

Investor Presentation

NASDAQ:IMDX

May 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.



MISSION

Decentralize access to
novel molecular diagnostic
testing to improve patient
outcomes

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⁽¹⁾
- 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**TM
Decentralized Transplant Monitoring

GraftAssure **CORE**TM
Personalized Transplant Monitoring

GraftAssure **IQ**TM
For Research Use Only

Transplant

DETERMA **IO**TM

DETERMA **CNI**TM

Onco**TIME**TM

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
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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, 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.

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

(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.
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(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)

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


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

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

(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**


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

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

(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, 2013¹
- ✓ Definitive Clinical Publication, 2019²
- ✓ US Patent Issued, 2021³
- ✓ 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

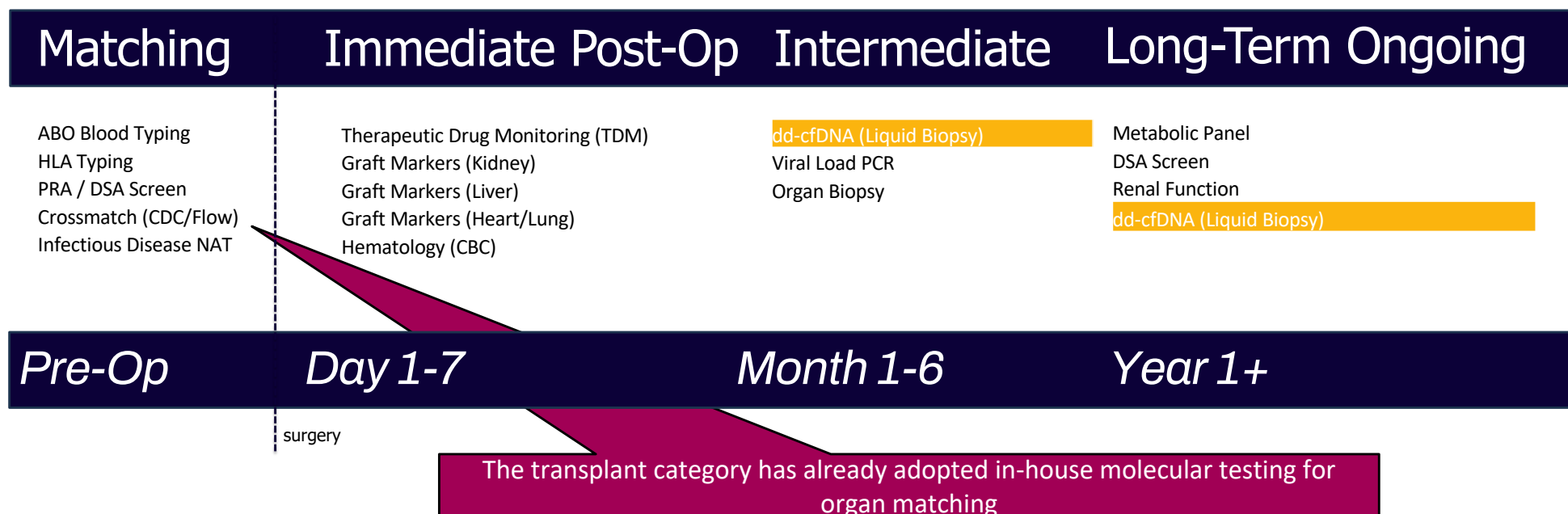
Lab Directors

- ✓ 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.



+



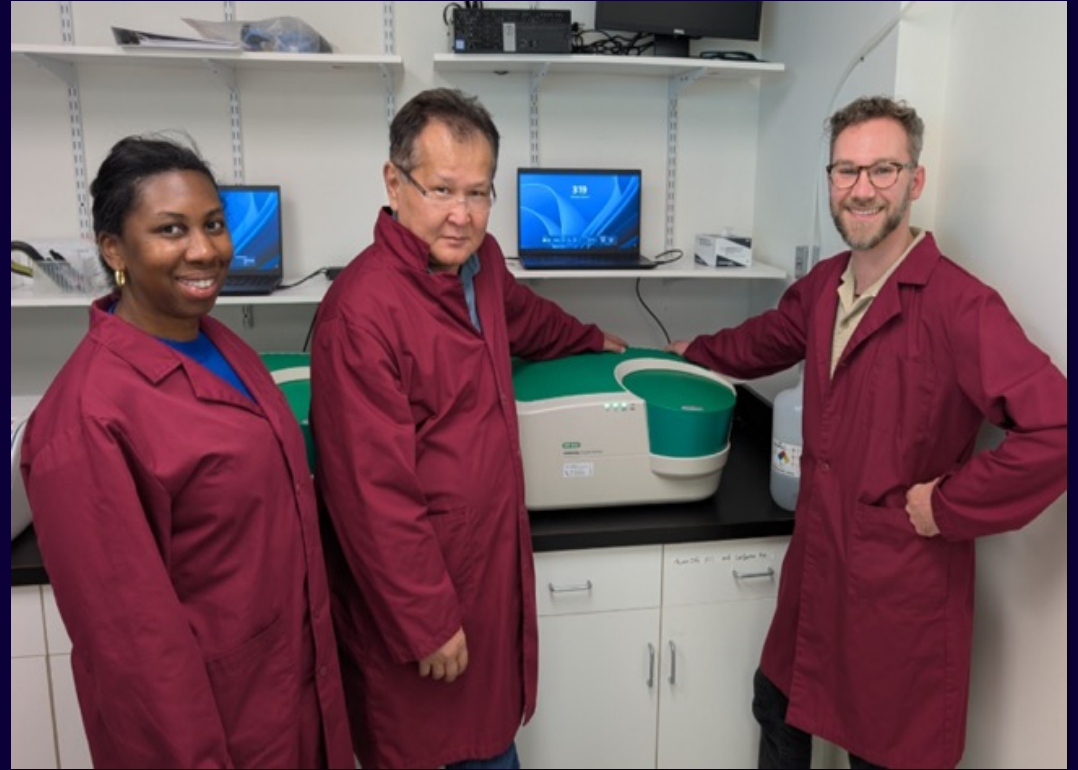
Strategic Partnership

- ✓ 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**

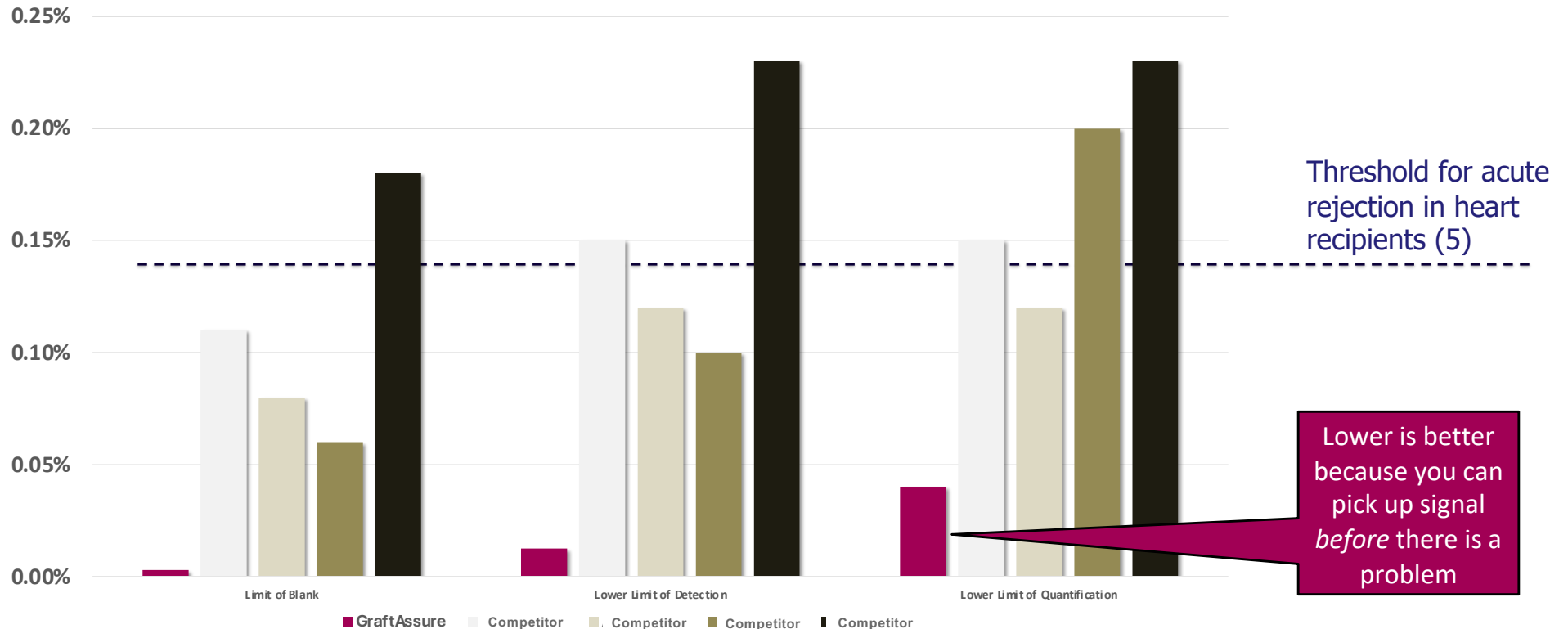
- ✓ Significance of cfDNA results of heart will increase site adoption
- ✓ Higher testing frequency per patient
- ✓ Higher clinical stakes
- ✓ Further adoption incentive for hospitals
- ✓ Rapid development: GraftAssure is designed to be organ-agnostic
- ✓ Target 2027 heart kit sales

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



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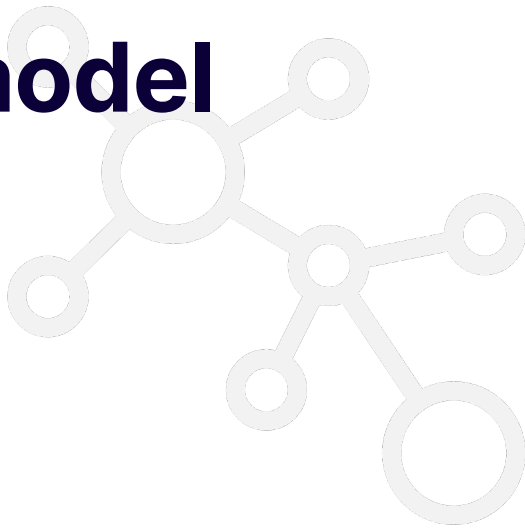
- (1) Yücel Altuğ, PhD, Analytical Validation of a Single-nucleotide, Polymorphism-based Donor-derived Cell-free DNA Assay for Detecting Rejection in Kidney Transplant Patients. *Transplantation* 2019 Vol 103 No: 12. doi: 10.1097/TP.0000000000002665
- (2) Wong L, The Evolution and Innovation of Donor-Derived 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^{Dx}TM Decentralized Transplant Monitoring</p> <p>GraftAssure^{CORE}TM Personalized Transplant Monitoring</p> <p>GraftAssure^{IQ}TM 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^{IQ}TM</p> <p>Onco^{TIME}TM</p>	Development letter of intent with major instrument maker signed Q2 2025	
Oncology Therapy Monitoring	<p>DETERMA^{CNI}TM</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

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.

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

