iMDx to Highlight In-House Transplant Testing Opportunity and Host Key Opinion Leaders at American Transplant Congress

Jun 09, 2026

- Multiple events and presentations will highlight potential benefits of in-house transplanted-organ-rejection testing, and of GraftAssure technology specifically
- Major transplantation conference in Boston will create additional awareness about GraftAssure technology and its differentiation and potential applications
- iMDx to also announce sponsorship of a grant for researchers to evaluate economics of in-house, transplanted-organ-rejection testing

NASHVILLE, Tenn., June 09, 2026 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc., (Nasdaq: IMDX), (iMDx), today announced it will be highlighting its GraftAssure™ technology at the upcoming American Transplant Congress, to be held in Boston from Saturday, June 20th through Wednesday, June 24th.

Favorable third-party head-to-head data will be showcased at the conference. The company will also announce the winners of a grant provided by iMDx and the American Society of Transplant Surgeons to evaluate the economics of in-house, transplanted-organ-rejection testing.

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.

American Transplant Congress events overview:

- iMDx will highlight the potential benefits and utility of its flagship GraftAssure technology at multiple events that will be held at the conference. GraftAssure technology is the company's transplant monitoring assay that is now available as a centralized lab-developed test that is run in its Tennessee Clinical Laboratory-Certified Amendments (CLIA) lab and is also under FDA review as a kit that can be shipped to local labs. The company believes that its assay offers unique characteristics that would allow clinicians to do more for transplant patients.
- Over time, iMDx sees three potential paradigm shifts in transplanted organ health monitoring:
    - **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 support 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 more 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.

- **iMDx-hosted private reception:** iMDx will host a private reception with leading transplant physicians and laboratory directors – or key opinion leaders -- to discuss the future of transplant monitoring and the growing role of dd-cfDNA testing. iMDx's GraftAssureDx, currently under FDA review, is designed to enable hospitals to perform dd-cfDNA testing locally using droplet digital PCR technology within their own laboratories. GraftAssureCore is iMDx's commercially available laboratory-developed CLIA test that provides clinicians with dd-cfDNA results through centralized testing services. iMDx also has a research-use-only version of GraftAssure, called GraftAssureIQ.
- **Researchers to host IRB development session on anti-CD38 therapies:** Independent researchers from several major institutions will be hosting an Institutional Review Board (IRB) development session and meeting on innovations regarding anti-CD38 therapies, which is described in more detail below.
  - Recently, better pharmaceutical solutions for organ rejection have started to gain a foothold – including anti-CD38 therapies. iMDx has previously stated it believes that 2026 could be the year that anti-CD38 therapies such as the investigational felzartamab and commercially approved daratumumab start to enter routine clinical practice in treating transplanted organ rejection, and this session at ATC is an important proof point.
  - Multiple studies are ongoing, and preliminary results show that the effective management of antibody mediated rejection (AMR) is likely to build on the excitement that was generated with the publication of the phase 2 study of felzartamab in the *New England Journal of Medicine* (*NEJM*). As a reminder, iMDx's assay was used in monitoring the transplanted organ health in the ground-breaking *NEJM* study published in 2024. An extension study has been concluded, and the results are submitted for publication.
  - iMDx is partnering with pharmaceutical companies and universities to conduct studies on additional novel therapeutics for the treatment of organ rejection.
- **Third-party, late-breaking poster featuring head-to-head data:** A third-party, late-breaking poster will be presented on Tuesday, June 23rd demonstrating a *second* instance of GraftAssure technology's comparable performance to a leading commercial assay. In this instance, a major transplant hospital laboratory compared GraftAssureIQ, which is the research-use-only version of the technology, to a commercially available centralized lab developed test. (This represents the second instance of favorable head-to-head data. Earlier results using a separate commercial assay as comparator are accepted for publication and show good comparability as well.)
- **Research winners announced for iMDx-sponsored grant with ASTS:** iMDx will seed a research grant with the American Society of Transplant Surgeons (ASTS) to research the economics of testing in-house versus ex-house at a centralized location. The grant winners will be announced at the conference.

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.

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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, 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, the company's endeavors to capture what it believes to be a $2 billion annual market opportunity, anticipated paradigm shifts in transplanted organ health monitoring, the company's planned research grant with the American Society of Transplant Surgeons to research the economics of testing in-house versus ex-house at a centralized location, 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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