Docket #: S13-456

Rapid, portable blood ammonia detection device (PAD)

Stanford researchers in the Kanan Lab have patented a low-cost, portable, and easy-to-use device designed to rapidly detect elevated ammonia levels from a drop of blood. This device can help manage treatment for patients with conditions like urea cycle defects and liver disease, or those undergoing certain chemotherapy treatments. With easy detection, patients can be treated to prevent cognitive impairment and other effects of hyperammonemia.

The device uses a fuel cell component to measure ammonia released from whole blood upon alkalinization, achieving the same sensitivity and accuracy as traditional lab assays but with a smaller blood sample that requires no special handling. It is suitable for point-of-care analysis at the bedside or in a patient's home, with applications in diagnostics, patient monitoring, and drug development.

Stage of Research
The inventors have tested a prototype Portable Ammonia Detector (PAD) using 100 microliters (2 drops) of blood. The results were highly correlated with conventional plasma ammonia testing ($r^2 = 0.97$) across a range of 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 (non-alcoholic 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: 20170030893
- Published Application: 20170082605
- Issued: 9,625,443 (USA)
- Issued: 10,151,743 (USA)

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