iMDx Reports Kidney Transplant Patient Achieved 'Immune Reset' with Novel Therapy and GraftAssure Monitoring

Oct 06, 2025

- *American Journal of Transplantation*study positions GraftAssure as potentially essential in managing immunosuppression treatment in kidney transplant patients with certain cancers
- GraftAssure used to help avoid overtreatment and preserve patient's immune system
- As transplant care evolves to include novel therapies, the need for ongoing molecular diagnostic monitoring should continue to grow

NASHVILLE, Tenn., Oct. 06, 2025 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc., (Nasdaq: IMDX), (iMDx), today announced results from a study conducted by iMDx researchers and partners published in the *American Journal of Transplantation*, that demonstrated the value of its GraftAssure assay for long-term monitoring of a kidney transplant patient with severe complications requiring novel therapy.

The study reports a unique case in which a 33-year-old transplant patient developed a type of lymphoma, necessitating the cessation of traditional immunosuppression for treatment. GraftAssure molecular testing proved essential for confirming the absence of transplanted organ rejection throughout the patient's treatment period with novel CD19 CAR-T therapy.

Remarkably, the patient maintained stable graft function for about two years without immunosuppression and stayed in remission, suggesting an "immune reset" because of treatment.

"Though it is just a case report, it clearly underscores that our assay measuring dd-cfDNA functioned as a reliable tool to confirm absence of rejection in a rare clinical scenario," said iMDx Chief Science Officer Dr. Ekke Schuetz. "As transplant care evolves to include novel immunomodulating therapies, such as CAR-T, we expect that the need for molecular monitoring of sustained treatment effects will continue to grow."

The company believes that this study adds to a body of research that may position GraftAssure as potentially essential in managing kidney transplant patients, and points to growing clinical use cases over time.

The GraftAssure family of assays represent iMDx's flagship technology. The assay family includes GraftAssureCore, the company's laboratory-developed test (LDT), currently reimbursed by Medicare and performed at its CLIA-certified laboratory in Nashville. GraftAssureIQ became available for purchase in summer 2024 for *research use only*, while GraftAssureDx is in development as a clinical molecular diagnostic test kit, which can be distributed to hospitals to expand and improve testing access for kidney transplant patients. The company expects that the clinical kitted version of its assay will deliver new value in the estimated $1 billion addressable market for kitted transplant rejection testing. As referenced by Dr.

Schuetz above, GraftAssure tests measure an established biomarker of transplant rejection, known as donor-derived cell-free DNA, or dd-cfDNA.

More details about the study:

Post-transplantation lymphoproliferative disorder (PTLD) is a type of lymphoma that can develop as a result of immunosuppression. The treatment for PTLD itself requires a robust immune response, which introduces a challenge for transplant patients who are given immunosuppressive regimens to prevent organ rejection.

In the case of the 33-year-old patient in this study who developed PTLD, CD19 chimeric antigen receptor T-cell (CAR-T) therapy, a type of immunotherapy designed to genetically engineer the patient's T-cells to fight the infected tumor cells, was administered as a fourth-line treatment after three previous treatments had failed or stopped working.

In the reported case, longitudinal monitoring using dd-cfDNA to confirm non-rejection allowed for successful CAR-T treatment, resulting in sustained graft health as monitored by dd-cfDNA, and oncological remission until month 23 of the observation period. This suggested a potential "immune reset", a sign of successful treatment, which is an unexpected finding for a transplant patient generally reliant on immunosuppressive medication to prevent organ rejection.

By nature, suppressing the immune system to prevent organ rejection can result in the development of certain cancers in transplant patients. This case exemplifies that non-invasive biomarkers such as dd-cfDNA measured by GraftAssure to monitor for organ rejection during and after therapy is instrumental to guide therapy.

To read the full study, visit:
Sustained allogeneic kidney graft operational tolerance despite discontinued conventional immunosuppression after CD19-CAR-T-cell therapy for relapsed/refractory post-transplantation lymphoproliferative disorder - ScienceDirect

iMDx Transplant Products and Product Candidates in Development

The company'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 crucial role over the past decade in developing the science that helped establish dd-cfDNA as a trusted biomarker of transplant rejection, and iMDx is now commercializing that technology using a market disruptive approach. Its transplant diagnostics under the GraftAssure brand include the following:

- **GraftAssureCore** – The company's laboratory-developed test (LDT), currently reimbursed by CMS and performed at its CLIA-certified laboratory in Nashville. The company is rebranding its VitaGraft assay (previously known as VitaGraft Kidney), which is a lab developed test, under the name GraftAssureCore. For purposes of this press release, references to "GraftAssureCore" shall be deemed to include the test previously marketed as VitaGraft.
- **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, which the company intends to submit for FDA authorization in 2025.

About Insight Molecular Diagnostics Inc.

Insight Molecular Diagnostics Inc., or iMDx, formerly Oncocyte Corp. (OCX), is a pioneering precision diagnostics technology company whose mission is to democratize access to novel molecular diagnostic testing to improve patient outcomes. iMDx utilizes a well-established proprietary approach to quantify dd-cfDNA, which is a widely used molecular biomarker of transplant rejection.

iMDx™, GraftAssure™, GraftAssureCore™, GraftAssureIQ™, GraftAssureDx™, and VitaGraft™ are trademarks of Insight Molecular Diagnostics Inc.

Insight Molecular Diagnostics (Nasdaq: IMDX) moved its headquarters from Irvine, Calif., to Nashville, Tenn., in June 2025. The company's new NASDAQ symbol became effective June 18. Investors may visit https://investors.imdxinc.com/ for more information.

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, iMDx's development and commercialization efforts and the potential value of GraftAssure to kidney transplant patients, 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 iMDx's 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 iMDx 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 iMDx, particularly those mentioned in the "Risk Factors" and other cautionary statements found in iMDx's 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. iMDx 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.

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Source: Insight Molecular Diagnostics Inc.

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