



Quest Diagnostics and Inserm Launch Multinational BRCA Gene Datashare Initiative, with LabCorp as First Participant, to Improve the Detection of Inherited Risk of Breast and Ovarian Cancers

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BRCA Share™ is a novel public-private initiative designed to enhance the clarity and quality of patient testing

MADISON, N.J. and PARIS and BURLINGTON, N.C., April 21, 2015 /PRNewswire/ -- [Quest Diagnostics](#) (NYSE: DGX), the world's leading provider of diagnostic information services, and Inserm, the French National Institute of Health and Medical Research institution, today launched BRCA Share™, a novel datashare initiative they co-founded to provide scientists and laboratory organizations around the world with open access to BRCA1 and BRCA2 genetic data. The program's goal is to accelerate research on BRCA gene mutations, particularly variants of uncertain significance, to improve the ability of clinical laboratory diagnostics to predict which individuals are at risk of developing hereditary breast and ovarian cancers.

[Laboratory Corporation of America® Holdings](#) (LabCorp®) (NYSE: LH), the world's leading healthcare diagnostics company, is the first participant in the initiative, which is structured as a user group. BRCA Share builds on a BRCA gene-data curation process developed by Inserm with BRCA data, maintained in its Universal Mutation Database, developed over a decade of patient testing by 16 laboratories in France that make up, together with associated University Hospital Centers, the Unicancer Genetic Group (UGG).

Members of BRCA Share will pool de-identified clinical laboratory patient data on BRCA1 and BRCA2. Although several mutations of BRCA1 and BRCA2 genes are established as cancer causing, there are instances when a patient receives an indeterminate test result because the individual's genetic information reveals a gene variant of uncertain significance (VUS). Greater insight into the cancer risk of VUS will reduce the potential for indeterminate test results, leading to improvements in risk-assessment for certain cancers.

BRCA Share provides several features unique to a gene datashare program. BRCA Share is a public-private initiative through which commercial entities will fund the program on a sliding scale to encourage participation from labs of all sizes; in the U.S., this obviates the need for government funding. Research entities and individuals with a research-only focus on BRCA can participate at no charge.

BRCA Share is also believed to be unique in its focus on functional studies to which commercial participants will contribute. These studies are designed to determine the pathogenicity of BRCA variants of uncertain significance. The program is also based on an established data VUS interpretation performed by geneticists of the sixteen UGG laboratories. Data curation, which includes review of shared data for duplicate entries and confirmation that all data provided meets the same level of scientific rigor, is imperative to ensure data can be used for commercial applications as well as for research. Inserm developed the UMD software over several years and this system was applied to many different genetic diseases.

"BRCA Share is a new model for public and private collaboration in an age of scientific openness and genomics discovery," said Steve Rusckowski, president and chief executive officer, Quest Diagnostics. "This initiative will harness the power of diagnostic insights to illuminate the role of genetics in inherited cancer. It reflects Quest's value as a provider of insights into disease that enable people to take actions to improve their health. Inserm and UGG's experience in BRCA data curation and excellence in BRCA science make it eminently well suited to co-lead this initiative with Quest."

"Public research entities in France and around the world have been making important discoveries of BRCA variants and their role in inherited cancer thanks to over 15 years of research, and this program will build on that wealth of quality data to take BRCA testing and research to the next level of sophistication. In addition, BRCA Share is positioned within one of the three pillars of the strategy newly designed by Inserm, Population Genomics," added Professor Yves Lévy, president and chief executive officer of Inserm.

"LabCorp is pleased to be the first participant in BRCA Share. We strongly support this initiative and believe that broader access to key UMD-BRCA1/2 database information through BRCA Share will yield significant improvements in BRCA diagnostics, and enhance patient care and treatment," said David P. King, chairman and chief executive officer of LabCorp.

"We are excited to lend the combined scientific expertise of the UGG to advance the understanding of BRCA genetics through BRCA Share," said Prof. Christophe Beroud, team leader in Inserm/Aix Marseille University (AMU) unit 910 Genetics and Bioinformatics. "Through this unique program, we expect to improve the detection of people at risk for breast cancer, not only in France but also in the United States and globally," added Augustin Godard, executive vice president, head of strategic industrial partnerships, Inserm Transfert, the affiliate technology transfer office of Inserm.

Under BRCA Share, all members will have access to the same pool of jointly contributed BRCA data. Quest Diagnostics will license BRCA data, including from Inserm's UMD-BRCA1/2 databases, and form sublicense agreements with any commercial lab or academic party that commits to share BRCA data with the group's members. User group members will also establish processes for reporting new findings to members, which commercial labs may use to update their clinical test reports for patients, including those whose prior test results may have been indeterminate. Quest and LabCorp are actively recruiting additional participants. For information on joining BRCA Share, visit www.umd.be/BRCA1/

"Hearing 'you have a high risk of cancer' is devastating, but for those who receive an inconclusive result, hearing 'you may have high risk, but we are not sure' can be worse," said Sue Friedman, executive director of the patient advocacy group, Facing Our Risk of Cancer Empowered (FORCE). "FORCE applauds current and future participants in the BRCA Share program for creating a platform that is structured to promote transparency of clinical-grade test data and to catalyze research leading to clinically significant discoveries."

"Inserm Transfert is excited to partner with Quest Diagnostics, LabCorp, and other commercial, research and academic entities that share our vision for transparent, high quality BRCA research in the United States and across the world in an open environment for better patient care. Their substantial expertise in advanced oncology testing will enable us to harness the commercial and research value of BRCA discoveries. This partnership also recognizes the insight and dedicated strivings from the French academic partners, strongly supported by INCa, which partly funded the project," said Pascale Augé, chief executive officer, Inserm Transfert.

"BRCA Share makes it possible for the best minds in science and medicine to come together to accelerate the pace of BRCA research and diagnostic innovation," said Jon R. Cohen, MD, senior vice president and chief medical officer, Quest Diagnostics. "It will generate novel insights to empower

patients to proactively manage their health."

An estimated five percent of female breast cancers are due to inherited gene mutations, with BRCA1 and BRCA2 gene mutations as the most commonly identified cause. BRCA1 and BRCA2 mutations are also associated with increased inherited risk of ovarian, male breast and other cancers. In consultation with their physician, patients that receive a laboratory test result indicating a BRCA gene mutation may consider options to reduce their risk of developing cancer in the future, including increased screening or prophylactic mastectomy or oophorectomy (removal of breasts or ovaries). Results indicating a variant of uncertain significance, however, inhibit a well-informed management strategy.

About Inserm

The Inserm is the French National Institute of Health and Medical Research institution. Ranked as the number one academic research institution in biomedical research in the European Union, Inserm operates under the dual auspices of the Ministry of Health and the Ministry of Research. It was created in 1964 as a successor to the French National Institute of Health. www.inserm.fr

About Inserm Transfert

Founded in 2000, Inserm Transfert SA is the private subsidiary of the French National Institute of the Health and Medical Research (Inserm), dedicated to technology transfer (from invention disclosure to industrial partnership). Inserm Transfert also manages European and International research projects, supports large scale projects in epidemiology and public health. Inserm Transfert runs a 2M€/year proof of concept fund. The company also supports entrepreneurs in the biotech sector, in partnership with Inserm Transfert Initiative, a € 39.7m life sciences seed investment company. www.inserm-transfert.fr

About the Unicancer Genetic Group and associated University Hospital Centers (Lyon, Montpellier, Nancy, Nantes, Paris)

The UGG is a National Cancer Genetics Network which gathers expert clinicians, biologists, and researchers who contribute to various national and international studies on predispositions to cancers, and develop and implement best practices in genetic diagnosis and care for people at high risk for cancer in partnership with the National Cancer Institute (INCa). BRCA1/2 genetic testing is performed exclusively in France by sixteen laboratories whose diagnosis developments and research studies are performed in the UGG thanks and through their close proximity with clinical cancer genetics teams belonging also to the UGG.

About Quest Diagnostics

Quest Diagnostics is the world's leading provider of diagnostic information services needed to make better healthcare decisions. In October 2013, Quest announced the availability of BRCAVantage™, becoming the largest clinical laboratory company to introduce a BRCA test since the U.S. Supreme Court's human gene patent ruling in June of that year. The company offers the broadest access to diagnostic information services through its network of laboratories and patient service centers, and provides interpretive consultation through its extensive medical and scientific staff. Quest Diagnostics is a pioneer in developing innovative diagnostic tests and advanced healthcare information technology solutions that help improve patient care. Additional information is available at QuestDiagnostics.com. Follow us at [Facebook.com/Quest Diagnostics](https://www.facebook.com/QuestDiagnostics) and [Twitter.com/QuestDX](https://www.twitter.com/QuestDX).

About LabCorp

Laboratory Corporation of America® Holdings, an S&P 500 company, is the world's leading healthcare diagnostics company, providing comprehensive clinical laboratory services through LabCorp Diagnostics, and end-to-end drug development support through Covance Drug Development. LabCorp is a pioneer in commercializing new diagnostic technologies and is improving people's health by delivering the combination of world-class diagnostics, drug development and knowledge services. With combined revenue proforma for the acquisition of Covance in excess of \$8.5 billion in 2014 and more than 48,000 employees in over 60 countries, LabCorp offers innovative solutions to healthcare stakeholders. LabCorp clients include physicians, patients and consumers, biopharmaceutical companies, government agencies, managed care organizations, hospitals, and clinical labs. To learn more about Covance Drug Development, visit www.covance.com. To learn more about LabCorp and LabCorp Diagnostics, visit www.labcorp.com.

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