



Biomarker for Predisposition and Diagnosis of Diabetes

Background:

Currently, diabetes testing is implemented later in life or at the onset of symptoms. Our diagnostic assay is significantly improved to be utilized in pre-diagnostic testing, and useful for the detection, prevention and/or treatment of diabetes. Our method has the unique ability to use any blood fraction to measure elevated concentrations of IGF-1 and to diagnose and detect for the predisposition to diabetes in as early as a newborn.

The following threshold values were developed to support a predisposition or a positive diagnosis by studying a human patient population of diabetic children, 2-3 years of age: IGF-1 concentration in whole blood, dried blood, serum or plasma of 3 ng/mL or above is a diagnosis for predisposition to developing diabetes and IGF-1 of 6 ng/mL or above supports a positive diagnosis of diabetes. Using the cut-off at 6 ng/mL, 37 out of 48 pre-diabetics would have been identified (77% sensitivity) and 13 out of 21 members of the control group (62% specificity) would have been correctly identified as not-at-risk for developing diabetes. Therefore, as the IGF-1 concentration cutoff is increased, fewer pre-diabetics are identified (lower sensitivity) but there are fewer false positives (higher specificity). Thus, a lower IGF-1 cutoff could be used as a screening tool for pre-diabetes, whereas a higher cutoff would be useful for eliminating false positives.

Applications:

- A novel diagnostic assay used to screen for predisposition to Type 1 diabetes
- A kit comprising reagents including antibodies against members of a given panel of analytes

Advantages:

- Accurate method of diagnosing diabetes in humans, preferably newborns
- Unique ability to expedite an early diagnosis for intervention in the pathological process
- Earlier diagnosis allows for earlier treatment. Earlier treatment mitigates life-changing organ damage & the cost of controlling future symptoms.
- Any blood fraction can be tested to determine levels of IGF-1

State of Development:

Diagnostic assay available for license

Patents:

USPTO US2010/0068729 A1

Licensing Potential:

HRI is seeking commercial partners to produce the diagnostic assay and develop the kits for large-scale newborn screening applications. Available for licensing.

The Inventors:

Samuel T. Labrie, Ph.D., Michael D. Spain, Ph.D., James P. Mapes, Ph.D., Ralph L. Mc Dade, Ph.D. and

Kenneth Pass, Ph.D.

For 28 years Dr. Kenneth Pass was director of the NYS Newborn Screening Program. During that time he introduced screening for biotinidase deficiency, congenital adrenal hyperplasia, and Krabbe disease. The NY program was the first to use a call-in system by which physicians could obtain test results on any day at any time, the first to provide a portion of the specimen form for the mother to facilitate acquisition of test results, the first to implement HIV testing of all newborns, and the first to test for the LSDs. He has published over 80 peer reviewed papers, eight book chapters, and delivered lectures all over the world on many different aspects of NBS. With funding from NICHD he has developed multiplex assays that screen for CH/CF/CAH (5-plex), SCID (2-plex), and autism (7-plex), all using a single 3mm spot. Currently his laboratory is developing a multiplex assay for hemoglobin variants that can be added to each of the above, thereby allowing calculation of the hematocrit and normalization of test results.

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