Semi-Quantitative Lateral-Flow Immunoassay Kit for the Detection of CSF Leaks

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SUMMARY

UCLA researchers in the Department of Bioengineering and the Department of Head and Neck Surgery have invented a novel lateral-flow immunoassay (LFA) to detect cerebrospinal fluid leaks quickly, inexpensively and semi-quantitatively.

BACKGROUND

Cerebrospinal fluid (CSF) leak is a common and dangerous complication that can occur naturally, traumatically or from surgical procedures near the skull base or spine. Failure to repair CSF leaks can lead to meningitis, brainstem herniation and death. It is difficult to distinguish CSF from normal nasal and otologic secretions, especially in outpatient settings or without Otolaryngology or Neurosurgery specialists on hand. Current methods for diagnosing CSF leaks include MRI and CT scans, gel electrophoresis, and immunological assays that are costly, time consuming and labor intensive. In addition, these assays are binary in their results and do not quantify the cerebrospinal fluid identified. When a diagnosis is still uncertain, operative management is often pursued, even in low likelihood situations given the devastating side effects of failing to treat a leak. A diagnostic tool that could help physicians to better select which patients necessitate operative intervention could significantly improve patient care and save valuable hospital resources.

INNOVATION

A novel approach for CSF leak detection was invented to achieve inexpensive, accurate and semi-quantitative diagnosis of the leak. This invention uses a lateral-flow immunoassay (LFA) to detect a biomarker specifically present in CSF. Through detection of this biomarker, this device can quickly and accurately determine the presence of CSF in the sample fluid, as well as provide an estimate of its concentration.

APPLICATIONS

- Detection of CSF leaks in nasal and otologic fluids
- Detection of traumatic injuries that violate the dura
- Preliminary diagnosis of disease progression using specific molecular markers

ADVANTAGES

- Easy to use and interpret
- Inexpensive
- Can be used in outpatient care and at bedside
- Fast
- Semi-quantitative
- Portable

STATE OF DEVELOPMENT

Prototype developed and tested in lab with clinical samples.

PATENT STATUS

Country	Type	Number	Dated	Case
United States Of America	Issued Patent	11,867,693	01/09/2024	2017-695
United States Of America	Issued Patent	11,209,427	12/28/2021	2017-695

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OTHER INFORMATION

KEYWORDS

Cerebrospinal fluid (CSF), Lateral-flow immunoassay (LFA)

CATEGORIZED AS

- **Biotechnology**
  - Health
- **Medical**
  - Devices
  - Diagnostics

RELATED CASES

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