Oregon State University
College of Engineering

The Making of POPPY: Final Product Report

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Executive Summary

The current women's health market is evaluated at 39.3 billion USD (2018) Compound annual growth rate (CAGR) of 4.2% over the forecast period. PCOS Currently affects 5 million+ women, and there is no cure, nor specific products on the market. Additionally, PCOS is the most common endocrine disorder found in women. Since the market value is quite large, we decided that creating a product to help the screening patients with PCOS would be beneficial to many women because the current diagnosis process is extensive, expensive, and invasive. The diagnosis process consists of transvaginal ultrasounds, pelvic exams, and blood tests which require multiple visits to the doctor. Our product aims to ease the diagnosis process for both patients and doctors. This is a urine-based test that will be quick, inexpensive, and easy to use. One of the main goals of POPPY is to expand healthcare to make it more accessible for the underserved or marginalized groups in healthcare. Our product was designed with accessibility in mind. Our product will come preassembled with two parts, a body, and a testing strip. The testing strip acts as the diagnostic device while the body acts as the casing and the display to allow for easy use and comfortability. The testing strip will work similarly to a pregnancy test strip, but in our case, we will test for over a threshold concentration of aldosterone present in the user's urine. The threshold concentration is tested for because aldosterone is present in urine already, but amounts of aldosterone in excess of the expected range indicate a problem. Our product has a clear market space and a social cause in mind. For all of these reasons, POPPY will be at the forefront of at-home diagnostic tests.

Mission Statement

Short Mission Statement:

PCOS affects over 5 million women, and can cause infertility, ovarian cysts, and physically painful and uncomfortable symptoms.The current diagnosis process for PCOS is expensive, intensive, and requires access to a physician and healthcare. The solution to this problem is POPPY, an at-home testing kit to screen patients and streamline the diagnosis process for Polycystic Ovary Syndrome (PCOS) by detecting aldosterone hormone levels in urine.

Extended Mission Statement:

Currently, PCOS affects over 5 million women, and can cause infertility, ovarian cysts, and physically painful and uncomfortable symptoms. Additionally, PCOS is the most common endocrine disorder found in women. The current diagnosis process for PCOS is expensive, intensive, and requires access to a physician and healthcare. However, there are currently no at-home diagnostic kits that explicitly address or aid in the screening process for PCOS.

The primary **customer base** for POPPY is women who have undergone puberty, as PCOS can occur at any age after anatomical maturity. The primary users of this product are women who are currently experiencing symptoms of PCOS, have a family history of PCOS or are preparing to undergo the extensive physician-based diagnosis process for PCOS but wish to be confident in their decision before undergoing the extensive medical testing and invasive procedures.

Customers **need** results quickly, therefore POPPY delivers results in five minutes, fitting into any schedule. To meet the customer's need for discreteness, POPPY is a small device that can easily fit in a pocket or purse. Additionally, POPPY can be shipped to your doorstep, allowing you to purchase and take the test in the comfort of your own home. Since PCOS is a lifetime condition, POPPY pairs with a free smartphone app to allow customers to easily 1) review their results, 2) track their physical symptoms over time similar to a period tracker app, and 2) take a supplemental test(s) and compare it to their previous results.

The incredible **benefit** that POPPY offers is, for just $15.00 women suffering from PCOS symptoms or hoping to alleviate the stress of the PCOS diagnosis symptoms by purchasing POPPY and rapidly receive an answer to whether or not they have elevated hormone levels indicating the possibility of PCOS and confirming the necessity for further diagnostic procedures.

The key **business goal** for POPPY is to expand the market and bring awareness to women’s healthcare and diagnostics through accessible, inexpensive, at-home testing for PCOS.

The **Primary Market** would be directed broadly toward direct consumers (people with the potential of developing PCOS or patients who may be experiencing PCOS symptoms).

The **Secondary Market** would be directed towards healthcare institutions that could incorporate this device into patients' regular checkups if they believe to be prone to PCOS.

Several **key assumptions** and constraints are as follows: even though aldosterone hormone-antibody competition kinetics have not yet been measured, they will act similarly to other hormone-antibody kinetics that has been tested and scientifically published. This is a single-use device, so if customers would like to continue to track their aldosterone hormone level over time, it would require multiple purchased devices.

Project Management Plan

Prototyping Plans for POPPY Diagnostic Test

Prototypes:

1) **3D Printed Physical Device Prototype**
   a) **Purpose**
      i) Confirm overall device design
      ii) Evaluate overall user experience
         (1) Is it intuitive?
      iii) Find unexpected design flaws
         (1) Structural integrity of the design, etc.
      iv) Overall device geometry evaluation
         (1) Are the dimensions satisfactory?
   b) **Level of approximation**
      i) Correct for user experience to ensure intuitive design with minimal instruction.
      ii) Correct for any unexpected geometry flaws such as the device being too short, too thin, etc.
   c) **Experimental plan**
      i) Refine device CAD model
      ii) 3D print to-scale device CAD model
      iii) Evaluate 3D printed model
      iv) Redesign CAD model based on the evaluation.
      v) 3D print new CAD model
      vi) Evaluate new 3D printed models.
      vii) If the second 3D printed model is unsuccessful, a 3rd 3D printed model may be necessary. Otherwise, proceed with the final presentation.
   d) **Schedule**
      i) Week 1: Finalize CAD model
      ii) Week 2: Submit CAD model to OSU library for printing.
      iii) Week 3: Pick up a 3D printed model from the library.
      iv) Week 4: Benchmark. Evaluate 3D models for the overall design, user experience, etc.
      v) Week 5: Adjust CAD model as necessary
      vi) Week 6: Print
      vii) Week 7: Benchmark. Evaluate 2nd 3D model for the overall design, user experience, etc.
      viii) Week 8: 3D print new CAD model

ix) Week 9: Evaluate new design. If necessary, prepare for the 3rd printing of the device.
x) Week 10: TBD
xi) Finals week: Present final design.

e) Budget

i) 3D Print Models 1 and 2:
(1) Charge 16 cents per gram of plastic used. The device will be about 75-100 grams of plastic.
(2) Library printers available (can pay via account or your own credit card).
(3) Approximate cost per model print: $12.00
(4) Total cost for two models: $24.00 (high estimate)
(5) If the 2nd 3D printed device needs additional work, a third printing may be necessary. Then, the total cost would be $36.00.

2) **Hormonal prototype**

a) Purpose

i) Select Antibody and anti-antibody type (eg. mouse, monoclonal, etc) and concentration to calibrate Aldosterone hormone level
ii) Confirm theoretical hormonal assay model is feasible as a physical product

b) Level of Approximation

i) Correct mass of each antibody and anti-antibody per site

c) Experimental plan

i) Buy a hormone 1 of known concentration online, and buy a respective B-Antibody 1 and an anti-B Antibody indicator.
ii) Place a range of corresponding masses of B-antibody 1 and Anti B Antibody indicators on strips of Whatman filter paper
iii) Perform a range of hormonal mechanics tests to determine if it is feasible to use given masses antibodies to consistently sense a hormonal threshold mass (and therefore concentration with a given volume).

d) Schedule

i) Week 3: Contact Dr. Fu and ask her if she is willing to help mentor us in our project
ii) Week 3: obtain hormone 1, respective B-Antibody 1, and anti-B Antibody indicators
iii) Week 5: Calculate respective range of masses of Antibody 1, and anti-B Antibody indicators and volume and concentration of Hormone 1

iv) Week 7: Perform the tests with the varying calculated range of masses of antibodies and the volumes of hormones to determine the feasibility and consistency of hormonal threshold assay.

e) Budget

i) Hormone 1 and Antibodies: Too expensive for our budget, will have to look for labs that will kindly donate/loan small portions for testing. Possibly Dr. Giers/K/Fu

ii) Whatman Filter Paper: Lewis has this in his lab, but normally $27

3) Fluid transfer prototype

a) Purpose: Select fluid transfer paper

i) How well the fluid (urine) flows through the device and thresholds

ii) This will be used for the final physical product, the prototype will confirm

iii) The paper wicks as expected by the Lucas-Washburn equation.

iv) Paper is chemically inert with respect to antibodies and antigens in urine

b) **Quantity to be built:** Six will be built, three replicates of two different paper types. Each paper type will use a control solution with marker antibodies on the paper, an antigen-containing solution with no antibodies, and an antigen-containing solution on antibody marker-coated paper.

c) Schedule

i) Week 1: COVID setback

ii) Week 2: Reach out to Dr. Fu for assistance with loading antibodies on paper diagnostics. Order paper, research, and order antibodies.

iii) Week 3: Construct experimental plan

iv) Week 4: Benchmark.

v) Week 5: Perform experiments with Dr. Fu's lab help.

vi) Week 6: Analyze results

vii) Week 7: Benchmark.

viii) Week 8: Incorporate the model into a full physical product.

ix) Week 9: Perform full model experiments.

x) Week 10: Analyze results, polish final product.

xi) Finals week:

d) Budget

i) Whatman Filter Paper: Lewis has this in his research lab, but normally $27

(1) This was changed to nitrocellulose based on guidance from Dr. Fu, and the materials were then provided to us at no charge

ii) Chromatography paper: $13

Gantt Chart

Throughout the term, we had tracked our progress using the following Gantt chart. Figure I shows the first outline of our Gantt chart for the beginning of the term. While prototyping, we would fill out the boxes with the progress that we had made in that task. Figure II shows our completed Gantt chart with all our tasks completed. More Gantt chart progression throughout the term can be found in the Appendix.

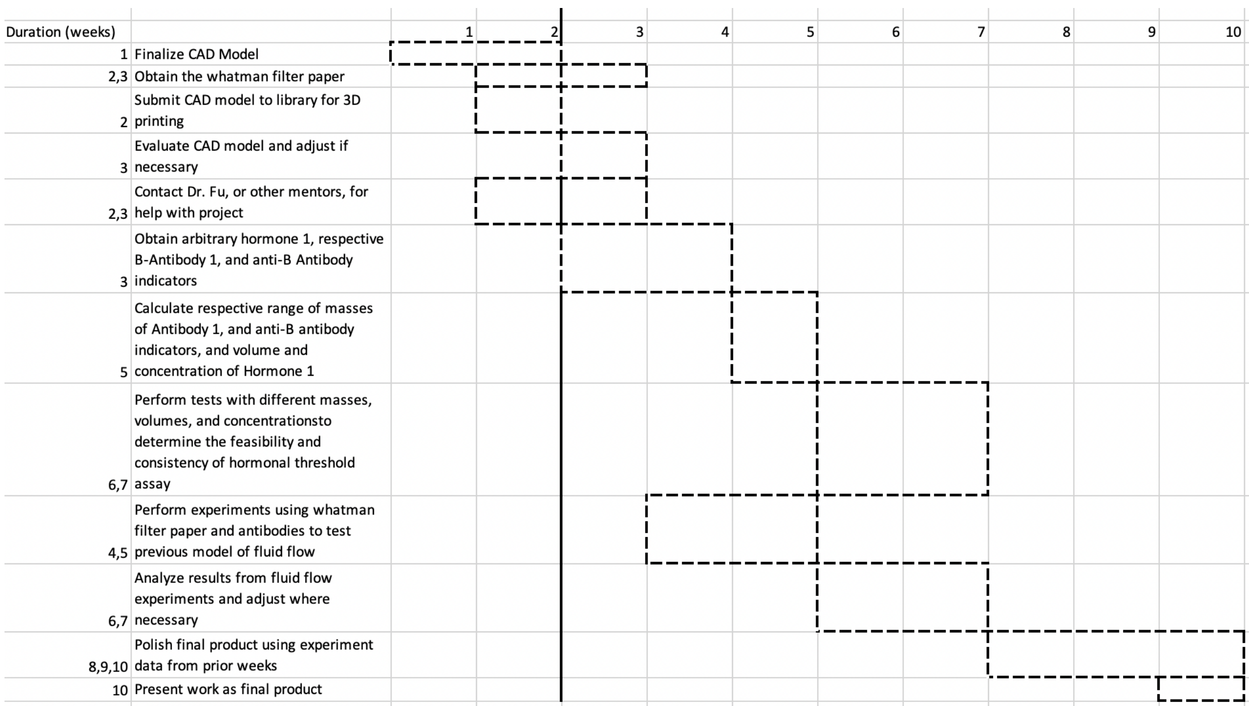


Figure I. Gantt chart at the beginning of the term made to track the progress of the prototyping stages.

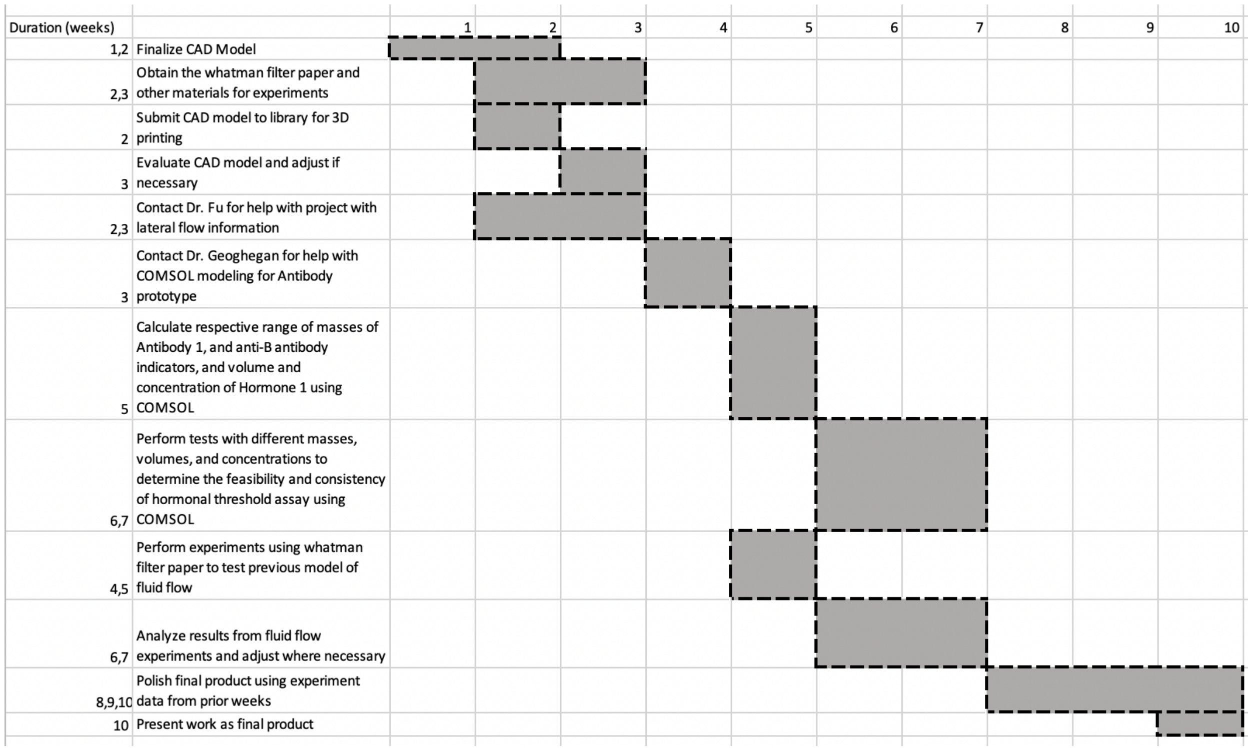


Figure II. Our completed Gantt chart at the end of the term with all our tasks completed in week 10.

Safety Plan

Some potential risks that we were worried about were working with antibodies and contaminating the antibodies. To fix this problem, while working with the antibodies we can use appropriate PPE and, possibly, find a potential lab setting that would allow us to work on our project. Ultimately, no actual antibodies were needed for the prototyping stage and mathematical modeling was used instead.

Design Structure Matrix

Our design matrix shown in Figure III below represents and analyzes the task dependencies of each specific job we want to get done. In order to complete some of our past tasks, they depended on other tasks for the completion of POPPY.

B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
		A	B	C	D	E	F	G	H	I	J	K	L	
Finalize CAD Model	A	A												
Obtain whatman filter paper	B		B											
Submit CAD model to library for 3D printing	C	X		C										
Evaluate CAD model and adjust if necessary	D	X		X	D									
Contact Dr. Fu, or other mentors, for help with project	E			X		E								
Obtain arbitrary hormone 1, respective B-Antibody 1, and anti-B Antibody indicators	F		X			X	F							
Calculate respective range of masses of Antibody 1, and anti-B antibody indicators, and volume and concentration of Hormone 1	G		X			X	X							
Perform tests with different masses, volumes, and concentrations to determine the feasibility and consistency of hormonal threshold assay	H		X			X	X	X	H					
Perform experiments using whatman filter paper and antibodies to test the previous model of fluid flow	I		X							I				
Analyze results from fluid flow experiments and adjust where necessary	J		X							X	J			
Polish final product using experiment data from prior weeks	K	X	X	X	X				X	X	X	K		
Present work as final product	L	X	X	X	X				X	X	X	X	L	

Figure III. Design Matrix for POPPY

Leftmost Column Enlarged:

Finalize CAD Model	A
Obtain Whatman filter paper	B
Submit CAD model to the library for 3D printing	C
Evaluate CAD model and adjust if necessary	D
Contact Dr. Fu, or other mentors, for help with project	E
Obtain arbitrary hormone 1, respective B-Antibody 1, and anti-B Antibody indicators	F
Calculate respective range of masses of Antibody 1, and anti-B antibody indicators, and volume and concentration of Hormone 1	G

Perform tests with different masses, volumes, and concentrations to determine the feasibility and consistency of hormonal threshold assay	H
Perform experiments using Whatman filter paper and antibodies to test the previous model of fluid flow	I
Analyze results from fluid flow experiments and adjust where necessary	J
Polish final product using experiment data from prior weeks	K
Present work as final product	L

Competitive Benchmarking

POPPY is an at-home screening testing kit that will aid the diagnosis process of polycystic ovary syndrome, PCOS. At-home diagnostic kits have been around for a while now and the most familiar one being pregnancy tests. Now with the pandemic, at-home COVID-19 testing kits have been popularized because it allows for a fast diagnosis at home. Similar to pregnancy tests, POPPY will be testing for hormone levels in urine, although the target is aldosterone which is different than in a pregnancy test. There are currently no at-home aldosterone hormone testing kits that are readily available. Getting your aldosterone hormone levels checked would require multiple trips to the doctors which can be an inconvenience for many reasons. POPPY would reduce this issue and allow for an easier screening process of PCOS that has not been done before. The current diagnosis process for PCOS requires transvaginal ultrasounds, blood tests, and pelvic exams which are extensive, expensive, and invasive. For this reason, POPPY is innovative in design and can be influential to many women that may be suffering from PCOS. By basing our design on the standard pregnancy test lateral flow design, we were able to focus our efforts on designing a product around how our test would work best, as described later in our prototyping efforts on page 17. We focused on matching or improving the ergonomics of the standard pregnancy test while maintaining enough of its physical attributes and functionality to make the product familiar to the user.

Metrics and Final Specifications

From our needs and specifications list, we chose to focus on usable at home with little to no assembly, fast and accurate diagnosis with clearly understood results, and simple and intuitive to use. POPPY will come pre-assembled to make it more convenient and comfortable for the user. POPPY will work similarly to a pregnancy test in terms of urine fluid flow but will be testing for aldosterone hormone instead of HCG hormone. This will allow the user to be comfortable using our product based on familiarity. The most important need that we wanted to focus on was a fast and accurate diagnosis with clearly understood results. It was concluded that using our competitive antibody assay and fluid flow experiments, POPPY will be able to deliver an accurate response to urine aldosterone hormone levels in about 5 minutes. The lateral flow experiments confirmed that the fluid flow through our device would take about 5 minutes and would allow time for the urine to bind to the antibodies. The test results will be displayed colorimetrically with visible lines, semi-visible lines, or no lines indicating aldosterone levels. The lines represent different threshold amounts of aldosterone hormone levels in one's urine, so a visible line will indicate that a low aldosterone hormone level is present while no visible line will indicate high aldosterone hormone levels. The comfortability of the physical prototype was surveyed by a group of users to ensure that POPPY is user-friendly. Figure IV below shows our ranking of the importance of our needs and how we were to measure them.

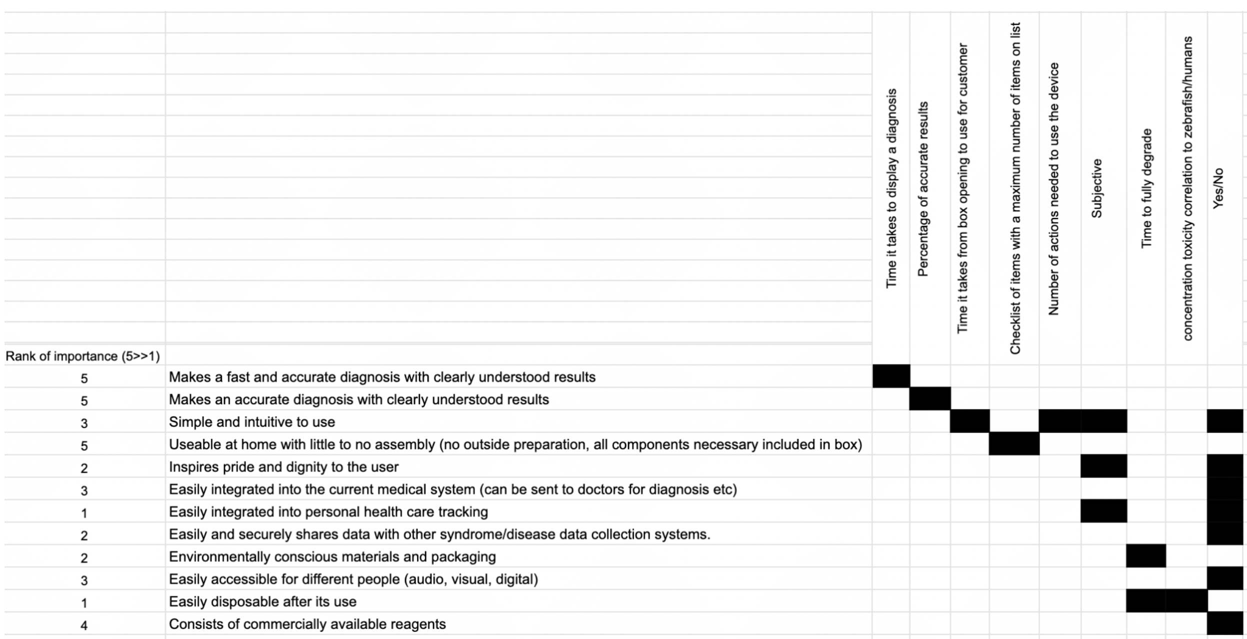


Figure IV. Need and specifications chart for POPPY

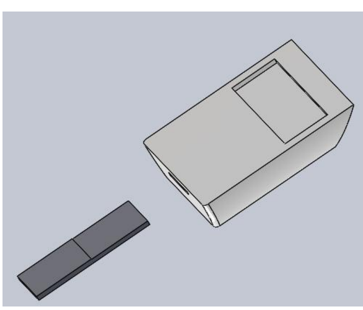
Design Solutions Concepts Considered

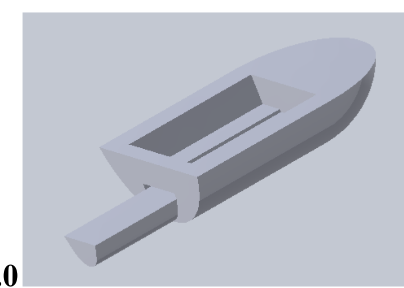
Multiple design concepts revolving around three key concepts were originally considered. 1. The sample for hormone analysis could have been taken from saliva, blood, or urine. 2. The assay considered to analyze the target hormone could have been an ELISA sandwich assay or a competitive assay. 3. The target hormone indicative of PCOS could have been either aldosterone, progesterone, or both.

Concept Selection

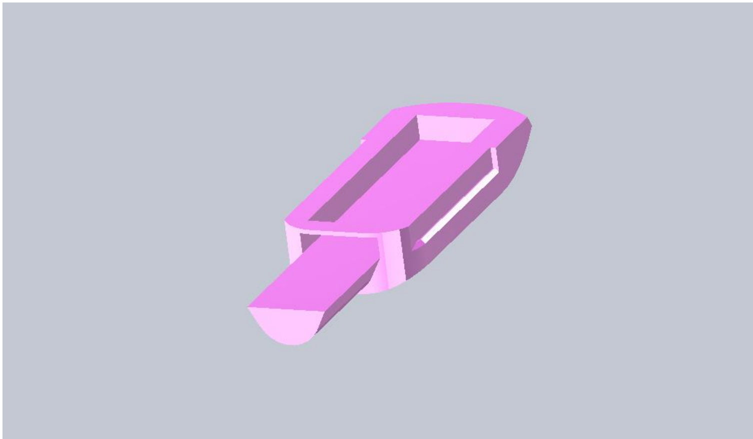
The method for which a sample is taken was ultimately decided by the most convenient method and lowest barrier to entry: a urine sample. Potential familiarity with pregnancy tests, easy access to large sample volumes (unlike saliva samples), and no pain (unlike blood samples) all factored into the decision to use urine samples. A competitive assay was used at the advice of Dr. Elain Fu, as our target hormone was too small to be bound by two antibodies at the same time. Finally, aldosterone was chosen as the target hormone as there was a study that specified a normal range of aldosterone in the blood that was incorporated in our model to screen for PCOS. For the physical model, iterations were created that evolved based on lab-tested fluid flow models, and surveys with user feedback.

Problems	Proposed solutions	methods				
			Abundance	Accuracy	Ease of Access	Total Score
		Saliva	1	2	5	8
		Blood	5	4	2	11
how to screen for PCOS	test for hormone concentrations in a sample	Urine	4	3	5	12

v1.0


v2.0


Final Project Concept



The final concept design for POPPY, is a lateral flow test carried out on this testing device shown above. The design will include an LDPE thin-film coating and be made of casein plastic at full scale-up, but for now, our physical design could be completed with 3D printing using PLA and a polyester lining with adhesive backing to model the behavior of each of the materials without access to injection molding. The ergonomics of the device were improved over iterations by creating a longer device with beveled edges for improved grips. See Figure 1 in the appendix for key dimensions and engineering drawings.

The case is designed to contain a sample pad made of glass fiber that will absorb 5 mL of urine. This metric was achieved by increasing the aperture between the sample pad and the display portion of the device. From there, the glass fiber will distribute liquid to two layers of nitrocellulose strips containing gold-labeled aldosterone and antibody capture regions. As the urine flows laterally across the strip, it will slow down based on the Lucas-Washburn equation modeling lateral flow. The length of the device allows for a five-minute flow period, in which the antibodies and aldosterone will have adequate time to bind.

Engineering Analysis of Design/Prototyping Efforts

In order to ensure proper fluid flow so that POPPY could function properly, different materials were tested within the physical prototype. The materials that were tested included Whatman filter paper, glass fiber, nitrocellulose paper, and polyester with adhesive on one side that were all provided to us by Dr. Fu. The first 3D printed physical prototype was used for testing and then the overall design was adjusted based on the results of the experiments. Throughout our testing, it was determined, for the sample channel, that the nitrocellulose paper absorbed the amount of water that was necessary to flow through the device in an adequate amount of time. In Figure V, you can see the initial materials being tested with our first physical prototype. To allow for more time for the water, which was acting as urine, to flow up the device, 2 nitrocellulose wicking layers were added to the final lateral flow prototype as shown in Figure VII. For the sample pad, glass fiber was the best choice. Glass fiber is an absorbent material that has been used for other lateral flow devices such as pregnancy tests, so it seemed fitting for POPPY. In order to absorb about 5 mL of liquid, 12 glass fiber layers were needed. This was determined by using different amounts of glass fiber strips and stacking them on top of each other and then adding about 5 mL until there was enough saturation without overflow as shown in Figure VI. The polyester with adhesive backing was added to the base of the physical model first which would act as our LDPE thin film layer to protect the integrity of the device. Once the lateral flow experiments were done and the proper materials were determined, the physical prototype was adjusted to allow for a sleeker design that better fit the needs of the customer. The physical prototype had a larger opening for the 12 glass fiber layers for the sample pad and a longer sample channel with the two nitrocellulose wicking layers. Then, the overall design was assembled and tested using about 5 mL of water on the sample pad along with timing the flow up the wicking layers. The total flow time was about 5 minutes which was on target for the antibody assay as well.

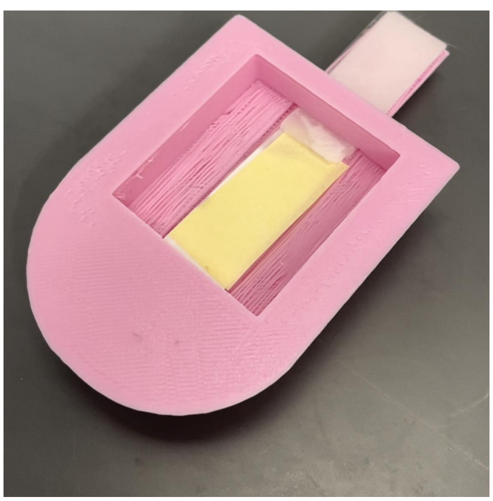


Figure V. Lateral flow experimentation with first physical prototype

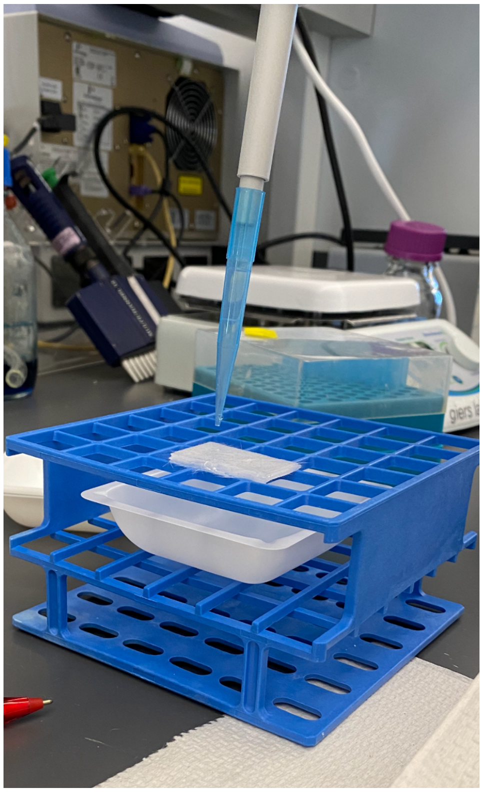


Figure VI. Performing lab experiments with glass fiber to test for absorbance through stacked layers for the sample pad of our device

Figure VII. Final physical prototype with nitrocellulose strips and glass fiber sample pad

Human Factors Considerations

To comprehensively understand the user perspective and take into the consideration user experience to better iterate POPPY's design a short Qualtrics survey was conducted with n=20 participants (14 females, 6 males, 0 nonbinary) ranging from 18 to 33 years of age. Of the 20 participants, 36% were previously familiar, experienced symptoms, or were diagnosed with PCOS.

The purpose of this survey was to collect feedback regarding the POPPY at-home diagnostic test's physical and aesthetic design, ergonomics, and overall user experience. Users were presented with the physical models for Poppy designs 2.0 and 3.0, and asked a series of questions pertaining to the device's geometry, color, usability, awkwardness level, and accessibility, such as:

- *Which device was easiest to grip and hold?*
- *Which device do you prefer visually (color, shape, overall device form)?*
- *Which device is the most awkward to hold?*

Additionally, users were asked to type short answer responses explaining which model was their favorite and why, and how POPPY's design could be improved.

Overwhelmingly, as shown in the figures below, the survey results concluded that POPPY model 3.0 was "easier to hold" and had a more "discrete" and "aesthetic" design. Overall, POPPY model 3.0 was "less awkward" and "would be easier to pee on."

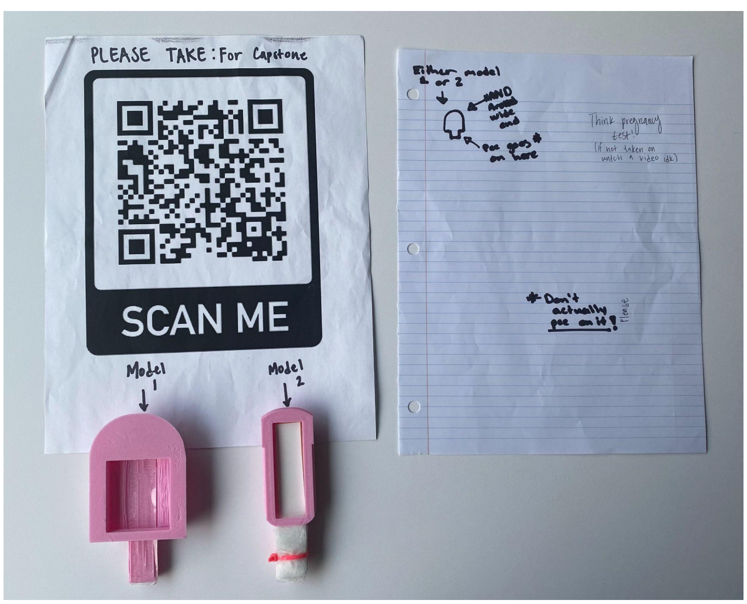


Figure VIII. Survey Set Up at Oregon State Campus

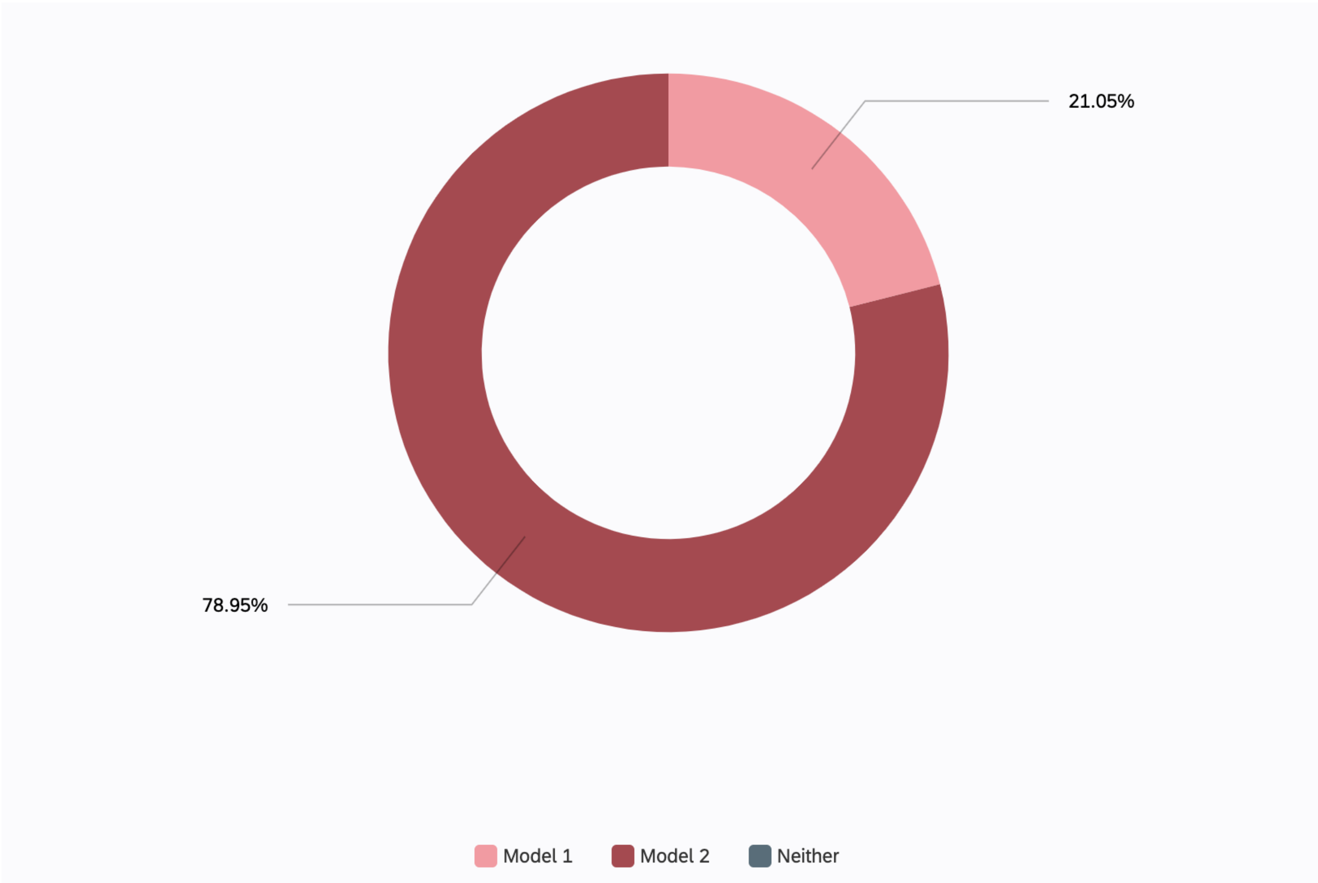


Figure IX. Qualtrics survey responses for the question "Which Device was Easiest to Grip and Hold?"

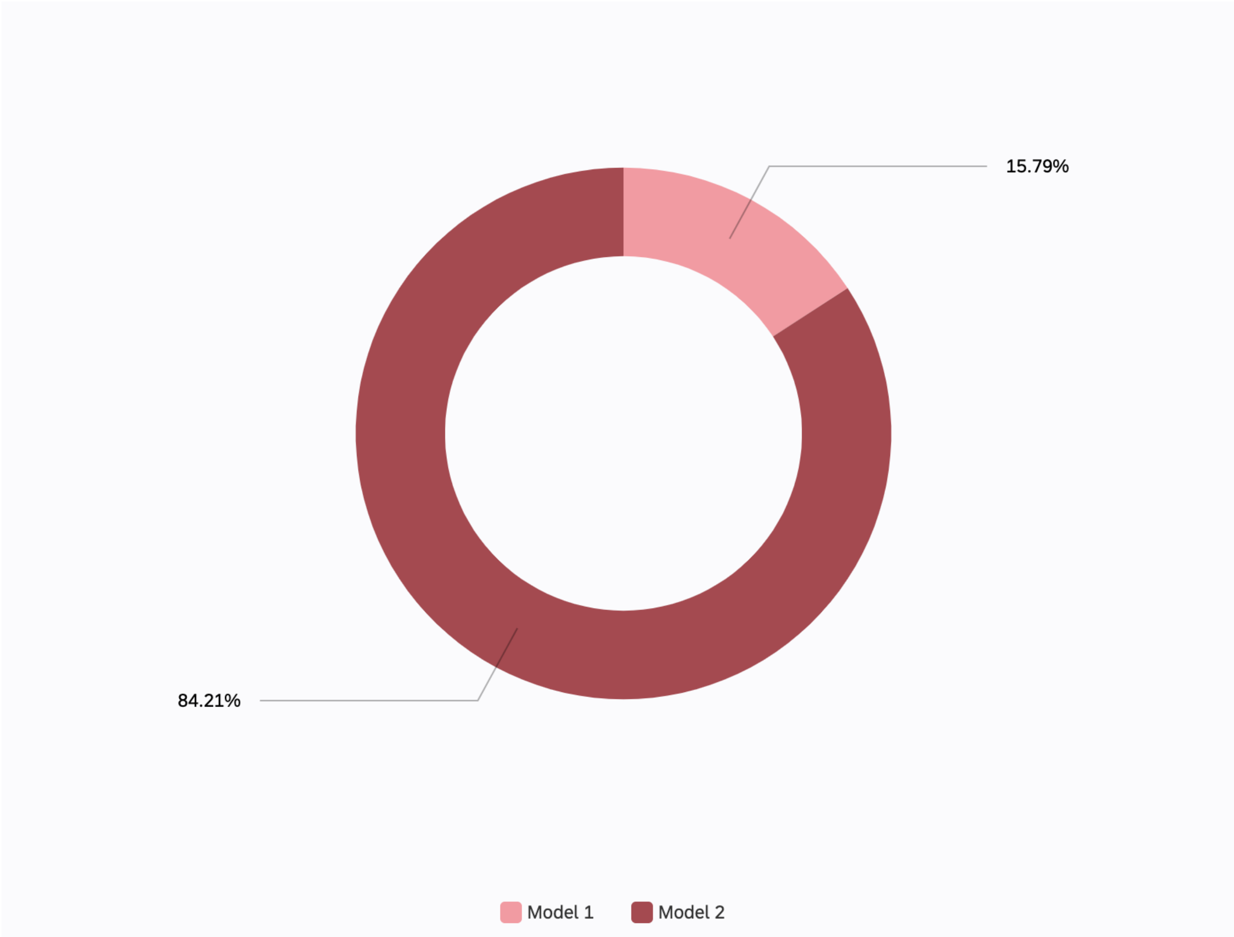


Figure X. Qualtrics survey responses to the question “Which device do you prefer visually (color, shape, overall device form)?”

In addition to the user experience, the user’s safety was also considered. Although the device itself poses no harm, it is clearly communicated to the user that POPPY is *not* an acceptable replacement for a professional physician's diagnosis, examination, or laboratory conclusion. POPPY is *not* meant to definitively diagnose PCOS; only acts *in accordance with* the professional medical council when appropriate and/or necessary. Legally, POPPY and the POPPY Design Team are *not* liable or responsible for any inconclusive or incorrect results.

Design For Manufacturing

The POPPY design team had identified principles of our device that contributed to the design for manufacturing from the first day after we had selected our solution. We wanted POPPY to be constructed from entirely commercially available materials and reagents. We were able to meet this expectation by using PLA as the case material, nitrocellulose as the wicking strip, glass fiber as the absorbent pad, and gold nanoparticles and anti-aldosterone antibodies that are all widely commercially available. From this constraint, we made a product that was more translatable into mass production than if we had made a solution that required specialty reagents.

The iterations of the POPPY case were designed with progressively less material. This makes the overall manufacturing cost go down dramatically when considering we reduced our original estimate of $12 per print of our design to under $2. Ergonomic improvements to POPPY such as beveled edges actually served to reduce the amount of material used for the manufacturing of POPPY, while improving the user experience with our product. Additionally. The estimate for unit cost becomes even lower per unit once considering the scale-up from 3D printing to injection molding.

Design Economics and Cost Analysis

Modeling have determined that POPPY has a net present value of $22.3 million. The assumptions made for this valuation are presented below. We prioritized marketing/support over other capital expenditures because the main concern for our product's success is the awareness of PCOS as a medical issue. Beyond that, other costs are smaller than that of other facilities because of the cheap cost and commercial availability of our raw materials. A difficult assumption to set a value on was the cost per unit, as it has the largest impact on our net present value. It is difficult to determine what effect the cost per unit will have on accessibility for healthcare and weigh that against making a profitable company. The production at a larger scale also made assumptions more difficult because it is difficult to account for discounts in bulk, as well as the efficiency of toolings like injection molds and thin-film coating.

Model Inputs	Model Values			
Quarterly Sales Profile, units	20%	25%	25%	30%
Sales Volume Growth, units	15%	per year		
Initial Sales Volume, units	2000000	units/year		
Initial Retail Price, units	$15	per unit		
Distributor + Retail Margin	40%			
Retail Price Growth, units	-10%	per year		
Product Development	0.4	$M over 1 year		
Equipment and Tooling	1.0	$M over 1/2 year		
Production Ramp-up	1.0	$M over 1/2 year		
Market Launch	3.0	$M over 1/2 year		

Marketing and Support	4.0 $M/year
Production Cost, units	$1 per unit
Production Overhead	1.0 $M/year

These assumptions yield the cash flow chart below.

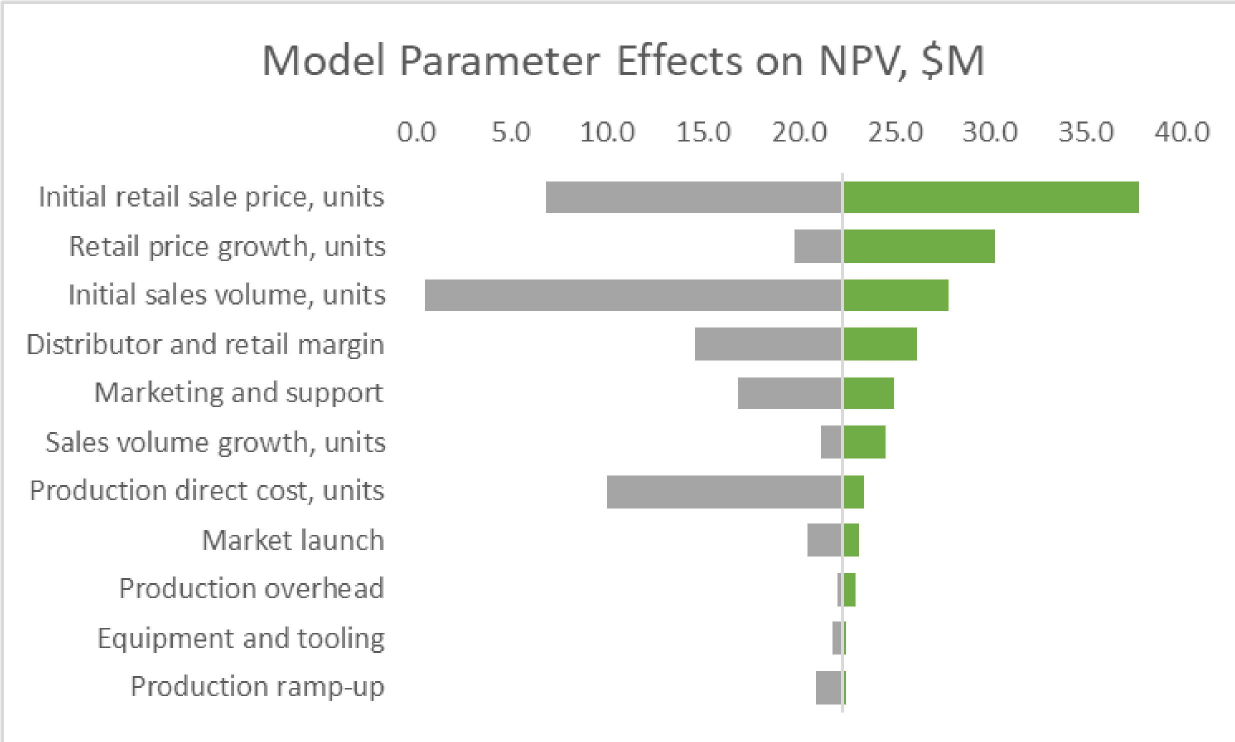
Values in $M *(except where noted)*	Year 1				Year 2				Year 3				Year 4			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Sales, units					3.60	4.50	4.50	5.40	3.73	4.66	4.66	5.59	3.86	4.82	4.82	5.78
Sales Volume, units (units/qtr)					400,000	500,000	500,000	600,000	460,000	575,000	575,000	690,000	529,000	661,250	661,250	793,500
Unit Wholesale Revenue, units ($/unit)					9	9	9	9	8	8	8	8	7	7	7	7
Total Revenue					**3.60**	**4.50**	**4.50**	**5.40**	**3.73**	**4.66**	**4.66**	**5.59**	**3.86**	**4.82**	**4.82**	**5.78**
Product Development	0.10	0.10	0.10	0.10												
Equipment and Tooling			0.50	0.50												
Production Ramp-up				0.50	0.50											
Marketing and Support				2.50	2.50	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Production, units					0.65	0.75	0.75	0.85	0.71	0.83	0.83	0.94	0.78	0.91	0.91	1.04
Total Costs	**0.10**	**0.10**	**0.60**	**3.60**	**3.65**	**1.75**	**1.75**	**1.85**	**1.71**	**1.83**	**1.83**	**1.94**	**1.78**	**1.91**	**1.91**	**2.04**
Period Cash Flow	-0.10	-0.10	-0.60	-3.60	-0.05	2.75	2.75	3.55	2.02	2.83	2.83	3.65	2.08	2.91	2.91	3.74
Period Present Value	-0.10	-0.10	-0.57	-3.36	-0.05	2.48	2.44	3.09	1.72	2.38	2.34	2.96	1.66	2.28	2.24	2.83
Net Present Value	**$22.3 million**															

For the sensitivity analysis, it was found that the most sensitive factor for the valuation of our product will be the total number of units sold off initial sales. We based our assumptions on many units being sold and matched our marketing budget as such. If only 30% of people affected by PCOS use this product, our sales model will be accurate, but it is crucial that the main mission of the product, to make the diagnosis of PCOS more accessible, is seen out. The most effective way to do this is through marketing, and thus our $4 million in investment towards marketing is justified.

Although some materials, such as antibodies and gold nanoparticles have high unit costs, they will be used at low concentrations, making the overall cost per unit still sit at 3 dollars for materials.

Another sensitivity that we are acutely aware of is the cost of each unit to the consumer. With our mission in mind, we are committed to keeping the price of these units as low as possible. This will also help our sales, but our sensitivity analysis shows that a $5 increase in cost per unit would add more than $10 million in value to our company.

The disparity of the effect of a best-case scenario and worst-case scenario as depicted for the production cost and initial sales volume was made to reflect the uncertainty we have around how cheap we can actually produce the model in bulk, and the effectiveness of our marketing in making this product available in retail to a large market.



Regulatory Review and Strategy

Our product would fall under the Class II medical device classification of the FDA. This is because the product's success does not mediate a life or death situation in any circumstance, but the metric it diagnoses would inform actual healthcare decisions, making its accuracy non-trivial. The secondary classification of this classification would mean that we would have to file for pre-market approval through the FDA, but there is a hope that we could demonstrate the similarities between our device and a device under product code 862.1485 that tests for urine concentrations of luteinizing hormone (LH) which is another indicator of PCOS. If we are able to get an exemption from this, it would ease the regulatory burden significantly for our company.

IP Review and Considerations

Group 4 IP Research	TIffanie A Murcia, Paris Myers	Lewis Shotton, Rees Alan Rosene		
PATENTS				
	Patent #	Date of Patent	Patent Name	List of inventors
	US20150094227A1	4/2/2015	PREGNANCY TEST DEVICE AND METHOD	David McCarthy, Saji Eapin
	US3579306A	1971-05-18	DIAGNOSTIC TEST DEVICE	Margaret Crane
	US6372516B1	2009-04-30	Lateral flow test device	Ming Sun
	US8152735B2	2012-04-10	Diagnosis of fertility status	Vaclav Kirsner
TRADEMARK				
	Trademark #	Date of Trademark	Patent Name	List of inventors
GENOVA DIAGNOSTICS	4860163	2015-11-24	GENOVA DIAGNOSTICS	Alicia Collin Edwards
1928 Diagnostics	5111718	2017-01-03	928 DIAGNOSTICS	Christina Maxi Riepel

List of inventors	Summary of pertinence for your design	
David McCarthy, Saji Eapin	Our design's main influence for ergonomics and overall shape/ physical appearance	com/c7/72/7a/652fd28f34973b/US20150094227A1.pdf
Margaret Crane	Hormonal testing for quantitative analysis of disease markers	pis.com/4d/bc/da/778944754b72e6/US3579306.pdf
Ming Sun	The design of a diagnostic test using lateral flow as the primary physical phenominon to produce a result	
Vaclav Kirsner	Using LH, a hormone related to PCOS in a diagnostic test to determine reproductive health status	

List of inventors	Summary of pertinence for your design
Alicia Collin Edwards	Genova Diagnostics was able to trademark their Drawing or design which also includes word(s)/ letter(s)/number(s) Typeset. We would like to do this with our name "POPPY" and the distinct font and specific color of pink its written in.
Christina Maxi Riepel	This is an Illustration trademark, which includes drawing or design which also includes word(s)/ letter(s)/number(s) Typeset

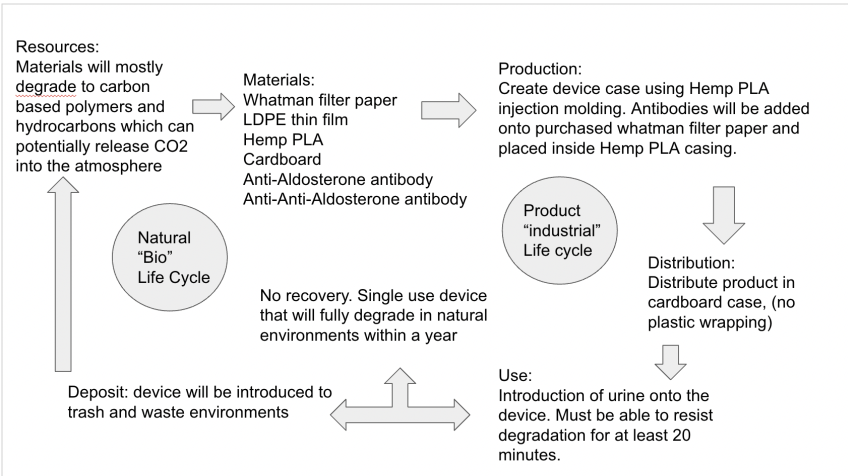
The pregnancy test patented by David McCarthy and Saji Eapin was our design's main influence on ergonomics and overall shape/ physical appearance. Margaret Crane holds a patent for hormonal testing for quantitative analysis of disease markers, which is a part of our overall design, though our actual application is in lateral flow. The design of a diagnostic test using lateral flow as the primary physical phenomenon to produce a result was patented by Ming Sun. Using LH, a hormone related to PCOS, Vaclav Kirsner holds a patent in a diagnostic test to determine reproductive health status, which could be crucial evidence for the FDA pre-approval process for our device.

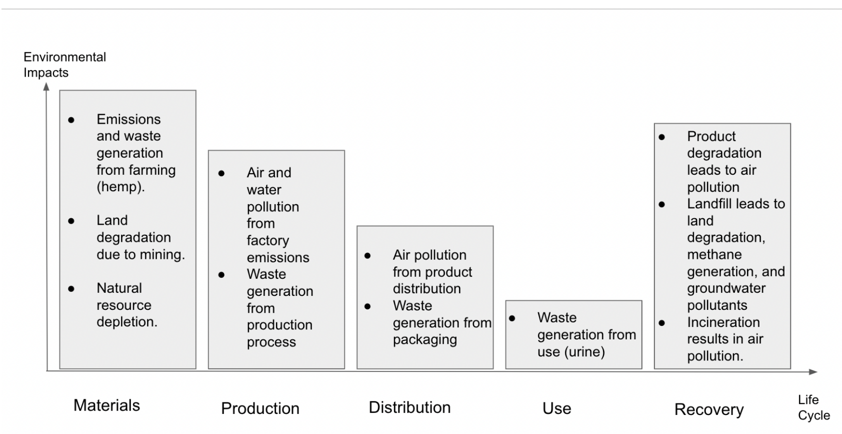
For trademarks, Genova Diagnostics was able to trademark their Drawing or design which also includes word(s)/ letter(s)/number(s) Typeset. We would like to do this with our name "POPPY" and the distinct font and specific color of pink it's written in. 1928 Diagnostics is an Illustration trademark, which includes drawing or design which also includes word(s)/ letter(s)/number(s) Typeset, which we would also like to hold for our own POPPY image for the logo.

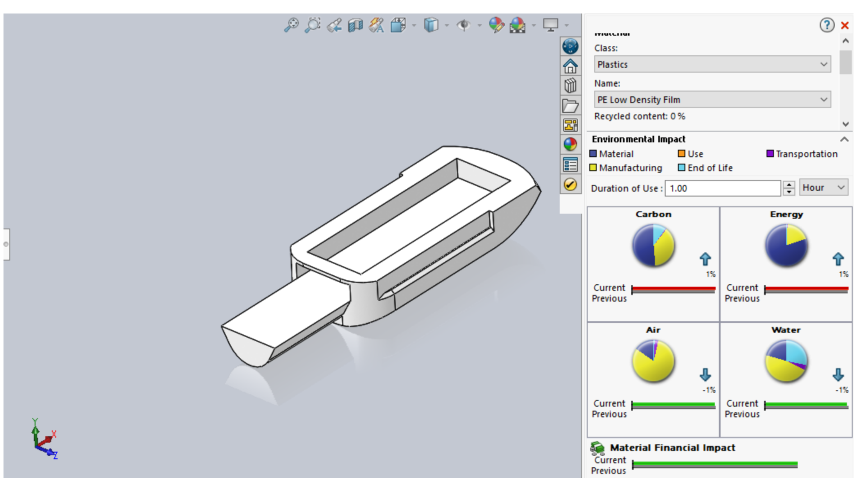
Claims Statements: A handheld device, comprising an absorbent fiberglass pad connected to a nitrocellulose strip housing specific concentrations of anti-aldosterone antibodies, all contained in a hemp plastic PLA casing coated in LDPE thin-film. Said concentration of anti-aldosterone antibodies in the device allows the device to sense if a urine sample contains above or below a target concentration of aldosterone. The device is single-use.

Design for the Environment Considerations

The material of the bulk of the device will be a form of processed hemp, the testing strip will be made of nitrocellulose, and a thin film of LDPE plastic with a thickness of 8 micrometers will cover the device.







To perform an initial analysis of the overall environmental costs of POPPY, we employed the use of the SOLIDWORKS sustainability tool. The overall cost assessed for each use of the device was higher than would be expected from the actual device, as our device would be using more sustainable materials once the product is scaled up to injection molding, allowing us to use more sustainable plastics than the ones made available inside of SOLIDWORKS. For this reason, we made our environmental analysis based on the worst-case scenario for the device. If we made the device entirely out of low-density polyethylene, instead of our intended casein or hemp-derived biodegradable plastics. Nonetheless, the device had a low overall environmental impact, and the areas that take up most of the impacts, materials, and manufacturing, will both be significantly reduced in actual production.

Summary and Conclusions

The inspiration for POPPY stemmed from a collective mission to fill the equity gap in healthcare accessibility for women by addressing PCOS, the most common endocrine disorder found in women who have undergone puberty. Globally, PCOS affects over five million women and is a lifelong condition, but it is under-researched and undertreated, and 75% of women go completely undiagnosed. There are no market-available diagnostic tests that directly confront PCOS. This startling absence in the medical device industry combined with a large, underserved customer base and projected global women's health market of an estimated 47.8 billion USD globally in 2027* lead us to a determined present net value of POPPY of $22.1 Million USD.

There is a glaring need for an innovative, discrete, and accessible device that aids in the diagnosis process for PCOS. POPPY achieves this through its fast results (5 minutes), inexpensive retail price ($15.00 USD), and convenience (app compatibility, shipped to the user, and taken at home).

The technology and material selection behind POPPY is based on three core models:
A 3D Printed Case Model, which is Refined through reduction of material, ergonomic, and application improvements; a Survey indicated an overwhelmingly positive result for model 3.0 (n=20, 84%); Competition Assay: gold nanoparticle-bound aldosterone provided in the strip will compete with aldosterone from the urine sample to bind to immobilize antibodies to create a visible line indicating the concentration of presented aldosterone in the sample; and lastly, a lateral Flow Model, which observed the Lucas-Washburn Lateral flow, providing dimensions of 5.5 cm of nitrocellulose and 12 layers of glass fiber to achieve the desired timespan for assay.

Potential future directions and considerations

1) Innovative Hemp Plastic Casing for POPPY

For the future of POPPY, the design team is excited to create strategic partnerships and collaborations with Oregon-based hemp plastic companies and manufacturers in Oregon to create a biodegradable and fully compostable plastic casing. Thereby reducing POPPY's carbon footprint and environmental impact by avoiding single-use plastics. Additionally, the use of biodegradable materials could be further explored to encompass the device's shipping and packaging.

2) Data-Driven PCOS Diagnostics and Research

Currently, the POPPY App serves as a space for the user's to access and record their test results via QR code, as well as record any physical symptoms they may be experiencing to share with their physician over time. However, the POPPY App, if deployed on a mass scale, could revolutionize the data-driven diagnosis by tracking and identifying difficult patterns and diverse displays of PCOS symptoms in the global women's health population. The goal of this would be to 1) collect biomarker data to help researchers and physicians better study PCOS, and 2) increase the percentile of women being *correctly* diagnosed with PCOS.

3) POPPY LABS

The future of POPPY is one dedicated to revolutionizing the treatment quality and accessibility to medical care for historically underrepresented and underserved communities through innovative research, product development, and community outreach. POPPY LABS is a multidisciplinary research and development campus located in the Pacific Northwest focusing on PCOS research, treatment, and human-centered diagnostic and quality of lifestyle product creation.

Individual reflection statements from the POPPY Design Team

Tiffanie Murcia

I am very grateful for this class and this process. It was a fun experience to work with different groups of people with different backgrounds working towards a common goal. The class overall has provided me with a set of skills that I can take wherever I go and it was a great opportunity to apply what I have learned throughout my years. I feel more confident in my skill set because of this class, especially with working in a group and collaborating on team ideas. I enjoyed the lateral flow testing of our device and being in a lab setting for something specific. I also enjoyed printing the SOLIDWORKS model that one of our team members did. The presentations in this class have also made me more confident in public speaking and am looking forward to the engineering expo. Overall this class was influential for me and showed me more about what engineering is.

Paris Myers

The last two terms have brought together so many different components of my engineering undergraduate education -- from chemistry and physics to fluid dynamics and renewable materials. It is honestly a bit surreal to create a product -- whose mission we truly believe in -- completely from scratch. I found myself really enjoying the lab experience of testing our lateral flow model with different materials to finalize our product. It really feels like we have created a mini company from scratch, and it was extremely exciting to do so with a group of people who all truly believe in the engineering and humanitarian value of POPPY. Additionally, rapidly integrating our 3D model with different solidworks designs, conducting UX tests, and applying the real-world feedback to our design process was an incredibly valuable learning experience. Lastly, I gained a lot of confidence in my ability to present in an engineering class setting -- I had been familiar with public speaking for humanitarian or liberal arts initiatives, but less so in the engineering classroom setting. At the beginning of the first term I was always nervous about misspeaking or forgetting a technical term, but over the last six months my comfort level has exponentially increased in this setting. Overall, I am really proud of our team -- we created a product we believe in and collaborated like a real-world engineering team (and had fun doing so).

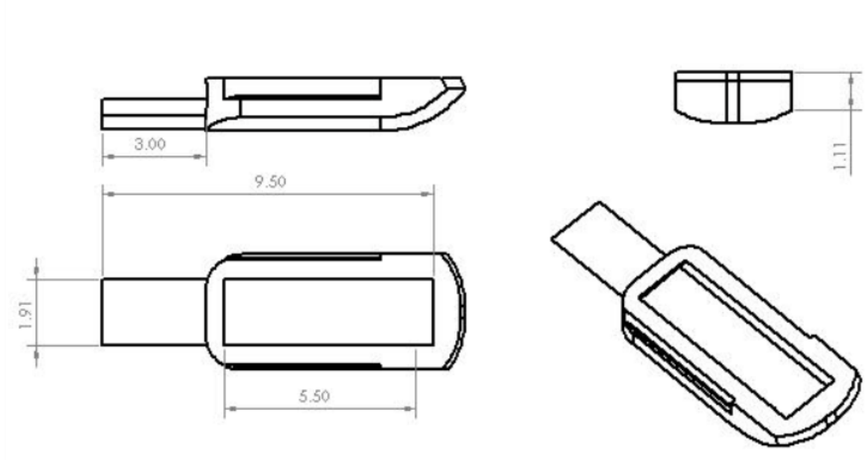
Rees Rosene

This process was extremely rewarding. I was able to work with a team of engineers to tackle small chunks of a large design task every week. In the end, it gave me a lot of confidence in my own technical skills as well as helping my teamwork, leadership, and communication skills immensely. I enjoy being able to physically hold a product that we developed as a team and see what all of the hours we put into it came out as. I particularly enjoyed doing the SOLIDWORKS rendering and 3D printing because each iteration that we produced was a lot better than the last and having a physical timeline of our efforts was really fulfilling in the end. I also enjoyed the lateral flow modeling portion of the assignment because it was the part of our design that was the most consequential to determining the dimensions of the final product, as well as giving our team valuable time to interact with our device and come up with more design refinements as we had the chance to handle our product. I found myself inspired by our mission and it made me proud to see that our team could do meaningful work to help create a more equity-centric outlook for the future of bioengineering.

Lewis Shotton

When I first started this project in the fall term, I did not realize how invested I would become in this product. I have finally been able to apply knowledge I have learned from my major courses to a real-life application that I actually care about. Throughout these two terms, our group tended to divide responsibilities within the project, and I found myself working a lot with the antibody kinetics of the product. At first, I felt as if I didn't even know how to approach the subject, but as I researched, I found myself recognizing figures and formulas in papers from specific classes that I took this year, and my confidence in my knowledge and skills grew. Along with my confidence in my knowledge, my confidence in speaking grew over these two terms significantly. I have had to give presentations before over my years at OSU, but I still felt nervous during our first few presentations in fall term, mostly because unlike any other presentation, I was being judged and critiqued by an attentive class over my technical knowledge. I am grateful I had this experience so that when I give future presentations to attentive critical audiences in a professional setting, I will be still able to comfortably present my knowledge and work like I have in the last few presentations of this term. Overall, I am grateful for all of the skills that were grown over these 2 terms (communication, teamwork, leadership, technical applications), I am grateful for the opportunity I have had to work with an amazing group of peers on a project that aptly simulated a real-world engineering project, and I am excited to continue doing this process again in a professional setting.

Appendices



units in cm

Figure 1. Engineering Drawing of POPPY

Figure 2. Engineering Expo Poster for POPPY

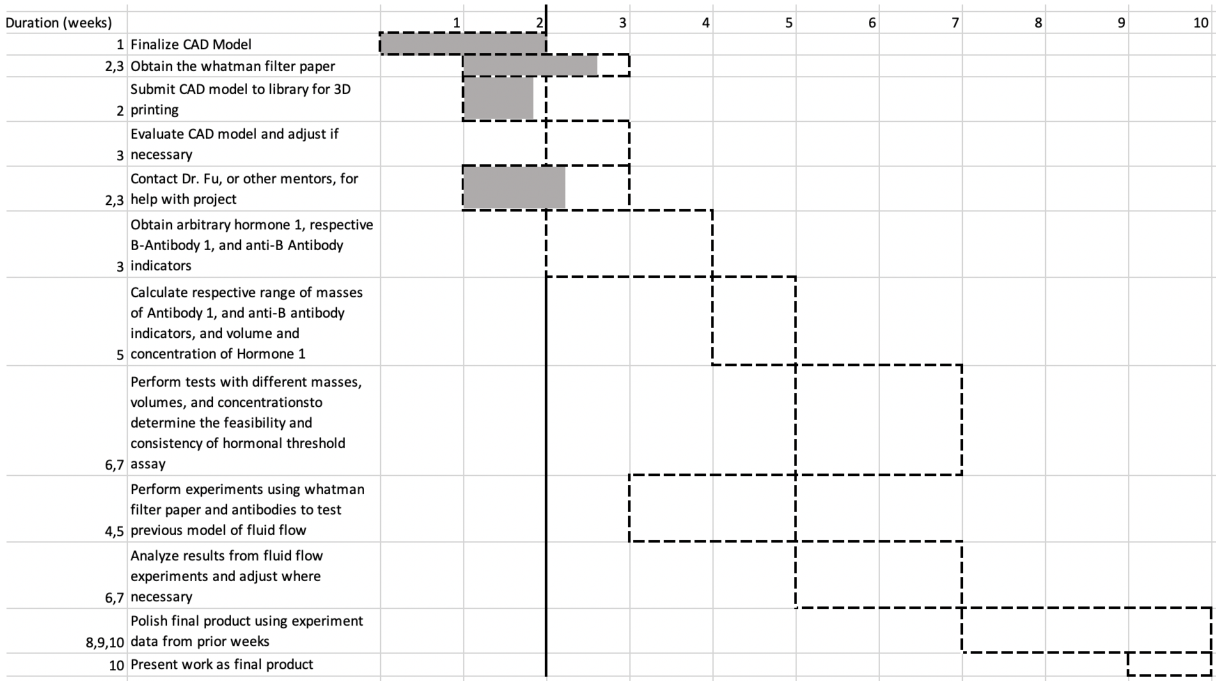


Figure 3. Gantt Chart from Week 2

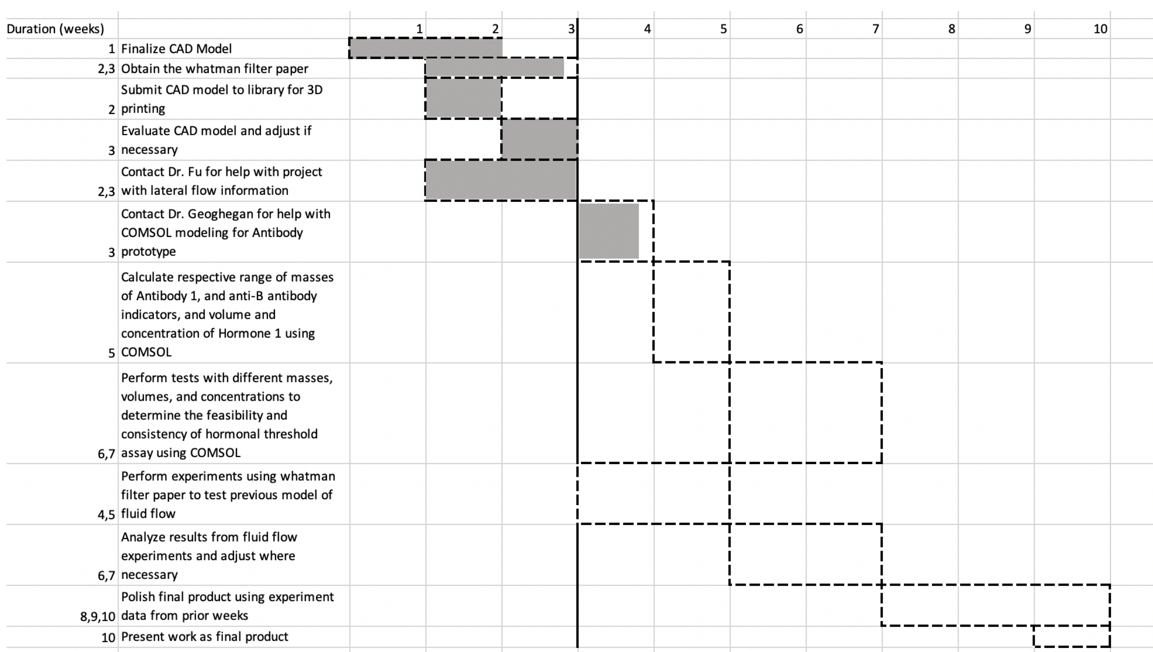


Figure 4. Gantt Chart from Week 3

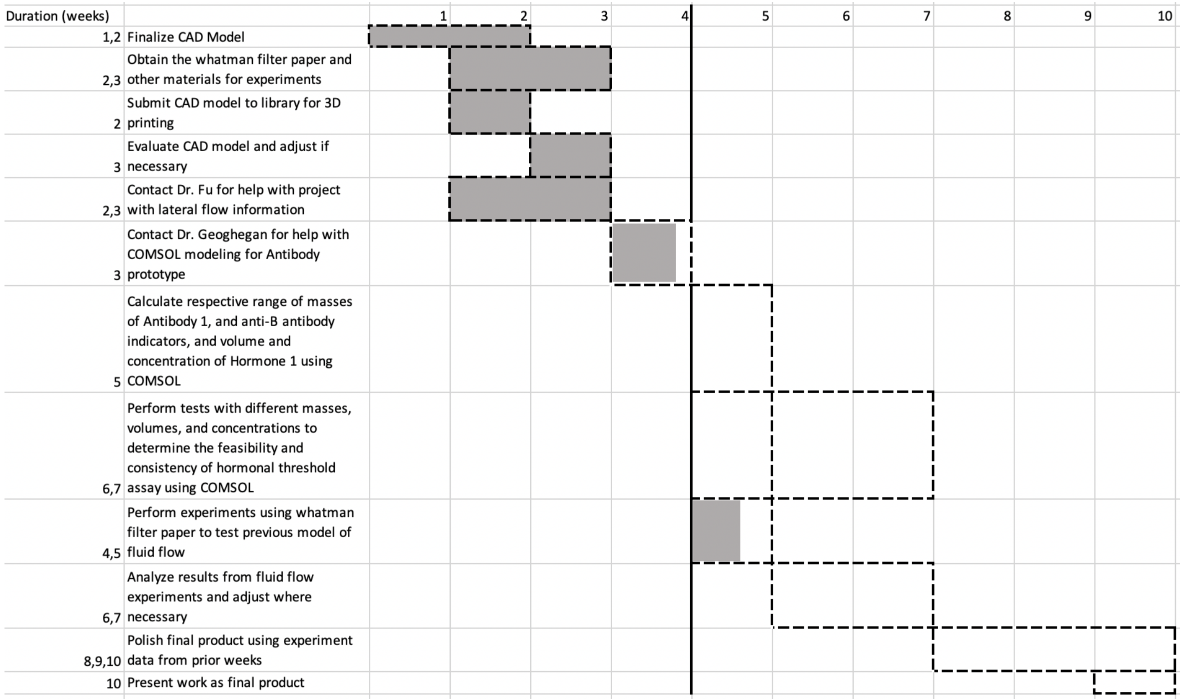


Figure 5. Gantt Chart from Week 4

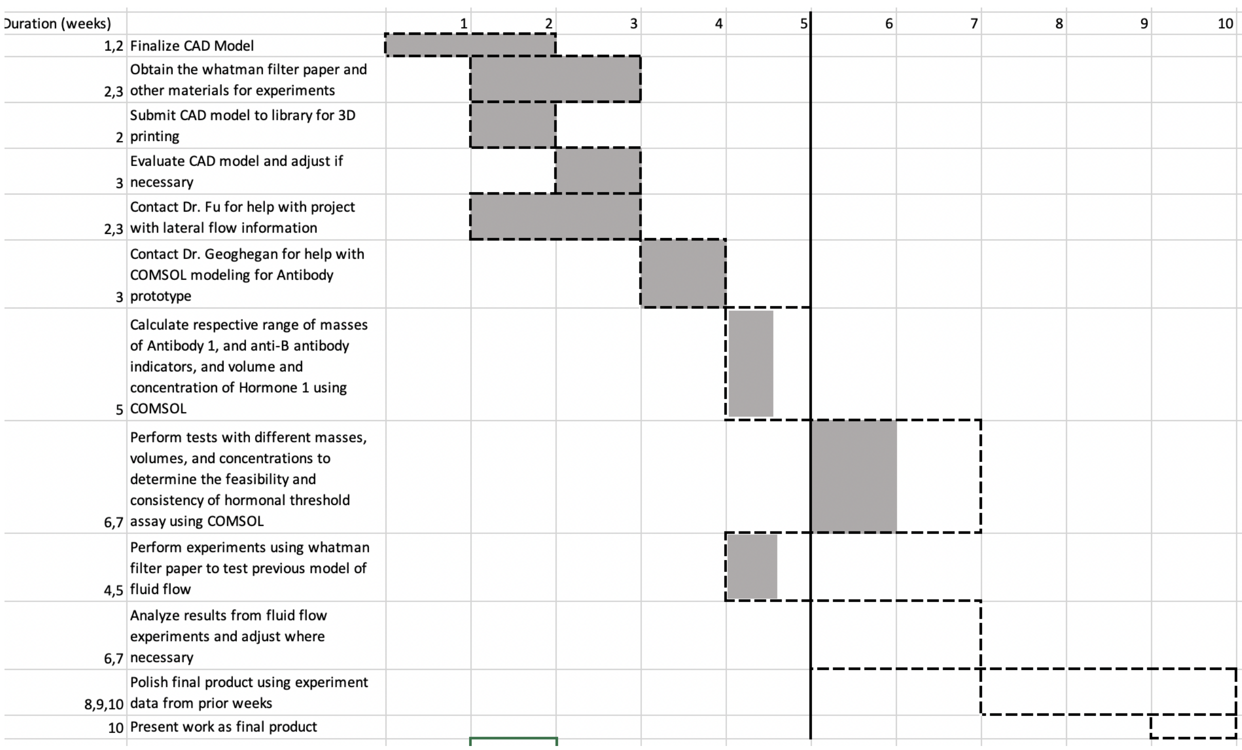


Figure 6. Gantt Chart from Week 5

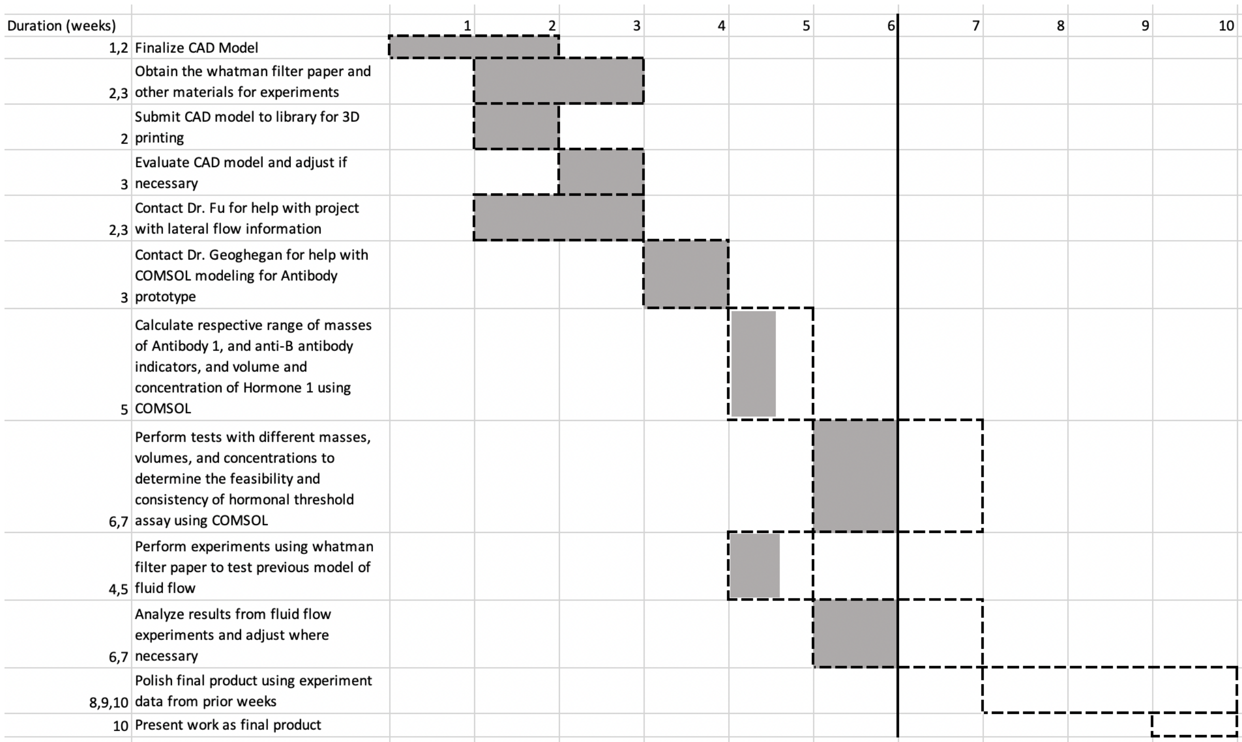


Figure 7. Gantt Chart from Week 6

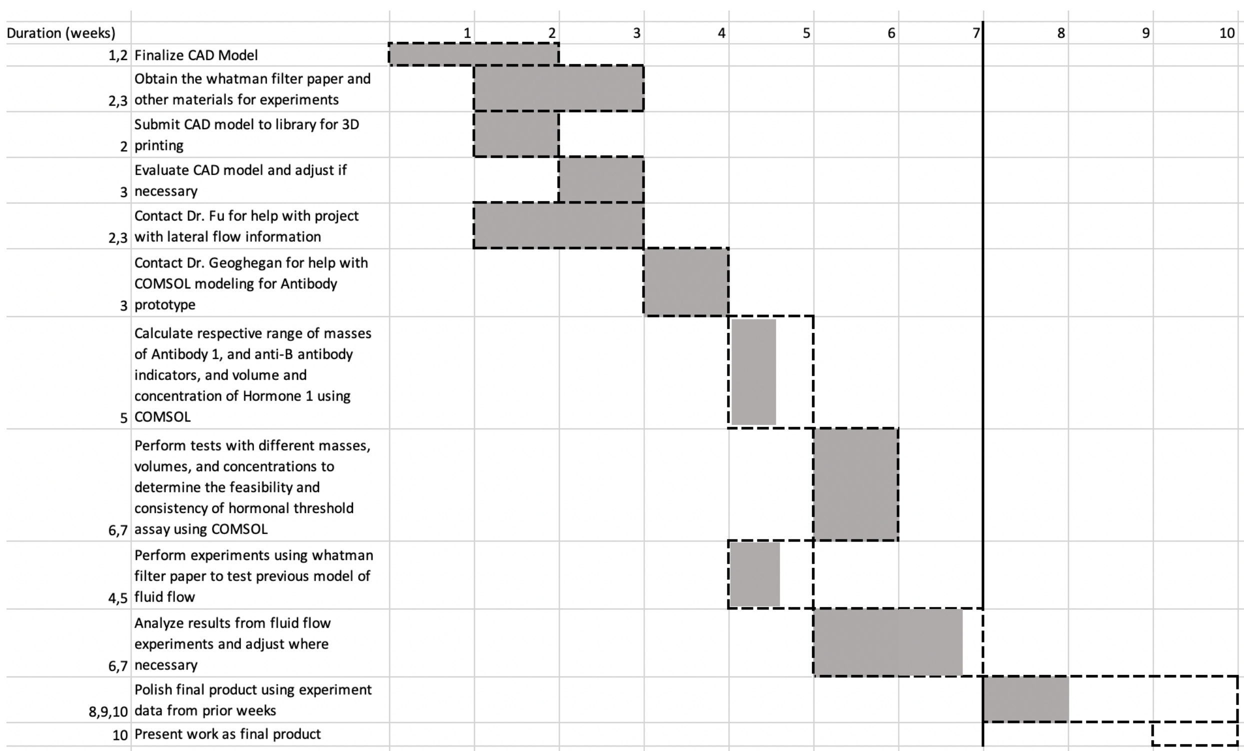


Figure 8. Gantt Chart from Week 7

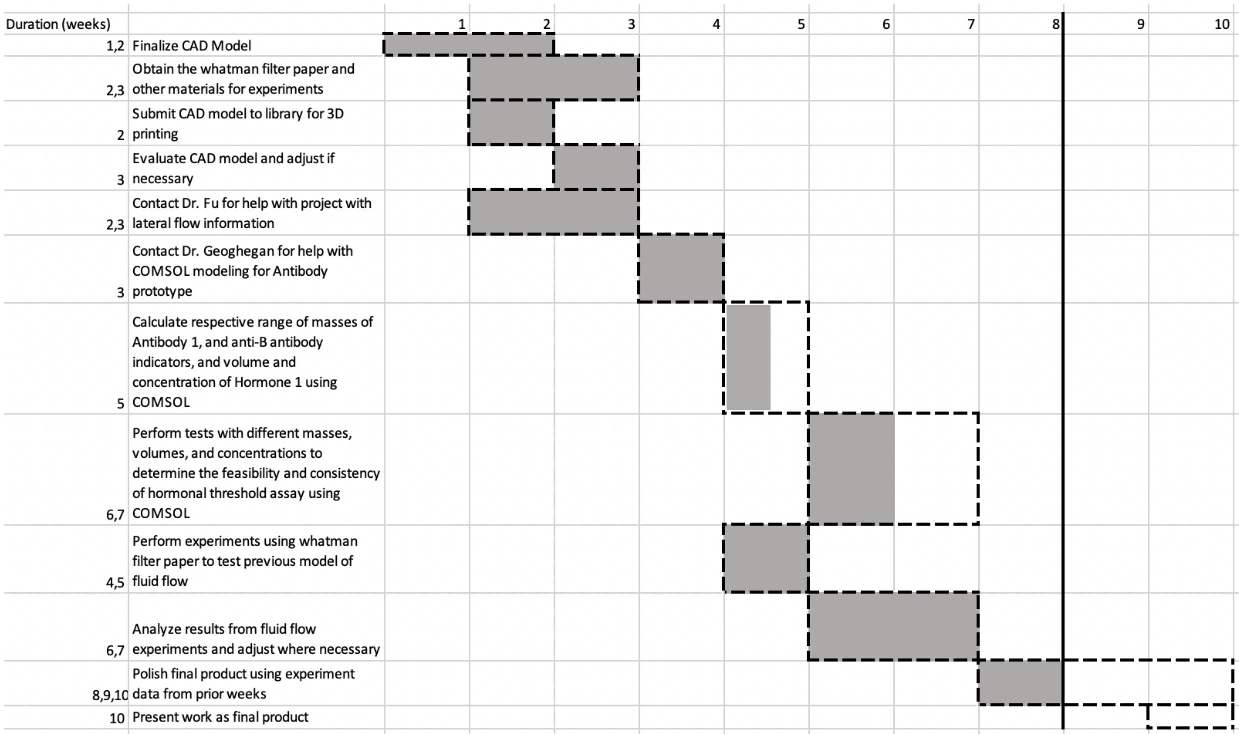


Figure 9. Gantt Chart from Week 8

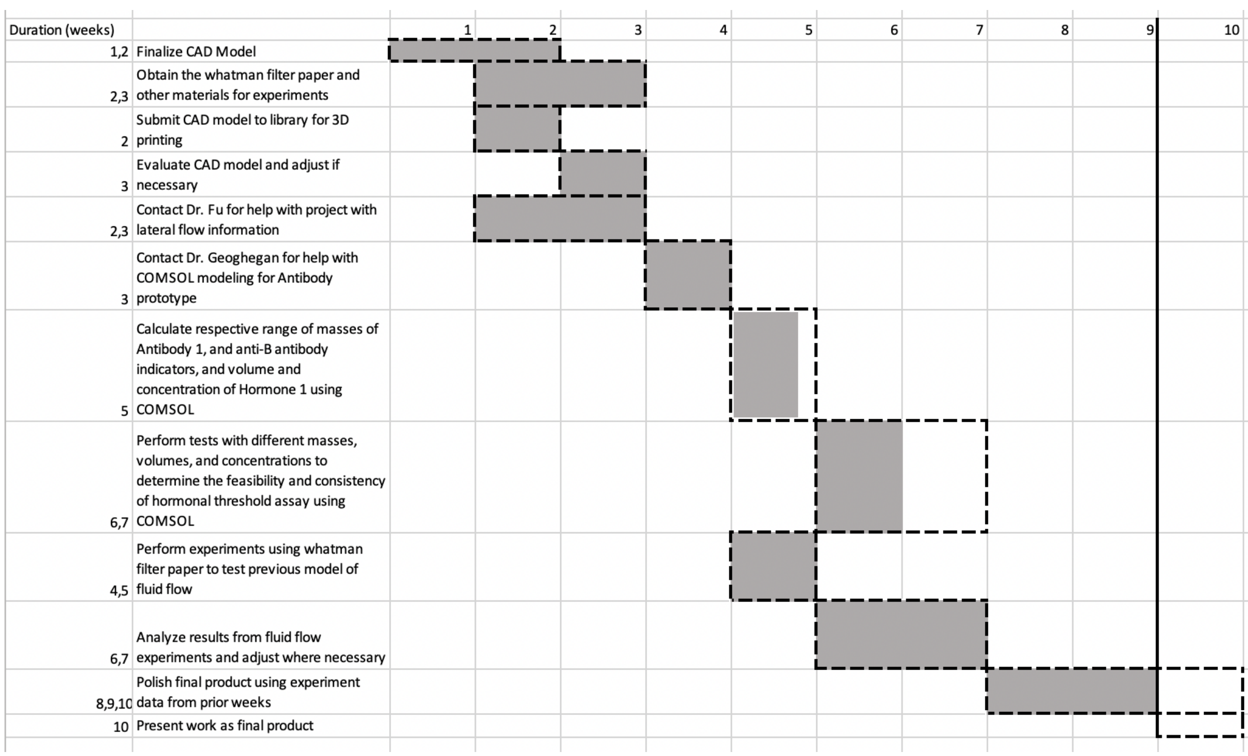


Figure 10. Gantt Chart from Week 9