Ridge Diagnostics, Inc.

DIAGNOSIS OF DEPRESSION

Currently, unipolar depression (MDD; Major Depressive Disorder) is diagnosed using a series of interview questions ranging from complex standardized tools such as the DSM IV to a few (2-3) subjective questions. Ridge's blood test provides the first objective, biologically based diagnostic aid for depression. At a company owned CLIA certified laboratory, quantitative immunoassay test results and a proprietary algorithm are used to generate MDDScore, a single numerical outcome that serves as an aid in diagnosis of MDD and a tool to manage difficult or non-compliant patients. MDDScore provides a physiological basis for depression diagnosis and serves to remove the stigma often associated with the disorder.

THE BIOLOGY OF DEPRESSION

Most clinicians assume that since depression is a brain disorder and as such, measurements of physiological functions related to depression can only be made by brain imaging or sampling of the cerebral spinal fluid. In addition to being invasive and costly procedures, application of these sophisticated research tools have not yielded results consistent with diagnosis. Neither imaging nor measurements of neurotransmitters or proteins in the CSF are useful in a clinical psychiatric practice. Nonetheless, the biology of depression suggests that a complex interaction between the brain and the peripheral circulation exists. We and others have observed that a delicate balance involving feedback control of multiple hormones, neurotransmitters and cytokines is involved in the changes in physiology associated with depression. Directional interactions between the brain, the immune and endocrine systems are controlled by the level of multiple soluble mediators present in serum. For these reasons, precise quantification of multiple analytes is necessary for a blood test to be useful as a physiologically-based aid to the diagnosis of MDD.

BIOLOGICAL MARKERS FOR DEPRESSION

The research team at Ridge utilized both our know-how and the exquisite sensitivity of our immunoassays to measure biological markers of inflammation, metabolic, Hypothalamic-Pituitary-Adrenal Axis and neuroendocrine modulation. We have developed a blood-based phenotype of patients with MDD as a basis for an algorithm capable of discriminating MDD populations from normal populations. This results in a practical, first in class, multi-analyte blood test to aid in the diagnosis and management of depression.
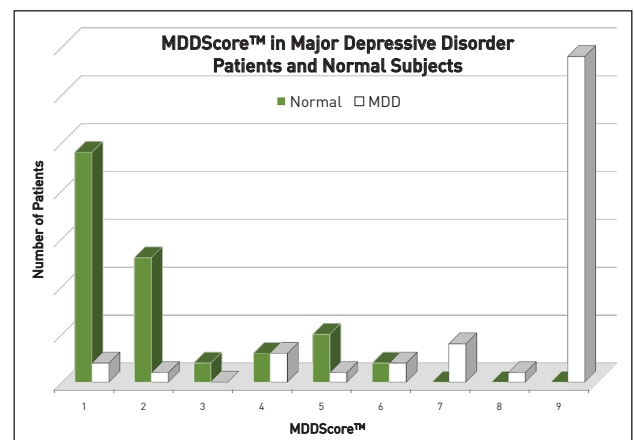
MDD Hypermap™ Structure

Figure 1 above shows the four physiological pathways which Ridge Diagnostics MDDScore™ assesses.

CLINICAL PERFORMANCE

In prior clinical studies of a total of 180 subjects, depressed patients were tested along with age and sex-matched normal controls. Using our proprietary multiple marker test and algorithm, we were able to discriminate depressed patients from normal subjects with a sensitivity of 87% and specificity of 95% based on 58 subjects.

In order to evaluate the diagnostic application and clinical value of the MDDScore in managing patients with MDD, a Clinical Experience Program (CEP) was conducted with a group of medical professionals in psychiatry who see and/or treat patients with various psychiatric disorders including MDD. Please request a copy of the CEP White Paper for more information. Additional studies are on-going at major academic centers in the US and Asia.