Insight Molecular Diagnostics Announces Positive Strategic Update and Novel Registry Database

Sep 08, 2025

- 5,000-participant, multi-center registry supported by iMDx's central lab and transplant center partners
- New hospital-based data seeks to further differentiate pending kitted assay that measures biomarker for transplanted organ rejection (dd-cfDNA)
- Novel registry expected to collect approximately 50,000 samples over three years for organ rejection assay combining both *percent* and *total* donor derived cell-free DNA into one score
- Registry expected to assess utility of "the Berlin protocol" of accelerated testing for certain patients at high risk for organ rejection
- Registry program is incremental, complementary and symbiotic to iMDx "kitted strategy"

NASHVILLE, Tenn., Sept. 08, 2025 (GLOBE NEWSWIRE) -- Insight Molecular Diagnostics, Inc. (Nasdaq: IMDX), ("iMDx"), today announced a positive strategic update and novel registry that will serve to gather real-world data on patient experiences and outcomes regarding its flagship kidney transplant rejection assay.

The company expects to enroll 5,000 patients into the registry across at least 25 centers, over three years. Data analyzed from the registry is intended to support the clinical utility of the company's unique assay that utilizes a "combined score" algorithm, as well the effectiveness of an accelerated monitoring protocol for certain high-risk patients. Both data points are logical follow ups to recently published favorable data regarding iMDx's signature assay (1)(2).

"Following several successful milestones achieved by the company so far in 2025, we are very pleased to announce another positive development – a designated registry that we believe will serve as a supportive data repository referencing 5,000 patients. We're excited to work with the clinical community as they explore how to draw on the data and use the methodologies that we've advanced over the past year," said CEO Josh Riggs. "After sampling, we expect that most centers in the registry will want to convert to in-house testing, after regulatory clearance, when it makes sense for them."

"We expect to roll out this registry alongside our planned accelerated commercial activity and revenue generation at our Nashville lab," said iMDx CFO Andrea James. "Executing on our growth strategy while also exhibiting strong capital stewardship and financial discipline remain a top priority."

The registry announcement follows several key developments from both iMDx and the broader industry. In January 2025, iMDx announced that it had achieved claims expansion for dd-cfDNA testing in CLIA certified labs for certain high-risk patients, and in May 2025, the Centers for Medicare & Medicaid Services (CMS) increased its reimbursement rate for GraftAssureCore to $2,753 per result. In addition, late-breaking data presented at the World Transplant Congress in August 2025 show significantly improved positive predictive value (PPV) for graft rejection, generating fewer false positive results, and reducing unnecessary invasive biopsies for patients.

“We have demonstrated two critical clinical innovations over the past year,” said Chief Science Officer Dr. Ekke Schuetz. “The first is what we call the Berlin Protocol for testing frequency of certain high-risk patients, which are those with new donor-specific antibodies, and the second is our use of an algorithmic approach to both absolute and relative quantities of dd-cfDNA to improve biopsy yields.”

The company seeks to deliver a best-in-class molecular diagnostic test kit, to expand and improve testing access for kidney transplant patients, which iMDx anticipates will deliver new value in the estimated $1 billion addressable market for transplant rejection testing.

References:

(1)
IMDX World Transplant Congress Late-Breaking Data Potentially Sets New Bar for Predicting Graft Rejection in Kidney Transplant Patients

(2)
IMDX dd-cfDNA Assay Detects Kidney Transplant Rejection 11+ Months Ahead of Standard Protocols, New Study Affirms

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 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 (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 diagnostics technology company whose mission is to democratize access to novel molecular diagnostic testing to

improve patient outcomes. iMDx utilizes a novel approach to quantification of donor-derived cell-free DNA, or dd-cfDNA, an established molecular biomarker of transplant rejection.

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.

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 novel registry described above (including but not limited to the study's goals and design, the number of expected patients and samples to be collected and the expected outcomes of the study), the belief that most centers in the registry will want to convert to in-house testing, expected regulatory clearance, planned accelerated commercial activity and revenue generation, the anticipation that the company will deliver a best-in-class molecular diagnostic test kit to deliver new value in the estimated $1 billion addressable market for transplant rejection testing, 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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Source: Insight Molecular Diagnostics Inc.