Insight Molecular Diagnostics to Showcase Leadership in Kidney Transplant Management at Conferences in Singapore and Orlando

Sep 24, 2025

- IMDX to host symposium on Wednesday, September 24th to discuss GraftAssureIQ™ at International Association of Therapeutic Drug Monitoring and Clinical Toxicology (IATDMCT) annual meeting
- Presenting on GraftAssureIQ at symposium on Thursday, October 9th at the American Society of Histocompatibility and Immunogenetics (ASHI) annual meeting

NASHVILLE, Tenn., Sept. 24, 2025 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics Inc., (Nasdaq: IMDX), (iMDx), today announced attendance at two key industry conferences where it will discuss its GraftAssure™ technology, including its clinical kitted test under development.

At the 23rd IATDMCT annual meeting, which is being held September 21st to 24th in Singapore, iMDx will host a symposium to discuss the growing clinical applications of transplant rejection testing into longitudinal surveillance and therapeutic response monitoring, and the benefits of in-house testing.

The symposium will highlight how GraftAssure, which is iMDx's flagship transplant rejection testing technology, can be used to detect transplant rejection, as well as to monitor treatment response in patients. The presentation will also include previously published data showcasing how iMDx's flagship transplant rejection testing technology significantly reduces time-to-rejection diagnosis in certain high-risk kidney transplant patients.

"Kidney transplant management is changing. Emerging medications such as anti-CD38 therapies have a chance at treating transplant rejection, and in-house testing will bring care where it belongs – closer to the patient," said iMDx CEO Josh Riggs. "Our presentations this fall in both Singapore and Orlando highlight the bright potential of our technology and the strong global interest in our assay."

In addition, both iMDx and its strategic investor and partner, Bio-Rad Laboratories, will be presenting on GraftAssureIQ, which is iMDx's research-use-only test kit, at the 51st ASHI annual meeting, which will be held October 6th to 10th in Orlando, Fla. The presentation will feature iMDx Chief Science Officer Dr. Ekke Schuetz as well as others, including Bio-Rad Southeast Field Application Scientist Regional Manager Eric Johnson, PhD. In addition to discussing how the GraftAssureIQ kits enable much-needed scientific research, the presentation will also highlight the promising potential of in-house transplanted organ rejection testing, which will offer convenience and efficiency for patients, physicians, laboratory managers and hospital administrators.

"We are pleased to be able to communicate the value of our kitted test to the many thought leaders in transplant and diagnostics who will be at the annual ASHI meeting," said Chief Science Officer Dr. Ekke Schuetz. "Our goal is to enable precise and accessible in-house dd-cfDNA testing for hospitals and

particularly their kidney transplant patients. Our ongoing study to support regulatory clearance of our clinical kitted assay is well underway at leading transplant centers and we look forward to submitting GraftAssureDx for FDA review by year end."

GraftAssureIQ became available for purchase in summer 2024 for research use only, while GraftAssureDx is being developed as a clinical molecular diagnostic test kit, 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, both tests measure an established biomarker of transplant rejection, known as donor-derived cell-free DNA, or dd-cfDNA.

Conference information:

IATDMCT 2025 Symposium (Singapore)

Title: "Donor-derived cell-free DNA for Personalized Immunosuppression in Transplantation"

Speakers: Michael Oellerich, MD, (George-August University, Göttingen, Germany), Klemens Budde, MD, (Charité University, Berlin, Germany), and Geoff Bien (iMDx)

Date: Wednesday, September 24, 2025

Time: 12:30 pm -1:25 pm SGT

ASHI Annual Meeting (Orlando, Fla.)

Title: "GraftAssureIQ: Enabling In-House dd-cfDNA Testing in Transplant Research"

Speakers: Ryan Andrews (iMDx), Eric Johnson, PhD, (Bio-Rad), Geoff Bien (iMDx), and Ekke Schuetz, MD, PhD (iMDx)

Date: Thursday, Oct 9, 2025

Time: 12:40 pm – 1:35 pm ET

About IATDMCT and the Annual Meeting

The IATDMCT is an organization formed by an international group of scientists and physicians, to promote the related disciplines of therapeutic drug monitoring (TDM) and clinical toxicology worldwide. IATDMCT is unique in that no other society promotes the interest of TDM and clinical toxicology internationally.

IATDMCT 2025 brings together leading international scientists and healthcare professionals who are actively working in the fields of TDM and Clinical Toxicology. The theme of the congress is *Creative solutions for global challenges.* The congress will consist of world class plenary speakers, innovative symposia and practical workshops across all the major areas of therapeutics and toxicology with a unique Asia Pacific flavor. The congress will provide the opportunity for researchers and clinicians from around the world to come together and share their research and experiences in TDM, basic and clinical and translational pharmacology and clinical toxicology.

For more information, visit: https://www.iatdmct2025.org/

About ASHI and the Annual Meeting

The American Society for Histocompatibility and Immunogenetics (ASHI) is a society of professionals dedicated to advancing the science, education and application of immunogenetics and transplant immunology.

The ASHI Annual Meeting is the largest and most successful event of the year, drawing over 1,000 attendees from around the world who specialize in histocompatibility, immunogenetics and transplant immunology. Attendees are society members and non-members of the society, industry partners, technologists, researchers, and trainees who join together to share updates on immunogenetics and immunology research as well as practical guidelines in clinical histocompatibility and immunogenetics. The 2025 Annual Meeting is at the Hyatt Regency Grand Cypress on October 6 - 10, 2025 in Orlando, FL. This five-day interactive conference will connect you to HLA professionals and the latest updates in immunogenetics and transplant immunology.

For information, visit https://www.ashi-hla.org/page/Meetings.

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 in the process of 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 participation at IATDMCT and ASHI, the expected submission of GraftAssureDx for FDA review by the end of the year, iMDx’s GraftAssure technology (including GraftAssureIQ and GraftAssureCore), 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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