Transparency From Hereditary Cancer Testing Laboratories is Essential for Patient Care and Outcomes

Surveys sent to 11 major labs to facilitate comparison of similarities and differences between test options

SANDY, UT, USA, June 15, 2023 /EINPresswire.com/ -- At the end of May, a transparency survey was sent to the CEOs of eleven major clinical laboratories requesting information on their laboratories' comprehensive hereditary cancer tests. The surveys were sent from the Utah Department of Health and Human Services Cancer Genomics Program, and are endorsed by genetics divisions within the Oregon Health Authority and the Washington State Department of Health. The survey questions aim at better defining each labs' technical specifications and patient support services. The laboratories have been given seven weeks to complete the survey, and participation is voluntary. Survey answers will be organized and posted publicly on the TestWisely.org website for patients, clinicians, insurance payers and other stakeholders to utilize. The contents of the survey are posted at TestWisely.org.

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> *Dr. Julie M. Eggington, CEO GCI*

Hereditary cancer is thought to contribute to approximately 5-10% of all cancers, and comprehensive hereditary cancer testing is used by clinicians to search for cancer causing genetic variants carried by patients. Test results often drive surgical and medical management decision making. Yet, not a single comprehensive hereditary cancer test has received FDA approval. All comprehensive hereditary cancer tests in the United States are presently Laboratory Developed

Tests, meaning that the laboratories have not been required by regulators to rigorously prove their tests' accuracy or clinical validity to any external party. Because of this, the accuracy and completeness of comprehensive hereditary cancer testing likely varies between different laboratories in ways that are not yet transparent to clinicians or patients.

The extremely weak transparency requirements for Laboratory Developed Tests has led the Utah Department of Health and Human Services Cancer Genomics program to contract with the nonprofit Center For Genomic Interpretation, in partnership with the Association for Utah Genetic Counselors, in this effort to collect much needed information from major hereditary cancer testing laboratories. The results of the project are being made available to the public at TestWisely.org. The project is being financially supported by the Utah Department of Health and Human Services Cancer Genomics Program by Cooperative Agreement Number, DP19-1905, funded by the Centers for Disease Control and Prevention (CDC). The CDC sourced funding was provided to improve patient access to high quality Hereditary Breast and Ovarian Cancer Syndrome testing and Lynch Syndrome testing. Additional support is provided by individual donors, the Center for Genomic Interpretation, and the Gordon and Betty Moore Foundation. (The project's contents are solely the responsibility of the authors and do not necessarily represent the official views of the CDC, the Utah Department of Health and Human Services, the Gordon and Betty Moore Foundation, and other donors).

"Laboratory participation in this survey is voluntary," says Dr. Julie M. Eggington, CEO of the nonprofit Center for Genomic Interpretation that has been contracted to conduct the project. "I expect that labs with high quality hereditary cancer tests will be eager to share details about their test. It takes a lot of work and ongoing commitment to make such complex genetic tests as accurate as current technology allows, and to make the test accessible to all those that need it. We hope that this project will provide a platform for labs with really accurate and carefully validated tests to shine. I think it will speak volumes if some labs choose not to participate in this transparency survey, so I hope all the invited laboratories participate. I hope that we, as the clinical and patient community, can find a way to make this type of transparency an ongoing expectation of genetic testing labs." Ambry Genetics, ARUP Laboratories, Color Health, Exact Sciences, Fulgent Genetics, GeneDx, Invitae, Labcorp, Myriad Genetics, Natera, and Quest Diagnostics have been invited to participate in this inaugural transparency survey.

Transparency from laboratories is essential in order to improve patient access to high quality genetic testing. A digital petition to encourage laboratory participation in the transparency survey can be found at https://www.testwisely.org/supporters/.

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The Center for Genomic Interpretation – www.genomicinterpretation.org

The Center for Genomic Interpretation (CGI) is an independent 501(c)(3) nonprofit organization with the mission to save and improve lives through encouraging careful stewardship of clinical genetics, genomics and precision medicine. Too frequently the precision medicine goals of patients and their providers are unknowingly thwarted by inaccurate or ineffective genetic or genomic testing. CGI facilitates the realization of value from among the confusing scramble of the precision medicine era. The CGI team consists of clinical genetics and genomics scientific leaders, healthcare policy veterans, experienced business professionals, and others dedicated to helping stakeholders achieve the vision and promise of precision medicine. CGI offers a range of programs and services targeted to all stakeholders including patients, providers, payers, pharmaceutical developers, policy makers and laboratories.

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