# IMDX World Transplant Congress Late-Breaking Data Potentially Sets New Bar for Predicting Graft Rejection in Kidney Transplant Patients

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- **iMDx first dd-PCR assay to combine relative and absolute measurements of dd-cfDNA into single combined score**
- **Data show significantly improved positive predictive value (PPV) for graft rejection, which potentially broadens clinical utility for dd-cfDNA with fewer false positives, further reducing unnecessary invasive biopsies for patients**
- **iMDx expects to evaluate combined score in ongoing FDA study (NCT07060716)**
- **iMDx will be exhibiting at Booth #324 at the World Transplant Congress**
- **National Principal Investigator and Key Opinion Leader call Friday, August 15th at 4 p.m. ET to discuss GraftAssure™ - branded family of assays**

NASHVILLE, Tenn., July 30, 2025 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics, or iMDx, (Nasdaq: IMDX), today announced two favorable oral abstracts, including one late-breaking, that will be presented at the World Transplant Congress from August 2 to 6, in San Francisco.

The late-breaking study validated iMDx's novel approach to quantification of donor-derived cell-free DNA, or dd-cfDNA, an established molecular biomarker of transplant rejection. The study analyzed 403 samples from five clinical cohorts by combining both *relative* dd-cfDNA quantification (expressed as a percentage) and *absolute* quantities (copies/mL plasma) of donor-specific DNA targets into a single score. The results show an unprecedented positive predictive value at 25% rejection prevalence of 79% compared to an average of 48% seen in published data from either percentage or quantities alone, while importantly retaining a high negative predictive value of 93%. Furthermore, only the combined model was able to distinguish all types of rejection from non-rejection pathologies.

The statistically significant increase in positive predictive value achieved by the combined model suggests that in addition to serving as a reliable tool to *rule out* transplanted organ rejection, the dd-cfDNA combination may also serve as a meaningful *rule-in* option. This dual utility has the potential to change the paradigm of dd-cfDNA testing, broaden the clinical use case and increase the assay's value in clinical decision-making. The combination model could also support earlier and more accurate identification of patients at risk for transplanted organ rejection.

"Putting an assay in the hands of transplant physicians that helps to 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 assay an exceptionally

useful biomarker for the daily clinical challenges after kidney transplantation," said iMDx Chief Science Officer Prof. Dr. Ekkehard Schuetz.

Added iMDx CEO Josh Riggs, "Accuracy matters. These data show that diagnostic accuracy can be improved by combining two of our assays together into one score. We congratulate the researchers on the presentation of this data and are working to bring this innovation into our CLIA lab and into our research-use-only and regulated clinical kitted product pipeline."

For further context on iMDx's novel approach to measuring dd-cfDNA, unlike some next- generation sequencing (NGS)-based approaches that measure *relative* DNA quantities, iMDx's digital PCR approach also provides *absolutequantities* of donor-specific DNA targets in a sample, where the method-inherent reliability of digital PCR for quantification is a crucial element for accuracy.

Additionally at WTC, iMDx will present a second abstract reconfirming the use of dd-cfDNA, iMDx's flagship technology, as a noninvasive standard for predicting kidney transplant rejection. The abstract concludes, "dd-cfDNA is the most eligible tool for noninvasive discrimination of rejection, since it enables dynamic injury assessment." This data has been selected for prominent discussion during the closing plenary session.

These positive findings add to the strong body of evidence supporting the GraftAssure product lines. Currently, iMDx offers GraftAssureCore, its laboratory developed test that has achieved Medicare reimbursement, and GraftAssureIQ, its research-use-only kitted assay that 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 has concurrently developed GraftAssureDx and intends to seek regulatory authorization for clinical use. In 2025 to date, iMDx is executing the key steps typically necessary to transition from product development to commercialization of its clinical test kit and capture value in the estimated $1 billion transplant rejection testing market.

**Citations:**


- Akifova A, Benning L, Beck J, et al. (2025). Combining Percentage and Concentration of dd-cfDNA in Kidney Transplantation Is Highly Sensitive and Specific for Rejections. Results from Five Clinical Cohorts. Abstract LOA09.6. Presented at the World Transplant Congress (WTC), San Francisco, CA
.
- Akifova A, Osmanodja B, Niemann M, et al. (2025). Combining PIRCHE-II and dd-cfDNA for Rejection Monitoring in Kidney Transplantation. Abstract OA26.5. Presented at the World Transplant Congress (WTC), San Francisco, CA
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**Key Opinion Leader Conference Call with National Principal Investigator**

Separately, Insight Molecular Diagnostics (iMDx) will host a virtual key opinion leader (KOL) event on Friday, August 15, 2025 at 4:00 PM ET featuring **Anthony Langone, MD (Associate Professor of Medicine, Division of Nephrology and Hypertension, Vanderbilt University).** To register, click here.

Dr. Langone, who serves as the national principal investigator (NPI) for iMDx's ongoing kidney transplant monitoring trial, will discuss the expanding role of donor-derived cell-free DNA (dd-cfDNA) in transplant care, patient management, and the benefits of enabling in-house testing.

In addition, the Company's management team will provide an overview of their kitted strategy, and the uniqueness of their GraftAssure™-branded in-house testing option. The GraftAssure™ family of assays, already available in lab-developed test form and as research-use-only kits, leverages advanced digital PCR (dPCR) technology to deliver highly quantitative, reliable dd-cfDNA results for transplant monitoring. The Company is developing a diagnostics test kit for clinical use, to enable hospitals to run their own tests, in-house.

A live question and answer session will follow the formal presentations. Those who are registered but unable to attend the virtual event live may send questions in advance of the event to questions@lifesciadvisors.com. Please send your questions at least 12 hours in advance of the event.

**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 laboratory-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 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.

**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 ongoing FDA study, product pipeline, anticipated World Transplant Congress exhibit, expected regulatory submissions and approval(s), development and commercialization, 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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