Docket #: S13-456

Rapid, portable blood ammonia detection device (PAD)

Stanford researchers have built a low cost, portable, simple-to-use device designed to rapidly detect elevated ammonia in a drop of blood. This device could be used to manage the treatment of patients with conditions such as urea cycle defects and liver disease or for individuals being treated with certain chemotherapeutic agents. With easy detection, patients can be treated to prevent cognitive impairment and other effects of hyperammonemia.

The device uses an inexpensive fuel cell component to measure the ammonia released from whole blood upon alkalinization. It can achieve the same sensitivity and accuracy of the traditional laboratory assay, but achieves this with a smaller blood sample that requires no special handling or plasma preparation. Thus, this device could be used for point-of-care analysis at the bedside, or in a patient's home. Its applications include diagnostics, patient monitoring and drug development.

Stage of Research

The inventors have tested a prototype Portable Ammonemia Detector (PAD) using 100 microliters (2 drops) of blood. The results from PAD analysis were highly correlated with conventional plasma ammonia testing ($r^2 = 0.97$) from normal to the most extreme ammonia concentrations seen in clinical practice.

Applications

- **Point of care diagnostics and home monitoring** detection of hyperammonemia, with applications such as:
 - monitoring patients with urea cycle defects, cirrhosis or NASH (nonalcoholic steatohepatitis)

- monitoring cancer patients undergoing chemotherapy with drugs that cause hyperammonemia
- newborn screening for inborn errors of metabolism
- newborn screening for compromised liver function associated with premature birth
- Drug development simple assay to evaluate efficacy of drugs for hyperammonemia in animal models and clinical trials

Advantages

- Fast device provides an accurate result within seconds
- **Small sample** analysis can be performed on blood obtained by finger or heel prick
- **Convenient** device can be used at the bedside or in-home (eliminating need for central laboratory and transport on ice)
- Low cost

Patents

• Published Application: 20150226702

Published Application: <u>20170030893</u>

• Published Application: 20170082605

• Issued: <u>9,625,443 (USA)</u>

• Issued: <u>9,835,613 (USA)</u>

• Issued: <u>10,151,743 (USA)</u>

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