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**RAPID BLOOD TEST FOR INTRACRANIAL HEMORRHAGE IN WELL APPEARING INFANTS:
A COMPREHENSIVE BRAIN INJURY STUDY USING AXELA'S FLOW-THRU CHIP PLATFORMS**

The University of Pittsburgh today revealed the results of an ongoing collaboration between Dr. Rachel Berger of the University of Pittsburgh and Children's Hospital of Pittsburgh of UPMC, and Axela Inc. The study, published in the journal JAMA Pediatrics, demonstrated that a multiplex protein biomarker panel has the potential to accurately identify infants with acute intracranial hemorrhage (ICH).

The serum based test, which requires validation in a larger population and regulatory approval before being used in clinical practice, would be the first of its kind to be used to detect acute ICH, or bleeding of the brain in children. Patients who test positive would then be subjected to further evaluation via brain imaging to determine the cause of the bleeding. An important application of the Biomarkers for Infant Brain Injury Score (BIBIS) is in cases of abusive head trauma (AHT), the leading cause of infant death from physical abuse in the United States. Sometimes referred to as shaken baby syndrome, approximately 30% of AHT diagnoses are missed because caretakers provide inaccurate histories and the infants present with nonspecific symptoms. Missed diagnoses can be catastrophic as AHT can lead to serious brain damage or even death. Routine use of BIBIS could also contribute to an overall reduction in frequency of head imaging in infants, eliminating unnecessary exposure to ionizing radiation in the developing brain.

This study involved well-appearing infants less than 12 months old, who presented to emergency departments for evaluation of soft neurologic signs such as vomiting or fussiness with no history of trauma. A simple blood test was developed to measure three protein biomarkers simultaneously. Test results were combined in an algorithm with patient total hemoglobin to discriminate between infants with and without acute ICH. The BIBIS formula was derived by first testing retrospective, banked samples from the Safar Center for Resuscitation Research at the University of Pittsburgh. Predictive capabilities of BIBIS were then tested prospectively in a second population of 599 patients at three sites in the United States. In addition to Children's Hospital of Pittsburgh of UPMC, infants were enrolled at Anne and Robert H. Lurie Children's Hospital in Chicago and Primary Children's Medical Center in Salt Lake City. The test correctly detected acute ICH due to AHT approximately 90 percent of the time, a much higher rate than the sensitivity of clinical judgement, which is approximately 70 percent.

"The test is not intended replace clinical judgement, which is crucial," said senior author Rachel Berger, M.D, M.P.H. chief of the Child Advocacy Center at Children's Hospital of Pittsburgh, and professor of Pediatrics at the University of Pittsburgh School of Medicine. "Rather we believe that it can supplement clinical evaluation and help physicians make a decision about whether an infant needs brain imaging in cases where symptoms may be unclear."

Dr. Berger utilized a new, rapid test developed in collaboration with Axela, based on its proprietary Flow-Thru Chip technology. The system measures the biomarkers simultaneously using 5 microliters of blood (less than a drop). Existing immunoassay approaches required blood volumes inconsistent with infant sampling or were too slow to have meaningful clinical impact. The test is compatible with Axela's current Zplex platform and identical results have been demonstrated on the next generation Z² sample to answer cartridge system. When launched, the Z² platform will enable

rapid, multiplex testing for both proteins and nucleic acids directly in both emergency department and doctors' office settings.

"This study illustrates the benefits of being able to perform highly sensitive multiplex assays at the point of care," said Paul Smith, President and CEO of Axela. "We are excited to continue our collaboration with Dr. Berger and other partners to validate the test on our new platform and prepare for regulatory submission." Preliminary studies indicate that the test may also be useful in identifying older children who have suffered intracranial injury due to accidental (sports and play) or abusive mechanisms. Investigating the utility of the test in this population is the subject of additional studies.

About Axela

Axela Inc. provides high performance, multiplex diagnostic solutions for both point-of-care and traditional laboratory environments. Superior time to result and sensitivity for both proteins and nucleic acids on the same device has been demonstrated in allergy, oncology, infectious disease, and neurology. Multiplex detection methodologies are complemented by proprietary sample preparation and amplification strategies adapted for simple, sample to answer platforms. These provide a significantly lower cost per test, allowing complex, high content assays to be competitive in both emerging markets and constrained reimbursement environments. Axela has partnered with international diagnostic companies and reference laboratories to commercialize clinical tests and develop custom market and application based solutions. The Toronto, Canada based company has a strong IP position, with more than 100 patents and applications owned or licensed worldwide.

About Rachel P. Berger MD, MPH

Dr. Berger is Chief of Child Advocacy Center Child Protection Team, Pittsburgh Child Advocacy Center, Children's Hospital of Pittsburgh of UPMC and, Director of Child Abuse Research, Safar Center for Resuscitation Research, University of Pittsburgh, and Professor of Pediatrics, University of Pittsburgh School of Medicine. Dr. Berger's research interests are focused on finding novel approaches to screening for abusive head trauma and using the electronic medical record to improve early diagnosis of child physical abuse. The Safar Center's current research programs include Traumatic Brain Injury, Child Abuse, Cardiac Arrest, Emergency Preservation and Resuscitation, Hemorrhagic Shock, Combat Casualty Care, and Rehabilitation of CNS Injury. This study was supported by NIH Funding: R01HD055986 and NIHK23HD43843.

For further information contact Paul Smith, President and CEO of Axela at paul.smith@axela.com