Real-world Utilization of a Novel Multi-analyte Blood-Based Biomarker Panel, the Octave® Multiple Sclerosis Disease Activity (MSDA) Test In Clinical Practice Across the United States

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Introduction

The complexity of multiple sclerosis (MS) underscores the urgent need for reliable and accessible biomarkers to improve disease management and patient care. Blood-based biomarkers offer a minimally invasive, cost-effective, and scalable solution for monitoring disease activity and guiding personalized treatment strategies. They hold potential for identifying inflammatory and neurodegenerative processes, treatment response, and subclinical disease activity. Incorporating blood-based biomarkers into routine care can optimize therapeutic interventions, and improve long-term outcomes for individuals living with MS.[1]

Objectives

To describe the real-world utilization of the Octave® Multiple Sclerosis Disease Activity (MSDA) Test, a clinically validated, multi-analyte, blood-based biomarker panel for MS in clinical practice across the United States (US).

Methods

The Octave® MSDA Test provides a quantitative, objective, validated disease activity (DA) score with established thresholds corresponding to low (1.0–4.0), moderate (4.5–7.0), and high (7.5–10) levels of disease activity (Figure 1).

We conducted a retrospective descriptive analysis of data elements collected and reported from the Octave® MSDA Test requisition form until March 2025. Demographic and disease related data includes gender, age, race and ethnicity, current disease modifying therapy (DMT), reason for test, and date of MS diagnosis.

A web-based customer experience survey & 1:1 interviews were conducted to measure qualitative & quantitative data of ordering healthcare providers (HCPs) satisfaction, ease of use, & real world clinical use of the MSDA test.

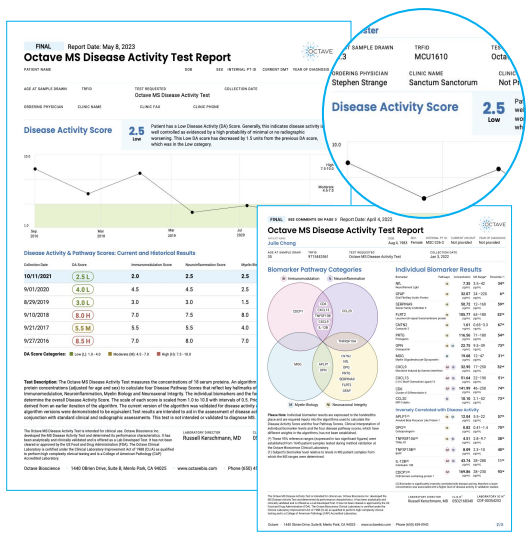


Figure 1: Example Octave® MSDA Test report.

Table 1: Patient Demographics and Disease Data at baseline.

Total tests	14,808
Total patients	11,411
Gender	
Female	77.3%
Male	22.7%
Age at baseline (mean)	52 years
Disease duration (mean)	13.8 years
Race (n=6,369)[1]	
White	79.5%
Black or African American	14.7%
Other	5.8%
Ethnicity (n=5,553)[1]	
Hispanic	4.3%
Non-Hispanic	95.7%
DMT efficacy at baseline (n=7,664)[2]	
High	42.6%
Moderate	16.1%
Low	7.0%
No current DMT	34.3%

[1] Patient data not reported: Race n=5 042; Ethnicity n=5,858
[2] Excludes DMT not entered (n=3,726) and Other/No Match (n=21)

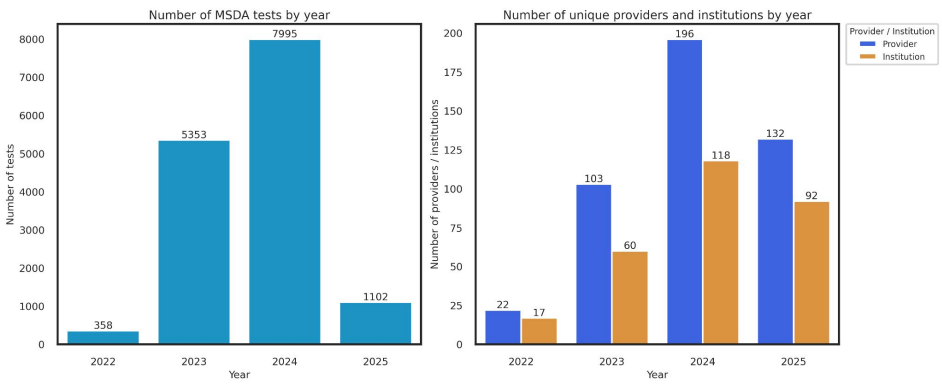


Figure 2: Number of MSDA tests (left), institutions, and unique providers(right) by year (until March 2025)

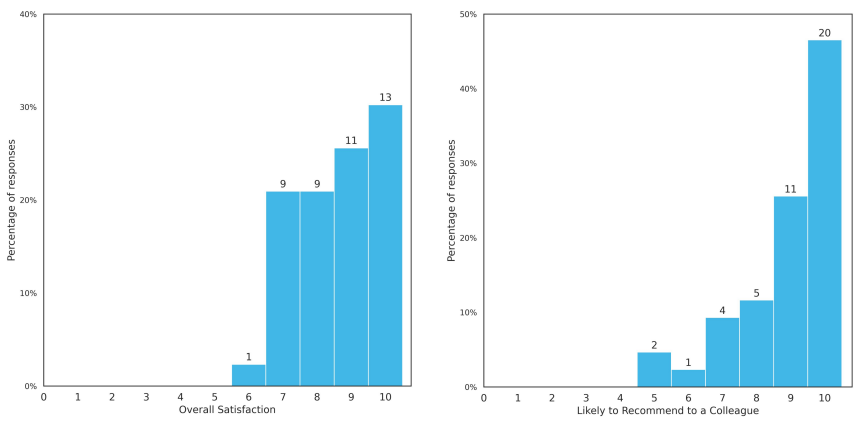


Figure 3: Frequency of responses from 43 HCPs to "On a scale from 0 to 10: 'How likely are you to recommend MSDA to a colleague?' (left) and 'What is your overall satisfaction with the MSDA test?' " (right).

Results

- **Demographics** | Baseline patient demographics include mean age 52 years; 77.3% female; mean disease duration 13.8 years; patient reported race and ethnicity 79.5% White, 14.7% Black, and 4.3% Hispanic. From HCP reported DMT use, 44% of patients were treated with a high efficacy DMT (anti-CD20s, natalizumab, cladribine, alemtuzumab) and 33.4% reported not currently on a DMT at baseline (Table 1).
- **Overall MSDA Utilization** | The Octave® MSDA Test has been commercially available in the U.S. since March 2022. As of March 2025, we report on **11,411 MS patients tested** with the Octave® MSDA Test. A total of 14,808 MSDA tests have been ordered from **137 institutions and 231 HCPs.** Figure 2 shows number of MSDA tests, institutions and HCPs by year.
- **MSDA User Experience Survey** | Overall customer satisfaction and likelihood to recommend the MSDA test to a colleague were rated highly by 43 HCPs (16/122 interviews, 27/129 web-based survey) (Figure 3). In the web-based survey, 27 HCPs used MSDA in 5.4 (3-9) clinical scenarios on average (Figure 6).
- **MSDA Scores** | Overall, MSDA scores across this cohort were **64.4% low, 29.1% moderate and 6.5% high; mean DA score of 3.8** (Figure 4). 76.3% of patients had 1 MSDA Test, 19.3% had 2 tests and 4.4% had 3 or more MSDA Tests. Statistically significant differences in changes in MSDA scores were observed between Tests 1 and 2 and Tests 2 and 3 across each MSDA categories. Mean significant changes were +0.17 for low, −1.00 for moderate, and −3.15 for high MSDA scores at Test 1. From Test 2 to Test 3, mean significant changes were +0.04, −0.65, and −2, respectively, for categories at Test 2. (Figure 5). Overall MSDA scores are reported by DMT mechanism of action (MOA) (Figure 7).

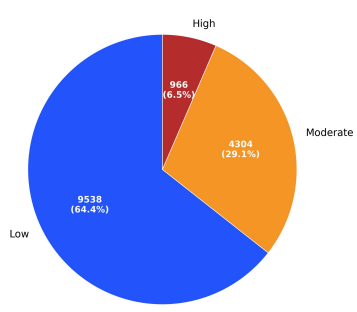
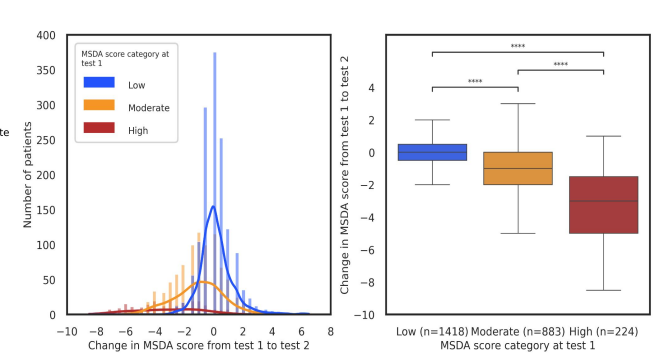


Figure 4: Percentage of MSDA tests by MSDA score category



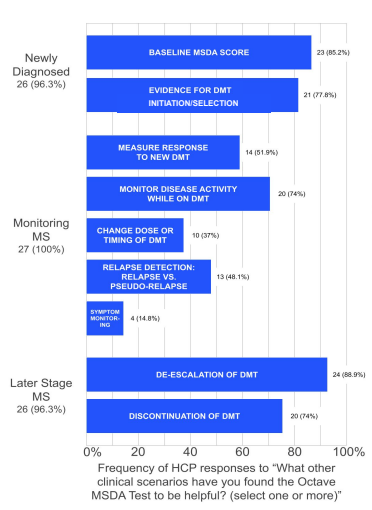


Figure 6: Percentage and count of clinical scenarios where HCPs reported the MSDA test to be most helpful (web survey, N=27).

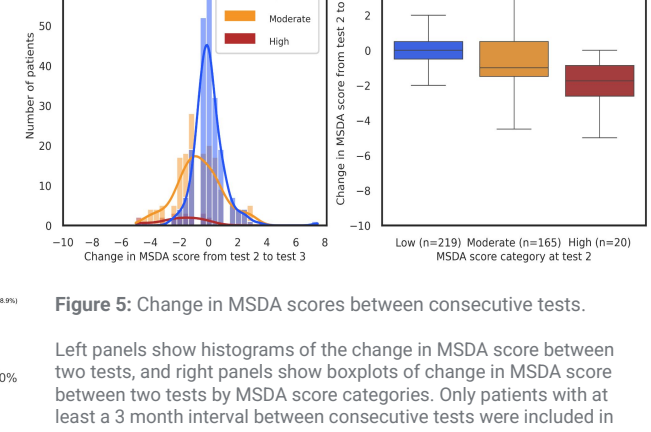


Figure 5: Change in MSDA scores between consecutive tests.

Left panels show histograms of the change in MSDA score between two tests, and right panels show boxplots of change in MSDA score between two tests by MSDA score categories. Only patients with at least a 3 month interval between consecutive tests were included in this analysis.
Bonferroni-corrected p-values were calculated using Welch's t-test for pairwise group comparisons. Significance thresholds:
**** p < 0.0001 *** p < 0.001 ** p < 0.01 * p < 0.05 ns: not significant

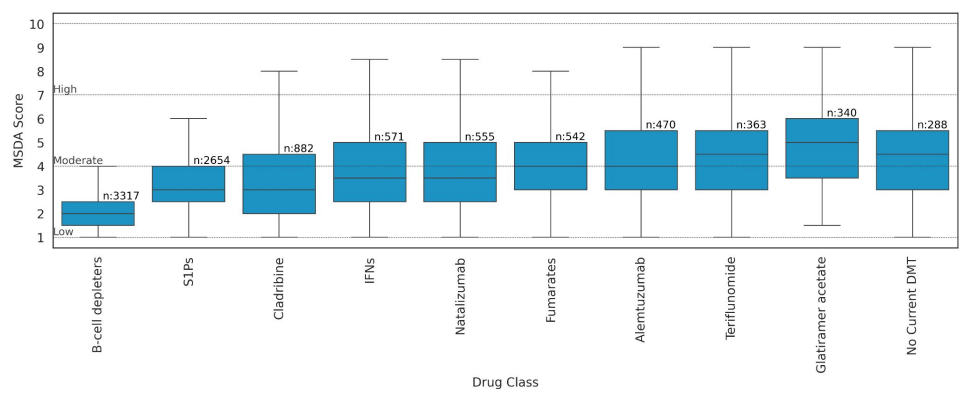


Figure 7: MSDA score by DMT MOA

Conclusions

This report highlights the increasing adoption of the Octave® MSDA Test in clinical practice across the US and its utility in informing provider decision-making. Acknowledging a limitation due to potential response bias among a subset of providers participating in the experience interviews and web-based survey, continued research is crucial to further establish the clinical utility of the Octave® MSDA Test on patient outcomes. The overarching goal is to ensure convenient, seamless integration of this critical tool into clinical workflows to improve patient care in MS.

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References: Paul A, Comabella M, Gandhi R. Biomarkers in Multiple Sclerosis. Cold Spring Harb Perspect Med. 2019 Mar 1;9(3):a029058.

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