BDi CH3 Behavioral Diagnostics, LLC

2500 Crosspark Road

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XXXXX XXXXX MD PhD, Director

Patient Name
John G. Smith
Patient ID: XX22092
Sample ID: XX22092A

Test Information
Order ID
Order Date: 11/12/23
Specimen Type: Blood
Date Received: 11/12/23
Date of Report:11/14/23

Ordering Clinician
Dr. James Kildare
Blair General Clinic
200 Hawkins Dr
Los Angeles, CA 12122
drkildare@tvland.com

Alcohol Signature™

Results

Alcohol Signature™ Patient T Score	X.YY
95th Percentile score for abstinent population	3.1
75th Percentile score for the abstinent population	
50th Percentile score for the abstinent population	0
50th Percentile Score for Heavy Alcohol Consumers	
5th Percentile Score for Heavy Alcohol Consumers	

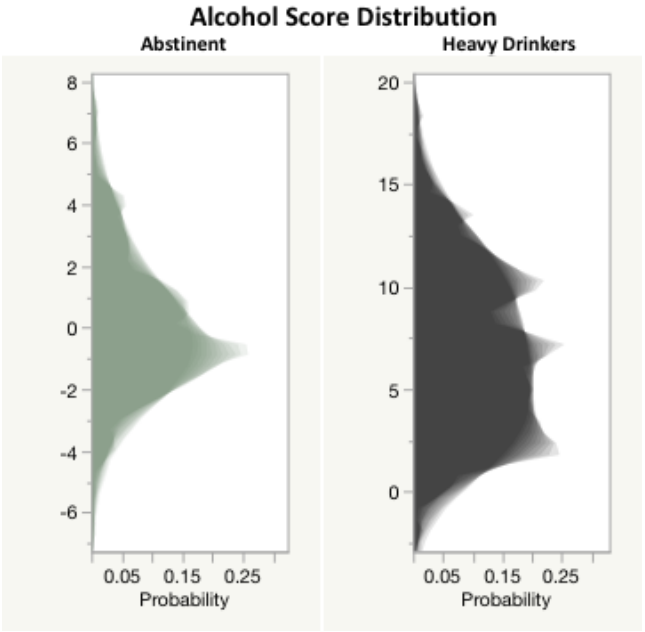

Figure 1. The smoothed distribution of Alcohol Signature in 200 abstinent adults and 143 adults admitted for the treatment of Heavy Alcohol Consumption.

About this test

The Alcohol Signature© test is designed to determine to predict the presence of Heavy Alcohol Consumption (HAC).

Interpretation of Results

Excessive alcohol use is traditionally the third leading preventable cause of death in the United States. [1] There are a number of manners through which the excessive use of alcohol is categorized. One of the more recent methods focuses on the amount of consumption irrespective of its clinical consequences. Although many terms and definitions for excessive alcohol consumption exist, Heavy Alcohol Consumption (HAC) is defined for these purposes as the chronic daily consumption of 6 to 8 standard drinks or more per day. Critically, numerous studies show that HAC is associated with a dose dependent change in DNA methylation.[2-4] This test measures methylation changes at four cytosine-phospho-guanine (CpG) residues that are associated with increased HAC to construct a metric known as the Alcohol T Score (ATS).[4, 5] In head-to-head testing with carbohydrate deficient transferrin (CDT), the current gold standard for HAC, the ATS significantly outperformed the CDT in predicting HAC. [5] With sustained abstinence, elevated ATS scores gradually revert with full reversion to population mean taking at least 3 months. [4]

Interpretation of Results

The ATS was produced using the data from 143 adults admitted for the treatment of HAC and 200 abstinent controls. [4] The ATS is not meant as a comprehensive epigenetic assessment and may be affected by rare genetic variation, other dietary factors or medical conditions affecting hematopoiesis. The performance characteristics of this test have been described and are available upon request upon request at info@bdmethylation.com. [4, 5] There is the rare possibility that laboratory errors may occur and their occurrence cannot be completely excluded. Possible sources of error include, but are not limited to, contamination, sample mix-up and assay-based errors. For example, errors in methylation can occur as a result of degraded DNA, contamination or rare genetic variation.

Disclaimers:

This test should be interpreted by the patient's healthcare provider(s) within the appropriate clinical context and with consideration of all other clinical information including the pre-test likelihood of HAC in the patient. This risk assessment for HAC is not intended to prevent, diagnose, cure, mitigate, treat HAC or any other alcohol related disease. There is no guarantee of benefit to the patient. Behavioral Diagnostics makes no promises or guarantees with respect to reimbursement of testing costs from insurers or other third parties. This risk assessment does not replace a comprehensive clinical assessment of smoking and tobacco use disorders. This test was developed and its performance characteristics determined by Behavioral Diagnostics. It has not been cleared nor approved by the Food and Drug Administration (FDA). This test should be used for clinical purposes and should not be considered investigational or for research purposes only. Behavioral Diagnostic's lab is certified under the Clinical Laboratory Improvement Amendments (CLIA) as qualified to perform high-complexity clinical laboratory testing.

References

1. Centers for Disease Control. Alcohol and Public Health: Alcohol Related Disease Impact (ARDI). 2014 [cited 2014 June 14]; Available from: https://nccd.cdc.gov/DPH_ARDI/default/default.aspx.
2. Philibert, R., et al., A pilot examination of the genome-wide DNA methylation signatures of subjects entering and exiting short-term alcohol dependence treatment programs. Epigenetics, 2014. 9(9): p. 1212-1219.
3. Liu, C., et al., A DNA methylation biomarker of alcohol consumption. Molecular Psychiatry, 2016. 23: p. 422.
4. Philibert, R., et al., A Four Marker Digital PCR Toolkit for Detecting Heavy Alcohol Consumption and the Effectiveness of Its Treatment. Journal of Insurance Medicine, 2019. 48(1): p. 90-102.

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5. Miller, S., et al., A Comparison of the Predictive Power of DNA Methylation with Carbohydrate Deficient Transferrin for Heavy Alcohol Consumption. 2019.