iMDx Expands GraftAssure Utilization as First Patient Samples Arrive for GALACTIC Registry Study

Nov 20, 2026

- *Patient samples arrive in Tennessee from UCLA Medical Center, officially kicking off 5,000-participant, multi-center novel registry first announced September 2025*
- *Registry program is designed to be incremental, complementary, and symbiotic to iMDx "kitted strategy" and allow clinical community to gain experience using GraftAssure testing technology*
- *Study involvement expected to expand access to GraftAssure technology ahead of potential FDA authorization of a kitted form of the clinical assay, currently under review*

NASHVILLE, Tenn., Nov. 20, 2026 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc., (Nasdaq: IMDX), (iMDx), today announced that the first several patients have been enrolled in its GALACTIC (**G**raft**A**ssure **L**owering **A**llograft reje**CTI**on by **C**ombination) registry study, a prospective, multi-center validation study evaluating GraftAssure™, the company's molecular test for monitoring rejection in kidney transplant recipients.

This study serves to introduce GraftAssure technology to new transplant centers and additionally builds validation data ahead of potential FDA authorization of GraftAssureDx, a kitted version of the company's clinical assay.

"Here at UCLA, we are always interested in innovative research and therefore, we are participating in the GALACTIC Registry, offered by iMDx," said UCLA Medical Center's Dr. Suphamai (Michael) Bunnapradist, MD, MS. "Through this registry we will be able to monitor our patients' transplanted kidney health, initially with a send-out test and ultimately through in-house testing. It is also very exciting to be the center that enrolled the first patient into this national registry."

iMDx seeks to deliver a best-in-class molecular diagnostic test kit, to expand and improve testing access for kidney transplant patients, which it anticipates will deliver new value in the estimated $3 billion addressable market for regulated transplant rejection testing.

"We are excited to enroll our first patients in the GALACTIC registry study, the goal of which is to gather performance metrics on GraftAssure to guide biopsy and treatment decisions and congratulations to the UCLA team on enrolling the first participants. UCLA played a foundational role in validating donor-derived cell-free DNA for transplant monitoring, and we are pleased to have them help answer an important clinical question: 'Can GraftAssure better identify patients whose biopsies will confirm rejection?'" iMDx CEO Josh Riggs said. "GALACTIC aims to demonstrate a positive predictive value above 80%, compared

with roughly 50% for current assays. Enrollment also allows more transplant teams to gain firsthand experience with GraftAssure."

Mr. Riggs continued, "We expect that the data from this registry is what payers and clinicians will look to for real-world evidence, and that it will support payer coverage decisions down the line for the family of products using GraftAssure technology."

About the GALACTIC Registry Study

The GALACTIC registry study is designed as an observational study of iMDx's GraftAssure clinical assay in kidney transplant patients to build evidence supporting the previously published Combination Model (CM)-Score and relate it to real-world outcomes.

Additionally, iMDx expects that the study will bridge findings directly from its CLIA lab-run GraftAssureCore test to its GraftAssureDx kitted test in development to be run in-house within transplant centers. The study also has a planned ~3-year follow-up period.

About the CM-Score Used with GraftAssure Technology

Through the launch of its study, iMDx is making progress toward driving clinical adoption and building a scientific case for why digital PCR, which is natively quantitative, can enable use cases for dd-cfDNA testing beyond what is currently on the market. To that end, iMDx established a multi-year target of engaging with 50 U.S. transplant centers to evaluate the clinical utility of its combined score.

This combined score, or CM-score, uses two independent measurements of dd-cfDNA, which the company believes improves the clinical performance of dd-cfDNA compared to currently available options. Specifically, the CM-score mathematically combines the relative (percentage, or %) and absolute (copies per milliliter, or cp/mL) measurements of DNA fragments from the transplanted organ, which in this case is the kidney. This data was first presented as late breaking at the World Transplant Congress in August 2025.

In a peer-reviewed study published in the *American Journal of Transplantation* in June 2026, and as highlighted in a press release issued the same month, the CM-Score demonstrated a positive predictive value of 81%, compared to a 54% published benchmark for single-metric dd-cfDNA measurement, while retaining a high negative predictive value of 91%. This means that there was a tight correlation between the novel GraftAssure CM-score and rejection, and further suggests that the assay is reliably assessing rejection in kidney transplantation versus non-rejection.

The GALACTIC registry is intended to confirm these findings prospectively in real-world clinical use, evaluate their impact on biopsy and immunosuppression management decisions, and generate long-term outcome data. Collection of these data points is intended to support validation as GraftAssure access is expected to expand to new transplant centers upon planned commercialization.

iMDx Transplant Products and Product Candidates in Development

iMDx's flagship transplant testing technology quantifies a molecular biomarker known as donor-derived cell-free DNA (dd-cfDNA). The Company's scientists in Germany and the U.S. have played a critical role over the past decade in developing the science that helped establish dd-cfDNA as a trusted biomarker of transplant rejection. iMDx is commercializing this technology using a market-disruptive business strategy. Under the GraftAssure™ brand, iMDx's transplant diagnostics include the following:

- GraftAssureCore – The company's laboratory-developed test (LDT), currently reimbursed by CMS MolDX at $2,753 per result and performed at iMDx's CLIA-certified laboratory in Franklin, Tennessee.
- GraftAssureIQ – A research-use-only (RUO) kit intended and labeled for non-clinical applications.
- GraftAssureDx – The in vitro diagnostic (IVD) kit currently under FDA review for use in clinical decision-making.

About Insight Molecular Diagnostics, Inc.

Insight Molecular Diagnostics is a pioneering diagnostics technology company whose mission is to democratize access to novel molecular diagnostic testing to improve patient outcomes. Investors may visit https://investors.imdxinc.com/ for more information.

GraftAssureCore™, GraftAssureIQ™, GraftAssureDx™, GraftAssure™, DetermaIO™, and DetermaCNI™ are trademarks of Insight Molecular Diagnostics Inc.

Forward-Looking Statements

Any statements that are not historical fact (including, but not limited to, statements that contain words such as "will," "believes," "plans," "anticipates," "expects," "estimates," "may," and similar expressions) are forward-looking statements. These statements include those pertaining to, among other things, expected FDA marketing authorization to sell GraftAssureDx, the GALACTIC Registry (including continued enrollment and anticipated data and results) the company's goals to seek a best-in-class molecular diagnostics test kit to expand and improve testing access for kidney transplant patients and deliver new value in the estimated $3 billion addressable market for transplant rejection testing, the clinical utility of the CM-score, transplant and other product candidates in development, and other statements about the future expectations, beliefs, goals, plans, or prospects expressed by management.

Forward-looking statements involve risks and uncertainties, including, without limitation, risks inherent in the development and/or commercialization of diagnostic tests or products, uncertainty in the results of clinical trials or regulatory approvals, the capacity of Insight Molecular Diagnostics' third-party supplied blood sample analytic system to provide consistent and precise analytic results on a commercial scale, potential interruptions to supply chains, the need and ability to obtain future capital, maintenance of intellectual property rights in all applicable jurisdictions, obligations to third parties with respect to licensed or acquired technology and products, the need to obtain third party reimbursement for patients' use of any diagnostic tests Insight Molecular Diagnostics or its subsidiaries commercialize in applicable jurisdictions, and risks inherent in strategic transactions such as the potential failure to realize anticipated benefits, legal, regulatory or political changes in the applicable jurisdictions, accounting and quality controls, potential greater than estimated allocations of resources to develop and commercialize technologies, or potential failure to maintain any laboratory accreditation or certification. Actual results may differ materially from the results anticipated in these forward-looking statements and accordingly such statements should be evaluated together with the many uncertainties that affect the business of Insight Molecular Diagnostics, particularly those mentioned in the "Risk Factors" and other cautionary statements found in Insight Molecular Diagnostics' Securities and Exchange Commission (SEC) filings, which are available from the SEC's website. You are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date on which they were made. Insight Molecular Diagnostics undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

FDA

CAUTION: This press release concerns certain products that are under clinical investigation, and which have not yet been cleared or authorized for marketing by the U.S. Food and Drug Administration. These

products are currently limited by federal law to investigational use, and no representation is made as to the safety or effectiveness of these products for the purposes for which they are being investigated.

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