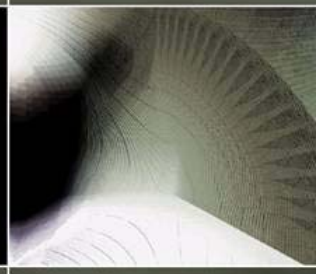
SENIOR ADVANCED DESIGN CAPSTONE PROJECT:
Chromogenic Immunoassays using Horseradish Peroxidase



WKS Assays, Inc.

Chromogenic Immunoassays using Horseradish Peroxidase

Business Plan

Chemical Engineering Senior Design Project

Group 7:
Patrick A. Williams
Ian. M. Klink
Brandon D. Shaw

TABLE OF CONTENTS

TABLE OF FIGURES

1.0 EXECUTIVE SUMMARY

Staphylococcus aureus is one of the major causes of hospital acquired infections, which is the fourth leading cause of death in the U.S. Some conditions caused by the bacterium are boils, impetigo, and staphylococcal pneumonia, as well as food poisoning. Furthermore, the bacterium has a doubling time of approximately 30 minutes. Due to the rapid doubling time, an assay to determine the level or presence of staph bacteria is critical to rapid disease assessment and treatment. WKS Assays has developed a immunoassay using horseradish peroxidase to test for *S. aureus* infections in humans, as well as a novel procedure evaluating time and money required for pre-testing procedures.

The market for this assay will be rural hospitals in the United States. The assay will be performed by a lab technician in the hospital, not by an automated machine; however the results are obtained by an ELISA plate reader/spectrophotometer. This provides for a lower capital cost to the hospital. There are approximately 2,178 registered rural hospitals in the United States.

Immunoassay sales in the U.S. in 1999 were approximately $3 billion. The projected sales of immunoassays in 2004 are approximately $4.5 billion. Worldwide projected immunoassay sales for 2004 are approximately $13.5 billion. Currently, only two companies have been identified as using horseradish peroxidase to test for *Staphylococcus aureus*.

WKS Assays, Inc. is seeking funding for start up costs associated with the construction of a business venture of this type as well as funds for pre-FDA testing. In this business plan, the investment provided is $5.8 million. The $5.8 million investment is for start up costs for the Fixed Capital Investment and FDA Approval for the process, with profit being used to fund business expansion and research and development of future products.

2.0 THE ENTERPRISE

Hospital infections are currently the fourth leading cause of death in the United States as reported by the Center for Disease Control. Since 1995, infection rates in hospitals have increased at an alarming rate causing more that 75% of hospitals to be cited for serious unsanitary and cleanliness violations. In 1995, 9.8 infections occurred per 1,000 days in a sampling of US hospitals.

A major cause of infections found in hospitals is from *Staphylococcus aureus*. While staphylococcal bacteria are ubiquitous in nature, and found on humans, when the bacteria enter into the internals of the human body, complications can arise. Some common conditions associated with staphylococcal infections are listed below:

1. ***Folliculitis*** – inflammation of the follicles
2. ***Boils*** – painful, pus-filled inflammation of the skin and subcutaneous tissue
3. ***Sties*** – Inflammation of one or more sebaceous glands of an eyelid
4. ***Impetigo*** – a contagious skin infection
5. ***Abscesses*** – A localized collection of pus in part of the body, formed by tissue disintegration and surrounded by an inflamed area
6. ***Staphylococcal pneumonia*** – inflammation of the lungs
7. ***Osteomyelitis*** – onset after surgery
8. ***Toxic shock syndrome*** – acute infection associated with tampon use during menstruation

In addition to the above conditions associated with staph infections, *S. aureus* can also be associated with food poisoning. Infections due to *S. aureus* are also of important concerns for chronically ill patients as to they lead to increased complications in treatment of their disease.

To combat the recent increase in infection rate and decrease the amount of complications that arrise from infection, a novel technique is needed to detect *S. aureus* infections at the onset since the doubling time for this bacterium is approximately 30 minutes.

WKS Assays, Inc. is a start up company that intends to reduce the number of deaths and nosocomial infections in hospitals. We are determined to provide the health care industry with a diagnostic procedure that will accurately detect these bacteria at concentration levels as low as four-hundred pico-grams per milliliter. A strong work ethic and pride in our products will be the driving force for providing high quality product at very competitive prices.

2.1 OBJECTIVES

WKS Assays, Inc. is tasked to minimize occurrences and reduce deaths and complications from *S. aureus* infections by providing a leading testing application for detection of this bacterium. To achieve this, WKS Assays, Inc. will:

* Provide leading immunoassays for detection of *S. aureus* at low concentrations.
* Reinvest in facilities and equipment to expand production and improve quality.
* Stay abreast of current technology trends and methods by having the Research and

Development department solely focused on quality improvement as well as new immunological methods.

2.3 ORGANIZATION

WKS Assays, Inc. was founded in 2004 by three motivated and highly qualified chemical engineering graduates from the University of Oklahoma: Ian Klink, Brandon Shaw and Patrick Williams. These founders will form the initial company management team with outside consulting as required. In anticipation of company growth, WKS Assays is currently pursuing well-qualified individuals for several key positions, including CEO, CFO and CMO. These positions will provide additional experience and insight into the company.

2.3.1 Personnel Plan

WKS Assays, Inc. plans to begin operations with 15 personnel. Our company is a young company with the majority of our personnel under the age of 35. We provide our employees and their dependents with insurance that covers medical, dental, and hospitalization. We offer the employees two weeks vacation and five holidays each year. Each employee is allowed fifteen sick days a year.

Initially, the growth of the organization will be slow. Growth is expected to increase rapidly after the first year of production. Our company has been selective about the personnel hired, which helps maintain a high quality of expertise. The organizational structure of the company is provided below.

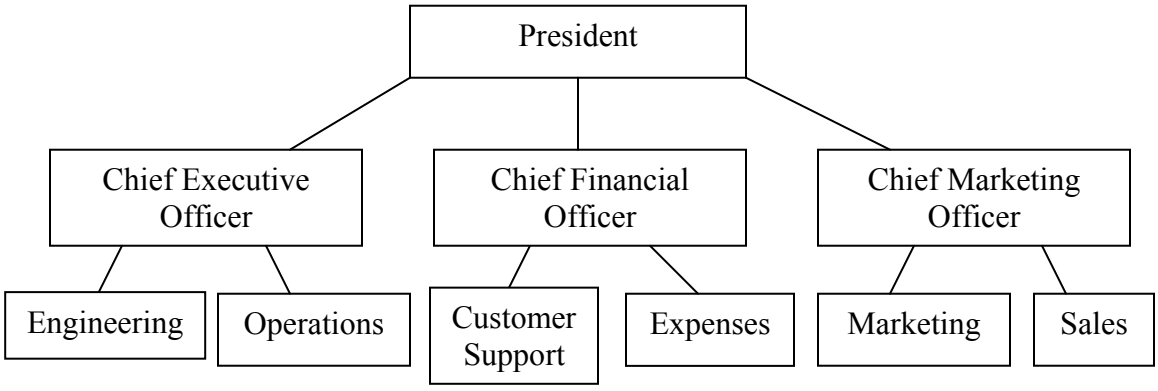


FIGURE 1: Organizational Chart

2.3.2 Personnel

WKS Assays is actively a recruiting well-qualified CEO with previous experience in the biotechnology field to lead the company. It is desired that the CEO have at least 10 years experience and preferably experience with another start-up venture with notable success. The CEO will help to recruit qualified individuals to fill the positions of CFO and CMO.

Ian Klink is currently acting as the Chief Executive Officer for WKS Assays, Inc. He is the primary innovator within the company with insight from Brandon Shaw and Patrick Williams. Mr. Klink has a doctorate in Chemical Engineering from the University of Massachusetts and bachelor's degree in Chemical Engineering – Premed from the University of Oklahoma.

Brandon D. Shaw is currently acting as the Chief Financial Officer. Previously Mr. Shaw was head of the Process Development Department at another company before joining his fellow colleagues to form WKS Assays, Inc. Mr. Shaw has a MBA from Purdue University and a BS in Chemical Engineering – Biotechnology with a minor in Biochemistry from the University of Oklahoma. He is currently a certified Engineer Intern (EI) and is awaiting results of the Professional Engineer Exam.

Patrick Williams is President of WKS Assays, Inc. Main proponent in the process development phase in previous company, Mr. Williams brings his knowledge of GMP's and intense vision to thrust WKS Assays, Inc into mainstream health care diagnostic applications. Also an Engineer Intern, Mr. Williams is a graduate of the University of Oklahoma with a Master of Engineering and Bachelor of Science degrees in Chemical Engineering – Biotechnology and Biochemistry.

2.4 FUTURE

WKS Assays, Inc is not limited to present goals, but also future goals. Plans for expansion and development of new assays for testing of different bacteria are a constant driving force for the success of the company. A strong Research and Development department is crucial to the success of WKS Assays, Inc as well as incorporation of new technologies for better assays.

Also possible for the future success of WKS Assays, Inc is to provide alternative methods for detection, such as luminescence assays and higher throughput automated methods, to compete in the large hospital market.

3.0 **THE MARKET**

WKS Assays, Inc. plans to market an immunoassay for the detection of *S. aureus*. Each year there are approximately 2 million nosocomial infections in U.S. hospitals as estimated by the National Nosocomial Infections Surveillance System (NNIS) (1). *S. aureus* is one of the most common causes of hospital infection and is estimated to be responsible for 500,000 infections each year (2). All patients showing signs of infection are tested to diagnose the cause and determine a method of treatment. WKS Assays, Inc. plans to take advantage of this diagnostic test market by manufacturing diagnostic immunoassays. These immunoassays will be provided to the consumer at lower costs compared to larger more established biotechnology companies.

3.1 TARGET MARKET SEGMENT

WKS Assays, Inc. will target rural hospitals as the initial market for their *S. aureus* immunoassay. They will appeal to rural hospitals by providing a reliable *S. aureus* diagnostic procedure at reduced cost. Rural hospitals are smaller and do not possess the expensive, automated equipment to analyze immunoassays as compared to larger hospitals with higher

throughputs. The only equipment required by the hospital to analyze a WKS Assays, Inc. product is an ELISA plate reader/spectrophotometer which is common in any pathology lab.

While WKS Assays, Inc. will not initially be able to compete with more established biotechnology companies in large urban hospitals, we will strive to gain a market share in rural hospitals as a foundation for future growth. As WKS Assays, Inc. becomes more established in the rural field, we will have the capability to expand and increase our available products and targeted market. The ultimate goal of WKS Assays Inc. is to provide diagnostic tests to large urban hospitals in addition to the initial rural market.

3.2 Market Trends - Rural Staph Cases

In the year 2000 there were 5.3 million discharges from rural hospitals and a total of 35 million discharges in all U.S. hospitals. Assuming that the rate of infection in each hospital is directly proportional to the number of discharges for the respective hospital, the total number of infections in all rural hospitals is calculated to be 300,000 corresponding to 76,000 cases of staph per year. The minimum number of *S. aureus* diagnostic tests required by rural hospitals each year to test all patients showing signs of infection is therefore 300,000. As criteria to estimate the rate of staph infection over the next ten years, this number is expected to remain proportional to the rate of rural hospital discharges.

3.3 Future Rates of Staph Infection

Between 1995 and 2000 the number of discharges from rural hospitals increased from 5.0 million to 5.3 million, a 6% increase in hospital discharges over the five-year period (AHA). This is consistent with the resurgence in the growth of the rural population over the past several decades as indicated with an 11% increase in the U.S. rural population between 1990 and 2000 (U.S. Bureau of the Census). As a result of these trends, the number of rural hospital discharges is estimated to increase 10% between 2005 to 2014. The number of *S. aureus* diagnostic tests is therefore expected to increase accordingly as indicated in Table 1.

TABLE 1: Estimated *S. aureus* tests required by rural hospitals from 2005 to 2014.

Year	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014
Tests	300,000	303,300	306,600	310,000	313,400	316,900	320,400	323,900	327,400	331,000

This estimation does not consider hospital practices associated with the acquisition of staph and assumes that changes in hospital sanitation, incision treatment and hygiene of hospital personnel will remain constant over the next ten years.

3.4 Competition

WKS, Assays Inc.'s main competitors will be larger biotechnology companies including Remel, Sure-Vue, Murex and BD BBL. These companies currently market coagulase and catalase tests for the identification of *S. aureus*. In order to administer these tests a sample must first be obtained from the patient and cultured overnight in either a solid or liquid medium. The application of the test provides a rapid color change to detect the presence of *S. aureus.* While the test is relatively quick, the rate-limiting step is the long period of time required to culture the

sample. In addition, these tests only qualitatively detect the presence of staph and do not determine the quantity of staph present in the infected person.

WKS Assays, Inc. will have an advantage over its competitors by marketing an immunoassay diagnostic procedure that does not require sample culturing. The results of the immunoassay will be available in three hours and will also indicate the quantity of *S. aureus* bacteria present in the patient's system. The *S. aureus* immunoassay can detect *S. aureus* antigen at a minimum concentration of 400 pg/mL. Quantitative detection of the antigen can allow health care workers to tailor treatment of the infection based on the bacterial level indicated by the assay. WKS Assays' test also only requires approximately 3 hours for test execution. The qualitative tests marketed by our competitors require approximately 24 hours, due to the need to culture the samples for testing.

4.0 FDA REGULATIONS

WKS Assays, Inc. requires approval from the Food and Drug Administration (FDA) in order to market its *S. aureus* immunoassay in the U.S. The FDA is responsible for the safety, efficacy, and security of medicines and medical devices intended for human use. Applying for FDA approval is a very intense process and many of the major risks critical to the success of WKS Assays, Inc. lie in the FDA approval process. WKS Assays has evaluated possible outcomes during each step and will complete a risk analysis over the FDA approval process. In order to increase the probability of FDA approval, WKS Assays will conduct testing of the immunoassay prior to entering the FDA approval process.

4.1 PRE-FDA TESTING

Pre-FDA testing of the *S. aureus* immunoassay will occur in four phases. Phase 1 testing consists of accuracy and reproducibility testing. This testing phase is expected to last one month and cost approximately $28,000. WKS Assays will provide a dose response curve with the immunoassay to correlate the assay's result to an antigen concentration. The assay will be evaluated for its measurement of *S. aureus* antigen concentration against what is predicted by the dose response curve. The test will be considered a failure if there is more than 5% error between the predicted and actual values.

Phase 2 testing consists of testing the immunoassay with actual human blood serum containing varying concentrations of the *S. aureus* antigen. This phase of testing is expected to last 1.5 months and cost approximately $46,000. The same criterion for test failure applies to this testing phase.

Phase 3 testing consists of testing the immunoassay with blood serum containing both varying antigen concentrations and also chemical precursors to common pharmaceuticals. This phase of testing is expected to last 3 months and cost approximately $82,000. Phase 4 is the final testing phase prior to application for FDA approval.

Phase 4 is expected to last 3 months and cost approximately $82,000. Upon successful completion of all four phases, WKS Assays will enter the FDA approval process. The probability of successful FDA approval will be significantly enhanced by the successful completion of the Pre-FDA approval process. Figure 1 illustrates the Pre-FDA testing process with possible scenarios and probabilities of success or failure for each path.

The total time frame for Pre-FDA testing for the immunoassay is approximately 8.5 months. The total cost for the Pre-FDA process is approximately $242,000. The time frame for FDA approval for the assay is approximately 6 months to 1 year. The total cost associated with FDA approval is $244,784. More detailed and accurate costs associated with FDA and pre-FDA testing can be found from our stochastic model of the testing phases. It is estimated to cost approximately $1.4 million for pre-FDA testing.

4.2 PRE-MARKET NOTIFICATION

The Pre-Market notification process will entail the same testing that is conducted by WKS Assays in the Pre-FDA testing process. The WKS Assay *S. aureus* immunoassay is classified as a Class II medical device. The first step for FDA approval is submission of form FDA 3602, which is the Medical Device User Fee and Modernization Act (MDUFMA) Small Business Qualification Certification. This form verifies that WKS Assays qualifies to receive discounted fees as a small business with gross annual sales and revenues that do not exceed $30 million. After discount, the resulting fee for the 510(k) Pre-market Notification application is $2,784. FDA Form 3602 will be reviewed and returned to us within 60 days.

Next WKS Assays must complete the Medical Device User Fee Cover Sheet, Form FDA 3601, to secure a payment identification number for FDA applications. The form is electronically transmitted to the FDA's Office of Financial Management. The payment identification number is located in the upper right-hand corner of the printed cover sheet. This payment identification number will be used on all of the applications submitted to the FDA.

The approval process is outlined below in Figure 2, with probable outcomes for each successive step of the testing process. Pre-market Notification, or 510(k) as it is more commonly known, is used in place of Pre-market Approval when a device has not previously been approved by the FDA.

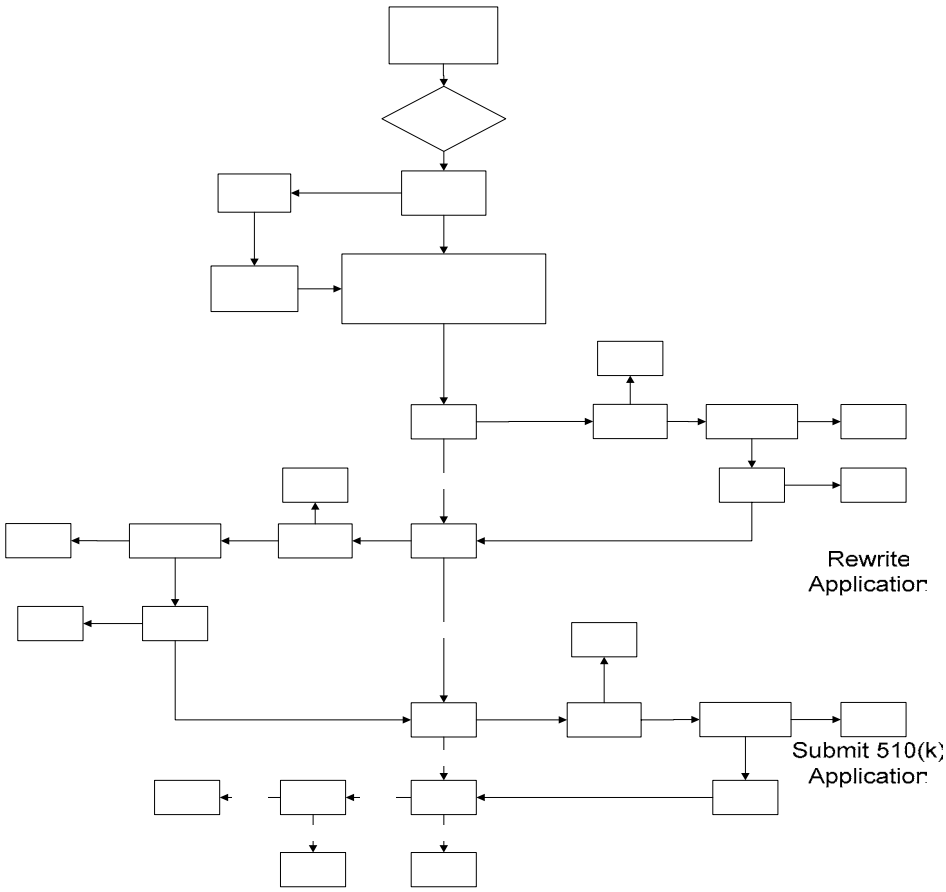


FIGURE 2: FDA Approval Pert Chart

A predicate device, Lin-Zhi International, Inc. Ecstasy Enzyme Immunoassay, is analogous to our product, however further evaluations are required after MDUF approval is received to evaluate previous 510(k) approvals for similar processes. The next step in the process is to locate guidance documents and to complete and submit the 510(k) application in duplicate, retaining one copy for our records.

After the submission of the 510(k) application, there are two possible outcomes; Approval or Approval with Revisions. Both outcomes lead to the following administrative steps: Medical Device labeling for *in vitro* devices must be completed according to FDA guidelines. Establishment Registration and Medical Device listing must be completed concurrently by submitting FDA Forms 2891 and 2892 respectively.

The final step in the FDA approval process is the FDA monitored testing of the immunoassay. As the immunoassay will have already been subjected to a rigorous testing and verification process prior to entering the FDA approval process, few difficulties are anticipated with this stage of the process.

6.0 INVESTMENT PLAN - $5.8 MILLION

6.1 THE OFFERING

WKS Assays, Inc.'s product is a diagnostic immunometric assay for the detection of *Staphylococcus aureus* in humans. *S. aureus* is a ubiquitous organism and is found on the human body, however, in instances when the bacterium appears in the internals of the human body, serious infection and complications can arise.

Our product is marketed as a detection device to identify *S. aureus* in hospitals and clinics. The initial investment would help fund the construction our facility, raw materials costs, and pre-FDA testing costs.

This investment stage is for the production and sale of the immunoassay in the United States after FDA approval

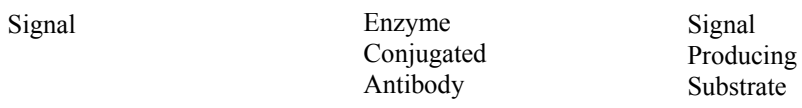
The components of the immunoassay kit that we will be selling will consist of the following:

- 2 96-well plates
- 1 Wash Solution, 100 mL
- 1 Stop Solution, 50 mL
- 1 Substrate & Peroxide vial, 11 mL
- 1 Labeled Antibody Solution, 11 mL
- 1 Antigen Standard Solution, 11 mL
- 1 Example Dose Response Curve

Description and elements of the components, including concentrations, amounts and the science and engineering behind the construction of our immunoassay can be found in the attached technical report.

6.1.1 Description

The *S. aureus* assay is designed to detect the staph pathogen at concentration levels as low as eight-hundred pico-grams per liter. The assay will include a plate for the obtaining of the results. Multiple testing can be done since the plate consists of 96 wells. The assay works by the diagram pictured below. Crucial components for successful and accurate results of the immunoassay are the wash steps in which any on bound particles are removed to prevent a false reading. The assays can then be sent to a signal analyzer more commonly known as a ELISA plate reader and using the dose response curve in the linear range of 800 pico-grams per liter to 4,000 pico-grams per liter.



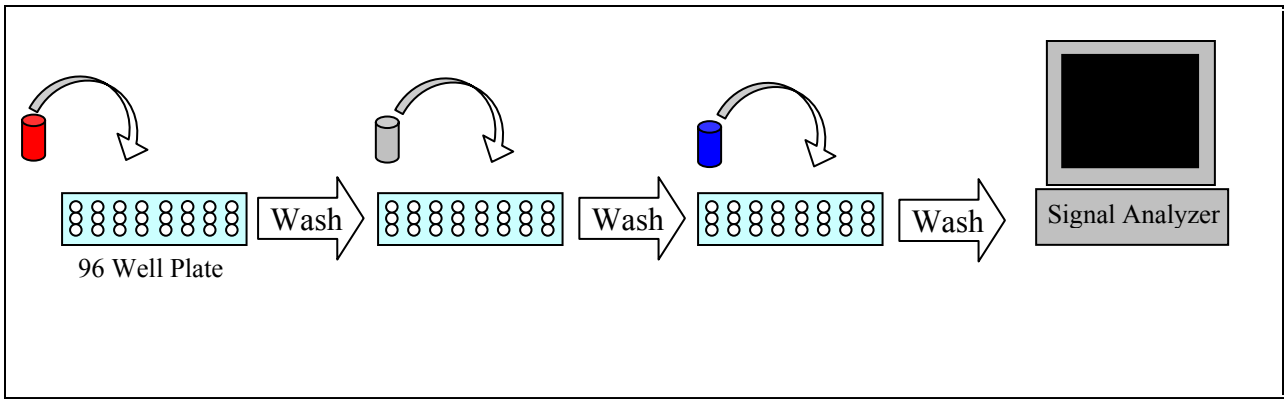


FIGURE 3: Immunoassay Protocol

6.1.2 Value

Our product value is of the utmost importance to the health care field as they try to decrease the rising infection rate due to bacteria and uncleanly facilities. The *S. aureus* assay produced by WKS Assays, Inc. has the potential to significantly decrease the spread of infections due to patient interaction and cross contamination. To assure the value of our product, we will implement quality control tests for 2.5% of every batch produced.

6.1.3 Cost to Produce

The actual materials required to develop the assay cost approximately $7,000,000 for the production of 250,000 immunoassay kits. The total cost per product is calculated to be $20.67 which includes packaging costs. This amount is low because of the minuscule amounts required to produce one 96-well immunoassay kit. Packaging is not taken into account for the cost per product, as to total packaging costs is approximately $25,000 per year. For this investment option, 250,000 immunoassay kits were used to develop the amount of reagents required for this operation.

6.3 PRICING

We intend to aggressively price the *S. aureus* assay below the expected pricing of the competition in order to capture as much market share as possible. The recommended retail price of the assay is $125. The price is about 12 times larger than our cost to manufacture the assay; however, it takes the company 3 days to produce a single plate.

6.4 SALES

We currently have a staff of 28 personnel who are responsible for interfacing with our distributors. They are responsible for creating all of the promotional materials that will be provide to the distributors. The sales managers will report to the Chief Marketing Officer.

6.5 DISTRIBUTION

The *S. aureus* assay will be stored within the facility so we can distribute our immunoassays as soon as the orders are received from the customer. The assay will be shipped directly from our facility due to the extreme care that is needed in the handling and refrigeration of the assay. Our product can be stored for 3 months before it must be discarded.

7.0 OPERATIONS / PRODUCTION

The manufacturing operation is the "backbone" of WKS Assays, Inc. Our process has a delay of three days for the production of our first set of plates. Since this is the slow part of the process, our kits will be coupled with already produced plates and reagent materials produced on a particular day. If we have any appreciable lag in these processes we will quickly see the impact in our revenue. The operation is managed by a very experienced individual, using adequate equipment and employing intelligent, but not highly experienced, personnel. Because some aspects of the operation are unique and extremely delicate to WKS Assays, Inc.'s process of manufacture, the only way the personnel can get the necessary experience is for us to train them.

7.1 SUPPLIERS

We will have several suppliers for our product development. Our major supplier is Sigma Chemical Company. We will purchase the reagents required for the successful operation of our immunoassay. We will be working on a continuous basis with them, and hope to have a business discount for large purchases, since our product will solely use Sigma chemicals.

WKS Assays, Inc will also be using E&K Scientific as the supplier for the 96-well plates. These plates will be purchased in bulk quantities.

7.2 MANUFACTURING

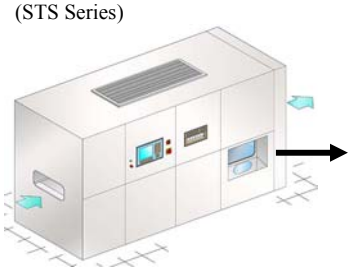
The process for the manufacturing of immunoassay kit is a very streamlined process. WKS Assays, Inc. will be using equipment from Groninger which is a leader in equipment for the pharmaceutical and cosmetic industry.

We will be using Amber Boston Round Glass bottles as the containers for our reagents. These bottles were chosen because exposure to light can damage and hinder the activity of our reagents.

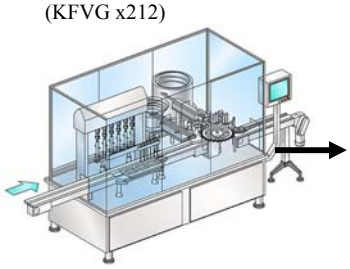
The manufacturing process is depicted below as a streamline process. First the bottles will be sterilized using the bottle sterilization machine, STS Series, which has a processing rate of 20,000 units per hour. The sterilization machine uses dry heat which is infrared in the center core of the unit.

After the bottles have been sterilized, they are then filled using the KFVG x212 which processes 6,000 units per hour. Aseptic techniques are used in the inner chamber of the machine to allow for bacteria free filling of our reagents. There is a system of pumps and a piping system to allow for quick and easy adaptability for varying bottles. The bottles will then be capped in the inner chamber and dispensed outside ready for labeling.

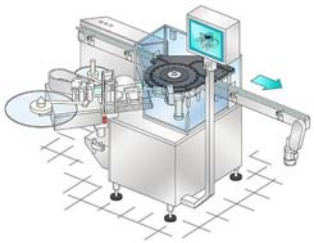
Bottle Sterilization
(STS Series)



Bottle Filling
(KFVG x212)



Bottle Labeling
(HEA 105)



Bottle labeling will occur after the bottles have been filled and closed and dispensed. The HEA 105 will be used for this process by preparing and affixing adhesive labels. The bottles will be labeled with the date of production and expiration date. Labeling will also be in accordance with the Food and Drug Administration regulation.

Since multiple bottles must the sterilized, filled, and labeled, a Gantt chart is shown below depicting the times of sterilization, filling and labeling of each reagent in Table 2.

***Table 2**: Manufacturing Gantt Chart*

ΙΔ	Τασκ Ναμε	Δυρατιον	Daily Operation									
			8	9	10	11	12	1	2	3	4	5
1	Assay Solution - Sterilization	0.5h										
2	Standard Solution - Sterilization	0.5h										
3	Wash Buffer - Sterilization	0.5h										
4	Conjugated HRP - Sterilization	0.5h										
5	Substrate (TMB) - Sterilization	0.5h										
6	Stop Solution - Sterilization	0.5h										
7	Assay Solution - Filling	0.5h										
8	Standard Solution - Filling	0.5h										
9	Wash Buffer - Filling	1.0h										
10	Conjugated HRP - Filling	0.5h										
11	Substrate (TMB) - Filling	0.5h										
12	Stop Solution - Filling	0.5h										
13	Assay Solution - Labeling	1.0h										
14	Standard Solution - Labeling	1.0h										
15	Wash Buffer - Labeling	1.0h										
16	Conjugated HRP - Labeling	1.0h										
17	Substrate (TMB) - Labeling	1.0h										
18	Stop Solution - Labeling	1.0h										

Since all of the machines are manufactured by Groninger, adaptability and interchangeability is easy. There is time allotted between the labeling procedures to manipulated change programs for the different bottles.

7.3 INVENTORY

For our component products we have large inventory requirements. In addition to the

components, instrumentation is also required such as pipettes, flask and general laboratory equipment for creation of stock solutions which are stored daily in glassware. The lead time required for an order of our assays is usually less than two weeks. The chemical materials can all be supplied within a week, but once again we maintain no less than a four week supply. All inventories are checked weekly.

Our finished inventory is packaged in predetermined quantities and stored, each marked by product name and date of production. The amount of any one product to be maintained in inventory is determined by our marketing department, who provide us a weekly "build" report that specifies what products are to be manufactured that week. The selection of components to be manufactured is based on marketing's projection of orders that will be coming from our distributors.

8.0 INVESTMENT CAPITAL

8.1 INITIAL FUNDING

Current projections indicate that an investment of $5,800,000 is required to carry the business through the start up year of introducing the *S. aureus* immunoassay. We are proposing that this be an equity investment for which the investors will receive 15% ownership in WKS Assays, Inc.

8.2 USE OF FUNDS

The initial investment will be used as the Fixed Capital Investment for WKS Assays, Inc. The investment will be used to buy the equipment, land, construction and installation of required materials, and fund the FDA approval process for the *S. aureus* immunoassay.

The chart below shows a break down of how the $5.8 million dollars will be utilized.

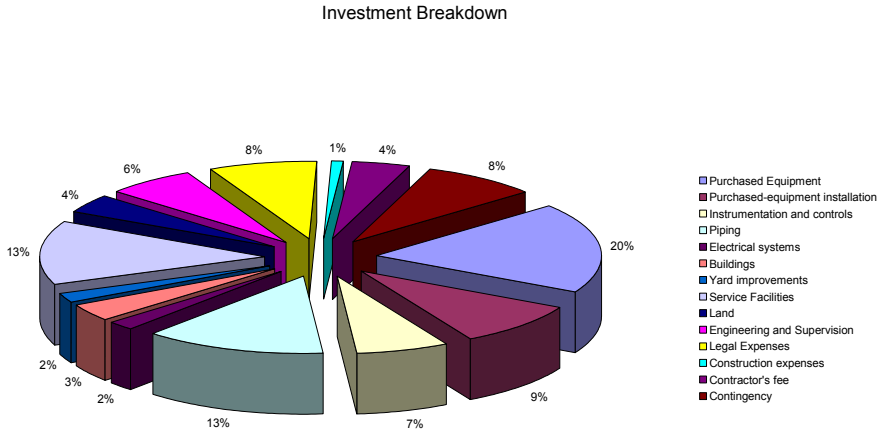


FIGURE 4: Investment Breakdown

8.3 PROJECT PROFITABILITY

The net present value for this undertaking is approximately -$2,000.000. This negative value is largely due to the large amount of risk present in the project. As stated previously, there is only a 42% chance of breaking even under the best case scenario.

The estimated net present worth for this venture is based on the stochastic model used to simulate the FDA approval process. The model takes into account the cash flow for ten years, which is shown below, an approximate total product cost of thirty million dollars, and the price per kit.

TABLE 2: Annual Revenue

Year	Kits	Price	Sales	TPC	Revenue
1	250,000	$125.00	$31,250,000.00	$30,013,422.00	$1,236,578.00
2	275,000	$125.00	$34,375,000.00	$30,914,481.00	$3,460,519.00
3	280,500	$125.00	$35,062,500.00	$31,112,714.00	$3,949,786.00
4	286,110	$125.00	$35,763,750.00	$31,314,911.00	$4,448,839.00
5	291,832	$125.00	$36,479,025.00	$31,521,164.00	$4,957,861.00
6	297,669	$125.00	$37,208,605.50	$31,731,531.00	$5,477,074.50
7	303,622	$125.00	$37,952,777.61	$31,946,104.00	$6,006,673.61
8	309,695	$125.00	$38,711,833.16	$32,164,970.00	$6,546,863.16
9	315,889	$125.00	$39,486,069.83	$32,388,192.00	$7,097,877.83
10	322,206	$125.00	$40,275,791.22	$32,615,920.00	$7,659,871.22

Detailed profitability analysis can be found in the full project report.