

The Science Behind the MDDScore™

Atlantic Diagnostic Laboratories MDDScore™ Blood Test for Major Depressive Disorder

Major Depressive Disorder has a complex systemic impact. Atlantic Diagnostic Laboratories has developed a multi-analyte blood test utilizing nine serum biomarkers associated with depression. The MDDScore™ biomarkers were selected from the ADL Biomarker Library based on the following:

- Relevance to MDD
- Reproducibility as a biomarker for MDD
- Accurate measurability in serum

Neuroendocrine

- Cortisol
- Epidermal Growth Factor (EGF)

Increased Hypothalamic Pituitary Adrenal (HPA) Axis activity, is due to a dysregulated stress response in MDD

Metabolic Response

- Prolactin (PRL)
- Resistin (RETN)
- Apolipoprotein C3 (APO C3)

MDD can alter peripheral signaling pathways that regulate metabolic processes e.g. sleep, weight gain/loss

Neurotrophic Factor

- Brain Derived Neurotrophic Factor (BDNF)

Stress and/or MDD reduces Brain Derived Neurotrophic Factor (BDNF) in the hippocampus as well as serum

Inflammatory Response

- Alpha 1 Antitrypsin (A1A)
- Myeloperoxidase (MPO)
- sTNF Receptor II (sTNFR2)

Depression is characterized by expression of biomarkers associated with chronic low-grade inflammation

The MDDScore™ test result is derived using algorithms that include:

- Serum Concentrations of Nine Biomarkers
- Gender Specific Assessment
- Cortisol Diurnal Adjustment
- Body Mass Index (BMI)



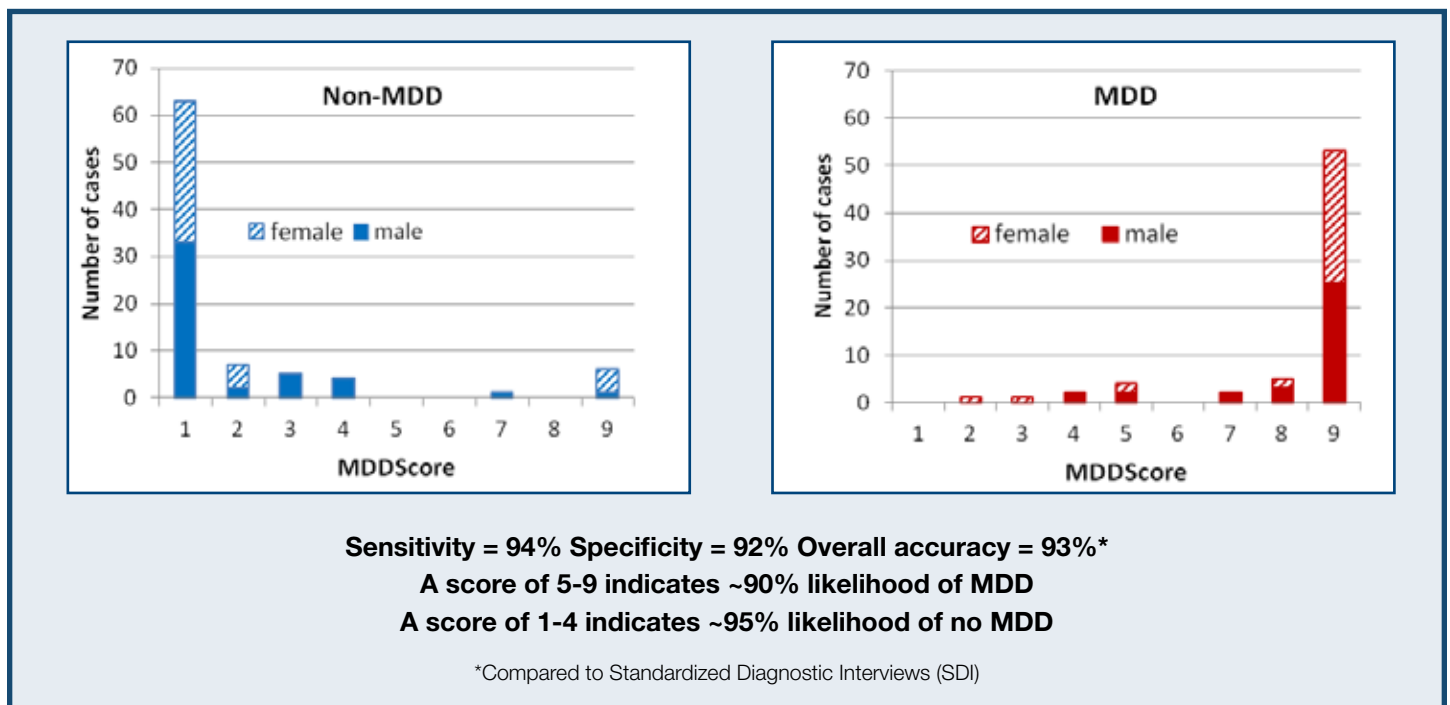
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The clinical performance of MDDScore™ has been demonstrated in clinical studies conducted by major academic centers, such as Harvard, Mass General Hospital, and University of Alabama Birmingham.

In the latest study, MDD patient diagnosis was established using the Hamilton Rating Scale for Depression (HAM-D) and Structured Clinical Interview for DSM-IV Axis I Disorders. The non-MDD samples were acquired from healthy volunteers and evaluated using standardized diagnostic instruments mentioned above, or the Patient Health Questionnaire 9 (PHQ 9). Gender-specific algorithms were derived and verified by multiple independent statisticians.



The clinical utility of MDDScore™ includes:

- Aiding in the diagnosis and management of patients with MDD
- Adding a quantitative biological measurement to assist clinical diagnosis
- Aiding in reducing the stigma of a mental disorder, thereby increasing patient acceptance of the disorder as a medical condition
- Guiding an open dialog and consultation which may result in improving patient management and adherence to treatment programs
- Aiding in deciphering complex clinical presentation

References

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