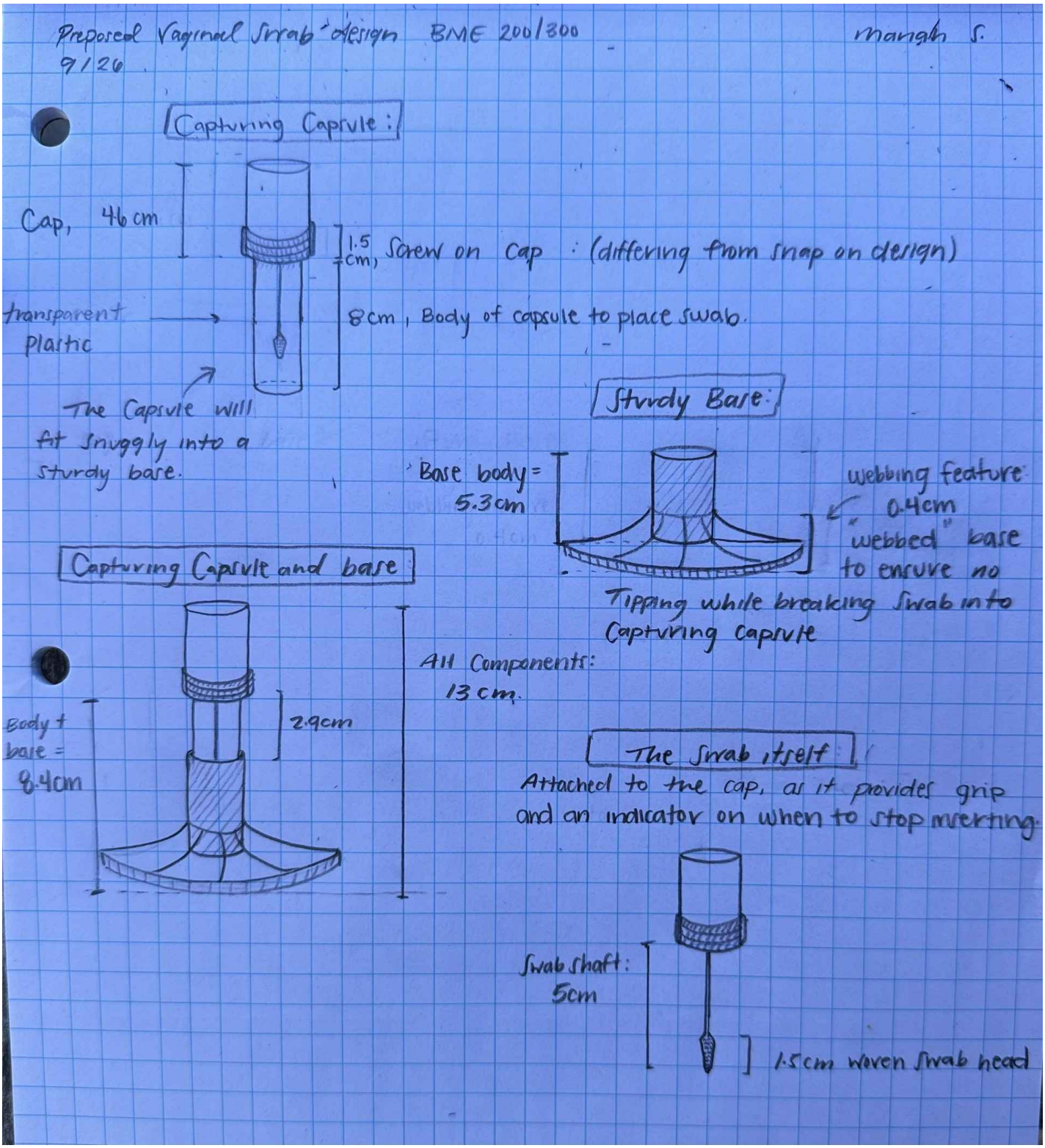
Content:

- microfluidics?
- Blood Draws are currently essential in healthcare.
- Their goal: create an at home blood drawing device with no knowledge on how to start a business.
    - Business side: push your ideas, started writing grants, 5 or 6 in a year, eventually received money from DARPA.
- Developing tech cheaply -
    - open microfluidics. Essentially just connecting a tube to blood collecting device.
    - The device contains vacuum to pull blood from skin.
- Developed tamper proof security case solving custody issues
- Provide blood tests for major sports teams for anti-doping
- Motto: focus on one problem at a time to solve correctly.
- Growing the Business
    - beginning - grants, new ideas, protypes
    - scaling up - quality is key, culture, communication and shared values and HR.
    - FDA - Diagnostic product, class II IVD, (very expensive tests, takes a lot of time). Their solution was to carefully understand FDA regulations: break up device to two parts. One part already had the clearance. Second was considered Class I medical device (not diagnostic and way easier clearance). First Lancet cleared this way.

Conclusions/action items: n/a

09/26/24 - design proposal - swab attached

MARIAH SMEEDING - Sep 27, 2024, 11:51 AM CDT



Here the major changes include:

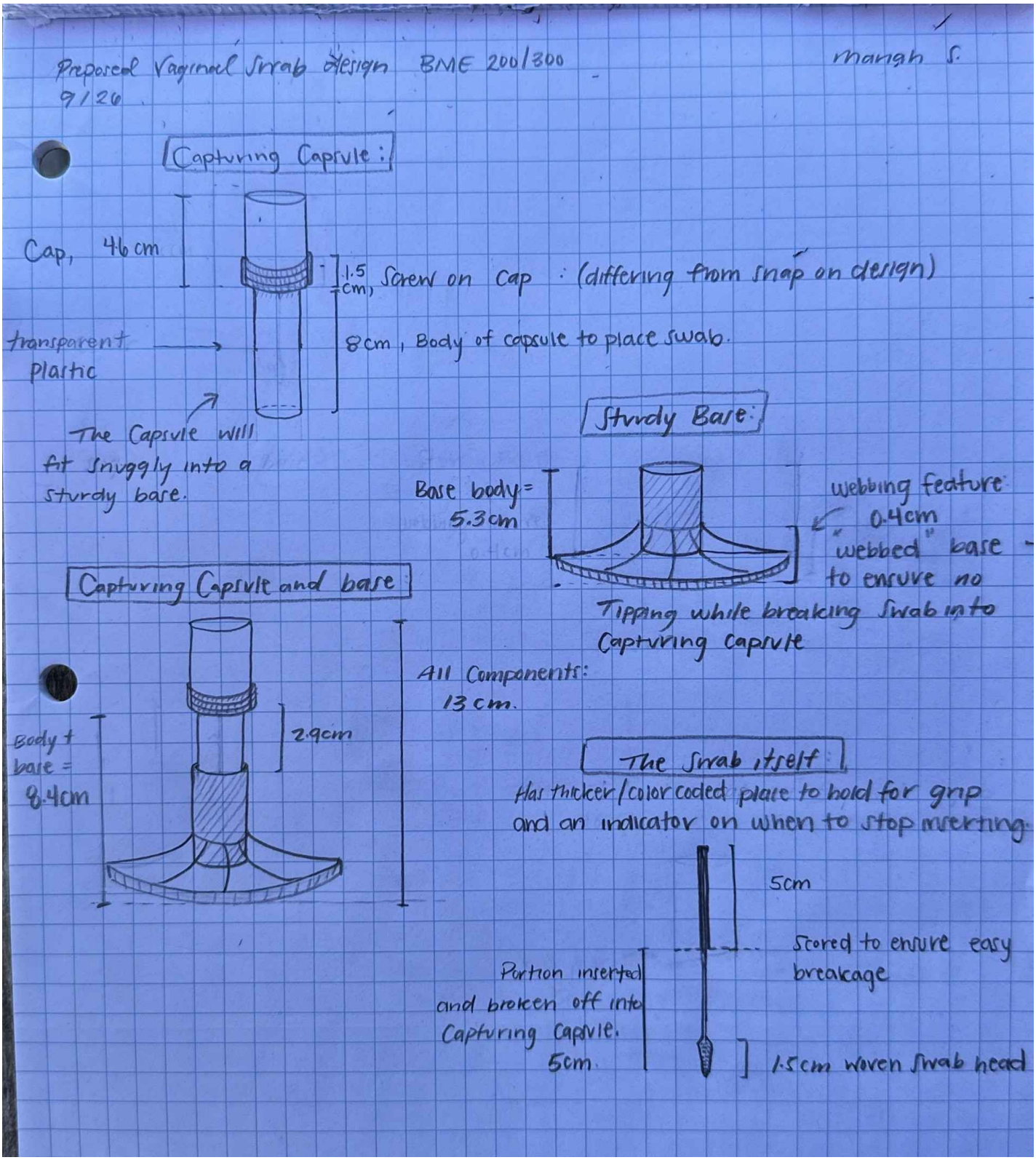
- screw on cap to ensure no transport media leakage.

- larger and sturdier webbed base to prevent tipping.

- The swab is connected to the cap itself.

09/26/24 - design proposal - swab detached

MARIAH SMEEDING - Sep 27, 2024, 11:54 AM CDT



Here the only difference this design has from the swab attached design is the swab is a separate object. It is longer and on a detachable handle instead of being connected to the cap. The intended use for this design is to break the swab

into the capturing capsule (transport media) at a scored mark so it breaks easy.

9/19/2024 - Vagina Anatomy

AVA FEVOLD - Sep 24, 2024, 11:18 AM CDT

Title: Vaginal Anatomy

Date: 9/19/24

Content by: Ava

Present: Ava

Goals: research anatomy of the vagina for the size requirements in PDS

Content:

For this project we need to know specifically the size of the vagina in order to make our model fit the need requirements.

"The average vagina (unaroused) is a little over 3.5 inches deep.

- vagina’s size depends on various factors
    - age
    - weight
    - whether or not you’ve gone through menopause
    - surgeries involving your pelvic cavity may shorten the overall length of vagina

Resources:

Cleveland Clinic, “Vagina: Anatomy, Function, Conditions & What’s Normal,”

Cleveland Clinic, Mar. 08, 2022. https://my.clevelandclinic.org/health/body/22469-vagina

Conclusions/action items:

The average depth of an unaroused vaginal canal is approximately 9 cm.

9/21/2024 - Swab Lab Testing

AVA FEVOLD - Sep 24, 2024, 11:18 AM CDT

Title: "Journey of a Swab" - Lab Testing

Date: 9/21/2024

Content by: Ava

Present: Ava

Goals: research how swabs are tested in the lab

Content:

- this video details the process of testing a swab for COVID-19
  - going to be a little different compared to the process of vaginal specimen testing
- checked for leaks, which could harm lab staff
  - swabs are not tested if they have been leaking, means they are contaminated
- the liquid in the tubes is transferred to a deep well plate with a lysis buffer
  - the lysis buffer deactivates and breaks apart the virus
  - there are also beads in this buffer which will bind the genetic material that is needed for testing
- after 15 minutes, the virus is deactivated and the fluid is put into a machine that uses the beads to extract the genetic material
- genetic material is extracted and the lab will look for specific genes that coincide with the virus/disease the swab is testing for

Resources:

Medicines Discovery Catapult, *Journey of a Swab*, (Nov. 10, 2021). Accessed: Sep. 21, 2024. [Online Video]. Available: https://www.youtube.com/watch?v=B2ZJ_YfMcR8

Conclusions/action items:

The process of swab testing in a lab is extensive and extremely sterile. The next thing I need to research is how the lab sterilizes the vital machines and containers that move fluid from one place to the next.

9/22/2024 - Cells/Vaginal Fluid

AVA FEVOLD - Sep 24, 2024, 11:19 AM CDT

Title: Vaginal Swabbing for Cells and Vaginal Fluid

Date: 9/22/2024

Content by: Ava

Present: Ava

Goals: research exactly what is being swabbed in a vaginal swab test - cells or fluid?

Content:

What is needed to be on the swab in order to test the vaginal canal?

- whether self or provider is running the test- the swab is used to collect vaginal fluid
- this vaginal fluid should contain cells
    - cells will contain vital information on whether the individual has a healthy vaginal canal
    - can be used to diagnose various infections and diseases

Resources:

“What Is a Bacterial Vaginosis Test?,” Cleveland Clinic. Accessed: Sep. 22, 2024. [Online]. Available: https://my.clevelandclinic.org/health/diagnostics/22123-bacterial-vaginosis-test

Conclusions/action items:

Vaginal testing is swabbing for vaginal fluid, which contains cells. These cells within the fluid are the most important thing for actually testing the vaginal canal.

9/22/2024 - Vaginal Microbiome

AVA FEVOLD - Sep 24, 2024, 11:19 AM CDT

Title: Vaginal Microbiome

Date: 9/22/2024

Content by: Ava

Present: Ava

Goals: research the microbiome in the vagina and how it is connected to sexually transmitted diseases

Content:

- bacterial diversity of the vagina:
  - in a recent study by Ravel et al. - 282 bacterial phylotypes were found in the mid-vagina
    - in most participants (73%), the microbiome was dominated (over 50%) by Lactobacillus
    - lactobacillus is considered the most dominant and protective vaginal bacterium
      - produces lactic acid as a fermentation product to lower the pH level
      - produces bacteriocins - proteins that inhibit the growth of bacteria
- increased pH (greater than 4.5) is one diagnostic feature of bacterial vaginosis
- Nugent Gram stain test: evaluates the morphology and Gram stain reactivity of bacteria
  - higher Nugent score indicates abnormal microbiota
    - associated with increased trichomonal, gonococcal, chlamydial infection
    - increased risk of HIV-1 and gonorrhea
- vaginal microbiota play major role in women's reproductive health

Resources:

R. M. Brotman, “Vaginal microbiome and sexually transmitted infections: an epidemiologic perspective,” *J Clin Invest*, vol. 121, no. 12, pp. 4610–4617, Dec. 2011, doi: 10.1172/JCI57172.

Conclusions/action items:

Understanding and researching vaginal microbiome is vital for understanding the diagnosis of abnormalities in the vagina.

10/6/2024 - STI Research

AVA FEVOLD - Oct 06, 2024, 9:33 PM CDT

Title:

Date: 10/6/24

Content by: Ava

Present: Ava

Goals: research for the preliminary report - learn the prevalence of STI

Content:

- Chlamydia is the most commonly reported bacterial sexually transmitted infection in the US
- 1.4 million cases were reported to the U.S. CDC from all 50 states and the District of Columbia
- estimated that 2.86 million infections occur annually
- many cases go unreported because most individuals with chlamydia are asymptomatic and do not seek testing
- the infection is especially prevalent among young people, with estimates suggesting that one in 15 sexually active females aged 14-19 is affected

Sources:

“Chlamydia.” Accessed: Oct. 06, 2024. [Online]. Available: https://dph.illinois.gov/topics-services/diseases-and-conditions/stds/chlamydia.html

Conclusions/action items:

Chlamydia affects one in 15 sexually active females (age 14-19).

10/6/2024 - Vaginal Diseases Asymptomatic

AVA FEVOLD - Oct 06, 2024, 9:39 PM CDT

Title: Prevalence of Asymptomatic Infections Study

Date: 10/6/24

Content by: Ava

Present: Ava

Goals: Are vaginal diseases asymptomatic?

Content:

The article by R. Rajalakshmi and S. Kalaivani investigates the prevalence of asymptomatic infections among individuals attending sexually transmitted disease (STD) clinics who were diagnosed with bacterial vaginosis, vaginal candidiasis, and trichomoniasis.

- identifying how often these infections occur without noticeable symptoms
- the findings highlight the significance of screening for asymptomatic infections in STD clinics
- cases may go undetected due to the lack of symptoms
- emphasizing the importance of early diagnosis and treatment to prevent further transmission

Sources:

R. Rajalakshmi and S. Kalaivani, “Prevalence of asymptomatic infections in sexually transmitted diseases attendees diagnosed with bacterial vaginosis, vaginal candidiasis, and trichomoniasis,” Indian J Sex Transm Dis AIDS, vol. 37, no. 2, pp. 139–142, 2016, doi: 10.4103/2589-0557.192121.

Conclusions/action items:

Researchers found that 48.37% of women with bacterial vaginosis were completely asymptomatic.

10/6/2024 - Barriers to Testing

AVA FEVOLD - Oct 06, 2024, 9:44 PM CDT

Title: Barriers to Self-Swab Testing

Date: 10/6/24

Content by: Ava

Present: Ava

Goals: find the various barriers to testing

Content:

This article explores the barriers to sexually transmitted infection (STI) testing in New Zealand through a qualitative study

- identifies key obstacles that prevent people from seeking STI testing, such as stigma, embarrassment, lack of awareness, and difficulty accessing services
- highlights the need for better public education, more accessible testing options, and strategies to reduce the stigma associated with STIs, aiming to improve public health outcomes by encouraging more individuals to get tested

Sources:

H. J. Denison, C. Bromhead, R. Grainger, E. M. Dennison, and A. Jutel, “Barriers to sexually transmitted infection testing in New Zealand: a qualitative study,” Aust N Z J Public Health, vol. 41, no. 4, pp. 432–437, Aug. 2017, doi: 10.1111/1753-6405.12680.

Conclusions/action items:

Sexually active women are recommended to be tested annually for vaginal infections, however, there are barriers to accessible testing. These barriers include the financial cost of the test, clinic locations, and even concern of being stigmatized.

10/6/2024 - Testing Preferences

AVA FEVOLD - Nov 14, 2024, 1:39 PM CST

Title: Testing Preferences

Date: 10/7/24

Content by: Ava

Present: Ava

Goals: find womens' preferences on testing for presentation

Content:

The article examines women's preferences for self-collecting vaginal swabs to diagnose *Chlamydia trachomatis* and *Neisseria gonorrhoeae* infections

- women generally find it easy and prefer to collect their own vaginal swabs compared to clinician-collected samples
- self-collection was seen as more convenient, less invasive, and more comfortable, contributing to a higher likelihood of participation in STI testing
- the findings suggest that promoting self-collected swabs could enhance screening and early diagnosis of these infections
    - improves sexual health outcomes
- around 76% of women prefer a vaginal swab over a pelvic examination and 60% over a urine collection test

Sources:

M. A. Chernesky et al., “Women find it easy and prefer to collect their own vaginal swabs to diagnose Chlamydia trachomatis or Neisseria gonorrhoeae infections,” Sex Transm Dis, vol. 32, no. 12, pp. 729–733, Dec. 2005, doi: 10.1097/01.olq.0000190057.61633.8d.

Conclusions/action items:

When it comes to vaginal testing, women greatly prefer self-swabbing over a pelvic examination. Overall, self-swabbing is more convenient and less invasive. An upgraded form of self-swabbing could lead to an increase in STI testing.

10/6/2024 - False Positives in Vaginal Testing

AVA FEVOLD - Oct 06, 2024, 9:56 PM CDT

Title: False Positives in Vaginal Testing

Date: 10/6/2024

Content by: Ava

Present: Ava

Goals: find info on false positives in vaginal self swabbing

Content:

The article investigates the risk of false-positive test results for *Chlamydia trachomatis* due to environmental contamination by its RNA

- the study reveals that contamination in clinical settings can lead to false-positive diagnoses when testing for the infection, even if the patient is not infected
- the findings emphasize the need for rigorous contamination control measures in laboratories to ensure accurate test results
- study highlights the importance of maintaining strict protocols to avoid diagnostic errors, which can lead to unnecessary treatment and anxiety

Sources:

M. Toepfe, B. Hermann, M. Sansone, C. Lilja, and P. Nolskog, “Environmental contamination by Chlamydia trachomatis RNA can cause false-positive test results in clinical samples,” Sexually Transmitted Diseases, vol. Publish Ahead of Print, Oct. 2020, doi: https://doi.org/10.1097/olq.0000000000001323.

Conclusions/action items:

Overall, contamination leads to 67% of women receiving a false positive result.

10/7/2024 - Side Effects of STIs

AVA FEVOLD - Oct 07, 2024, 6:30 PM CDT

Title: Side Effects of Sexually Transmitted Diseases

Date: 10/7/24

Content by: Ava

Present: Ava

Goals:

Content:

- rates of sexually transmitted infections (STIs) reached an all-time high in 2021 among both females and males and all racial and ethnic groups
- the number of combined cases of gonorrhea, syphilis, and chlamydia was more than 2.54 million in 2021 up from 2 .4 million in 2020
- the current rise of STIs is a serious public health concern that requires immediate attention
- if untreated - STIs can lead to severe health complications, including pelvic inflammatory disease (PID), increased risk of getting HIV, certain cancers, and even infertility

Sources:

O. of I. D. and H. Policy (OIDP), “Sexually Transmitted Infections (STIs).” Accessed: Sep. 29, 2024. [Online]. Available: https://www.hhs.gov/programs/topic-sites/sexually-transmitted-infections/index.html

Conclusions/action items:

Sexually transmitted infections require immediate attention due to severe health complications, including pelvic inflammatory disease, increased risk of getting HIV, certain cancers, and even fertility.

10/25/2024 - Contamination in PCR Testing

AVA FEVOLD - Oct 25, 2024, 12:39 PM CDT

Title: rRNA PCR Contamination

Date: 10/25/24

Content by: Ava

Present: Ava

Goals: learn more about how contamination affects the PCR testing results

Content:

The sensitivity of this testing makes it vulnerable to contamination.

Potential sources of contamination include:

- the large numbers of target organisms in clinical specimens that may result in cross-contamination
- plasmid clones derived from organisms that have been previously analyzed and that may be present in large numbers in the laboratory environment
- most importantly, repeated amplification of the same target sequence, which leads to the accumulation of amplification products in the laboratory environment

Sources:

J. Aslanzadeh, “Preventing PCR Amplification Carryover Contamination in a Clinical Laboratory,” *Ann Clin Lab Sci*, vol. 34, no. 4, pp. 389–396, Oct. 2004.

Conclusions/action items:

The sensitivity of the PCR test leads to contamination concerns from cross-contamination of clinical specimens, plasmid clones in lab previously, and repeated amplification of the same target sequence.

9/10/24 - Evvy Vaginal Health Test (Competing Design)

AVA FEVOLD - Sep 24, 2024, 11:20 AM CDT

Title: Evvy Vaginal Health Test - Competing Test

Date: 9/10/24

Content by: Ava

Present: n/a

Goals: Research competing designs of a vaginal self-swab testing device.

Content:

Evvy is a vaginal health test.

Tests for:

- ureaplasma
- mycoplasma
- chlamydia
- gonorrhea
- trich
- 700+ more bacteria and fungi

Random:

- the at-home test uses metagenomics that sequence the entire genome of microbes in vaginal microbiome
- considered most accurate for testing vaginal health
- can identify new microbes that other tests miss
- uses PCR (polymerase chain rxn), tests 11 common microbes
- Clinical Labrotary Improvement Amendments (CLIA) and College of American Pathologists (CAP) certified.

How does it work?

the test comes with:

- 1 swab
- 1 collection tube
- 1 return box
- 1 biosafety bag
- instructions

directions (straight from Evvy website):

1. Activate your test

[...] evvy.com/activate. [...]

2. Prepare the swab

[...] Start by unwrapping the swab. Be careful not to touch the swab with your hands or any other surface to avoid contamination.

3. Insert the swab

With clean hands, gently insert the swab into your vagina about 1-2 inches deep. This shouldn't cause any discomfort.

4. Collect the sample

Move the swab in several full circles along the vaginal walls for about 20 seconds. Make sure to cover all sides of the swab tip to collect a thorough sample.

5. Secure the sample

Carefully remove the swab from your vagina and place it into the collection tube. You'll notice a breakpoint on the swab; snap off the top part of the swab at this point so that the swab fits securely in the tube. Finally, screw the cap onto the collection tube to seal it.

6. Send it back

That's it! Your sample is now ready to be sent back for analysis. Simply follow the instructions in your test kit to package the swab in the included biosafety bag, place it in the pre-paid return box, and drop it in the mail.

Resources:

"Evvy - Vaginal Microbiome Test & Care." Accessed: Sep. 20, 2024. [Online]. Available: https://www.evvy.com/

Conclusions/action items:

Overall directions of this competing design. Very similar to the swab that we will be using for our project.

9/15/2024 - Aptima Swab Research

AVA FEVOLD - Sep 24, 2024, 11:21 AM CDT

Title: Aptima Swab Research

Date: 9/15/2024

Content by: Ava

Present: Ava

Goals: Research the swab type.

Content:

The Aptima swab is what we were given for testing. Specifically - the Aptima "Multitest Swab Specimen Kit"

- the swab measures 15 cm in length a circumference of 3-5 mm
- uses nucleic acid amplification test technology
- simplifies testing to provide answers involving sexual and vaginal health
- "one step process"
    - uses a penetrable cap which eliminates uncapping and recapping for transfer
    - reduce human error
    - prevent cross contamination
    - non-toxic

Resources:

Hologic, “APTIMA® Instructions for obtaining patient-collected ... - hologic,” Aptima, https://www.hologic.com/sites/default/files/package-insert/IN0146-IFU-PI_004_01.pdf?msclkid=9e992e29ba8511eca52a9bfa2c519604 (accessed Sep. 19, 2024).

Conclusions/action items:

The most important thing that I learned from this research was the length and circumference of this swab. This information will be needed when creating the holding device.

9/19/2024 - Self-Swab Instructions

AVA FEVOLD - Sep 24, 2024, 11:21 AM CDT

Title: Self-Collected Vaginal Swab Directions

Date: 9/19/24

Content by: Ava

Present: Ava

Goals: research the directions of vaginal self-swabbing for the performance requirements of the PDS

Content:

In these instructions, it says that for premium results, the user must "Carefully insert the soft tip end of the swab into your vagina about 2 inches (5 cm) past the opening of the vagina (see picture 3). Gently rotate the swab for 10 to 30 seconds, making sure the swab touches the walls of the vagina so that moisture is absorbed by the swab."

Another important note is that the user should withdraw the swab while avoiding contact with the user's skin.

Resources:

"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

Conclusions/action items:

The swab will need at least 5 centimeters of the swab head available for specimen collection.

9/19/2024 - Instructions for Aptima Kit

AVA FEVOLD - Sep 24, 2024, 11:21 AM CDT

Title: Aptima Specimen Transfer Kit

Date: 9/19/24

Content by: Ava

Present: Ava

Goals: read the necessary instructions for the kit we will be using for this project, specifically kit storage

Content:

The instructions for the kit storage state:

"Store specimen transfer tubes prior to use at room temperature (15°C to 30°C). Store the Aptima Transfer Solution at 2°C to 8°C (refrigerated) upon receipt. Do not use reagents beyond expiration date indicated on the vials."

Other important notes:

- "Take care to avoid cross-contamination during the specimen handling steps. Specimens may contain high levels of organisms. Change gloves frequently and always change gloves when they come in contact with specimen. Discard used materials without passing over open containers. Avoid specimen container contact with one another."
- "Do not use this kit after its expiration date."
- "Maintain proper temperature conditions during specimen shipping and storage to ensure the integrity of the specimen. Refer to the appropriate Aptima assay package insert for specific shipping and storage conditions."

Resources:

“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.

Conclusions/action items:

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

9/19/2024 - Additional Instructions for Self Swabbing

AVA FEVOLD - Sep 24, 2024, 11:22 AM CDT

Title: Additional Instructions for Self Swabbing

Date: 9/19/24

Content by: Ava

Present: Ava

Goals: find more information on swab storage

Content:

- important to rotate swab for at least 10-15 seconds
- test must be stored and transported to the laboratory at 2-30°C within 14 days of collection
- samples can be stored and transported to the laboratory frozen (-20°C) within 180 days of collection

Resources:

“Instructions for Self-Collection of Vaginal Swabs,” Hull University Teaching Hospitals NHS Trust. Accessed: Sep. 18, 2024. [Online]. Available: https://www.hey.nhs.uk/pathology/departmentofinfection/virology/vaginal-swabs/

Conclusions/action items:

Most important thing from this article is that the test can be stored for a max of 14 days or up to 180 if frozen.

11/15/2024 - Tong Distinguished Entrepreneurship Lecture

AVA FEVOLD - Nov 15, 2024, 12:46 PM CST

Title: Tong Lecture

Date: 11/15/24

Content by: Ava

Content:

Tasso

- at-home blood collection kit
- biomedical engineering background
- the core of research is blood samples
    - 10 billion blood draws a year
- everything is being sent to homes, how can we collect blood by mail?
- taking the leap
    - prototyping
    - using Wisconsin resources
    - funding and grants
- evolution of the technology
    - kill product when needed
    - don't be afraid to disappoint if you are doing it for the right reason
- finding a key customer
    - example: professional athletes (major league baseball) anti-doping tests
    - focus on key problem - don't try to do everything
- scaling up - culture within the company is key
- regulatory strategy
    - two separate pieces - tube and lancet
        - class 1 medical device, super easy clearance
    - read the labels - easy to over analyze what regulators say they "want" to do

Tasso is Italian for badgers

Conclusions/action items:

Overall, if you have an idea - just go for it. You are going to hit roadblocks, so collaborate and use your resources. Tasso is an example of that.

11/21/2024 - Agar Plates Research

AVA FEVOLD - Nov 21, 2024, 8:52 PM CST

Title: Prepping Agar Plates

Date: 11/21/2024

Content by: Ava

Present: Ava

Goals: learn how to prep agar plates before the designated testing

Content:

prepping the media:

- label the clean glass autoclavable 500 mL autoclavable bottle with media name, date, and initial
- for a 500 mL bottle, calc the weight of powdered media to make 250 mL (subtract that from 250 to determine the vol of water to add)
- add that amount of water to bottle
- add that amount of media with agar powder to same bottle
- stir or shake until fully mixed
- add a piece of autoclave tape to cap or bottle

setting up the autoclave:

- place prepared media bottles into metal tray
- add distilled water until it covers bottom of tray
- place into autoclave
- autoclave at 121 degrees for 15 minutes at 15 psi
- once the cycle is complete, wear heat-resistant gloves to remove the tray&bottles from the machine
- allow bottles to cool

pouring the plates:

- once the media has cooled to 60 degrees celsius, liquid is ready to be poured
- an antibiotic may be added to media and gently stirred
- pour the media into the bottom of the plate until it just covers the surface
  - hold cap at an angle (as if on a hinge)
- close and allow to cool to solid
- leave plates out for a day if possible before use

Source:

“1.19: Pouring Agar Plates,” Biology LibreTexts. Accessed: Nov. 21, 2024. [Online]. Available: https://bio.libretexts.org/Bookshelves/Biotechnology/Lab_Manual%3A_Introduction_to_Biotechnology/01%3A_Techniques/1.19%3A_Pouring_Agar_Plates

Conclusions/action items:

To prepare media, label a clean 500 mL bottle, mix the calculated amounts of powdered media, agar, and water, then secure it with autoclave tape. Sterilize the bottle in an autoclave at 121°C for 15 minutes, allow it to cool, and, if needed, mix in antibiotics before pouring the media into plates. Pour the media evenly, let it solidify, and leave the plates out for a day before use if possible.

9/26/2024 - "Tunnel" Design

AVA FEVOLD - Sep 26, 2024, 12:14 PM CDT

Title: "Tunnel" Design

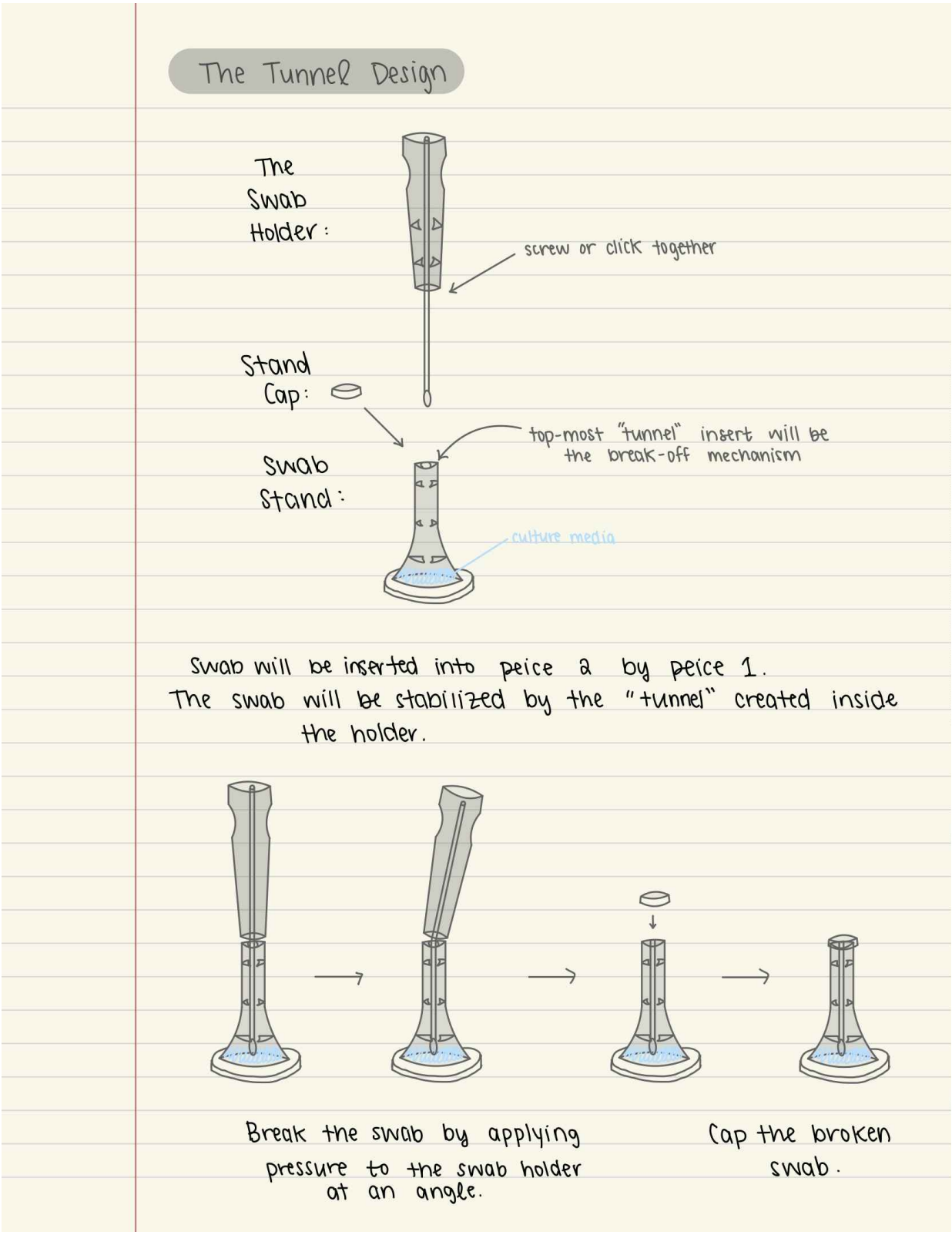
Date: 9/26/2024

Content by: Ava

Present: Ava

Goals: create a possible design for the design matrix

Content:



Conclusions/action items:

The "tunnel" design minimizes the size variability after the swab is broken. The swab is inserted into a stabilizing "tunnel" inside the stand. These stabilizing inserts will hold the swab as the user breaks the swab in half. Then the user will cap the stand and everything inside will be contained.

9/26/2024 - Revised "Tunnel" Design

AVA FEVOLD - Nov 14, 2024, 1:34 PM CST

Title: Revised "Tunnel" Design

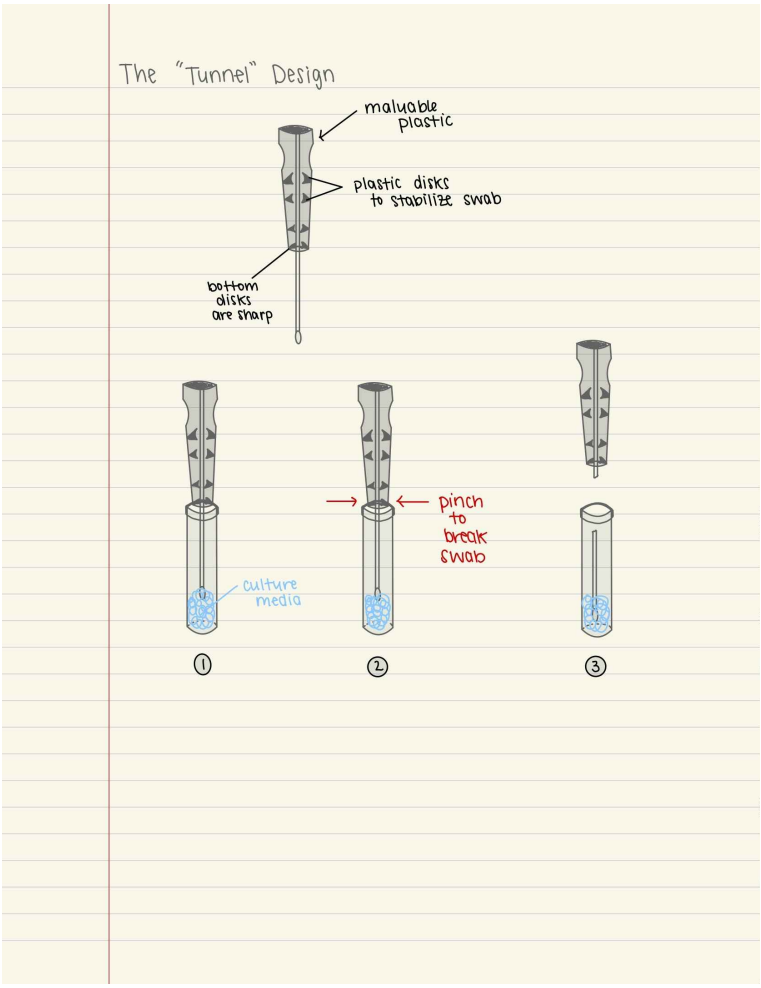
Date: 9/26/2024

Content by: Ava

Present: Ava

Goals: redo a possible design for the design matrix

Content:



three components:

1. the swab holder
2. Hologic's 'Aptima' swab
3. 'Aptima' media tube.
    - swab holder is completely hollow with varying-sized disks in the interior
    - disks align to stabilize the swab while being used to swab the vaginal canal
    - base is wider than the bottom opening - protection from tipping and spills
    - cutouts at the top for ease of use

How to use:

- patient would receive the device with the swab already placed inside the holder
- patient would then use the grips to hold the swab holder and insert the swab into the vaginal canal, collect the specimen, and remove the swab
- after removing the swab from the canal, the user would then transfer the swab to the Aptima transport media tube
    - pinching the bottom opening to break the swab
    - since the bottom-most disk is sharp, the swab will break at the perforated line due to the pressure
- after the swab is broken and in the culture media, cap the tube and follow the transfer instructions

Advantages of this design:

- the ability to limit contamination and leakage/spillage
    - holder acts as a barrier between the environment and the swab
    - user can set down the swab without the risk of spreading contaminated vaginal fluids

Disadvantages of this design:

- can to be dangerous for the user
    - the inside contains a sharp disk, the patient could pinch or cut themselves in the swabbing and breaking process
- not extremely user-friendly due to the force needed to break the swab by pinching

Conclusions/action items:

This revised "tunnel" design minimizes the size variability after the swab is broken. The swab is inserted into the provided swab container. These stabilizing inserts will hold the swab as the user pinches the tip of the mechanism to break the swab in half. Then the user will cap the container and everything inside will be contained.

9/27/24 - Biomedical Purchasing & Accounting Group

AVA FEVOLD - Nov 14, 2024, 1:21 PM CST

Title: Biomedical Purchasing & Accounting Group Presentation

Date: 9/27/2024

Content by: Ava

Present: other BPAGs

Goals: learn BPAG's roles and responsibilities

Content:

- goal is to get your client to do the buying
- what is the budget?
  - around 200 but no limit
- have all expenses approved by client before purchasing
- table of expenses in:
  - notebook (as well as receipts)
  - progress report
  - report
- depending on the type of client - how you can buy things
  - UW affiliated
    - uw funds
      - follow purchasing guidelines
      - seek reimbursement within 90 days
    - out of pocket
      - you can buy anything from anywhere
  - no UW affiliation
    - rehab project or prepaid
      - submit request for BME funding
    - no?
      - anything is fair game
- find vendors on ShopUW+
  - plastics, screws, nuts, etc: Fastenal or Grainger

<u>possible resources:</u>

- design innovation lab @ wendt
  - $50 budget per team ("BME Design Payment Account")
- design innovation lab @ ECB
  - machine, woodworking

<u>reimbursement:</u>

- only the BPAG will be reimbursed - no one else!!
- e-reimbursement from UW-clients

<u>non-reimbursable expenses:</u>

- poster printing (50 each team)

- poster printing (50 each team)
- labarchives fee

accounting:

- use the table the course gives in all the places needed

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Category 1										
									$0.00	
									$0.00	
Category 2										
									$0.00	
									$0.00	
								TOTAL:	**$0.00**	

Conclusions/action items:

Track all expenses correctly and stay on top of the reimbursement process.

11/14/2024 - BPAG Table

AVA FEVOLD - Nov 23, 2024, 4:37 PM CST

Title: BPAG Table

Date: 11/1/4/2024

Goals: keep track of all purchases

Content:

Item	Description	Manufacturer	Mft Pt#	Vendor	Vendor Cat#	Date	QTY	Cost Each	Total	Link
Category 1										
									$0.00	
									$0.00	
Category 2										
									$0.00	
									$0.00	
								TOTAL:	$0.00	

2014/11/03-Entry guidelines

John Puccinelli - Sep 05, 2016, 1:18 PM CDT

Use this as a guide for every entry

- Every text entry of your notebook should have the **bold titles** below.
- Every page/entry should be **named starting with the date** of the entry's first creation/activity. subsequent material from future dates can be added later.

You can create a copy of the blank template by first opening the desired folder, clicking on "New", selecting "Copy Existing Page...", and then select "2014/11/03-Template")

Title: Descriptive title (i.e. Client Meeting)

Date: 9/5/2016

Content by: The one person who wrote the content

Present: Names of those present if more than just you (not necessary for individual work)

Goals: Establish clear goals for all text entries (meetings, individual work, etc.).

Content:

Contains clear and organized notes (also includes any references used)

Conclusions/action items:

Recap only the most significant findings and/or action items resulting from the entry.

2014/11/03-Template

John Puccinelli - Nov 03, 2014, 3:20 PM CST

Title:

Date:

Content by:

Present:

Goals:

Content:

Conclusions/action items: