Internship at Kit.com - Health Diagnostics through Mail

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INTRODUCTION



Currently the most common way to run a diagnostic test is to go to a doctor's office for a blood draw, but this has drawbacks – offices can be crowded, lead to exposure to illness, and take a large amount of time out of your day. At the Biotech startup company, Kit.com, we hope to provide the ability for clients to use our diagnostics kits in the comfort of their own home. Due to the use of the mail to deliver our kit anyone can use it and there are no needles involved to help assuage anxiety. We use a fringerprick test that uses lancets that provides a quick method that doesn't require the user to see a needle. The amount of blood needed for our tests is approximately 700uL while conventional draws can take multiple milliliters. Some examples of some tests we provide are HbA1c, Triglyceride and multiple enzyme level panels. My role is to test the components of the kit for quality and to test the user experience with volunteers.

PAST - THE NEED TO PIVOT



Kit.com underwent a pivot towards at-home health kits from its original position of a diagnostic assay that used vaginal blood or menses. The purpose of the assay was to allow a convenient option for people who menstruate to get testing without any effort beyond mailing in the used tampon. Initially the test used in the beginning was an HA₁C test for diabetes. This test was chosen as diabetes is an ailment that people would check for regularly if pre-diabetic. However, once the study was finished, no one wanted to use the assay as there are more easy and quick tests like a fingerprick test. This caused the need to pivot or else the company would dissolve. Since the menstrual blood test required us to have blood assay analyzers it made sense to switch to a product that utilized those. Our CEO landed on the idea of at-home health diagnostic kits as we already had a system in place for sending and receiving the menstrual kits. From there it was just about refining how we wanted the kit to be presented and what will be included.

PRESENT

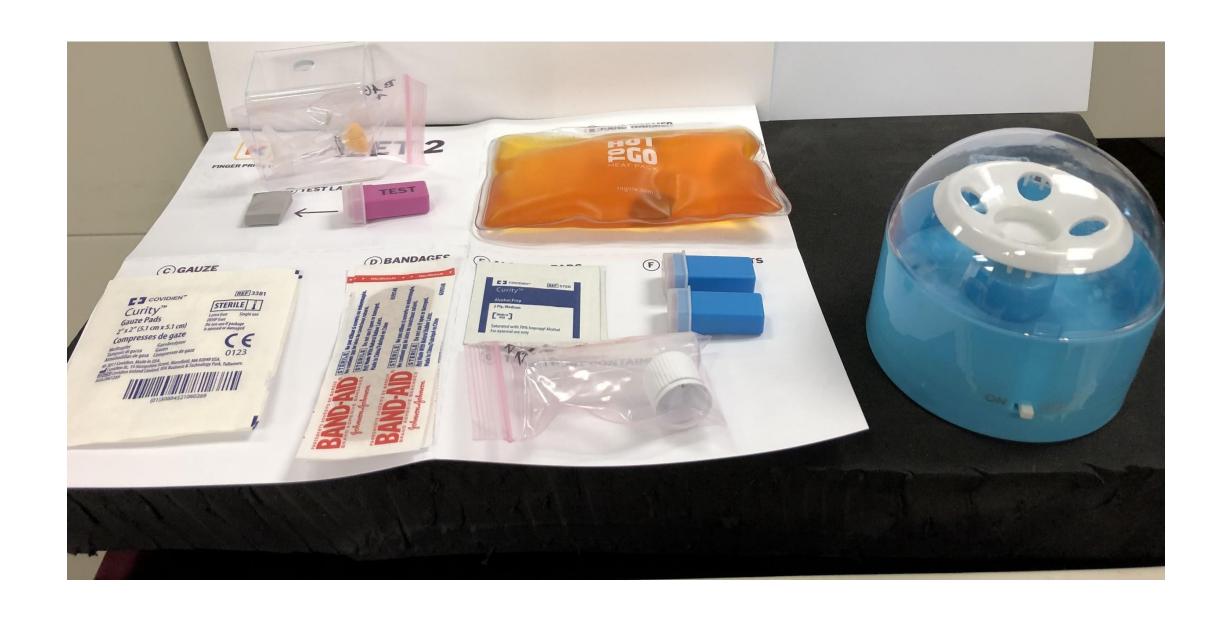


Figure 1: A prototype of the finger pricking portion of the kit. Starting clockwise from the top left corner is a piece of foam that is used with the magenta lancet so the user can use the lancet before using it on themselves. Above those is the plastic stand, the blood collection tube and the tube funnel. The next piece is a hand warmer used to increase blood flow in the finger. The large teal device is a centrifuge to separate the serum from the blood after the filling the collection tube. The two blue pieces are the lancets used on the user. Next to it are alcohol wipes to clean the target area on the user's finger. Below that is the tamper evident tube to place the separated blood after using the centrifuge. The last two pieces are the bandages and gauze which are used after lancing the finger to clean up and protect the wound.



Figure 2: The Beckman–Coulter AU400e Analyzer. As a blood serum diagnostics we require this machine in order to do assays. Since our kit uses capillary blood rather than venous blood we have to do comparative studies to prove that the results between those two are the same or similar enough to be used in place of the other. Another study that needs to be done is a "stability" test due to the fact that our service involves sending blood through the mail, we need to make sure that the analytes in the serum can survive the journey and the temperatures it will encounter. We are comparing our values to those of other established companies in order to show that our method works.

My Role







- 1. I run serum through the assay machine to collect the data and enter it into the appropriate spreadsheet.
- . Talk to suppliers for product samples and to negotiate bulk deals to keep costs down.
- . Talk to the investors who have questions or ideas regarding the company or product.
- 4. Interface with volunteers who are testing our product to see if any usability issues arise.
- 5. I help write the protocols and Standard Operating Procedures for our company.
- 6. Write scripts and record videos to create tutorials or show off our product to investors or buyers.
- 7. Build kits for testing or to show to investors or buyers.

FUTURE DIRECTION

- My company will need to finish a method comparison study in order for 'capillary blood' to be seen as equal to 'venous blood' for these blood assays.
- 2. We will need to finish the "stability" study to proof that the analytes can be used after going through the mail and being exposed to various temperatures.
- 3. We need to prove that our analyzer can provide reliable results.
- 4. We need to do a pilot so companies can see that we can do what we sya and that our kit works and that people are willing to use it.

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