Chromogenic Horseradish Peroxidase Immunoassays

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CH E 4273—Advanced Design Capstone Project

Executive Summary

This project deals with the design, production, and marketing of an immunoassay from initial theory to final product. The immunoassay has been developed to test for the presence of *Staphylococcus aureus* via the antigen Protein A. The assay can test for Protein A at concentrations as low as 400 pg/mL.

The immunoassay that has been developed is an immunometric, or enzyme-linked immunosorbent assay. It is commonly known as an ELISA. The main concept behind the development of this assay is the use of the kinetic equations to optimize the amount of reagents used in the assay, as well as design to desired specifications the sensitivity of the assay.

To market the immunoassay, Food and Drug Administration approval must be obtained. A novel procedure was done in which a stochastic model of the FDA approval process for our product was used to estimate time and money requirements The FDA approval process model found that there is a 42% chance of obtaining a positive net present value (NPV) when 500 tests are completed in Phases 1 & 2 of Pre-FDA testing, and 1000 tests are completed in Phases 3 & 4 of Pre-FDA testing. Due to the FDA approval part of the process, this project will either be profitable or not. There is no in between area.

The total capital investment for this project is $5,800,000. This accounts for manufacturing equipment, reagents, location, facilities and FDA approval costs. The total estimated time for Pre-FDA testing and FDA approval is 1.7 years.

While this project has a less than 50% chance of being profitable, the theoretical design for the antibody-antigen interactions and the risk model can be adapted to different immunoassays and target diseases. This lends itself to future development of a wide variety of immunoassays.