Clinical Utility of GBinsight Comprehensive Genetic Testing Showcased at the 2020 National Lipid Association's Scientific Sessions.

GB HealthWatch collaborated with preventive cardiologists to explore and validate the clinical utility of its GBinsight comprehensive genetic testing and analysis. The impacts of genetics on clinical practice were presented by leading physicians at the 2020 National Lipid Association's Scientific Sessions.

San Diego, CA- Genetics was a major theme of the National Lipid Association's (NLA) Scientific Sessions, December 2020. Genetic testing for lipid disorders, polygenic risk scores for atherosclerotic cardiovascular disease (ASCVD) and the implications of genetics on clinical care, medical ethics and identifying individuals at high risk and preventive strategies were among the headlining topics. The clinical utility of GBinsight comprehensive genetic testing and analysis was highlighted by several leading physicians and scientists throughout the sessions.

Dr. Christie M. Ballantyne, Professor of Medicine and Genetics at Baylor College of Medicine, started off his presentation reflecting on the current state of clinical cardiovascular genetics, noting how "wonderful it is to see where we are now and what the impact of genetics will be on how we practice preventive cardiology." Dr. Ballantyne then reinforced the statements of a previous presenter and another client of GBinsight, Dr. Zahid Ahmed, Assistant Professor of Medicine at the University of Texas, Southwestern, highlighting the clinical benefits of genetic testing for dyslipidemias and ASCVD patients including how definitive diagnoses increase the likelihood of payer coverage and provide more accurate risk stratification, enhance cascade screening that may prompt initiation of therapies at an earlier age, and allow for more precise medication regimens.

Drs. Christie Ballantyne and Zahid Ahmed, both GBinsight collaborators, emphasized that there is a 50% chance of passing on heterozygous familial hypercholesterolemia (FH) to one's children. Genetic testing is the preferred method for screening young family members of adults with FH. The earlier a person is diagnosed, the sooner he or she can begin lifestyle and drug therapies that reduce risk of ASCVD.

The clinical applications of GBinsight were demonstrated by several presentations and posters from Baylor College of Medicine, UT Southwestern, and the University of Pennsylvania. Case studies of patients referred for severe hypertriglyceridemia, pancreatitis, and type 2 diabetes were showcased. GBinsight's Comprehensive Dyslipidemia Panel identified pathogenic genetic variants causal for familial partial lipodystrophy (FPLD) in these patients and allowed physicians to identify precise diagnoses and offer precise therapies. GBinsight analyzes the multitude of pathways that cause severe hypertriglyceridemia beyond LPL deficiency.

“GBinsight recognizes the biological complexity and heterogeneity of humans and, through comprehensive genetic analysis, facilitates precise diagnosis. GBinsight comprehensively analyzes the genetics of the multitude of pathways that can cause dyslipidemia and ASCVD in a single assay,” said Dr. Mendel Roth, Senior Scientist at GBinsight.

GBinsight differentiates itself from other genetic testing services in several important ways: 1) Since ASCVD risk is ultimately determined by additive risk factors, GBinsight analyzes broad risk categories within a single comprehensive assay. This includes hypercholesterolemia, hypertriglyceridemia, reverse cholesterol transport defects, high Lp(a), homocysteinemia, familial obesity and familial diabetes. The analysis includes copy number variations that are a common cause of dyslipidemias. 2) Analyzes both rare, large-effect sized, monogenic variants largely in coding and splicing regions of genes as well as common, small-to-moderate-effect sized variants that contribute to polygenic risk in a single assay. 3) This assay includes full coverage of the APOE gene that is an underappreciated genetic cause of dyslipidemias and ASCVD. The APOE gene presents a technical challenge in getting quality sequencing results. 4) Analyzes both single nucleotide polymorphisms (SNP) known to increase and decrease Lp(a) levels as well as directly quantifies the variable Kringle-IV region. 5) Analyzes pharmacogenomics including the multiple genetic causes of statin intolerance.

“GBinsight is the only next-generation sequencing (NGS) test that can directly quantify the variable region within the LPA gene which is the single greatest cause of high Lp(a),” said Dr. Roth. “GBinsight employs a machine-learning algorithm that assesses the comprehensive genetic basis of high Lp(a).”

GBinsight’s scientific team has collaborated with key clinical opinion leaders to explore and validate the clinical utility of comprehensive genetic analysis for dyslipidemia and ASCVD. For example, using monogenic and polygenic analysis, up to 80% of patients referred to GBinsight for FH and other dyslipidemias was correctly identified. Of those with high Lp(a), validation results showed an overall accuracy of 84% with a sensitivity of 82% and specificity of 87%. Including the direct quantitation of the variable polymorphism increased the accuracy call by 23 percentage points. These results were formulated in partnerships with Drs.

Christie M. Ballantyne, Michael Davidson at University of Chicago, Patrick Moriarty at University of Kansas, and Sotirios Tsimikas of University of California, San Diego and presented at the NLA Scientific Sessions.

GBinsight NGS services are performed at a CLIA-certified and medically licensed genetic testing laboratory using Illumina's HiSeq platform.

GBinsight's Test Catalog includes the following:
- Dyslipidemia Comprehensive Panel
- Familial Hypercholesterolemia Panel
- Familial Hypertriglyceridemia Panel
- Coronary Heart Disease Comprehensive Panel
- Type 2 Diabetes Comprehensive Panel
- Diabetes MODY Panel
- Obesity Comprehensive Panel
- Non-Syndromic Monogenic Obesity Panel
- Alzheimer's Comprehensive Panel

Because genetic risk for most common metabolic diseases can be mitigated by dietary and lifestyle factors, in addition to GBinsight comprehensive genetic analysis, GB HealthWatch also developed the HealthWatch 360 mobile app for delivering dietary and lifestyle interventions to the general population. The app works in conjunction with the HealthWatch 360 Research Portal, which allows researchers to manage and analyze the diet, exercise and health data collected with the mobile app. Integration of GBinsight genetics panels with the research portal advantageously enables researchers to study gene-gene and gene-lifestyle interactions in observational and interventional cohort trials. With this system, prevention and medical intervention strategies, and especially dietary interventions, for complex diseases can be experimented with, validated and refined. Given the epidemic of diet-induced chronic diseases in the United States and worldwide, it is imperative that we focus our efforts on precision nutrition as a key preventive strategy for improving the health of our future.

GBinsight was developed by GB HealthWatch in partnership with the Otogenetics Corporation, a CLIA- certified and licensed medically licensed genetic testing company.

About GB HealthWatch

GB HealthWatch is a nutritional genomics company. We develop state-of-the-art technologies to facilitate research on the molecular mechanisms, clinical efficacy and cost-effectiveness of translating genetic insights into personalized prevention and treatment strategies for complex diseases. GB HealthWatch offers the following tools:

GBinsight Genetic Testing and Analysis.
bit.ly/gbinsight
HealthWatch 360 mobile app and online tool for tracking dietary intake, exercise and health.
bit.ly/healthwatch360app
HealthWatch 360 Research Portal for academics and research institutes to study diet and health interactions.
bit.ly/h360-research
Visit the GB HealthWatch website to learn more:
www.gbhealthwatch.com

About Otogenetics Corporation

Otogenetics Corporation is a CLIA-certified and licensed medical genetic testing company specializing in next generation sequencing services. Otogenetics offers high quality services for genome, exome, and RNA-seq for government and academic institutions, biotechnology and pharmaceutical companies, as well as medical doctors and clinics. Additional services and products provided by Otogenetics Corporation can be found at www.otogenetics.com