

# Investor Presentation

**NASDAQ:IMDX**

March 2026

**[iMDxinc.com](http://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](http://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.



## MISSION

**Decentralize access to novel molecular diagnostic testing to improve patient outcomes**

[iMDxinc.com](http://iMDxinc.com)



# 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 Investment Summary

- **Disruptive approach** to molecular diagnostic testing: Empower local labs to test in-house with kits, versus sending out to central labs
- **Proven credibility** in first strategic market: Kidney transplant<sup>(1)</sup>
- Go-to-market **strategic partner** and investor, Bio-Rad Laboratories
- **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

(1) See appendix slides 33, 34 and 35

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





# Innovative science **meets** simple business model

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# 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**
- ✓ **Strong Reimbursement**
- ✓ **IP Protected**



# Full R&D pipeline to fuel decade of growth

GraftAssure **Dx**<sup>TM</sup>  
Decentralized Transplant Monitoring

GraftAssure **CORE**<sup>TM</sup>  
Personalized Transplant Monitoring

GraftAssure **IQ**<sup>TM</sup>  
For Research Use Only

## Transplant

DETERMA **IO**<sup>TM</sup>

DETERMA **CNI**<sup>TM</sup>

Onco**TIME**<sup>TM</sup>

## Oncology

The rest of the presentation will focus on transplant, our near-term priority



# Regulated transplant testing is a **\$2B+ greenfield** global opportunity

Source:

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 Draft of 4-2 for kidney, 12-2 for heart, and 12-2 for lung. Management estimated per-test value benchmarked to ~25% of expected reimbursement rate; actual 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

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# 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 MoDx Test Registry pricing for GraftAssureCore

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





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**

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

OTHER PUBLICATIONS

(71) Applicant: **CHRONIX BIOMEDICAL**, San Jose, CA (US)  
Submitted SNP(ss) Report in Submission Format, Human IM-Duov3\_B\_GA002729-0\_T\_F\_1533418701, NCBI Assay Id(ss#): ss168890814.

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

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

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

(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)

(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**

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

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

(21) Application number: **14804474.6**

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

(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**

(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**

(21) Application number: **15848055.8**

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

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

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



# Customers want a kitted product

## Large market opportunity



# GraftAssureDx ... planned for 2026

- ✓ Transplant Product Design, 2012
- ✓ Initial Peer-Reviewed Publication, 2013<sup>1</sup>
- ✓ Definitive Clinical Publication, 2019<sup>2</sup>
- ✓ US Patent Issued, 2021<sup>3</sup>
- ✓ US LDT Validation, 2022

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

✓ **Medicare (CMS) Reimbursement, 2023** *major milestone*

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

✓ **RUO Kits Launched 2024; Revenue Began Q2 2025**

➡ **FDA IVD Submission For Clinical Use March 2026**

# How we win: Deliver what decision makers want

## Transplant Physicians

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

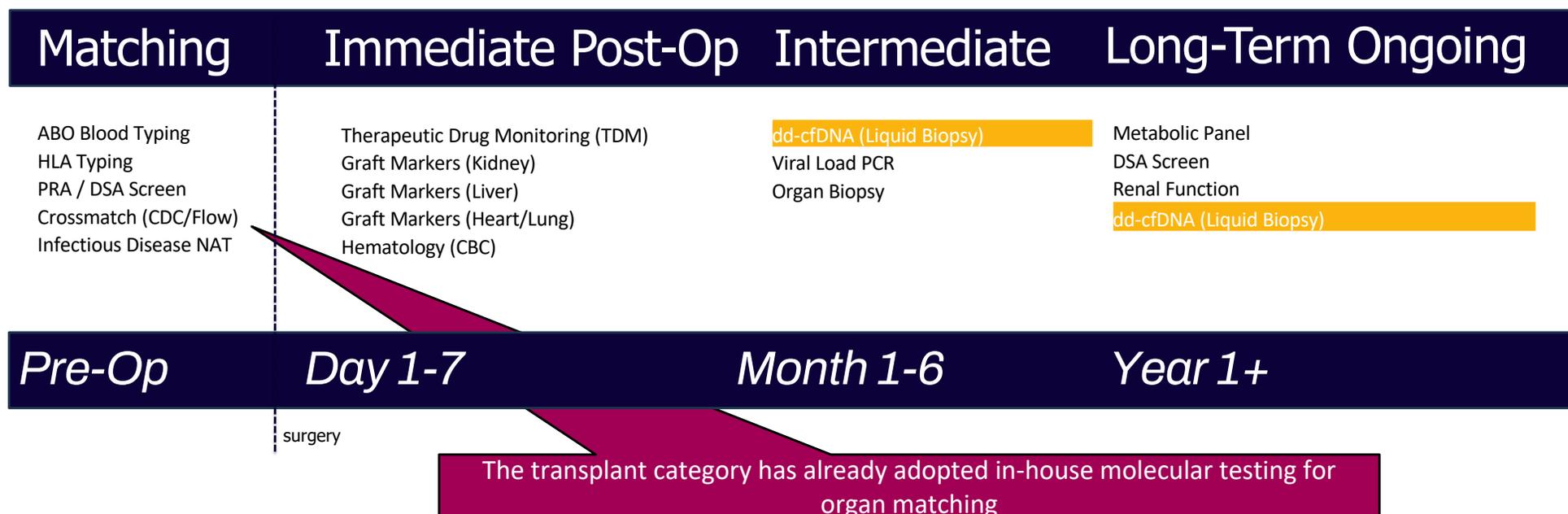
## Lab Directors

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

## Hospital Administrators

- ✓ Revenue generation opportunities
- ✓ Research-forward reputation

# 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.



+



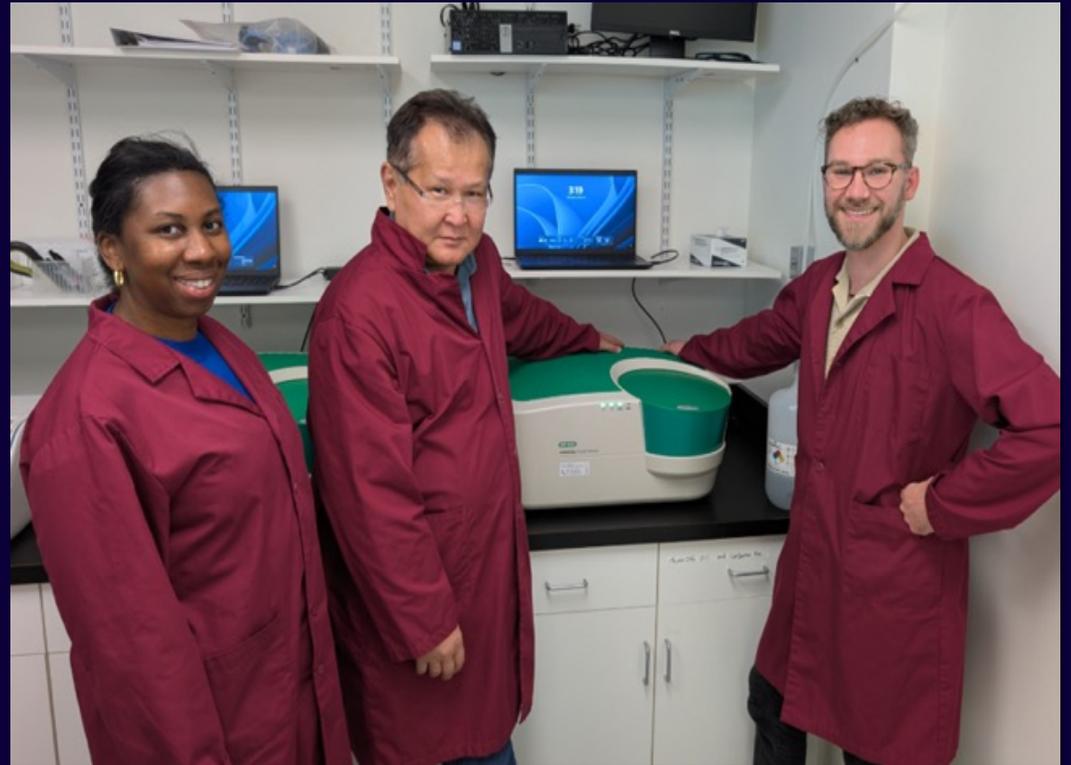
## Strategic Partnership

- ✓ 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 + Bio-Rad

- ✓ Demonstrating clinical utility of digital PCR
- ✓ 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.*

# GraftAssure Deployments

- 22 Sites
- 9 Countries
- 3 Continents
- Institutes planning to publish multiple abstracts in 2026
- Third party head-to-head data emerging that is favorable to iMDx

Transplant Center Laboratory Customer	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	✓	
Heidelberg 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	✓	

Many names redacted for competitive sensitivity

**After FDA submission for GraftAssureDx (kidney) in March 2026  
Goal of expanding rapidly into heart transplant testing**

**\$105 million estimated TAM in the United States  
\$240 million estimated TAM globally**

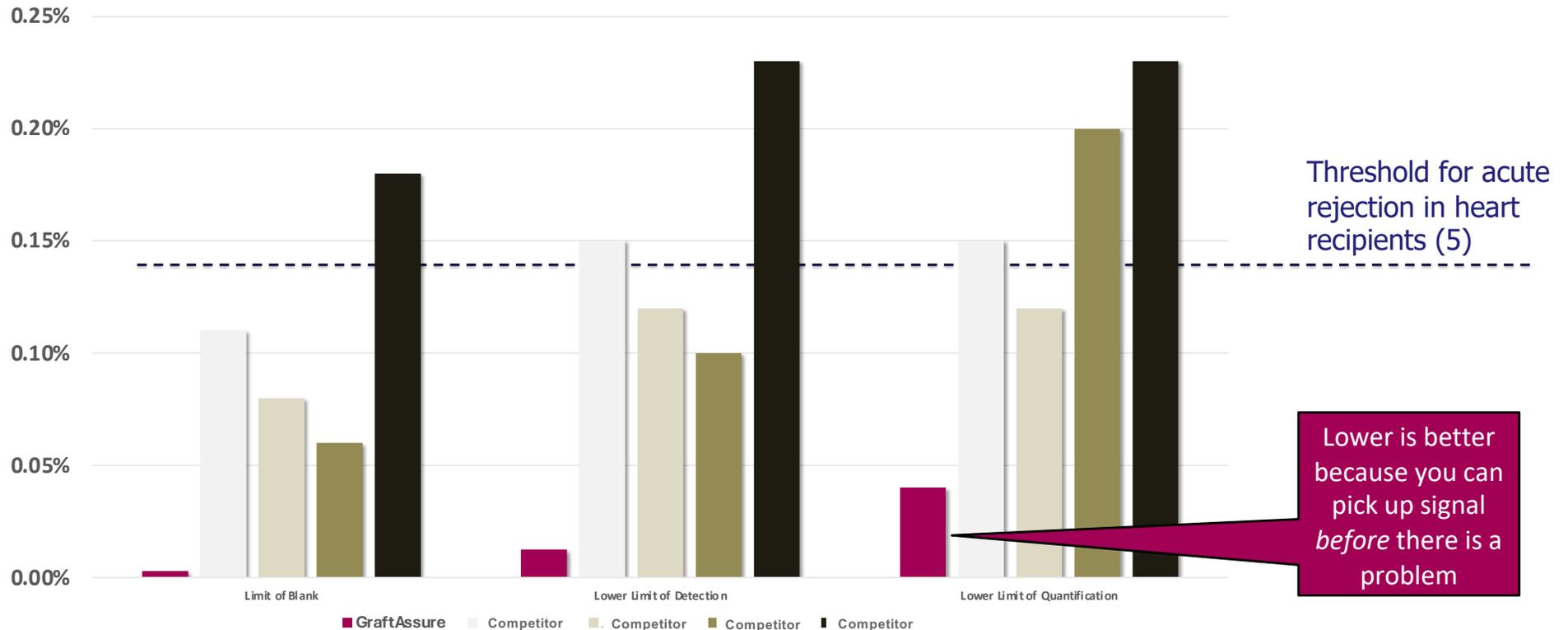
- ✓ Significance of cfDNA results of heart will increase site adoption
- ✓ Higher testing frequency per patient
- ✓ Higher clinical stakes
- ✓ Further adoption incentive for hospitals
- ✓ Rapid development: GraftAssure is designed to be organ-agnostic
- ✓ Target 2027 heart kit sales

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 MoDx 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.

# Heart: The Digital PCR *Advantage*

Analytical Performance



## References

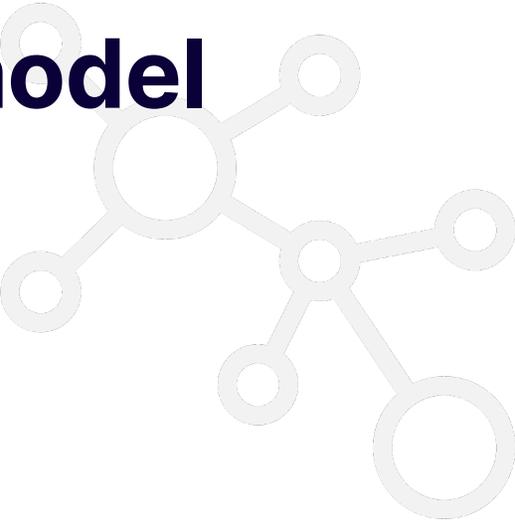
- (1) Yücel Altuğ, PhD, Analytical Validation of a Single-nucleotide, Polymorphism-based Donor-derived Cell-free DNA Assay for Detecting Rejection in Kidney Transplant Patients. *Transplantation* 2019 Vol 103 No: 12. doi: 10.1097/TP.0000000000002665
- (2) Wong L, The Evolution and Innovation of Donor-Derived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

# IP attractive to industry partners

## Multiple strategic partnership opportunities

IP Category	Products	Product Partner	Service Lab Partner
Organ Transplant	<p>GraftAssure <b>Dx</b><sup>TM</sup> Decentralized Transplant Monitoring</p> <p>GraftAssure <b>CORE</b><sup>TM</sup> Personalized Transplant Monitoring</p> <p>GraftAssure <b>IQ</b><sup>TM</sup> For Research Use Only</p>	Bio-Rad signed Q2 2024, potential for expansion	National reference lab signed Q1 2026, potential for expansion
Oncology Therapy Selection	<p>DETERMA <b>IQ</b><sup>TM</sup></p> <p>Onco<b>TIME</b><sup>TM</sup></p>	Development letter of intent with major instrument maker signed Q2 2025	
Oncology Therapy Monitoring	<p>DETERMA <b>CNI</b><sup>TM</sup></p>		

# 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 **lifetime value** often exceeds 30 years.

# A pure play on **major industry tailwinds**

## Precision medicine

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**Genomics** innovation enables personalized medicine.

## Localized care

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

## Rapid care

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

# iMDx Investment Summary Recap

✔ **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

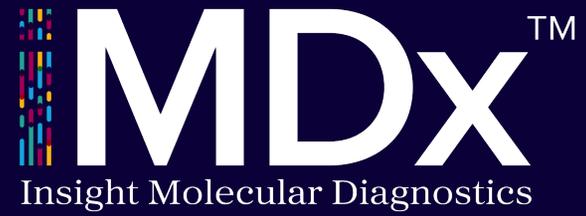
✔ Go-to-market **strategic partner** and equity investor

- Industry leader Bio-Rad Laboratories, Inc. (NYSE:BIO) signed in Q2 2024
- Opportunities for future milestone-based investments

✔ **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



# Appendix

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# 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

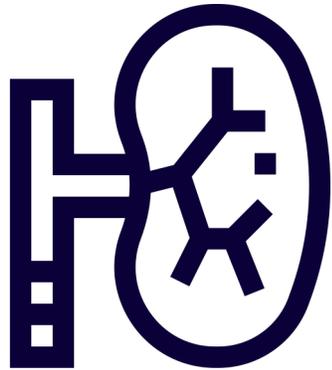
**Molecular** – relating to or consisting of molecules, which are groups of atoms bonded together, representing the smallest fundamental unit of a chemical compound that can take part in a chemical reaction

**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**<sup>TM</sup>  
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**

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

# Transplant: Leading the science

**Our centralized assay, GraftAssureCore, has been validated in clinical studies with an aggregate of 1,214 patients and 4,917 samples.**

## 226 Liver Recipients

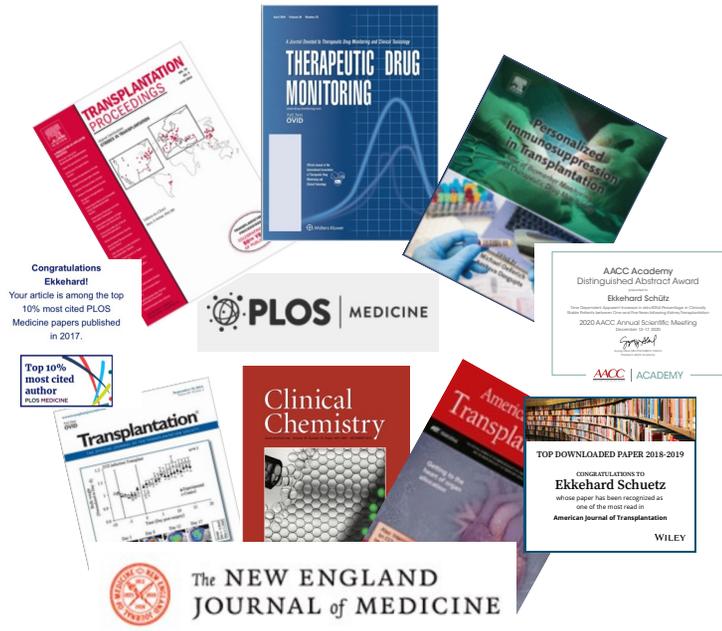
PLoS Med (2017)<sup>1</sup>, Liver Transpl (2022)<sup>2</sup>, Transplantation (2014)<sup>3,4</sup>

## 901 Kidney Recipients

ERA Congress (2025)<sup>5</sup>, Transplant Direct (2025)<sup>6</sup>, Nephrology Dialysis Transplantation (2024)<sup>7</sup>, NEJM (2024)<sup>8</sup>, Transplant International (2024)<sup>9</sup>, Kidney International Reports (2023)<sup>10</sup>, J Clin Med (2023)<sup>11</sup>, Transplant Direct (2021)<sup>12</sup>, Clin Chem (2020)<sup>13</sup>, Am J Transplant (2019)<sup>14</sup>

## 87 Heart Recipients

Transplantation (2022)<sup>15</sup>



1. Schütz E, Fischer A, Beck J, et al. (2017) Graft-derived cell-free DNA, a noninvasive early rejection and graft damage marker in liver transplantation: A prospective, observational, multicenter cohort study. *PLoS Med* 14(4):e1002286. 2. Baumann AK, Beck J, Kirchner T, et al. (2022) Elevated fractional donor-derived cell-free DNA during subclinical graft injury after liver transplantation. *Liver Transpl* 28(12):1911. 3. Oellerich M, Schütz E, Kanzow P, et al. (2014). Use of Graft-Derived Cell-Free DNA as an Organ Integrity Biomarker to Reexamine Effective Tacrolimus Trough Concentrations After Liver Transplantation. *36(2):136-40*. 4. Kanzow P, Kohlmar O, Schütz E, et al. (2014). Graft-derived cell-free DNA as an early organ integrity biomarker after transplantation of a marginal HELLIP syndrome donor liver. *Transplantation* 98(5):e43-5. 5. Loi L, Reineke M, Zeller M et al. (2025). Presented at ERA Congress, Vienna, Austria, June 2025, Abstract #1269. 6. Akifova A, Budde K, Choi M, et al. (2025). Association of Blood Donor-derived Cellfree DNA Levels With Banff Scores and Histopathological Lesions in Kidney Allograft Biopsies: Results From an Observational Study. *Transplant Direct* 11: e1794; doi: 10.1097/TXD.0000000000001794. 7. Akifova A, Osmanodja B, Amann K, et al. (2024). Donor-derived cell-free DNA monitoring for early diagnosis of antibody-mediated rejection after kidney transplantation: a randomized trial. *Nephrology Dialysis Transplantation* DOI: 10.1093/ndt/gfae282. 8. Mayer KA, Schrezenmeier E, Diebold M, et al. (2024). A Randomized Phase 2 Trial of Felzartamab in Antibody-Mediated Rejection. *NEJM* DOI: 10.1056/NEJMoa2400763. 9. Osmanodja B, Akifova A, Budde K, et al. (2024). Donor-Derived Cell-Free DNA as a Companion Biomarker for AMR Treatment With Daratumumab: Case Series. *Trans Int* 37:13213. 10. Akifova A, Budde K, Choi M, et al. (2023). Donor-Derived Cell-Free DNA in Biopsy-Proven Antibody-Mediated Rejection Versus Recurrent IgA Nephropathy After Kidney Transplantation. *Kidney International Reports* doi:10.1016/j.ekir.2023.07.011. 11. Osmanodja B, Akifova A, Oellerich M, et al. (2023). Donor-Derived Cell-Free DNA for Kidney Allograft Surveillance after Conversion to Belatacept: Prospective Pilot Study. *J Clin Med* doi/10.3390/jcm12062437. 12. Osmanodja B, Akifova A, Budde K, et al. (2021). Absolute or Relative Quantification of Donor-derived Cell-free DNA in Kidney Transplant Recipients: Case Series. *Transplant Direct* 7(11):e778. 13. Schutz E, Asendorf T, Beck J, et al. (2020) Time-dependent apparent increase in dd-cfDNA percentage in clinically stable patients between one and five years following kidney transplantation. *Clin Chem* 66(10):1290. 14. Oellerich M, Shipkova M, Asendorf T, et al. (2019) Absolute quantification of donor-derived cell-free DNA as a marker of rejection and graft injury in kidney transplantation: Results from a prospective observational study. *Am J Transplant* 19(11):3087. 15. Knüttgen F, Beck J, Dittlich M et al. (2022). Graft-derived Cell-free DNA as a Noninvasive Biomarker of Cardiac Allograft Rejection: A Cohort Study on Clinical Validity and Confounding Factors. *Transplantation* 106(3):615-622.

# Our formula

**Regulated**  
**+ Reimbursed**  
**+ Clinically Useful**  

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**= Rapid Adoption**



# 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.

