iMDx™
Insight Molecular Diagnostics

Investor Presentation

NASDAQ:IMDX

August 2026

iMDxinc.com

Forward-Looking Statements

This presentation contains certain "forward-looking statements" within the meaning of the "safe harbor" provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "target," "believe," "expect," "will," "may," "anticipate," "estimate," "would," "positioned," "future," and other similar expressions that predict or indicate future events or trends or that are not statements of historical matters. Forward-looking statements are neither historical facts nor assurances of future performance. Instead, they are based only on management's current beliefs, expectations and assumptions. These statements include, among others, those pertaining to iMDx's development and commercial model (including margin and cost, reimbursement, revenue and profitability, transplant commercialization strategy, strategic partnerships, market positioning and competitive advantage, scalability, capital efficiency, accelerated adoption and clinical development), anticipated timing of regulatory clearance(s), 2026 plans for GraftAssureDx, planned expansion into heart transplant testing, product development (including R&D pipeline, product launch and milestone opportunities), along with 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. Because forward-looking statements relate to the future, they are subject to inherent uncertainties, risks and changes in circumstances that are difficult to predict and many of which are outside of our control. Actual results and outcomes may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. You should review additional disclosures we make in our filings with the Securities and Exchange Commission (the "SEC"), particularly those mentioned in the "Risk Factors" and other cautionary statements which are available on the SEC's website at www.sec.gov. Except as required by law, we are under no duty to (and expressly disclaim any such obligation to) update or revise any of the forward-looking statements, whether as a result of new information, future events or otherwise.

FDA

CAUTION: This presentation concerns certain products that are under clinical investigation, and which have not yet been cleared 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.

iMDx™
Insight Molecular Diagnostics

MISSION

Decentralize access to novel molecular diagnostic testing to improve patient outcomes

iMDx Investment Summary

- **Science-driven** team, experienced in molecular diagnostics and managing rapid **growth**
- **Full R&D pipeline** to fuel portfolio expansion over the next decade
- **IP portfolio** attractive to partners and enables value protection
- **Disruptive approach** to molecular diagnostic testing: Empower local labs to test in-house with kits, versus sending out to central labs in large, concentrated markets
- **Proven credibility** in first strategic market: Kidney transplant(1)
- Go-to-market **strategic partner** and investor, Bio-Rad Laboratories

(1) See appendix slides on transplant testing, dd-cfDNA, the New England Journal of Medicine study, and the "leading the science" summary

Experienced Leadership

Pioneering Molecular Diagnostics & Disruptive Growth

Josh Riggs
President & Chief Executive Officer

Ekkehard Schütz, MD, PHD, FADLM
Chief Science Officer

Yuh-Min (Johnson) Chiang, PHD
Chief Technology Officer

Andrea James
Chief Financial Officer

iMDx™
Insight Molecular Diagnostics

Sending patient samples across the country is a waste of time.

Kitted: Designing a lab test for a box

iMDx CTO Johnson Chiang holds up GraftAssureIQ kitted test

Building a kitted product engine

✓ **High Clinical Demand**

Will doctors order it?

✓ **Strong Reimbursement**

Can we get paid?

✓ **IP Protected**

Do we have a right to sell it?

iMDx™
Insight Molecular Diagnostics

Innovative science meets simple business model

Compelling business model

High-value creation

Empowers doctors to reduce uncertainty to **make better decisions** to save lives. Enables researchers to measure biomarkers to **inspire innovation.**

High-value capture

Intellectual property protects our market position, commands high reimbursement rates, and therefore, may lead to **high margins and profitability.**

High-quality recurring revenue

Once a standard of care is proven or adopted, customer **life-time value** often exceeds 30 years.

iMDx™
Insight Molecular Diagnostics

A pure play on major industry tailwinds

Precision medicine

Genomics innovation enables personalized medicine.

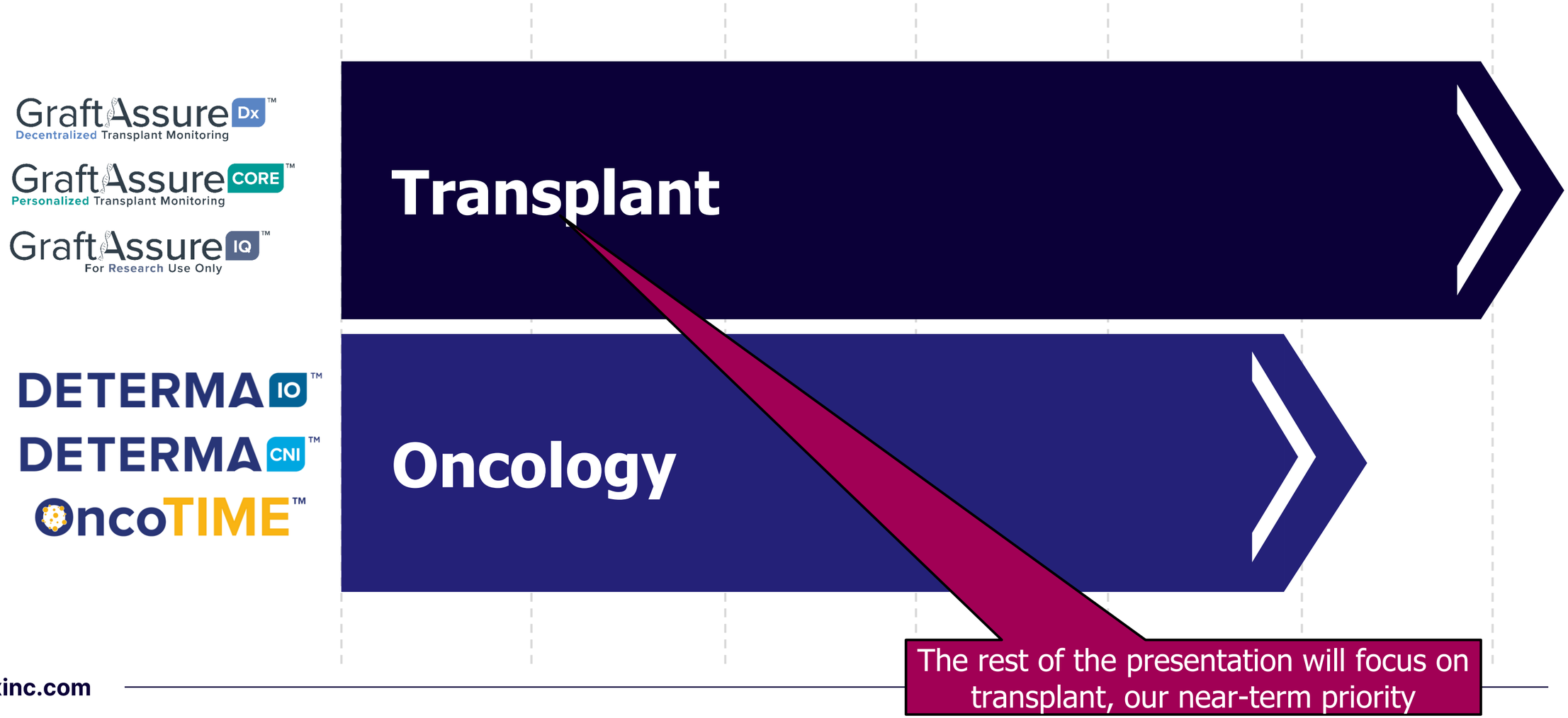
Localized care

Diagnostics trend toward the patient. **Decentralized healthcare** means the market trends toward point-of-care testing.

Rapid care

Liquid biopsy is less invasive. **Digital PCR** is simple, fast, and easy to use.

Full R&D pipeline to fuel decade of growth



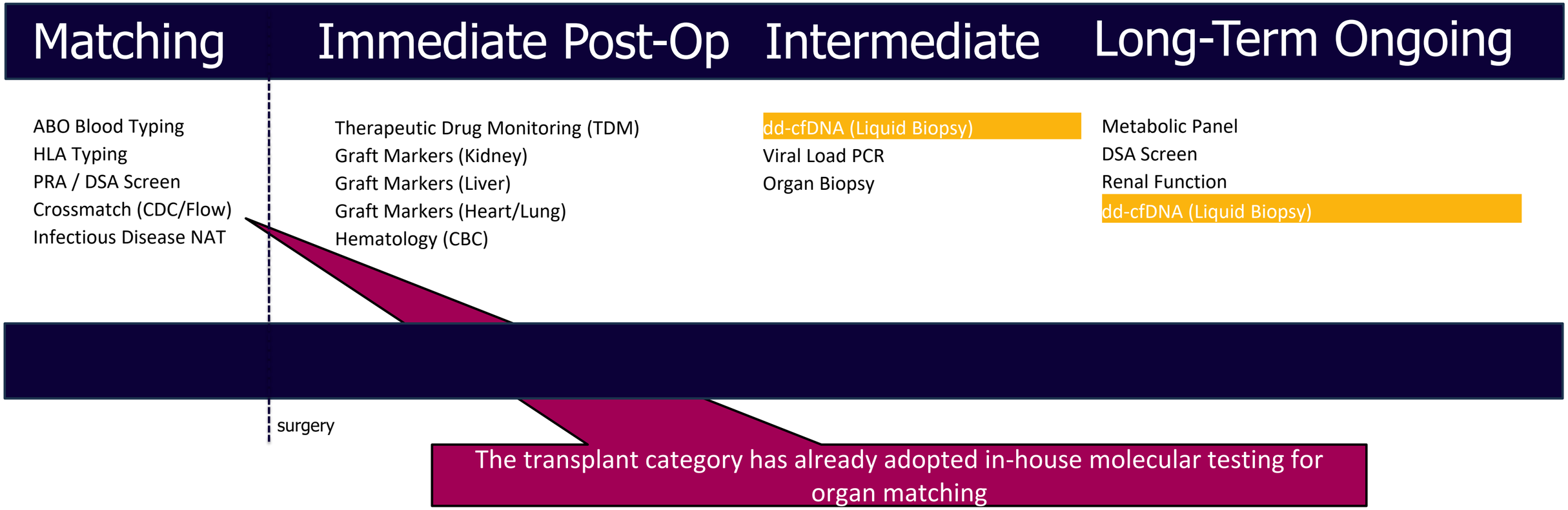
GraftAssureDx: Advancing since 2012, available soon

- ☑ Transplant Product Design, 2012
- ☑ Initial Peer-Reviewed Publication, 2013[1]
- ☑ Definitive Clinical Publication, 2019[2]
- ☑ US Patent Issued, 2021[3]
- ☑ US LDT Validation, 2022
- ☑ **Medicare (CMS) Reimbursement, 2023** ***major milestone***
- ☑ **RUO Kits Launched 2024; Revenue Began Q2 2025**
- ☑ **FDA IVD Submitted For Clinical Use March 2026**

CMS – Center for Medicaid Services
LDT – Lab Developed Test
RUO – Research Use Only
FDA – US Food and Drug Administration
IVD – In Vitro Diagnostic

1. Beck et al. ddPCR for Tx Injury, Clinical Chemistry 59:12 1732–1741 (2013)
2. Oellerich et al. Kidney Validation Cohort 2019 AJT
3. U.S. Patent No. 11,155,872

Transplant hospitals already perform most tests in house. Our kits are a *natural fit.*

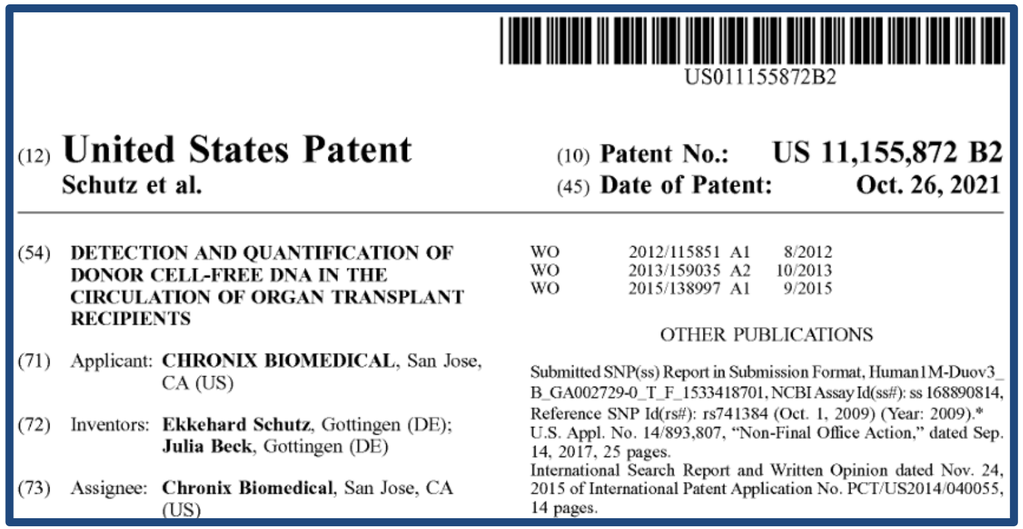


iMDx in the transplant patient care diagnostic value chain

Key:
ABO – blood typing system based on A and B red blood cell antigens; HLA – human leukocyte antigen; PRA – panel reactive antibody; DSA – donor-specific antibody; CDC – complement-dependent cytotoxicity; NAT – nucleic acid testing; TDM – therapeutic drug monitoring; CBC – complete blood count; PCR – polymerase chain reaction; dd-cfDNA – donor-derived cell-free DNA.

iMDx™
Insight Molecular Diagnostics

IP Protected



US011155872B2

(12) **United States Patent**
Schutz et al.

(10) **Patent No.: US 11,155,872 B2**
(45) **Date of Patent: Oct. 26, 2021**

(54) **DETECTION AND QUANTIFICATION OF DONOR CELL-FREE DNA IN THE CIRCULATION OF ORGAN TRANSPLANT RECIPIENTS**

(71) Applicant: **CHRONIX BIOMEDICAL**, San Jose, CA (US)

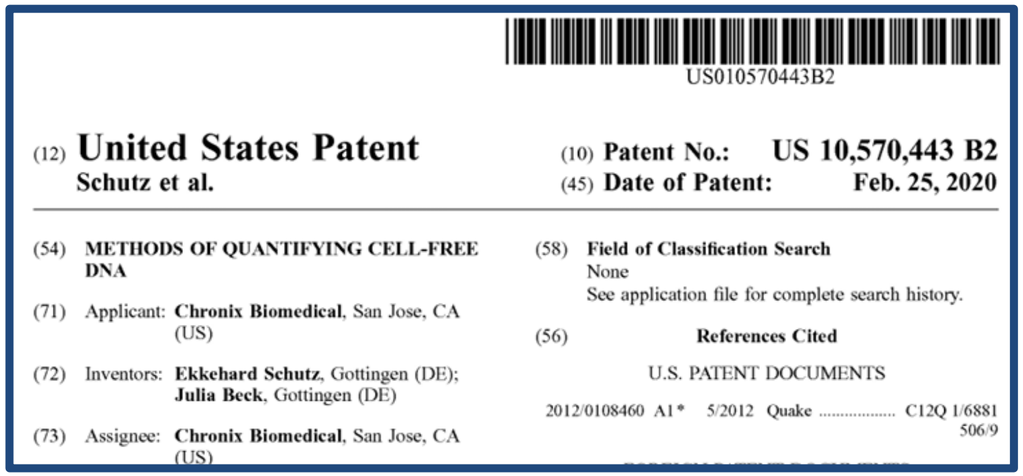
(72) Inventors: **Ekkehard Schutz**, Gottingen (DE); **Julia Beck**, Gottingen (DE)

(73) Assignee: **Chronix Biomedical**, San Jose, CA (US)

WO	2012/115851 A1	8/2012
WO	2013/159035 A2	10/2013
WO	2015/138997 A1	9/2015

OTHER PUBLICATIONS

Submitted SNP(ss) Report in Submission Format, Human1M-Duov3_B_GA002729-0_T_F_1533418701, NCBI Assay Id(ss#): ss 168890814, Reference SNP Id(rs#): rs741384 (Oct. 1, 2009) (Year: 2009).*
U.S. Appl. No. 14/893,807, "Non-Final Office Action," dated Sep. 14, 2017, 25 pages.
International Search Report and Written Opinion dated Nov. 24, 2015 of International Patent Application No. PCT/US2014/040055, 14 pages.



US010570443B2

(12) **United States Patent**
Schutz et al.

(10) **Patent No.: US 10,570,443 B2**
(45) **Date of Patent: Feb. 25, 2020**

(54) **METHODS OF QUANTIFYING CELL-FREE DNA**

(71) Applicant: **Chronix Biomedical**, San Jose, CA (US)

(72) Inventors: **Ekkehard Schutz**, Gottingen (DE); **Julia Beck**, Gottingen (DE)

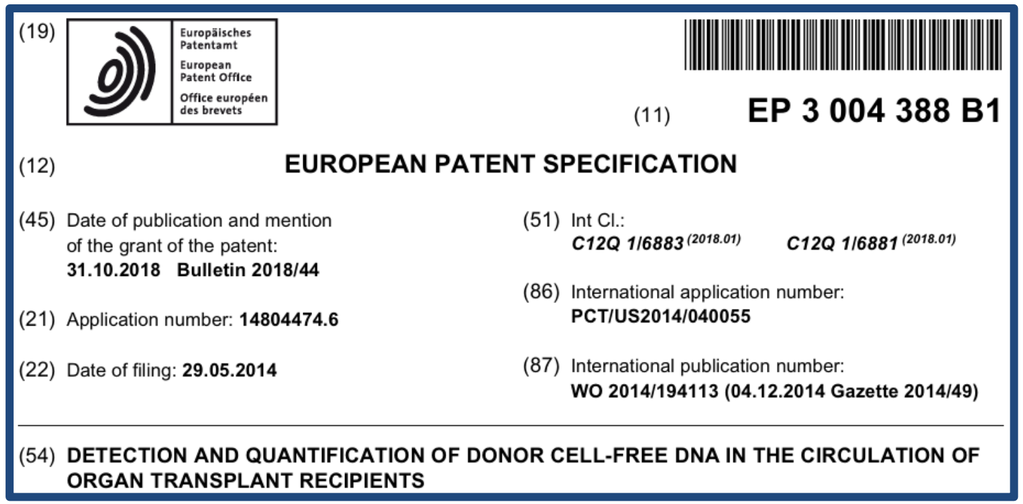
(73) Assignee: **Chronix Biomedical**, San Jose, CA (US)

(58) **Field of Classification Search**
None
See application file for complete search history.

(56) **References Cited**

U.S. PATENT DOCUMENTS

2012/0108460 A1* 5/2012 Quake C12Q 1/6881 506/9



(19) Europäisches Patentamt / European Patent Office / Office européen des brevets

(11) **EP 3 004 388 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
31.10.2018 Bulletin 2018/44

(21) Application number: **14804474.6**

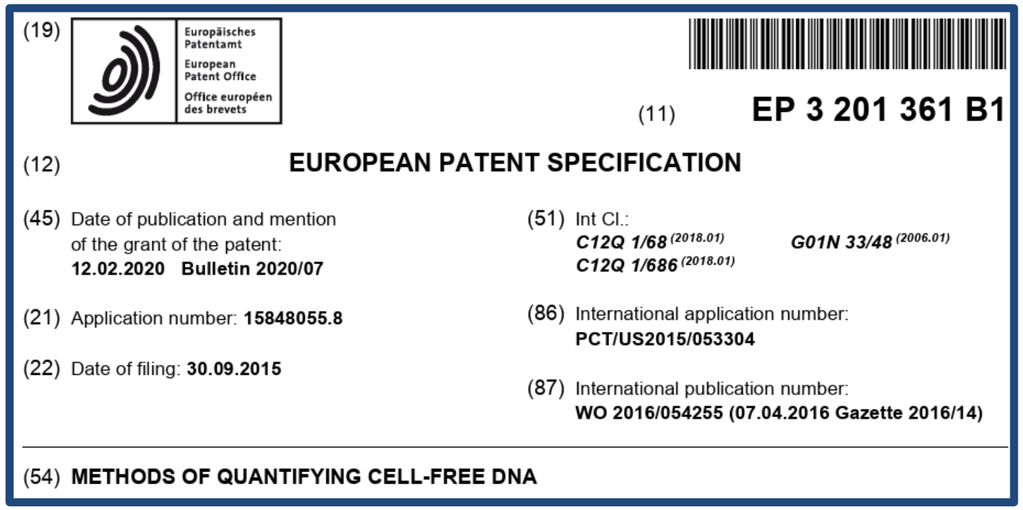
(22) Date of filing: **29.05.2014**

(51) Int Cl.:
C12Q 1/6883 *(2018.01)* ***C12Q 1/6881*** *(2018.01)*

(86) International application number:
PCT/US2014/040055

(87) International publication number:
WO 2014/194113 (04.12.2014 Gazette 2014/49)

(54) **DETECTION AND QUANTIFICATION OF DONOR CELL-FREE DNA IN THE CIRCULATION OF ORGAN TRANSPLANT RECIPIENTS**



(19) Europäisches Patentamt / European Patent Office / Office européen des brevets

(11) **EP 3 201 361 B1**

(12) **EUROPEAN PATENT SPECIFICATION**

(45) Date of publication and mention of the grant of the patent:
12.02.2020 Bulletin 2020/07

(21) Application number: **15848055.8**

(22) Date of filing: **30.09.2015**

(51) Int Cl.:
C12Q 1/68 *(2018.01)* ***G01N 33/48*** *(2006.01)*
C12Q 1/686 *(2018.01)*

(86) International application number:
PCT/US2015/053304

(87) International publication number:
WO 2016/054255 (07.04.2016 Gazette 2016/14)

(54) **METHODS OF QUANTIFYING CELL-FREE DNA**

IP attractive to industry partners

Multiple strategic partnership opportunities

IP Category	Products	Product Partner	Service Lab Partner
Organ Transplant	GraftAssure Dx™ Decentralized Transplant Monitoring GraftAssure CORE™ Personalized Transplant Monitoring GraftAssure IQ™ For Research Use Only	**Bio-Rad signed Q2 2024, potential for expansion**	**National reference lab signed Q1 2026, potential for additional partners and expansion**
Oncology Therapy Selection	DETERMA IO™ OncoTIME™	**Development letter of intent with major instrument maker signed Q2 2025**	
Oncology Therapy Monitoring	DETERMA CNI™		

iMDx™
Insight Molecular Diagnostics

Customers want a kitted transplant assay

Large market opportunity

High Clinical Demand

"High-quality, standardized **decentralized dd-cfDNA testing is the essential** prerequisite for conducting real-world evidence-generating multicenter studies to establish the appropriate context of use for this promising assay."

– January 2026 conclusion by the American Society of Transplantation (AST) and the American Society for Histocompatibility and Immunogenetics (ASHI) STAR working group in the American Journal of Transplantation

Strong Reimbursement

U.S. Medicare reimbursement listing of **$2,753** per result based on MolDx Test Registry pricing for GraftAssureCore

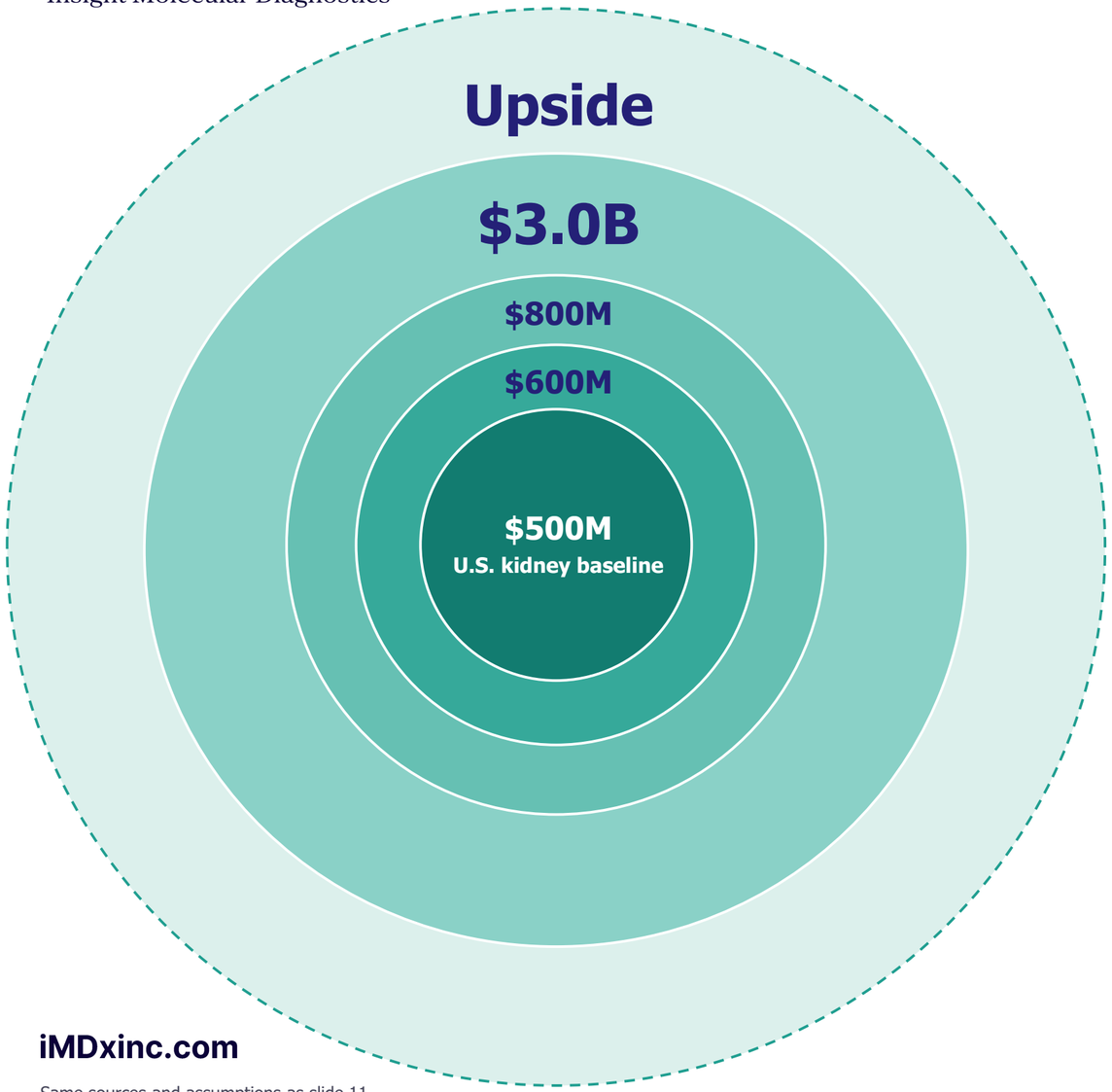
– per CPT code 81479 and DEX Z-code Z0507 (https://app.dexzcodes.com)

Regulated transplant testing is a ~$3B greenfield global opportunity

Sources:
2024 GODT data supports 128,990 global annual transplants (110,467 for kidney, 10,287 for heart, and 8,236 for lung transplants.) Median graft survival rate of 11.7 years for kidney per SRTR, 11.9 years for heart per ISHLT, 6.2 years for lung per ISHLT. Surveillance testing frequency per MolDx LCD of up to 6-4-4 for kidney, 12-4-4 for heart, and 12-4-4 for lung (years 1-3). The LCD sets no timepoint allowance beyond year 3, basing later-year frequency on demonstrated clinical validity and utility; management assumes 2 tests per year thereafter across the remaining graft life. Management estimated per-test value benchmarked to ~25% of expected reimbursement rate; actual pricing may vary. Both U.S. Medicare-based frequency and pricing assumptions are applied to global transplant volume; ex-U.S. reimbursement frameworks and pricing may vary.

Key:
TAM – Total Addressable Market
GODT – Global Observatory on Donation and Transplantation
ISHLT – The International Society for Heart & Lung Transplantation
SRTR – Scientific Registry of Transplant Recipients
MolDx – MolDx is a program run by Medicare to help decide which genetic and molecular tests they will pay for and under what conditions.
LCD – Local Coverage Determination

Large growing opportunity



Concentric Circles: ~$3B Total Addressable Market

$500M — **U.S. kidney, baseline**

Living kidney transplant patients receiving 2 tests per year over the median kidney graft survival rate supports a $500 million TAM

$600M — **+ 2026 MolDx Local Coverage Determination (LCD)**

Higher surveillance testing frequency supports an average of 2.68 tests per living kidney transplant patient per year

$800M — **+ Multi-organ expansion**

The U.S. TAM grows by adding heart & lung transplant testing

$3.0B — **+ Rest of world**

We estimate the *global* total addressable market to be about $3 billion

Upside — **+ TAM growth**

We believe that over the next three years, the organ transplant rejection testing market is likely to shift from one that is primarily dominated by tests used to *avoid biopsies in for-cause patients* to tests that *actively manage patients post-transplant.* This will enable a new era of surveillance, prophylaxis and therapy monitoring: Clinicians will be trying to catch organ rejection as early as possible so that kidneys express less damage *and* stay in patients longer.

Same sources and assumptions as slide 11.

iMDx™
Insight Molecular Diagnostics

Large, Concentrated Testing Market

ANNUAL TRANSPLANTS

27,000

U.S. adult kidney recipients in 2025

110,467 kidney transplants globally in 2024, The U.S. market is roughly a quarter of that volume.

TARGETED CHANNELS

2

National reference laboratories *and* transplant centers

Transplant centers influence patient care through the life of the graft. Testing from smaller centers and local clinics concentrates at large reference laboratories.

CENTER CONCENTRATION

80%

Top 100 centers do **80%** of transplants

Top 50 centers do **54%** of transplants

Most transplants are performed at top transplant centers. These centers also guide graft management after surgery.

MEDICARE COVERAGE

14 surveillance tests per patient in the first three years post-surgery, reimbursed at

$2,753 per test

MolDX LCD L38582 covers six tests in the first year after a transplanted kidney surgery and up to four tests per year in years two and three. After year three, there is no fixed annual limit. In addition, *for cause testing,* (as opposed to mere surveillance), is covered in addition and separately.

KEY TAKEAWAY iMDx is targeting a large and concentrated market with a well-established, high-value, reimbursed test.

Sources:
U.S. kidney transplants and center-level volume: OPTN National Data, 2025; 248 U.S. kidney transplant centers (233 performed at least one kidney transplant in 2025).
Global volume: Global Observatory on Donation and Transplantation, 2024 Report.

How we win: Deliver what decision makers want

Transplant Physicians

- ✓ Control
- ✓ Fast turnaround times
- ✓ Ability to conduct their own research

Lab Directors

- ✓ In-house testing
- ✓ Simple workflow
- ✓ Full data access

Hospital Administrators

- ✓ Revenue generation opportunities
- ✓ Research-forward reputation

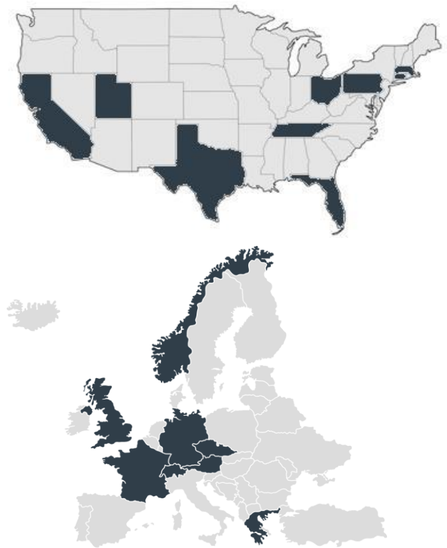
GraftAssure Deployments

iMDx™
Insight Molecular Diagnostics

22 Sites | **9** Countries | **3** Continents

Benefits of pre-revenue deployments:
- ✓ Institutes publishing multiple favorable abstracts in 2026
- ✓ Third party head-to-head data favorable to iMDx

RUO = Research Use Only
Some customer names redacted for competitive sensitivity



Transplant Center Laboratory (names redacted for competitive sensitivity)	Location	RUO Pilot	FDA Trial
Thomas Jefferson University	Pennsylvania, US	✓	✓
University Hospital Lab	Singapore	✓	
Large Hospital Lab	Switzerland	✓	
The Charité, Humboldt University of Berlin	Berlin, Germany	✓	✓
University Hospital Lab	UK	✓	
University Hospital Lab	Austria	✓	
University Hospital Lab	UK	✓	
Heidelburg University Hospital	Heidelberg, Germany	✓	✓
Tampa General Hospital	Tampa, Florida	✓	✓
University Hospital Lab	Texas	✓	
Baylor Scott & White Health	Dallas, Texas		✓
Mayo Clinic in Florida	Jacksonville, Florida		✓
University of Pittsburgh Medical Center	Pittsburgh, Pennsylvania		✓
Cleveland Clinic	Cleveland, Ohio		✓
Intermountain Medical Center	Murray, Utah		✓
Vanderbilt University Medical Center	Nashville, Tennessee		✓
Major transplant hospital laboratory	Czech Republic	✓	
Transplant Hospital Lab	France	✓	
University of Southern Calif. Keck School of Medicine	Los Angeles, California		✓
University Lab	British Columbia, Canada	✓	
Ivy League University Lab	Northeast, US	✓	
University Hospital Lab	Mountain West, US	✓	

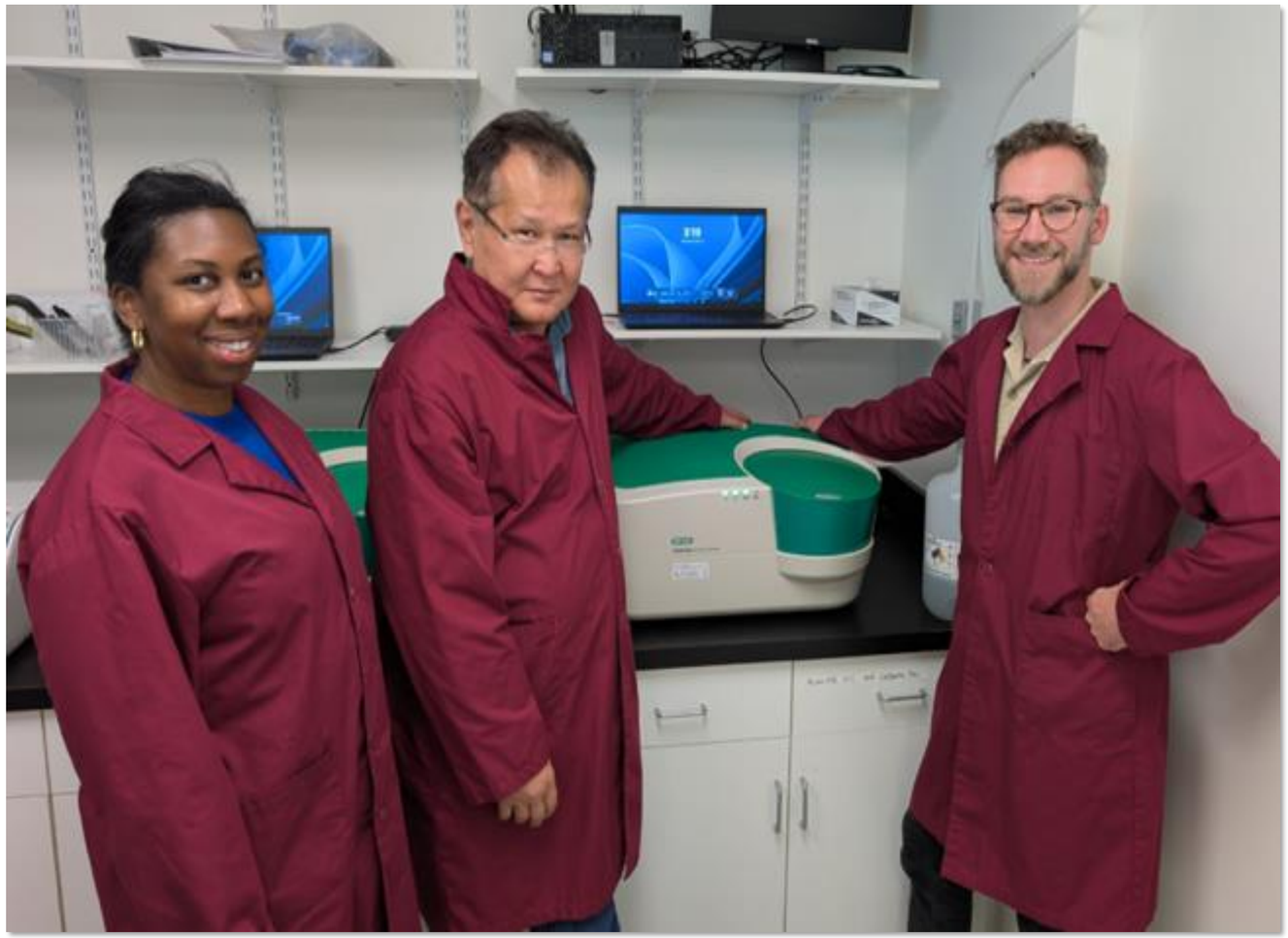
iMDx™ + BIO-RAD Strategic Partnership

- ✓ Bio-Rad (NYSE: BIO) is a top five shareholder and has made **four equity investments** in iMDx
- ✓ Our test runs on the Bio-Rad platform
- ✓ Coordinated rapid development of test kits
- ✓ Opportunity for partnership expansion, milestone-based investments

We are not building this alone.

iMDx™
Insight Molecular Diagnostics

- ✓Opening academic hospital core and HLA labs to Bio-Rad platform
- ✓2026: Expect to receive FDA clearance for GraftAssureDx (kidney) for the QX600Dx
- ✓Goal of showcasing the digital PCR advantage in heart transplant management



iMDx product development team members receiving a Bio-Rad QX600Dx ddPCR System (IUO), upon which the GraftAssureDx assay is performed.

iMDx™
Insight Molecular Diagnostics

Not stopping at kidney . . .
. . . Goal of expanding rapidly into heart transplant testing

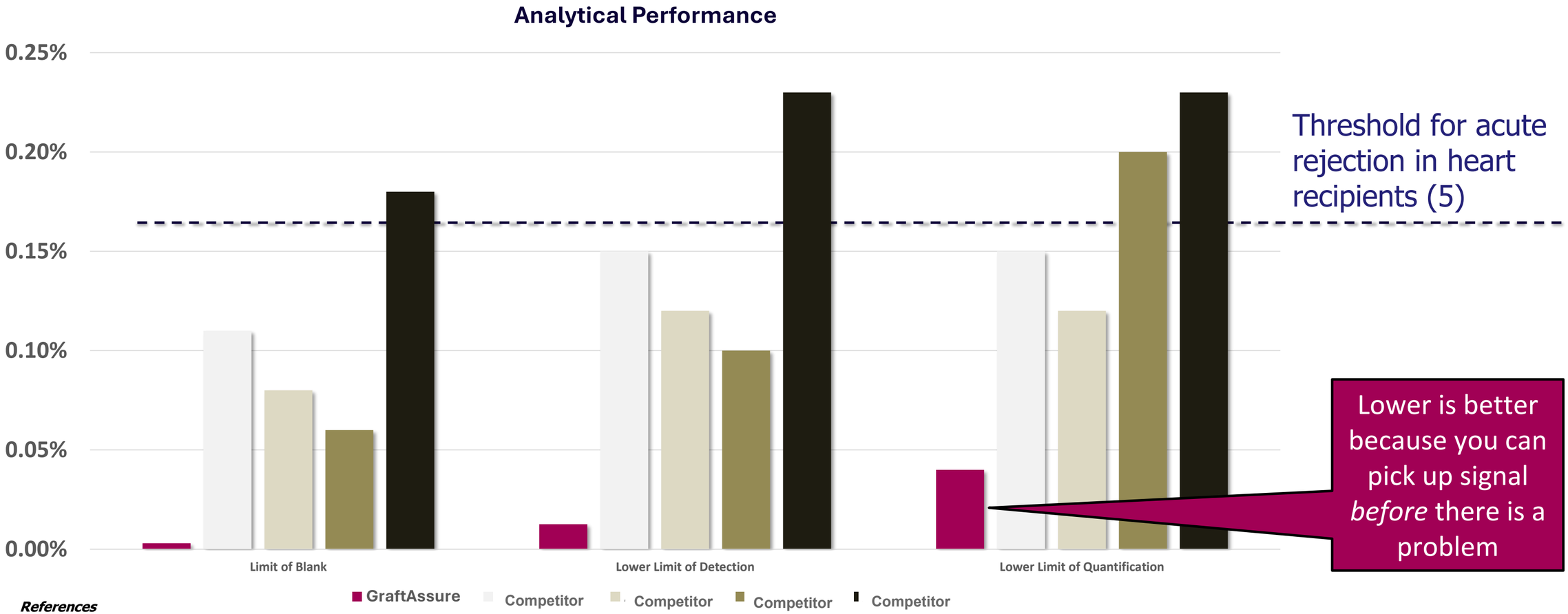
>$100 million estimated TAM in the United States
~$250 million estimated TAM globally

- ✓ Rapid development: GraftAssure is designed to be organ-agnostic
- ✓ Higher testing frequency per patient
- ✓ Higher clinical stakes
- ✓ Further adoption incentive for hospitals

Sources:
- 2024 GODT data supports 10,287 global annual heart transplants. 2025 OPTN data supports 4,587 annual heart transplants in the United States. Median heart graft survival of 11.9 years per ISHLT. Surveillance testing frequency per MolDx LCD Draft of 12-2 for heart. Management estimated per-test value benchmarked to ~25% of expected reimbursement rate; actual pricing may vary.
- Moeller et al., Significance of Elevated Donor-Derived Cell-Free DNA in Heart Transplant Recipients With Negative Endomyocardial Biopsies: A Dawn of a New Era, AHA/ASA Journals, Circulation: Heart Failure, Volume 18, Number 11.

iMDx™ Heart: The Digital PCR *Advantage*

Insight Molecular Diagnostics



References

(1) Yücel Altuğ, PhD, Analytical Validation of a Single-nucleotide, Polymorphism-based Donor-derived Cell-free DNA Assay for Detecting Rejection in Kidney Transplant Patients. Transplantation 2019 Vol 103 No: 12. doi: 10.1097/TP.0000000000002665

(2) Wong L,The Evolution and Innovation of Donor-Derived Cell-Free DNA Testing in Transplantation J Med Diagn Meth, 2020 Vol. 9 Iss.5. doi: 10.35248/2168-9784.2020.9.302

(3) Daniels L. et al. Performance assessment of the One Lambda Devyser Accept cfDNA assay in lung transplantation. 50th ASHI Annual Meeting, Anaheim, CA October 21-25 2024 (P605)

(4) Casas S et al. Multi-centre analytical performance verification of an IVD assay to quantify donor-derived cell-free DNA in solid organ transplant recipients HLA. 2024;103:e15518. doi: 10.1111/tan.15518

(5) Rodgers N et a. Comparison of two donor-derived cell-free DNA tests and a blood gene-expression profile test in heart transplantation. Clin Transplant 2023 37(6): e14984. doi: 10.1111/ctr.14984.

iMDx Investment Summary Recap

- **Science-driven** team, experienced in molecular diagnostics and rapid **growth**
- **Full R&D pipeline** to fuel growth and portfolio expansion over the next decade
- **IP portfolio** protects market position and is attractive to potential partners
- **Disruptive approach** to molecular diagnostic testing
  - Empower local labs with kits
  - Stronger business model
  - Proven, more affordable, faster tests
- **Proven credibility** in first strategic market: Kidney transplant
  - U.S. Medicare (CMS) reimbursement for GraftAssureCore received 2023, boosted 2025
  - *New England Journal of Medicine* (NEJM) study published May 2024
- Go-to-market **strategic partner** and equity investor
  - Industry leader Bio-Rad Laboratories, Inc. (NYSE:BIO) signed in Q2 2024
  - Opportunities for future milestone-based investments

iMDx™
Insight Molecular Diagnostics

Appendix

Molecular diagnostics 101

Molecular diagnostic testing *combines laboratory testing with the precision of molecular biology and has revolutionized the way clinical and public health laboratories investigate the human, viral, and microbial genomes, their genes, and the products they encode.*

Molecular diagnostic tests are increasingly being used, and have supplanted numerous conventional tests, in many areas of laboratory medicine including oncology, infectious diseases, clinical chemistry, and clinical genetics.

Advancements in molecular diagnostic testing will continue to improve the accuracy and speed by which we can detect microbial pathogens or analyze a patient's genes, and is becoming an essential aspect of patient-tailored interventions and therapeutics.

-- U.S. Department of Health and Human Services

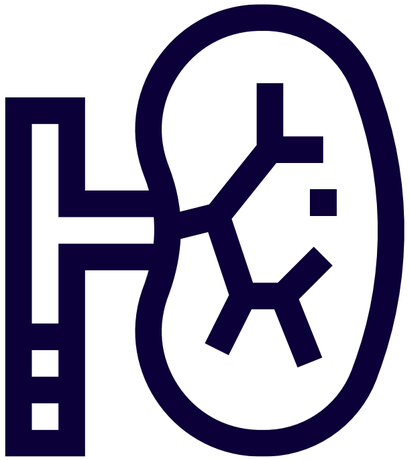
Molecular – *relating to or consisting of molecules, which are groups of atoms bonded together, representing the smallest fundamental unit of a chemical compound that can take part in a chemical reaction*

Molecular biology – *the branch of biology that studies the molecular basis of biological activity*

DNA – *a molecule that stores the genetic information of living beings, and the substance on which molecular biology focuses its research.*

iMDx™
Insight Molecular Diagnostics

Transplant testing matters

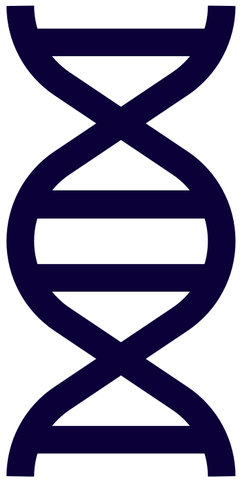


Kidney transplant patients face a 1 in 5 chance that their body will reject the donor kidney.

iMDx's test finds early evidence of organ damage in the blood.

Source on "1 in 5 chance:" Specifically, Antibody-mediated rejection (AMR) is a leading cause of kidney allograft failure. Up to 20.2% of kidney transplant patients will develop AMR within 10 years of transplant and up to 70% of those patients will progress to graft failure. Reference: Mujtahedi, S.S., Yigitbilek, F., Ozdogan, E. et al. Antibody-Mediated Rejection: the Role of Plasma Cells and Memory B Cells. Curr Transpl Rep 8, 272–280 (2021). https://doi.org/10.1007/s40472-021-00342-1

Source on "iMDx's test finds early evidence of organ damage in the blood." Reference: https://investors.iMDxinc.com/news-releases/2023/09-18-2023 and https://investors.iMDxinc.com/news-releases/2024/12-02-2024-210612022



Donor-derived cell-free DNA (dd-cfDNA)

We helped to establish this biomarker

Sources: Our timeline slide supports this statement, as well as the fact that MolDX, a program that identifies and establishes coverage and U.S. government reimbursement for molecular diagnostic tests, cited our publications twice when it established the LCD (Local Coverage Determination) for Medicare and Medicaid reimbursement coverage for cell free DNA testing.

Source: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdId=38671&ver=4

New England Journal of Medicine study

- Favorable iMDx GraftAssureCore study **results published in *NEJM*,** May 30, 2024
- Data show potential to monitor for therapeutic efficacy and recurrence
- **Potential** repeat testing opportunities with **claims expansion**

The NEW ENGLAND JOURNAL of MEDICINE

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

A Randomized Phase 2 Trial of Felzartamab in Antibody-Mediated Rejection

K.A. Mayer, E. Schrezenmeier, M. Diebold, P.F. Halloran, M. Schatzl, S. Schranz, S. Haindl, S. Kasbohm, A. Kainz, F. Eskandary, K. Doberer, U.D. Patel, J.S. Dudani, H. Regele, N. Kozakowski, J. Kläger, R. Boxhammer, K. Amann, E. Puchhammer-Stöckl, H. Vietzen, J. Beck, E. Schütz, A. Akifova, C. Firbas, H.N. Gilbert, B. Osmanodja, F. Halleck, B. Jilma, K. Budde, and G.A. Böhmig

ABSTRACT

BACKGROUND

Antibody-mediated rejection is a leading cause of kidney-transplant failure. The targeting of CD38 to inhibit graft injury caused by alloantibodies and natural killer (NK) cells may be a therapeutic option.

METHODS

In this phase 2, double-blind, randomized, placebo-controlled trial, we assigned patients with antibody-mediated rejection that had occurred at least 180 days after transplantation to receive nine infusions of the CD38 monoclonal antibody felzartamab (at a dose of 16 mg per kilogram of body weight) or placebo for 6 months, followed by a 6-month observation period. The primary outcome was the safety and side-effect profile of felzartamab. Key secondary outcomes were renal-biopsy results at 24 and 52 weeks, donor-specific antibody levels, peripheral NK-cell counts, and donor-derived cell-free DNA levels.

RESULTS

A total of 22 patients underwent randomization (11 to receive felzartamab and 11 to receive placebo). The median time from transplantation until trial inclusion was 9 years. Mild or moderate infusion reactions occurred in 8 patients in the felzartamab group. Serious adverse events occurred in 1 patient in the felzartamab group and in 4 patients in the placebo group; graft loss occurred in 1 patient in the placebo

iMDx™
Insight Molecular Diagnostics

Transplant: Leading the science

Our centralized assay, GraftAssureCore, has been validated in clinical studies with an aggregate of 1,248 patients and 5,025 samples.

226 Liver Recipients

PLoS Med (2017)[1], Liver Transpl (2022)[2] , Transplantation (2014)[3,4]

935 Kidney Recipients

Kidney International (2026)[5], AJT (2026)[6], Transplant International (2026)[7], Clinical Chemistry (2026)[8], Transplant Direct (2025)[9], Nephrology Dialysis Transplantation (2024)[10], NEJM (2024)[11], Transplant International (2024)[12], Kidney International Reports (2023)[13], J Clin Med (2023)[14], Transplant Direct (2021)[15], Clin Chem (2020)[16], Am J Transplant (2019)[17]

87 Heart Recipients

Transplantation (2022)[18]

iMDx™
Insight Molecular Diagnostics

Our formula

Regulated

+ Reimbursed

+ Clinically Useful

= Rapid Adoption

iMDx™
Insight Molecular Diagnostics

iMDx's product appeal

Transplant centers want a test that is

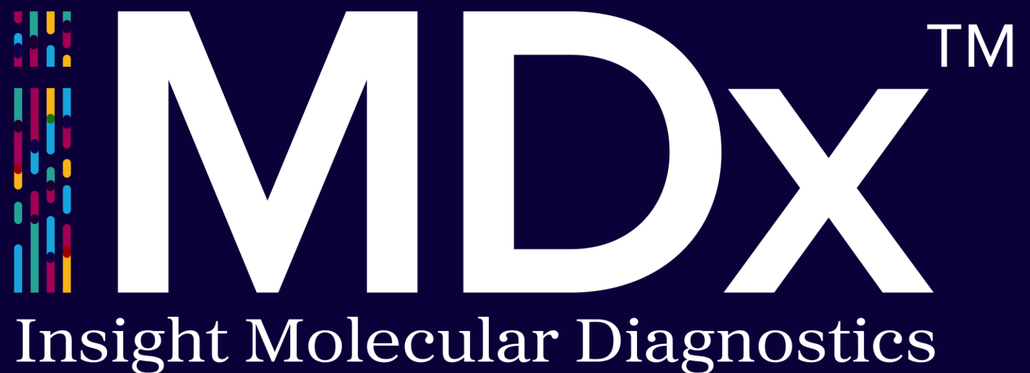
- ✓ **easy to use** and
- ✓ returns a **same day answer** that is
- ✓ **clinically actionable** and
- ✓ **cost effective**

Important regulatory note: GraftAssureCore, formerly known as VitaGraft Kidney LDT, has clinical claim. iMDx is pursuing regulatory IVD authorization for kitted products

Compelling Patent Portfolio

TEST	TITLE	COUNTRY	STATUS	PATENT NUMBER	ISSUED DATE	PATENT EXPIRATION
DetermaCNI*	Prostate Cancer Associated Circulating Nucleic Acid Biomarkers	United States of America	Issued	10214775	Feb 26, 2019	Dec 7, 2032 + 687 days PTA
DetermaCNI	Breast Cancer Associated Circulating Nucleic Acid Biomarkers	United States of America	Issued	10047397	Aug 14, 2018	Apr 18, 2031
DetermaCNI	Breast Cancer Associated Circulating Nucleic Acid Biomarkers	United States of America	Issued	11377695	Jul 5, 2022	April 18, 2031 + 629 days PTA
DetermaCNI	Breast Cancer Associated Circulating Nucleic Acid Biomarkers	Canada	Issued	2796578	Nov 23, 2021	Apr 18, 2031
DetermaCNI	Breast Cancer Associated Circulating Nucleic Acid Biomarkers	European Patent Office-validated in 12 countries	Issued	2558854	Oct 10, 2018	Apr 18, 2031
DetermaCNI	Method Of Determining A Numeric Index Of Tumor-Associated Copy Number Changes Of Circulating Nucleic Acids Associated With Prostate	United States of America	Issued	11414706	Aug 16, 2022	June 1, 2031 + 777 days PTA
DetermaCNI	Prostate Cancer Associated Circulating Nucleic Acid Biomarkers	Canada	Issued	2801468	Sep 4, 2018	Jun 1, 2031
DetermaCNI	Prostate Cancer Associated Circulating Nucleic Acid Biomarkers	European Patent Office - validated in 12 countries	Issued	2576837	Sep 6, 2017	Jun 1, 2031
DetermaCNI	Colorectal Cancer Associated Circulating Nucleic Acid Biomarkers	Canada	Issued	2852098	May 2, 2023	Oct 19, 2032
DetermaCNI	Colorectal Cancer Associated Circulating Nucleic Acid Biomarkers	European Patent Office - validated in 12 countries	Issued	2768985	Mar 20, 2019	Oct 19, 2032
DetermaCNI	Personalized Biomarkers For Cancer	United States of America	Issued	9909186	Mar 6, 2018	Dec 13, 2033
DetermaCNI	Personalized Biomarkers For Cancer	European Patent Office - validated in 12 countries	Issued	2931922	Oct 17, 2018	Dec 13, 2033
GraftAssure*	Detection And Quantification Of Donor Cell-Free DNA In The Circulation Of Organ Transplant Recipients	United States of America	Issued	11155872	Oct 26, 2021	May 29, 2034 + 136 days PTA
GraftAssure*	Detection And Quantification Of Donor Cell-Free DNA In The Circulation Of Organ Transplant Recipients	European Patent Office - validated in 28 countries	Issued	3004388	Oct 31, 2018	May 29, 2034
GraftAssure	Methods Of Quantifying Cell-Free DNA	United States of America	Issued	10570443	Feb 25, 2020	Sep 30, 2035
GraftAssure	Methods Of Quantifying Cell-Free DNA	European Patent Office - validated in 29 countries	Issued	3201361	Feb 12, 2020	Sep 30, 2035

** Indicates foundational patent covering the core technology.*


MDx™
Insight Molecular Diagnostics