I. Project Title
   Point-of-Care Diagnostic Device for the Quantitative Analysis of Human Estradiol at Low-Picomolar Concentrations

II. Project Completion Date
   April 15, 2017

III. Student(s), Department(s), and Major(s)
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V. Cooperating Industry, Agency, Non-Profit, or University Organization(s)
   N/A

VI. Executive Summary
   A fundamental issue in healthcare is the development of cost-effective and reliable diagnostic assays. While still a relatively new field, paper-based analytical devices are emerging as inexpensive and portable methods of providing healthcare professionals with real-time diagnostic information. Furthermore, these devices can often be used at the point of care, thus eliminating the need for a myriad of time-consuming laboratory techniques.

   While the original goal of this project was to develop a paper-based lateral flow immunoassay capable of colorimetric quantitation, the device design was altered over the course of the past year. Upon testing, the originally proposed lateral flow assay lacked adequate sensitivity and reliability. Therefore, a novel three-dimensional paper-based analytical device was developed. This new device design utilizes enzymatic amplification to break down a biomatrix, ultimately producing a chronometric readout. This unique biomatrix can detect <1 femtomole ($10^{-15}$) of analyte, with degradation time being directly correlated to analyte concentration. Thus far, device storage conditions, viable pH ranges, and viable temperature ranges have been determined. While further refinement is still needed, these diagnostic devices have the potential to revolutionize point-of-care assays through the quantification of analytes in both field and clinical settings.
VII. Major Accomplishments

(1) **Device Storage:** Device longevity was examined through storage at room temperature over a three-month period, with functionality being tested monthly. The biomatrix displayed no appreciable indication of auto-degradation, while applied pro-enzymes displayed slightly reduced functionality over time. This data indicates assay viability in field settings where specialized storage conditions (ie. refrigeration) may be unavailable.

(2) **pH:** Device functionality was tested using a series of buffers with a wide range of pH values. The device biomatrix displayed functionality at pH values 1-9. This indicates device viability with analytes of varying pH requirements.

(3) **Temperature:** Device stability at varying temperatures was also tested. Our findings indicate that standard device functionality remains consistent between 17-29°C (with 40-50% humidity). This allows for assay viability in a wide range of ambient environments, even without specialized storage equipment.