iMDx Reports Strong Head-to-Head Data in Kidney Transplant Rejection Testing

Jun 23, 2025

- **Study indicates iMDx flagship technology's equivalence with commercially available dd-cfDNA test kits**
- **Head-to-head comparison of iMDx's digital PCR-based test kits with NGS kits shows consistent results in 96 transplant patients**
- **Data was presented at the European Renal Association (ERA) 2025**
- **Extended data to be presented at the European Society of Organ Transplantation (ESOT) Congress in London, June 29 – July 2**
- **Upcoming National Principal Investigator and Key Opinion Leader call planned**

NASHVILLE, Tenn., June 23, 2025 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics, or iMDx, (Nasdaq: IMDX), today announced positive results from a study evaluating its flagship test kit technology in a head-to-head comparison with another commercially available test kit.

The findings indicated equivalent measurements of donor-derived cell-free DNA (dd-cfDNA), a molecular biomarker used to assess the risk of transplant rejection, between the two platforms studied.

This positive data supports iMDx's top priority of launching its first clinical molecular diagnostic test kit and capturing value in the estimated $1 billion transplant rejection testing market. In 2025 to date, iMDx is executing the key steps typically necessary to transition from product development to commercialization.

"This first of its kind, head-to-head comparison demonstrates that digital PCR and NGS platforms deliver equivalent dd-cfDNA results in kidney transplant recipients. We believe the tight correlation across all biopsy-proven pathology categories (BANFF 2022) confirms the clinical interchangeability of both methods," said iMDx Chief Science Officer Dr. Ekkehard Schuetz. "Furthermore, while both approaches aligned clinically, digital PCR showed improved analytical sensitivity, suggesting potential advantages in detecting dd-cfDNA in low quantities."

Added iMDx CEO Josh Riggs, "Head-to-head data like this is highly valuable as we prepare for commercial launch following expected regulatory approval next year. The study results give us confidence that our platform performs on par with NGS-based options currently on the market."

More Details About the Study

The study was conducted by the University Hospital Heidelberg in Germany and represents the first direct comparison of two commercially available dd-cfDNA test kits based on single nucleotide

polymorphisms (SNPs). One test uses next generation sequencing (NGS), while the other – iMDx's GraftAssure, now branded as GraftAssureIQ – uses digital polymerase chain reaction (digital PCR). (A single nucleotide polymorphism, or SNP, is a variation at a single position in a DNA fragment that can be used to distinguish between donor and recipient DNA.)

Unlike sequencing-based approaches, digital PCR does not sequence DNA but instead precisely quantifies specific DNA targets in a sample.

GraftAssureIQ enables both absolute and relative quantification of dd-cfDNA using validated patient-specific variants. The study evaluated 96 kidney transplant recipients undergoing for-cause biopsies. Results showed equivalent measurements between the two platforms, supporting their reliability and reinforcing the role of dd-cfDNA testing in routine transplant care.

For the avoidance of doubt, GraftAssureIQ, which was studied, is iMDx's research-use-only kitted assay and is available for sale for research purposes. Importantly, and as previously communicated by iMDx, GraftAssureIQ *may not be used* to support clinical treatment decisions. The company is concurrently developing GraftAssureDx and intends to seek regulatory authorization for its clinical use.

ESOT in London: Data Presentation and Booth Exhibition Invitation

Extended data from the study will be presented in a poster abstract at the upcoming European Society of Organ Transplantation (ESOT) Congress, being held in London from June 29th through July 2nd. This follows the data that was presented at the European Renal Association 2025 in Vienna, Austria, from June 4th to June 7th 2025.

The company will also be exhibiting at ESOT throughout the duration of the conference. Attendees are invited to visit the iMDx booth (D46) to learn more about GraftAssureIQ, and the different initiatives that iMDx is offering to support transplant centers engaged in cutting-edge R&D.

The company encourages research institutions to stop by to explore collaboration opportunities, accelerating scientific discovery in transplant medicine, and how GraftAssureIQ could help advance their respective center's research goals.

Key Opinion Leader Conference Call with National Principal Investigator

Separately, Insight Molecular Diagnostics (iMDx) plans to host an upcoming Key Opinion Leader (KOL) webinar featuring Dr. Anthony J. Langone of Vanderbilt University Medical Center, who also serves as the national principal investigator (NPI) for iMDx's ongoing kidney transplant monitoring trial.

Additional details, including registration information, will be provided in the weeks leading up to the event and as part of the company's Q2 2025 earnings announcement.

About Insight Molecular Diagnostics Inc.

Insight Molecular Diagnostics Inc., or iMDx, formerly Oncocyte Corp. (OCX), is a pioneering diagnostics technology company whose mission is to democratize access to novel molecular diagnostic testing to improve patient outcomes.

iMDx™, 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.

iMDx Transplant Products and Product Candidates in Development

The company's flagship transplant 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, 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 lab-developed test (LDT), currently reimbursed by CMS and performed at its CLIA-certified laboratory in Nashville. The company is in the process of rebranding its VitaGraft assay (also 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 for non-clinical applications and clearly labeled as such.

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.

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 regulatory approval(s) and commercial launch, 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 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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