Electrochemical Quantitation of Antinuclear Antibodies (ANA) in Patients at the Point-of-Care

The University of New Mexico
Inventors: Robert Rubin, PhD; Konstantin Konstantinov, MD, PhD; David Wall, PhD

(STC Ref. 2014-071)

Background

Measurement of serum autoantibody is a critical tool in the diagnosis and management of autoimmune diseases. Detection of antinuclear antibodies (ANA) in blood is widely used as an initial screening tool to suggest an autoimmune connective tissue, infectious, neurologic, liver, or neoplastic disease. However, rapid and convenient methods to measure ANA are unavailable because this test requires specialized laboratory equipment and expertise and must be carried out in a centralized clinical laboratory. The requirement for blood drawing, transport to the testing lab, blood processing, test execution, and communication of results creates a cumbersome, time consuming, error prone and expensive process which detracts from its diagnostic value.

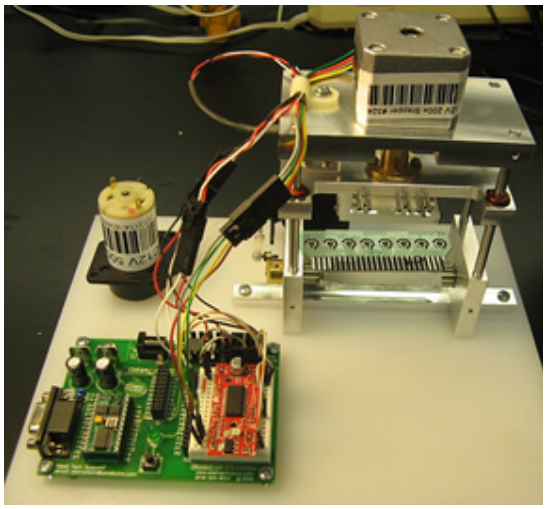
Point-of-care (POC) testing has the potential to overcome these problems and is showing increasing use in aiding clinical diagnosis. Biosensor technology offers the promise to streamline diagnostic laboratory testing, thereby improving productivity of health care systems by minimizing costs, time and errors. A reliable and inexpensive POC test for ANA can improve diagnostics in primary or urgent/emergency care clinics and expedite medical intervention for patients.

Technology Breakthrough

University of New Mexico researchers have developed an electrochemical biosensor capable of quantifying total ANA during the time a patient would remain in a clinic, making it feasible to use as a portable POC diagnostic aid. The prototype is a semi-automated device that can measure autoantibodies in fresh human serum, employing a flexible design using inexpensive materials, reagents, and electronics. This technology is capable of achieving total assay time of under 30 minutes with results that compare with those of a standard immunoassays performed in clinical laboratories.

Key Advantages

- *Improves productivity of health care systems by minimizing costs, time, and errors*
- *Flexible design applicable to any analyte*
- *Low fabrication cost for biosensor*
- *Uses inexpensive disposable materials*
- *Operation requires minimal training*
- *Automated processing of sample*
- *Near real-time results*
- *Aids clinical diagnosis at the point-of-care for individual patient*
- *Second generation prototype under development*



Prototype of electrochemical biosensor

Intellectual Property

U.S. Utility Application 15/115,033
(Published Patent Application US 2016/0341687 A1)

Contact

For more information, contact Arlene Mirabal, Marketing Manager, STC.UNM at amirabal@stc.unm.edu or (505) 272-7886.

Visit STC.UNM at www.stc.unm.edu.

STC.UNM
SUPPORTING TECHNOLOGY TRANSFER AND CATALYZING ECONOMIC DEVELOPMENT AT THE UNIVERSITY OF NEW MEXICO

References

Konstantinov, K., Tzamaloukas, A., and Rubin, R.L., Detection of autoantibodies in a point-of-care rheumatology setting, Autoimmunity Highlights, 4: 55-61, 2013

Rubin, R.L., Wall, D., and Konstantinov, K.N., Electrochemical biosensor for quantitation of anti-DNA autoantibodies in human serum, Biosensors and Bioelectronics, 51, 177-183, 2014

Rubin, R.L. and Konstantinov, K.N., Biosensor for total antinuclear antibody determination at the point-of-care, Biosensors and Bioelectronics, 83, 306-311, 2016

Rubin, R.L. and Konstantinov, K.N., Point-of-care electrochemical sensors for antibody detection, In Portable Biosensors and Point-of-Care Systems, Chapter 4, S.E. Kintzios, ed., Institution of Engineering and Technology. UK, 2016

Konstantinov, K. and Rubin, R.L., The Universe of ANA Testing – a Case for Point-of-Care ANA Testing, Autoimmunity Highlights, 8:1-4, 2017