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BIOSITE® INCORPORATED TRIAGE® STROKE PANEL

Novel Biomarker Diagnostic Test Useful in the Assessment and Diagnosis of Stroke

According to the American Heart Association, stroke is the third leading cause of death and number one cause of disability in the United States, with more than 700,000 Americans suffering strokes each year (*1*). Almost one out of every three stroke victims will be permanently disabled (*2*) and one out of every four will die within one year. Ischemic strokes are the most common, accounting for 88% of all strokes, while hemorrhagic strokes make up the smaller percentage. Both require timely diagnosis and treatment. It is estimated that in 2005, the direct and indirect costs associated with stroke in the United States will exceed $56 billion (*3*).

Optimal treatment of a patient who has suffered a stroke requires rapid assessment and early intervention. This can often mean the difference between life and death. According to Daniel T. Laskowitz, MD, Associate Professor of Medicine (Neurology and Neurobiology), Duke University Medical Center (Durham, NC), a major limiting factor in the effective diagnosis of stroke is the lack of a rapid diagnostic test. "Hundreds of millions of dollars have been spent on the development of therapeutic interventions, but unless physicians can quickly and reliably diagnose stroke, they are not going to treat it."

Currently, only a small minority of patients with stroke (4%) actually receives fibrinolytic treatment within the three-hour window needed to achieve benefit. Dr. Laskowitz said that diagnosing a stroke is often difficult. "Unlike heart disease, which presents in a relatively stereotypical fashion, the manifestation of stroke can include a range of symptoms resembling other illnesses, and many emergency physicians don't feel comfortable making that diagnosis."

One method currently used to help diagnose stroke is a non-contrast CT scan of the brain. While widely used and sensitive for hemorrhagic stroke, interpretation of these scans is subjective, and CT is usually unable to detect early ischemic changes or positively diagnose acute ischemic stroke in the early hours after symptom onset (*4*). "There are also specialized MRI techniques, but they are not practical—99% of the community hospitals don't have 24-hour sophisticated MRI facilities."

With the absence of a widely available and sensitive diagnostic test, the diagnosis of stroke is one of exclusion and remains primarily based on clinical exam (*5*). Early evidence suggests that a biomarker test could be two to three times as sensitive as CT scans for detection of ischemic strokes. A recent study showed that certain biochemical markers may be helpful in diagnosing acute stroke, with sensitivity and specificity in excess of 90%, when compared with age-matched normal controls (*4*). While the study focused on utility for diagnosing acute stroke, it suggested that such a test also may have potential benefits for identifying the presence of cerebral vasospasm after aneurysmal subarachnoid hemorrhage before it is identified clinically (*4*).

An earlier study evaluated whether certain protein biomarkers would be helpful in predicting acute stroke within the first six hours of symptom onset, and suggests that a rapid diagnostic test, coupled with CT scan, would be a significant diagnostic tool (*5*). A five marker panel showed 91.7% sensitivity at 93% specificity for predicting ischemic stroke, compared with healthy donors, in the subset of patients presenting within six hours from symptom onset (*5*). Oral abstracts presented at this year's International Stroke Conference indicate that the use of biomarkers for stroke assessment and diagnosis is an important area of continuing research at many institutions worldwide (*6*).

The **Triage® Stroke Panel**, being developed by **Biosite® Incorporated** (San Diego, CA), **"**has the potential to impact the practice of acute stroke diagnosis," said Dr. Laskowitz. The Triage Stroke Panel, currently under review by the U.S. FDA, is a rapid, *in vitro* diagnostic immunoassay intended to be used as an aid in the assessment and diagnosis of cerebral ischemia (stroke). The Triage Stroke Panel consists of multiple biomarkers and utilizes a proprietary algorithm to calculate a single MultiMarker Index™ result. Using a small sample of blood, the test is designed to generate a quantitative result in approximately 15 minutes. The chief benefit of this test is that it can help identify patients who are very unlikely to have suffered a stroke or those with a high probability of having suffered stroke. "The availability of a rapid immunoassay that can be performed in the emergency department to aid in the assessment and diagnosis of stoke within about 15 minutes will greatly benefit the patient."

For more information concerning Biosite, call 1-800-745-8026, or visit the company's Web site at www.biosite.com.

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