

BioCentury

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EMERGING COMPANY PROFILE

FASTER THAN McDONALD

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IQuity Inc. is developing assays to diagnose autoimmune diseases as soon as symptoms appear based on differences in RNA expression of both coding and non-coding genes. The company's first test could help physicians confirm difficult multiple sclerosis diagnoses three to five years earlier than standard criteria.

MS is diagnosed via the McDonald criteria, which assess the number and timing of attacks, lesions detected by MRI and findings such as elevated IgG antibodies or oligoclonal bands in cerebrospinal fluid, among other factors.

Though treating MS early is thought to lead to better outcomes, IQuity CEO Chase Spurlock said when the McDonald criteria are inconclusive, it can take physicians three to five years to reach a diagnosis and start treatment. He said IQuity's IsolateMS test could help physicians reach a diagnosis earlier in inconclusive cases, but declined to say how often this happens.

"When those criteria create a gray area, you could say let's look at the molecular portrait and see where it's steering. You have to have something to tip the balance," said Spurlock.

Founders Spurlock and Tom Aune developed IQuity's technology at [Vanderbilt University](#), where they were looking for changes in gene expression patterns in whole blood samples that could be used to detect autoimmune disease. Spurlock is a research instructor, and Aune is a professor in Vanderbilt's Department of Medicine.

Spurlock said compared to healthy people or those with an infection, "the autoimmune signature was really striking."

He said previous attempts to define an MS signature focused on differences in protein expression. By measuring expression at the RNA level and including RNAs transcribed from non-coding DNA regions — such as long non-coding RNAs (lncRNAs) — IsolateMS could increase sensitivity to disease-related changes because only a small proportion of the RNA transcripts in a cell encode proteins. Furthermore, while levels of coding RNAs tend not to change by more than twofold across cell types or in healthy vs. disease states, levels of lncRNA can vary by 2⁵.

IQUNITY INC.

Nashville, Tenn.

Technology: RNA expression assays to diagnose autoimmune disease

Disease focus: Diagnostic, autoimmune, gastrointestinal

Clinical status: Validation (diagnostic)

Founded: 2013 by Chase Spurlock and Tom Aune

University collaborators: [Vanderbilt University](#); Accelerated Cure Project for Multiple Sclerosis

Corporate partners: Undisclosed

Number of employees: 4

Funds raised: \$2 million

Investors: Undisclosed angel investors

CEO: Chase Spurlock

Patents: None issued

In *Genome Biology* last year, IQuity's founders reported differences in RNAs found in relapsing-remitting MS compared to other autoimmune or neurodegenerative conditions. These differences included reduced expression of the ribonucleoprotein particles TROVE domain family member 2 (TROVE2; RO60) and La and defects in processing of structural RNA proteins in mononuclear cells.

The company plans to publish data on the test's accuracy this summer. Spurlock declined to give details for MS but said IQuity's assays can diagnose autoimmune diseases with greater than 90% sensitivity and specificity.

Across the development program, IQuity tested IsolateMS using samples from 347 MS patients, 241 subjects with other neurologic diseases and 285 healthy controls. Spurlock said the test could identify MS in patients with clinically isolated syndrome who were later diagnosed with MS at the time they first presented with symptoms.

IQuity plans to launch IsolateMS as a CLIA test in September. To develop the assay, IQuity's founders used next-generation

sequencing, including whole-genome RNA sequencing, to identify biomarkers. The clinical assay will use RT-PCR to quantitatively analyze 46 undisclosed transcripts, including mRNAs and lncRNAs.


Diatherix Laboratories Inc., a CAP-accredited laboratory, will process the samples and calculate gene expression levels. IQuity will then run the gene expression data through an algorithm to generate an IQ isolate score and assign a yes or no result based on a predetermined threshold.

Avant Diagnostics Inc. is also developing an early MS diagnostic. MSPrecise is a next-generation DNA sequencing assay in development to diagnose patients with RRMS at first clinical presentation. The company said in March that MSPrecise could launch in 2017.

While IQuity's test is performed on a blood sample, MSPrecise requires a spinal tap.

Avant did not respond to requests for comment. In 2015 researchers at predecessor company **DioGenix Inc.** and colleagues published data

showing MSPrecise is 84% accurate in identifying patients who have or will develop RRMS.

IQuity's IP is licensed from Vanderbilt and covers the assay, algorithm and its inputs. Terms are undisclosed. 

COMPANIES AND INSTITUTIONS MENTIONED

Avant Diagnostics Inc. (OTCQB:AVDX), Scottsdale, Ariz.

Diatherix Laboratories Inc., Huntsville, Ala.

IQuity Inc., Nashville, Tenn.

Vanderbilt University, Nashville, Tenn.

REFERENCES

Rounds, W., et al. "MSPrecise: a molecular diagnostic test for multiple sclerosis using next generation sequencing." *Gene* (2015)

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