Stroke continues to be a killer and disabler in the United States. Every year, more than 795,000 people in the United States have a stroke. About 610,000 of these are first or new strokes. In fact, stroke kills about 140,000 Americans each year – that’s 1 out of every 20 deaths.

Approximately one-third of all ischemic strokes are cryptogenic. When a person has a stroke, treatment usually depends on what caused the problem with blood flow to the brain. In some cases, despite an extensive workup, the cause of the stroke may not be evident, and the diagnosis is cryptogenic, meaning of unknown origin.

While there is research to help uncover the most effective treatments, most cryptogenic stroke patients are given aspirin — the kind you find in the average person’s medicine cabinet.

The ability to more clearly define the cause of cryptogenic stroke has remarkable potential for treatment and reduction of recurring events. Ischemic Stroke Lab™ provides a new and unique approach to predicting stroke etiology (cause) that leverages gene expression profiling to provide a new source of information that may guide treatment decision-making.

795,000 Strokes Per Year in the US
265,000 Strokes of Unknown Cause
140,000 Stroke Deaths Per Year

Strokes kill twice as many women as breast cancer every year.

One-third of Ischemic Strokes are of Unknown Cause

Ischemic Stroke Lab takes the mystery out of cryptogenic strokes. We use gene analysis to provide definitive diagnosis. Know the cause. Change the outcome.

An estimated 265,000 annual US stroke patients, or one-third of the population, have unknown stroke etiology. Accurate etiology is a challenging, but critical component of physician care for secondary stroke prevention.

When the cause of ischemic stroke is unknown, risk of recurrence may be increased. Knowing the cause can lead to improved outcomes and reduced costs.

Explaining the Genes

When a stroke or TIA occurs, the immune system changes gene expression in multiple cell types. Each stroke subtype produces a unique gene pattern. Using genes validated in the BASE clinical trial (NCT02014896), Ischemic Stroke Lab is offering the ISCDx blood test to stratify stroke patients by cause.

How Ischemic Stroke Lab Helps

Early action to diagnose the cause is important – patient outcomes are improved when guideline driven treatment begins quickly. Working in partnership with Ischemic Stroke Lab, hospitals draw blood samples within 16-30 hours of stroke symptom onset. Ischemic Stroke Lab then provides their proprietary ISCDx test results back to the physician to support their diagnosis.

Introducing ISCDx™ A Revolutionary Blood Test

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In BASE clinical trial data, 100% of patients with a score above 31 were cardioembolic, and 90% of patients with a score below 9 were atherosclerotic.

ISCDX is a testing service performed in a single CLIA laboratory, assessing the gene expression profile, using whole blood as a source of RNA, to aid in differentiating likelihood of cardioembolic and atherosclerotic cause of ischemic stroke, when hemorrhagic stroke is ruled out, for suspected stroke patients, where samples are collected in the acute hospital setting within 30 hours of symptom onset, with optimal collection between 16 hours and 30 hours from symptom onset. The ISCDX test results based upon the BASE analytical validation study (NCT02014896). The prevalence of cardioembolic stroke and atherosclerotic stroke in this population is 65% and 35% respectively. Overall specificity and sensitivity were 95% and 81.25% (61.71%, 94.53%), respectively. This test should be used by clinicians in conjunction with standard clinical evaluation, patient risk assessment, and in the context of the patient’s clinical history and other diagnostic test results, in developing patient specific clinical management plans.

This test was developed, and its performance characteristics determined by Ischemia Care LLC. The test is used for clinical purposes. The Ischemia Care Commercial Laboratory is regulated under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) as qualified to perform high complexity clinical testing.

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