Rapid Diagnostic Test Kit *(RDTK)*

Project Opportunity Proposal Report

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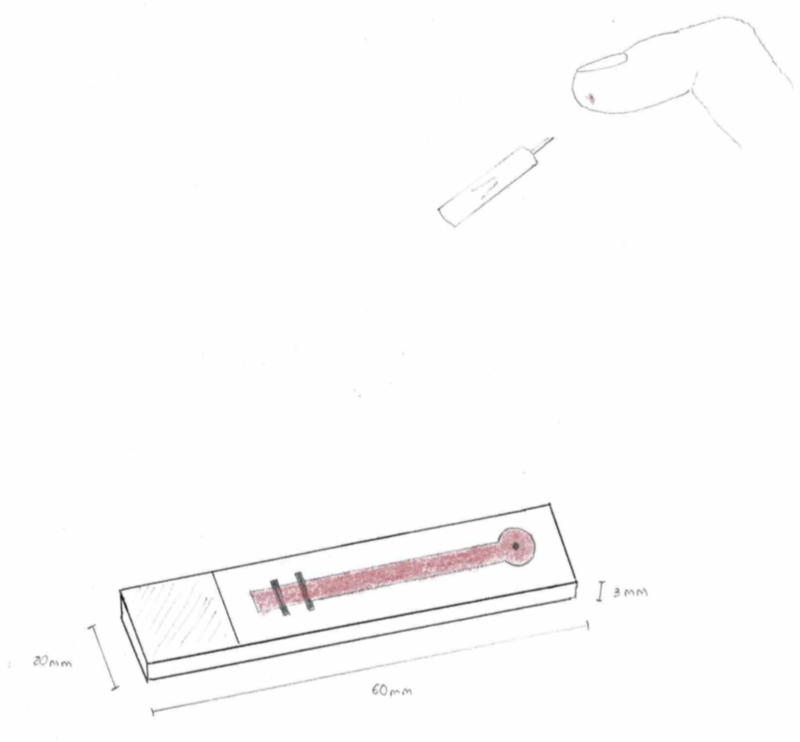


Executive Summary

The following report will discuss the design, implementation and feasibility of the *Rapid Diagnostic Test Kit (RDTK)* that will be used to detect Malaria within poor rural communities, such as the Duse Village in Kenya.

The conceptualisation and design of the product stemmed from the analysis of health care needs within the Duse Village in Kenya, which targets basic safety requirements in Maslow's hierarchy of needs. More specifically, the product targets the ability to diagnose, and therefore treat Malaria, which is responsible for over 3.5 million cases and 10000 deaths in Kenya each year. Malaria is a particularly serious issue in less developed rural communities that don't offer the necessary equipment for diagnosis and treatment of malaria. It affects young children and pregnant women more seriously which accounts for over 60% of all deaths. (World Health Organisation, 2014).

The RDTK aims to provide a widely accessible test kit that offers all that is needed for a quick 15-30 minute detection test for malaria in communities that don't have access to typical testing equipment. It will consist of a visual test stick and disposable lancet needle, which will adopt a very minimalistic portable design with the use of cheap materials.

Introduction

The following report encompasses the design, features and feasibility of the Rapid Diagnostic Test Kit (RDTK). The RDTK is an innovation on existing rapid testing methods for the diagnosis of Malaria, which seeks to achieve greater frugality, ease of use and accessibility. The device is to be implemented in the rural Duse VIllage community within Kenya, East Africa which can be expanded to other rural regions.

The **main objectives** of the RDTK is as follows:

1. To increase the number of detected cases of the disease, malaria.
2. Ultimately, lower the fatalities and illness (or contraction) of or due to malaria in the smaller region or town/village.
3. Low cost distribution and design of the portable test kits.
4. Provide fast and accurate diagnosis of malaria.

The Proposed Community

The Duse Village is located in Kenya, East Africa and has an estimated population of 2000 to 3000 people *(last recorded from 2017-2018)* who are primarily pastoralists, small-scale miners and agricultural workers. Given the low level of economic development and location, the village possesses the possibility of high level transmission of Malaria.

The community has a great potential to strive from the fairly recent implementation of Huawei 2G and 3G rural cellular and communication network system, with healthcare specifically allowing for ambulance services, online health information for nurses and staff members, health reports and stockage information and a greater reliance on telecommunications for relief notifications. However, despite the recent development in the standard of living made accessible through 2G and 3G networking, Duse Village still has a low educational level, low healthcare quality, scarce amenities and low hygiene. This living condition causes residents to be prone to common diseases, particularly focusing on Malaria. Furthermore, Duse Village is seen to have a balanced settlement pattern between dispersed and nucleated, which slightly reduces the gap between residences and the amenities available, ultimately increasing the ease of access to healthcare available.

Figure 1. An aerial Image of the settlement pattern of Duse Village (Huawei, 2018).

Malaria in the Region

Through research it was found that about 70 percent of Kenya's population was at risk of malaria in 2017. All four species of Plasmodium parasites that are parasites capable of infecting humans are in Kenya. The population in Kenya in 2017 was recorded to be 49.7 million people with the population in 2016 having a 100 percent estimated spread through the population in individuals contracting malaria (Sultana et al., 2017). This is stating that the population is very vulnerable to contracting malaria since there is a great rate of transmission due to living conditions and healthcare. Therefore, the RDTK is a necessary implementation into Duse Village with the objectives of the project. The average GDP per capita in Kenya is estimated to be $2,151 U.S. dollars with some sources even estimating as low as $1,000 U.S. dollars *(in 2018).* (Kenya Average Person Income 2018 - Google Search, 2020). From this, It can be estimated that the average income in a month for a citizen is approximately $150 (conservative) for the greater region than Duse. Therefore, the cost of the RDTK is made cheap. A full production and consumer breakdown is provided in later sections of the report. All costs for the project and its production has been estimated at the maximum potential cost and the consideration of income for the population has been regarded as the absolute minimum $(< \$150\ per\ month)$.

Issues to be Addressed

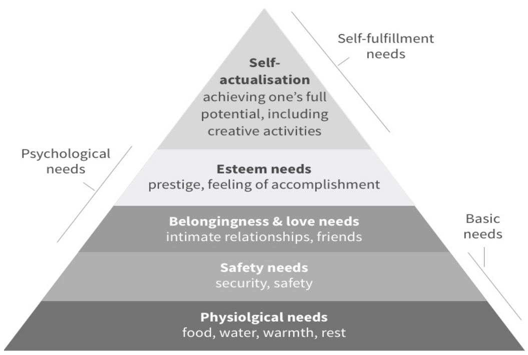
The following section highlights the issues to be addressed regarding the effective implementation of RDTK and its need. The issues that will be aimed to be discussed and resolved in this project are as follows:

1. Improvement of malaria diagnosing rate
2. Reduction of manufacturing cost
3. Reduction of testing cost
4. Cross infection
5. Sterilization

Need for the Diagnosis of Malaria

The need for the diagnosis of malaria in the region and the RDTK as a whole can be reasoned with reference to the Maslow's Hierarchy.

Figure 2: Maslow's Hierarchy



The RDTK aims to improve the provision of healthcare in Duse Village (and other rural areas), through the improved accessibility of diagnostic tools for Malaria. Through its improvement in healthcare, the RDTK assists in meeting fundamental safety needs of individuals.

How Product will Address Issues and Meet Community Needs

This product is designed to detect malaria specifically in the Duse Village in order to increase the diagnosis rate. The design of this kit is minimalistic, excluding all aesthetics and packaging, so that the cost of manufacturing decreases. Additionally, this product is aimed to be portable and display results quickly. The single-use lancet is used only once per test to avoid blood cross-infection. The community currently has no method to detect malaria

The goal of decreasing malaria related illness and fatalities, will be achieved through the employment of the RDTK which will allow early detection. The RDT's that are already in place around the world are evident to perform malaria diagnosis accurately and through such a test appropriate prescribed treatment can be delivered to the patient. Early treatment with artemisinin-based combination treatment *(ACT)* with low-dose primaquine prevents further transmission from human to mosquito. Therefore, the kit allows for the decreased rate of transmission and spread of malaria in the community and allows for early treatment to be delivered to the patient ultimately decreasing the spread of the disease. This in turn reduces cases of illness and further fatalities from ongoing untreated cases.

Benefits and Impact the RDTK will provide for the community

The benefits of the RDTK stems directly from its impact on healthcare and safety within the community. Through improved diagnosis, the threat of Malaria is dramatically reduced, lowering its potential burden on the community. This can particularly be seen within working areas, gatherings and classrooms which can offer a safer environment.

Details of Malaria Test Kit Product

The design and development of the malaria test kit was underpinned by a number of goals which was deemed necessary for the product to offer practicality in the market and provide financial benefit. These goals include achieving effective frugality to distinguish itself from other products and meet specific operational aims to ensure its use is effective. The details of the product and its goals are outline in the sections below:

How Frugality is Achieved

The RDTK is a product that aims to provide all necessary tools for a rapid diagnostic test whilst achieving increased frugality over existing rapid diagnostic tests. It's primary design features aim to achieve a low cost, accurate and easy to use device consisting of:

- The test kit, made from a thin cardboard stick.
- A small disposable lancet (*needle*)
- A lysing agent used on markers to break up blood cells.

Frugality is achieved by focusing on the core functionalities of the device as well as through substantial cost reductions (via alterations in materials used and use of local supply chains).

The test kit adopts a minimalistic design which excludes any aesthetic features and unnecessary packaging in order to lower material costs. Cheaper and more accessible materials will also be (i.e. cardboard as base of the testing kit) as an alternative to typical hard plastic materials used in rapid diagnostic tests (which is more costly and requires greater outsourcing of production chains).

The removal of unnecessary elements of RDTs , will allow the test kit to be smaller in size and even more portable, translating to lower material, transport and storage costs. Additionally, a microfluidic technique will be adopted in order to minimise the blood sample required, further reducing the size required.The smaller design also corresponds to a reduction in wastes produced. Using materials such as soft plastics and cardboards (which are also recyclable) which can be sourced from local villages, results in greater frugality to be achieved.

Major Requirements

The preliminary objectives set for the malaria test kit during the early design stages (which is considered vital for successful implementation) includes minimising the size of the device, reducing the materials required for manufacturing, simplifying its manufacturing and procurement process, and adopting use of inexpensive materials. These objectives were translated into the following requirements:

- Maximum size of the testing stick to be (60mm x 20mm x 3mm - L x W x H)
- Maximum pricing cost of producing a single unit to be $0.50 USD.

  (This reflects cost research regarding the minimum willingness-to-pay price for an RDT in Nigeria, which bares similar level socio economic development as Kenya). Pricing of $0.25 USD (A$0.39) corresponds to approximately 90% of people willing to pay (Ezennia, Nduka, and Ekwunife 2017)
- Accuracy rate of test must provide at least 90% sensitivity (accuracy in detecting positive cases) and 70% specificity (accuracy in detecting negative cases) (Baiden et al., 2012)
- A minimum of 5 microlitres of sample blood is required for desired effectiveness of the test (defined by its detection accuracy).
- Time required for testing to yield visible results ranges between 15 and 30 minutes.

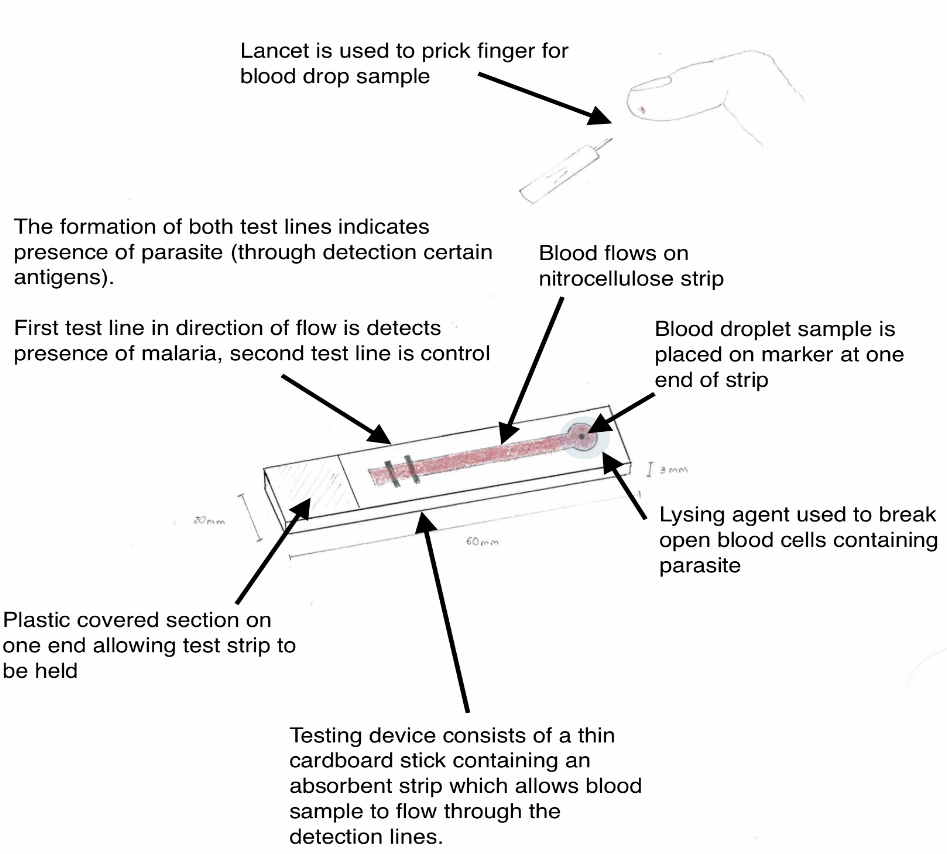
Preliminary Design

The Malaria test kit has a very simplistic design consisting of a thin plastic cassette stick which forms the body of the test kit. A nitrocellulose strip will sit on the top of the cassette stick which will allow for the lateral flow of blood (even at very minute amounts) through testing lines. The stick can be held from one end (which will contain a thin plastic cover), whilst the blood sample is placed on the other end indicated by a marker. This marker also contains a lysing agent which breaks open the red blood cells releasing the parasite. Blood is obtained from a quick needle prick to the finger providing a small droplet of blood.

The blood flows through the absorbent nitrocellulose strip through two testing lines (one testing the presence of malarial parasite and the other being a control ensuring blood reaches the end of the stick). The first test band will detect the presence of malarial antigens produced by the different species of parasite (including plasmodium falciparum, plasmodium vivax, plasmodium malariae and plasmodium ovale), by containing a number of specific immobilized antibodies (dyed) that capture the malaria antigens. If malaria is present, then the buildup of antigens forms a visible test strip (with intensity of the line qualitatively indicating the level of infection). The control line will appear if the blood has properly traversed through it.

The test kit will also contain concise instructions and description of the test and meaning of given result (diagrams will be used in order to simplify this communication to people).

Figure 3: Labeled diagram of RDTK



Operational Description

The training or more so required operations for this kit is relatively low and not complex to operate or carry-out properly. The test kit will first require the sampling of a small amount of blood (minimum 5 microliters) through a quick prick of the finger after sterilization with alcohol swab. Following the finger pricking procedure provided by WHO (n.d.) and assuming other equipment mentioned in the procedure is available (gloves, alcohol swab, etc.), our RDTK frugal innovation will then be used here:

1. Hold the test kit with the plastic covered section, making sure that there is no direct contact to the strip.
2. Use a single-use lancet provided with the test kit to perform finger pricking.
3. The blood from the finger is placed on the end of the stick at the marker which contains a lysing agent.
4. Let the blood flow through the strip, past two test lines (first is the malarial test line and the second is control) by capillary action.
5. Wait for 15 minutes for the test kit to yield results.
6. Properly dispose the test kit and any other contaminated disposables used during the process in a sealing plastic bag, making sure it is out of reach from anyone except assigned staff.

An Analysis Providing Proof of Concept

The designed RDTK adopts the same method of malaria detection as that outlined by the WHO. The RDTK employs a lateral flow test (immunochromatographic assay) which utilises antigen and antibodies to detect the presence of parasites (World Health Organisation, 2015) . The effectiveness of laminar flow test is demonstrated through its widespread use in various RDTs for tests (e.g. dengue, typhoid, HIV, etc) and its reliability to detecting malaria is indicated by numerous types of existing malaria RDTs with proven accuracy results (given by research and testing). The time frame in which the test returns results is given by the mechanism that drives the laminar flow test (i.e.speed of blood flow, and the time taken for antigens and antibodies to react); this has been demonstrated to typically take between 15 to 30 minutes for.

The device is expected to operate as required despite certain design changes (such as use of cardboard stick instead of plastic, removal of plastic cases) since it has no impact on the testing method. The cardboard stick will offer a high enough level of rigidity to ensure the components on the test stick are not affected by bends, dropping etc. The ability for the innovations made in the product to provide effective frugality in order to meet WTP assumptions of the community is demonstrated in the cost benefit analysis of the report.

The viability of the design to generate expected results can also be demonstrated through prototype testing which is explained in further detail below.

Materials and Cost

The table below shows the materials needed for our frugal innovation and the costs. The costs are rounded off to two significant figures and in Australian currency, using the currency rate at date 12/5/20:

Table 1: Materials & Cost Breakdown

Materials	Costs
Polystyrene (Packaging) **Obtained Locally**	$1cm^3 = A\$0.000018$ (Styrofoam, 2020)
Cardboard (Manufacturing) **Obtained Locally**	$1cm^3 = A\$0.000037$ (Medium, 2020)
HDPE (Manufacturing) **By Import**	$1kg = A\$1.2$ (PT. Kartika Plasindo Pratama, 2020)
Nitrocellulose strip (Manufacturing) **By Import**	$1cm^2 = A\$0.017$ (eBay, 2020)
Lysing Agent (Manufacturing) **By Import**	$1mL = A\$0.55$ (BioLegend, 2020)

Several assumptions are made to simplify the cost analysis and to find the total amount needed:

- Simple formulas are used in the cost calculation of each material
- The weight of our RDTK is equal to $10g$. This is made to be equal to the weight of a malaria testing kit sold by BUZZOFF (2020).
- Length of the plastic-covered section has a ratio of 1 : 5 with respect to the length of the test kit. ($12mm : 60mm$)
- Maximum size mentioned in the major requirements section is used as the dimensions of our RDTK. ($60mm\ x\ 20mm\ x\ 3mm$)
- Nitrocellulose strip has the same length and width as our RDTK. ($60mm\ x\ 20mm$)
- The volume of lysing agent is equal to $25\mu l = 0.025ml$. This is made to be equal to the mean volume of a blood droplet mentioned by NCBI (2009).
- Density of HDPE is $970kg/m^3$ (PlasticsEurope, 2020).
- Packaging fits exactly 10 RDTKs in a row and 50 RDTKs in a column.
- All imported goods come from Australia

Not all of the materials used to manufacture the RDTK is being imported (i.e. the cardboard) as buying local products is usually cheaper than having imported goods. Instead, the materials that cannot be obtained locally will be imported and then manufactured locally. As for the imported goods, due to the low volume of materials needed to make a test kit, standard postage will be used to deliver the materials. Australia Post (2020) shows that the standard postage fee from Sydney to Kenya is **A$30.15**. This method has been chosen to simplify the shipping, import prices, handling, local courier prices, etc, as the exact location of Duse Village cannot be found.

Cost-Benefit Analysis of Frugal Innovation

For the styrofoam packaging of RDTKs, with the packaging condition above, the dimensions of the packaging will be $600mm\ x\ 200mm\ x\ 150mm$, fitting 500 RDTKs and the corresponding cost will be **A$0.324**. The packaging price is significantly cheaper compared to the price of 500 RDTKs with a ratio of about 1:332. This fact allows us to determine that the price of packaging affecting the net total fund needed for one package to be sent to Duse Village, is almost negligible. As for the manufacturing of the RDTK, with the assumptions mentioned above, the net total to manufacture the RDTK is **A$0.21497**. The raw cost analysis can be seen attached to the appendix below. Poyer et al. (2015) has shown that the median price of RDT's in Kenya was A$0.58. Moreover, our price falls with a significant difference below the willingness-to-pay price margin of $A0.39, prompting more than 90% of the residents to pay for our RDTK. From the two prices given, it is evident that for the main benefit of malarial testing, the price of our RDTK is less than half of the median price of RDT's in Kenya, achieving frugality. Additionally, since the frugal innovation is a single-use item, there is no maintenance cost involved.

Prototype & Testing of Product

The reliability of diagnosis of the RDTK is to be tested to ensure it meets requirements. In order to examine diagnostic rate, two groups of experimenters are required, containing 100 people per group. Group one are patients who have been diagnosed positive with Malaria, while group two all show the negative results. Each tester is required to collect five microliters of blood from the finger and test for Malaria in the test kit. Once the second control line shows results, which means that the blood has passed through all testing lines, the experiment can be considered as completed. Otherwise, this test should be labelled as failed. Both groups will follow the same instructions and record the testing results in a table, as shown in Table 2. The percentage of diagnosis in group one is calculated to check if it achieves the expectation, while that in group two is required to check if there exists misdiagnosis.

Table 2: Quality testing regime of testkit

	Group 1			***Group 2***		
	Positive Result	**Negative Result**	**Failed**	**Positive Results**	**Negative Results**	**Failed**
1						
...						
100						
Sum						
Percentage (%)						

Risk Management and Uncertainties

Table 3: Risk Assessment

Risk	Threat level	Impact	Prevention
Cross contamination due to improper disposal.	Extreme	Malaria is spread through the test-kit, increasing the spread of the disease at an unprecedented rate. The test results may become invalid due to the contamination	• Having a hazardous waste bin for disposal after use. • Ensuring the community is educated on the correct procedures to dispose of the test kit after use.
False diagnosis due to patient testing too early for effective use.	High-Extreme	Those with malaria would continue to interact with others while having malaria, thus causing harm to others.	• Determine the period symptoms develop and determine if diagnosis is needed. If symptoms persist, advise seeking medical help
Enabling a false sense of security, where if patients feel if they do not have malaria then they are fine for all diseases.	Low-Mid	Patients become reliant on test kits, where having malaria becomes the standard metric of health.	• Advise that not having malaria does not mean they do not have a less lethal disease since the symptoms of malaria are shared by numerous other diseases

What makes our Solution Different?

Rapid Diagnostic Tests for Malaria currently exist which offer a more accessible (and cheaper) solution to more accurate and conventional methods of diagnosis (i.e. through visual detection using a microscope. The product offered by our team follows the same concept of rapid diagnosis however consists of some basic differences which aim to improve frugality and accessibility. These differences include:

- The very minimalistic design which consists only of the testing casete strip made of cardboard (with no HDPE encasing) with a nitrocellulose layer which provides the path the blood will flow through.
- Product will come with a small single-use lancet to allow a small blood sample to be obtained through a quick finger prick.
- Test kit will be provided in an easily transportable styrofoam package (providing all necessary components for a test).

The primary benefit of choosing our product over the conventional RDTK is the cheaper price that we offer, stemming from the procurement of overall cheaper materials to manufacture and delivery of the RDTK.

Response to board feedback

The feedback provided primarily focused on the level of detail provided regarding the Duse Village community and the product itself. The demographic data that was able to be obtained for the village was used (i.e. population, services etc), however, for statistics unable to be obtained given its relative isolation, general national data was used from Kenya. Details of the product was more clearly defined, particularly regarding its major requirements (e.g. accuracy, size), design and operation specifics (e.g. packaging, materials, costing), and production process (e.g. what will be obtained locally and what imported).

Appendix

Project Reflection

How well your chosen product and/or service met the project objectives/requirements?

The project overall encompassed a frugal innovation being the RDTK which in turn over the period of designing has seen to have met all the proposed design requirements and objectives of the proposed opportunity. If the requirements as revisited, it is clearly concluded that the design:

- Is portable with a small size.
- Improves the healthcare of the proposed community.
    - Reduces fatalities from Malaria with increased treatment, early detection and tests.
- Pricing of the RDTK is relatively low with consideration of the income of the population $(priced\ at\ \$0.25\ US)$.

What did your team learn from this project?

The team behind this project has learned skills around investigation of communities that require healthcare and improvement to lifestyle on a scope of frugality. Moreso, this team has acquired the capability to design a product in such a scope of frugal innovation. However, with the chosen rural community, information regarding the community is exceptionally difficult to obtain. This challenge prevented the team from making more accurate analyses and judgement that could otherwise improve the frugal innovation in any way.

The team has gained a further understanding of malaria treatment, blood sampling and the process of testing for a disease such as this.

What would your team do differently next time?

In future investigations such as this, it is recommended that, specifically, the accuracy of the testing be increased using a combination of microscopic techniques while still maintaining frugality.

Why and what would be the expected outcomes of these changes?

The outcome of the frugal microscopic technique included in the testing process of malaria, would increase the accuracy of the RDTK while also keeping a lower price and ease of use (which is the primary challenge and is why this investigation/project did not utilize this method directly).

Figures

Appendix Figure 1: Cost Analysis of Materials & Frugal Innovation.

Stick: $V_s = 60mm \times 20mm \times 3mm = 3600mm^3 = 3.6cm^3$

$A_s = 60mm \times 20mm = 1200mm^2 = 12cm^2$ (Dimensions)

$m_s = 10g = 0.01kg$

Cardboard: $C_c = \$3.7\times10^{-5}/cm^3$

$Price_c = V_s \times C_c = 3.6\cancel{cm^3} \times \$3.7\times10^{-5}/\cancel{cm^3} \approx \$1.3\times10^{-4}$ (2 sf)

HDPE: $C_{HD} = \$1.2/kg$

$\rho_{HD} = 970kg/m^3$

$l_{HD} : l_s = 1:5$

$V_{HD} : V_s = 1:5 = 0.72cm^3 : 3.6cm^3$

$V_{HD} : V_s = 7.2\times10^{-7}m^3 : 3.6\times10^{-6}m^3$

$m_{HD} = \rho_{HD} V_{HD} = 970kg/\cancel{m^3} \times 7.2\times10^{-7}\cancel{m^3}$

$= 6.984\times10^{-4}kg$

$m_{HD} \approx 0.7\times10^{-3}kg$

$Price_{HD} = m_{HD} \times C_{HD} = 0.7\times10^{-3}\cancel{kg} \times \$1.2/\cancel{kg} = \$8.41\times10^{-4}$ (2 sf)

Lysing Agent: $C_{L.A} = \$0.55/ml$, Volume of blood droplet = Volume of Lysing Agent per test

$V_{L.A} = 25\mu l = 0.025ml$

$Price_{L.A} = V_{L.A} \times C_{HD}$

$= 0.025\cancel{ml} \times \$0.55/\cancel{ml}$

$Price_{L.A} \approx \$0.014$

Nitrocellulose Strip: $A_{N.S} = A_s = 12cm^2$ $C_{N.S} = \$0.017/cm^2$

$Price_{N.S} = A_{N.S} \times C_{N.S} = 12\cancel{cm^2} \times \$0.017/\cancel{cm^2}$

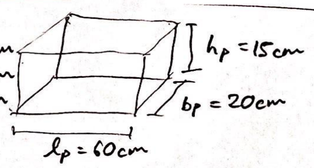
$Price_{N.S} \approx \$0.2$

Styrofoam (Package): 10RDTKs/row & 50RDTKs/col

$l_p = l_s \times 10 = 60mm \times 10 = 600mm = 60cm$

$b_p = b_s \times 10 = 20mm \times 10 = 200mm = 20cm$

$h_p = h_s \times 50 = 3mm \times 50 = 150mm = 15cm$



$\therefore V_p = l_p \times b_p \times h_p = 60cm \times 20cm \times 15cm$

$V_p = 18000cm^3$

$C_p = \$1.8\times10^{-5}/cm^3$

$Price_p = V_p \times C_p = 18000\cancel{cm^3} \times \$1.8\times10^{-5}/\cancel{cm^3} = \$0.324$

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