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Introduction:

Purpose:

The purpose of this project is to make a quicker ELISA system that can be taken into the field for testing.

At the beginning of our design process, our goal was to create a field test that would detect Anti NMDA Receptor Encephalitis in the homeless population to prevent misdiagnosis of schizophrenia. Our design began by finding three different tests that could be used on people with this specific disease, this is how we discovered the blood test paired with the ELISA system. Our target disease was changed from ANTI NMDA Receptor Encephalitis when we discovered that this disease was very rare but also shared similarities with symptoms in the late stages of syphilis. The one thing that has stayed consistent throughout the process was the desire to have our testing method be fast and portable, as well as the central dogma of increasing the enzyme concentration in an Elisa based immunoassay test. We later changed the focus to be shortening the incubation period of the ELISA test in order to provide a plausible comparison test.

Problem Statement and Description:

What is the problem addressed and why is it important?
Homeless people are typically the last thought when it comes to targeted medical care. Schizophrenia and Syphilis are both extremely common in homeless people and display similar symptoms. Our test aims to address misdiagnoses between the 2.

How did you arrive at this problem?
Our problem originated from anti-NMDA receptor encephalitis which also shows similar symptoms to Schizophrenia. Throughout the design process it found to be not practical to target such a rare disease, especially in a specialized population like homeless people thus Syphilis was chosen as the easier and more prominent disease to combat.

Who does this effect?

This product is targeted towards shelters, hostels, and soup kitchens where a large portion of homeless people frequent. This test will not require certified lab technicians to operate and can be carried out by volunteers or a community service program.

Prior Art?

There currently exists a relatively new ELISA test called the p-ELISA which uses a paper base as the binding posts for the antibody and antigen. Although not as empirically accurate as a traditional ELISA test, it is faster, cheaper, and easier. When comparing the the paper vs lab test despite being overall faster, it was discovered that the signal amplification stage took 30 mins to complete when compared to 3 mins in the lab test. This led us to find that to speed up signal amplification you can increase the amount of substrate that binds to the enzyme or heat it up. By utilizing different materials for the binding post we can find materials with higher absorbance rates and thus speed up the reaction, cutting down more time.

Solution Selection

Brief description of design goals.

1. Must be free to homeless people without insurance.
2. Needs to be readily available at soup kitchens, homeless hostels, clinics, or anywhere homeless people frequent.
3. Should take no more than 3 minutes to administer, and less than an hour in total.
4. There is no margin of profit so test materials must be as cheap as possible.
5. Under no circumstances should the test cause severe harm or have long term negative effects.

Matrix

Selection Criteria	A) Lab ELISA	B) EEG	C) p-ELISA
Ease of handling	0	+	+
Ease of use	+	+	+
Easy to understand	+	+	+
Accuracy	++	0	-
Durability	0	-	+
Ease of manufacture	0	-	+
Portability	-	-	++
Speed	-	0	+
Sum +'s	4	3	8
Sup 0's	3	2	0
Sum -'s	2	3	1
Net Score	2	0	8
Rank	2	3	1

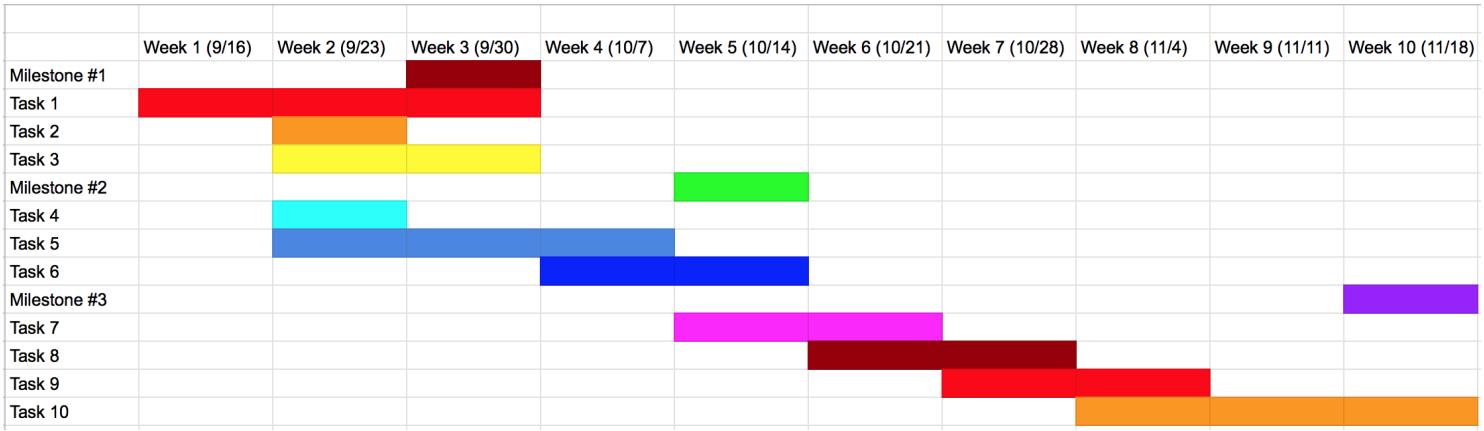
Continue	No	No	Yes

Comments

According to the Pugh Chart is clearly the most practical when trying to create a field test. It is easier to build and distribute, easier to use, faster, and is far more portable and practical when applied to large scale mass production scenario. Current implementations of the p-ELISA are fast in comparison to the lab implementations but aren't quite fast enough to be practical in a field test setting. Not having to implement a custom spectrophotometer into the design makes the end product much cheaper and easier to transport.

Design

Block Diagram



Milestone #1: Solidify our project

What is our problem, our population, how do we address it?

Task #1: Determine a Needs Statement

We need to connect our main problem to our population in order to determine a feasible solution to the problem we had determined. In our case, this took a lot of iteration before coming to our official needs statement, which is still subject to change. However, it will still connect our population of the homeless to our problem of undiagnosed syphilis being misdiagnosed as schizophrenia and therefore going untreated.

Task #2: Determine Functional Requirements

In order to determine the best solution to our problem, we needed to determine a set of functional requirements, attributes that our device must have in order to serve our population in the most effective way possible. The functional requirements that we

decided upon are as follows: the device must be readily available at places with high homeless populations, must be a quick preliminary test that screens for syphilis, must not be painful nor leave long term negative effects, must be portable and durable, and must be easily sterilized.

Task #3: Assess Prior Art

In terms of our project, when we were assessing prior art, our problem was still undiagnosed Anti NMDA Receptor Encephalitis being misdiagnosed instead of syphilis, but the two diseases can be tested for in very similar ways. We found three different methods of testing: spinal tap, EEG, and an ELISA blood test.

Milestone #2: Determine Best Model and Deliverables

What will our device be and how can we prove that it works?

Task #4: Use a Pugh Chart to Determine the Best Model

Our best way to compare the prior art we found was to place them in a Pugh chart, a chart that compares multiple designs based on specific requirements.

When entering our functional requirements into a Pugh chart, we found that the most feasible solution was a blood test, due to its overall net positive score.

Task #5: Break Down our Specific Model

Using a Block Diagram, we were able to (and continue to now) break down our device into individual parts and describe them, as well as how they work together to complete our task of testing blood for antigens present in syphilis quickly and effectively.

Task #6: Determining Deliverables (Outcome of the Project)

Based on the budget we were given ($100), we need to determine the cheapest way to prove that our idea is feasible. At the moment, we feel as though the best way to go about this is to prove that we can speed up the incubation period of the ELISA test in order to optimize it for a field test for the homeless population.

Milestone #3: Prove and Prototype

Test our deliverable for feasibility and possibly build a prototype.

Task #7: Design a Test

In order to prove that we can speed up the reaction time for the ELISA mechanism, we must design an experiment involving the concentration of enzymes in the incubation solution. More to come on this as we continue to iterate over our design.

Task #8: Iterate over this Test

Once our test is determined, we will need to conduct multiple iterations of our experiment in order to determine if it is possible to effectively speed up the reaction time after time.

Task #9: Organize and Report Results

Once we have concluded experimenting, we will need to concisely report our results, whether they are successful or not. This will go into our final presentation.

Task #10: Prototype (If Possible)

If budget allows, we would like to build a baseline prototype of the device, incorporating the most cost effective elements of our design.

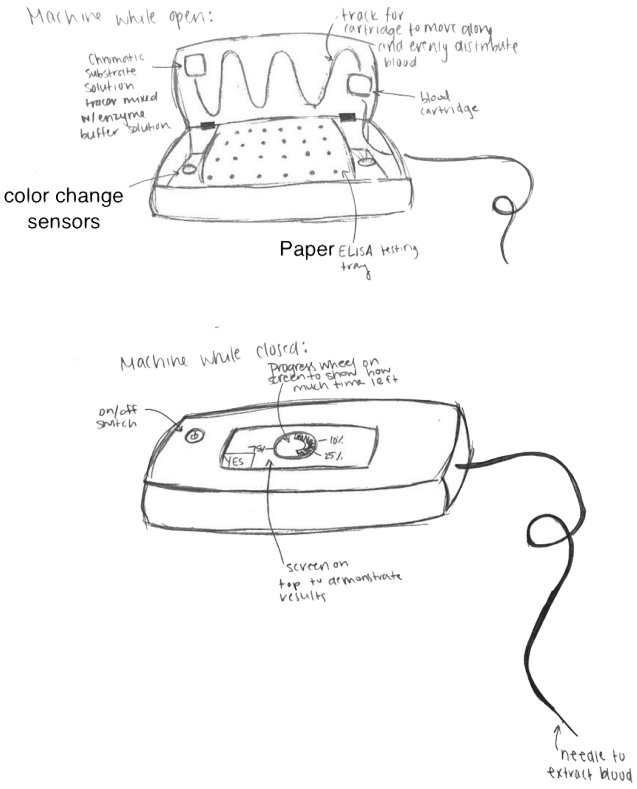
3. List of Materials (Before Prototype)

- Papyrus $7
- Cotton $3
- Copy paper $10
- HRP and Conjugate $202
- HRP Color Changing Tracer $106

4. From the beginning of the design process, our project has undergone immense revision varying from differing target populations to changes in the disease being tackled. The one thing that has stayed consistent throughout the process was the desire to have our testing method be fast and portable, as well as the central dogma of increasing the enzyme concentration in an Elisa based immunoassay test. The materials and steps stated will hopefully result in a quantitative result that will determine whether or not the idea has failed based on whether or not we can speed up the signal amplification process.

Design summary:

Our machine will draw blood from the patient and then distribute blood evenly on the ELISA system using a cartridge. After this is done, an enzyme is added on top of the blood using a seperate cartridge on another track. Our machine will differ from conventional ELISA system tests in the lab because of the type of ELISA tray that we will use. We will make three different trays out of different materials. One will be out of cloth, another out of paper and the final will be out of papyrus, all of which will be precoated with the antibody consistent with the harmful antigen in syphilis. These different ELISA testing systems will absorb more of the antigen, therefore speeding up the signaling amplification process. By having our ELISA tray be flat, the ratio of surface to volume is higher and allows an overall shorter incubation period because the antigens, antibodies, and reagents only have short distances over which they need to diffuse to reach the surface of a paper fiber. All in all, all of these designs will speed up the ELISA process immensely and allow us to take this test into the field. After the blood is distributed on the ELISA system, it will eventually change color which will then be picked up by sensors and displayed on the screen on the top of the box. The screen will display if the harmful antigen is present and will give a preliminary answer to if the patient has syphilis.



Major Issues and Potential Problems:

Our design has the potential to bring about various problems and issues. The machine relies on electricity. A source of electricity may not always be available or powerful enough. The track on the inside of the box may cause issues if it gets stuck. The design uses an excessive amount of substrate. We will soak the material with the substrate and then only evaluate a small portion of the paper. This device creates a lot of waste due to the amount of disposable parts. These parts have been made disposable for sanitary purposes.

Deliverable Experiment:

Our plan is to test on the absorbances of different materials (paper, papyrus, and cloth) for the model of paper ELISA test in comparison to a regular ELISA test with a well plate. We will prep each paper ELISA test with an antibody (whichever is cheapest just for the sake of experimentation) and layer on blood with a matching antigen. Once this has been done, we will coat the system in an enzyme substrate solution with a tracer that will change color once the antigen has been detected. We will time the color change of each material with a simple timer and tracking the change by eye. What this will show us is how much we can control the speed of incubation by changing the absorbance of the material.

Conclusion:

Recap the main steps of the process that have been completed:

From the beginning of the design process, our project has undergone immense revision varying from differing target populations to changes in the disease being tackled. The one thing that has stayed consistent throughout the process was the desire to have our testing method be fast and portable, as well as the central dogma of increasing the enzyme concentration in an Elisa based immunoassay test. The materials and steps stated will hopefully result in a quantitative result that will determine whether or not the idea has failed based on whether or not we can speed up the incubation process.

Where are you now and what will you accomplish?

Currently, we have finalized our design and are hoping to make an experiment that will prove that we can speed up the ELISA testing system significantly enough to make this machine a field test.

What is the significance of this?

The significance of this project is that we are making a testing device that can be brought into a population that doesn't have easy access to doctors offices to get tested often for STDs. Syphilis is very prominent in the homeless population and is also very easily treatable through penicillin. By making this test, we will be curing massive amounts of people from a disease that can be very harmful and changing lives because of it.