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BIBIS – Improved Identification of Intracranial Hemorrhage in Infants and Young Children Using Serum Biomarkers ID: 2655

Featured Innovators: Rachel P. Berger, MD, MPH and Brian J. Pak, PhD

Intracranial hemorrhage (ICH) in infants with non-specific symptoms is frequently misdiagnosed. Currently, patients are selected for additional testing – such as brain scans – on the basis of clinical judgement alone, which can be difficult because caregivers often do not provide an accurate history of abusive head trauma. The misdiagnosis of these infants can lead to further abuse and associated injuries. Now a biomarker blood test called Biomarkers for Infant Brain Injury Score (BIBIS) can take some of the guesswork out of diagnosing ICH in infants. The BIBIS score is highly sensitive and specific to ICH and significantly improves the accuracy of infant ICH diagnosis. BIBIS enables physicians to rapidly and accurately confirm ICH in suspected cases, allowing them to provide swift and appropriate intervention. BIBIS will also allow physicians to more confidently rule out ICH, avoiding radiation exposure from unnecessary head scans.

Technology Description

BIBIS is a rapid multiplex immunoassay of four blood biomarkers coupled with a multivariate algorithm. The BIBIS assay is performed on a proprietary microporous silicon substrate which enables the rapid multiplex analysis of biomarkers from small volumes of biological samples. The resultant biomarker concentrations are processed using a multivariate algorithm to provide a score that is highly predictive of ICH. BIBIS was prospectively tested on 599 patients and demonstrated 89.3% sensitivity and 48.0% specificity for ICH. This technology uniquely enables rapid, automated multiplex biomarker testing, making it conducive for use in acute care settings where rapid diagnosis is important.

Advantages

- Improved sensitivity for identifying ICH in infants over clinical judgement alone
- High negative predictive value provides confidence that ICH diagnosis was not missed
- Small volume of sample required
- Fully automated after sample application
- Rapid results, which facilitates use in acute care settings

Applications

- Highly predictive diagnostic testing enabled by multiplex biomarker analysis
- Diagnostic screening (e.g., infections, allergy)
- Tests that currently require central laboratory facilities – due to complexity or analytical sensitivity – which are beneficial if performed immediately in near patient settings

Stage of Development

prototype for point-of-care testing is currently in development.

IP Status

PCT has been filed

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Innovators

Rachel P. Berger, MD, MPH

Chief of the Division of Child Advocacy
Children's Hospital of Pittsburgh UPMC

Professor of Pediatrics
Assoc. Director of Child Abuse Research
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University of Pittsburgh

Dr. Berger has more than 15 years of clinical and research experience in the field of child abuse. Her research has been funded by the NIH, CDC, DOD, PCORI as well as multiple foundations for her child abuse-related research.

Education

MD Columbia University College of Physicians and Surgeons
MPH University of Pittsburgh School of Public Health
BA Harvard University

Publications

- Berger RP, Pak BJ, Kolesnikova MD, Fromkin J, Saladino R, Herman BE, Pierce MC, Englert D, Smith PT, Kochanek PM. Derivation and validation of a serum biomarker panel to identify infants with acute intracranial hemorrhage. *JAMA Pediatrics* (2017) 171:e170429.
- Berger RP, Fromkin J, Herman B, Pierce MC, Saladino RA, Flom L, Tyler-Kabara EC, McGinn T, Richichi R, Kochanek PM. Validation of the Pittsburgh Infant Brain Injury Score for abusive head trauma. *Pediatrics* (2016) 138:e20153756.
- Berger RP, Dulani T, Adelson PD, Leventhal JM, Richichi R, Kochanek PM. Identification of inflicted traumatic brain injury in well-appearing infants using serum and cerebrospinal markers: A possible screening tool. *Pediatrics* (2006) 117:325.

Brian J. Pak, PhD

Director, Assay Development
Axela, Inc.

Dr. Pak has over 16 years of industry experience in proteomics, biomarker discovery/validation and assay development. He completed his postdoctoral fellowship in cancer biology at Johns Hopkins University School of Medicine and the University of Toronto.

Education

PhD Queen's University, Canada
MSc Queen's University, Canada
BSc Queen's University, Canada

Publications

- Pak BJ, Vasquez-Camargo F, Kalinichenko E, Chiodini PL, Nutman TB, Tanowitz HB, McAuliffe I, Wilkins P, Smith PT, Ward BJ, Libman MD, Ndao M. Development of a rapid serological assay for the diagnosis of strogyloidiasis using a novel diffraction-based biosensor technology. *PLOS Neglected Tropical Diseases* (2014) 8:e3002.
- Iqbal SM, Ball TB, Levinson P, Maranan L, Jaoko W, Wachihi C, Pak BJ, Podust VN, Broliden K, Hirbod T, Kaul R, Plummer FA. Elevated elafin/trappin-2 in the female genital tract is associated with protection against HIV acquisition. *AIDS* (2009) 23:1669.

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