Favorable Head-to-Head Data on iMDx's GraftAssure with Competing NGS Assay Published in Clinical Chemistry

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- Peer-reviewed journal *Clinical Chemistry* published the first head-to-head study comparing GraftAssure™ to industry-leading competitor
- GraftAssure's industry-leading reference change value (time-point to time-point change) supports transplanted organ health screening and rejection recurrence monitoring

NASHVILLE, Tenn., June 16, 2026 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc., (Nasdaq: IMDX) ("iMDx") today announced the online publication of a favorable article in Clinical Chemistry, the premier, peer-reviewed scientific publication of the Association for Diagnostics & Laboratory Medicine. The article highlights the concordant performance between iMDx's digital-PCR-based flagship transplant monitoring test, GraftAssure™, and a competing next-generation-sequencing-based assay kit that is sold outside of the U.S.

The publication titled, "
High Concordance between ddPCR- and NGS-Based Quantification of Donor-Derived Cell-Free DNA Percentage after Kidney Transplantation
," concludes: "This study provides the first comparison of two established dd-cfDNA testing methods and demonstrates excellent diagnostic agreement. These findings support flexibility in assay selection based on availability and cost, supporting the integration of dd-cfDNA testing into routine [clinical] practice."

GraftAssure demonstrated 99.2% agreement with a leading next-generation sequencing (NGS)-based donor-derived cell-free DNA (dd-cfDNA) assay at the clinical threshold of 0.5% for the assessment of kidney transplant rejection risk.

"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 demonstrated high concordance in patient samples, digital PCR showed improved analytical sensitivity, suggesting advantages in detecting dd-cfDNA in low quantities."

Added iMDx CEO Josh Riggs, "Congratulations to the Heidelberg team on the publication. We are happy to partner with them on research like this and for our planned upcoming regulatory submission in the EU."

Context for the scientific and clinical communities:

The reference change value (RCV) describes the minimally significant difference between two serial measurements in one individual. The RCV of GraftAssure was assessed to be 41% at an unprecedentedly low median of 0.17% dd-cfDNA, in 55 samples from 18 patients without any evidence of graft dysfunction. This low RCV enables more precise longitudinal assessments, which has the potential to allow for earlier interventions compared to what can be achieved with older technologies. The RCV could not be calculated for the comparator NGS assay, since over 50% of the dd-cfDNA measurements were below its lower limit of quantification in the 55 samples used.

The analytical validation of GraftAssure demonstrated a lower limit of quantification of 0.04%, which is several folds lower compared to NGS technologies, which are published to be between 0.12%-0.23%.

GraftAssure also enables the precise quantification of the absolute dd-cfDNA content with a lower limit of quantification of 4 copies/mL of patient plasma, empowered by the strength of the primarily quantitative droplet digital PCR technology. This is particularly important for the use in combination with percentage in iMDx's GraftAssure Combination Model Score(1, 2).

"It is exciting to see how the development of our GraftAssure assay has reached a quality that we believe is poised to improve patient care when using dd-cfDNA. We expect to see a better longitudinal assessment and improve clinical use in other organs with particularly low dd-cfDNA, such as heart. Having an assay that can quantify well below the clinical thresholds with a tight RCV enables an earlier warning for the benefit of our patients," Dr. Schuetz added.

GraftAssure leverages Bio-Rad's QX600 droplet digital PCR (ddPCR) system. Digital PCR is a more recently developed and primarily quantitative analytical technology, with high inherent precision and accuracy. In contrast to NGS, digital PCR technologies have been developed for precision quantification of DNA and are considered as "reference measurement procedure" (ISO 17511-2020).

The competing kitted assay for dd-cfDNA determination is available outside of the U.S. Several publications claim an equivalent clinical performance between this competing kitted assay and a similar leading lab-developed test available inside the U.S., (3, 4), which is the centralized dd-cfDNA assay provided by this same competitor.

The data from this study and the potential impact of a dd-cfDNA assay that has shown head-to-head correlation to NGS while offering more precise analytics, will be shared at the American Transplant Congress in Boston from June 20 to June 24, 2026. Please visit the iMDx team at booth #527.

These findings were first presented in 2025 at the European Renal Association and at the European Society of Organ Transplantation (ESOT) Congress.

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 Clinical Chemistry supports these 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:

1. Benning L, Akifova A, Osmanodja B, Morath C, Beck J, Schuetz E et al. Donor-Derived Cell-Free DNA as a Non-Invasive Readout of Activity Across the Rejection Continuum. Transpl Int 2026;39:16099.
2. Benning L, Akifova A, Oellerich M, Osmanodja B, Morath C, Beck J et al. Improving diagnostic performance of kidney allograft rejection with a model combining relative fraction and absolute copies of donor-derived cell-free DNA - results from five independent cohorts. Am J Transplant 2026 doi: 10.1016/j.ajt.2026.06.004
3. Vaulet T, Koshy P, Wellekens K, Aubert O, Bottomley C, Callemeyn J et al. Continuous indices to assess the phenotypic spectrum of kidney transplant rejection. Nat Commun 2025;16(1):10417.
4. Loupy A, Certain A, Tangprasertchai NS, Racape M, Ursule-Dufait C, Benbadi K et al. Evaluation of a Decentralized Donor-Derived Cell-Free DNA Assay for Kidney Allograft Rejection Monitoring. Transpl Int 2024;37:13919.

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.

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 belief that the tight correlation across all biopsy-proven pathology categories (BANFF 2022) confirms the clinical interchangeability of digital PCR and NGS platforms, the company’s planned upcoming regulatory submission in the EU, GraftAssure’s potential to improve patient care when using dd-cfDNA, the expectation to see a better longitudinal assessment and improve clinical use in other organs with particularly low dd-cfDNA such as heart, upcoming presentations and attendance by iMDx and other presenters at the American Transplant Congress, the company’s plans to 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, 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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