IMDX GraftAssure Assay Sets New Standard in Screening Kidney Transplant Patients Per American Journal of Transplantation

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- American Journal of Transplantation publishes public pre-proof showing novel CM-score superior to either fractional or absolute measurement of dd-cfDNA alone
- GraftAssure™ assay doubles reliability of positive results in screening cohort
- In for-cause testing of kidney transplant patients, the positive predictive value using the CM-Score increased to greater than 80%

NASHVILLE, Tenn., June 11, 2026 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc., (Nasdaq: IMDX), (iMDx), today announced an online published article in the American Journal of Transplantation asserting statistical superiority of the company's flagship GraftAssure transplant rejection monitoring assay.

IMDx's newly developed GraftAssure Combination Model (CM)-score mathematically combines the relative (percentage, or %) and absolute (copies per milliliter, or cp/mL) measurements of DNA fragments from the transplanted organ. In this study, the tight correlation between the novel GraftAssure CM-score and rejection suggests that the assay is reliably assessing rejection in kidney transplantation versus non-rejection. This data was first presented as late breaking at the World Transplant Congress in August 2025.

"We believe that putting an assay in the hands of transplant physicians that can help distinguish the cause of suspected organ damage, as rejection versus other common pathologies, with high and unprecedented rule-in and retained high rule-out power, makes our GraftAssure dd-cfDNA combination model score an exceptionally useful new tool for the daily clinical challenges after kidney transplantation," said iMDx Chief Science Officer Prof. Dr. Ekkehard Schuetz.

The data and its implications for the future of transplanted organ rejection testing will be shared at the American Transplant Congress in Boston from June 20 to June 24, 2026.

Key takeaways for the scientific and clinical communities:

- The CM-Score was derived from a random sub-cohort and has superior diagnostic performance compared to single-metric dd-cfDNA.
- Diagnostic performance was validated in 81 rejections and 282 non-rejections and compared to 11 published cohorts. For all evaluations, CM-Score was better than dd-cfDNA in copies/mL, which was better than dd-cfDNA in percent.

- The CM-Score retained a high NPV of 91% (89%–93%), while significantly improving **PPV to 81%** (72%–89%; P<0.0001, prevalence: 25%) in the full clinical cohort of 106 rejections and 308 non-rejections, compared to published values (weighted average NPV: 90% (89%–92%); **PPV: 54%** (52%–55%), N=6,536). Decision curve analysis yielded a significantly higher net benefit for the CM-Score (P<0.003).
- This study establishes that the CM-Score has superior diagnostic performance compared to single-metric dd-cfDNA.
- The company has initiated prospective clinical validation via its GALACTIC registry to confirm these findings, to verify the impact of these findings on clinical decision-making, and to evaluate long-term patient outcomes when using the CM-Score to guide biopsy decisions and immunosuppression management. (The company's GALACTIC registry study (**G**raft**A**ssure **L**owering **A**llograft reje**CTI**on by **C**ombination) is designed to drive clinical adoption and build a scientific case for the Combination Model score (CM-score)).

Contextual overview for investors:

iMDx is at a pivotal stage in commercializing its GraftAssure™ technology, which iMDx expects to be an industry-transforming transplanted organ rejection monitoring test. The company aims to deliver proven, more affordable, faster tests that can be run in-house at local transplant center laboratories. iMDx has designed a molecular test that it can sell as a test kit to help enable transplant center laboratories to run tests locally and deliver critical test results far more quickly than the current send-out tests. The company is now seeking FDA marketing authorization to sell these kits to transplant centers in the U.S.

Over time, iMDx sees three potential paradigm shifts in transplanted organ health monitoring and this latest data published in the American Journal of Transplantation directly supports *the second and third shifts:*

- **Bringing testing closer to the patient:** The first is a shift in where donor-derived cell-free DNA (dd-cfDNA) testing is performed – migrating out of centralized reference laboratories and into hospital-based laboratories capable of delivering results locally. (As a reminder, dd-cfDNA is an established biomarker for assessing the health of a transplanted organ through a simple blood draw.)
- **Expanding the clinical role of dd-cfDNA:** The second is the growing potential for dd-cfDNA testing, powered by digital PCR technology, to enable earlier detection of allograft injury, longitudinal monitoring of transplant health, and assessment of response to emerging anti-rejection therapies.
- **Advancing from rule-out to comprehensive decision support:** The third is a transition from the current rule-out-biopsy testing paradigm toward a comprehensive rule-out and rule-in approach, enabled by GraftAssure's ability to measure both dd-cfDNA percentage and absolute, or true, concentrations as copies per milliliter of plasma.

References:

- Link to the paper: https://www.amjtransplant.org/article/S1600-6135(26)02586-4/fulltext

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 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 in development 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, the company's GraftAssure dd-cfDNA combination score, upcoming presentations and attendance at the American Transplant Congress, the GALACTIC registry, the company's plans to commercialize and deliver GraftAssureDx as an industry-transforming transplanted organ rejection monitoring test, the goal to deliver proven, more affordable, faster tests that can be run in-house at local transplant center laboratories, expected FDA marketing authorization to sell GraftAssureDx, anticipated paradigm shifts in transplanted organ health monitoring, 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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