IMDx™
Insight Molecular Diagnostics

Investor Presentation

NASDAQ: IMDX | November 2026

IMDXINC.COM

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MISSION

Decentralize access to novel molecular diagnostic testing to improve patient outcomes

iMDx Investment Highlights

Disruptive approach	Empower local labs to test in-house with kits, versus sending out to central labs in large
Full R&D pipeline	Expected to fuel portfolio expansion over the next decade with organ-agnostic technology
Multi-billion $ mkt opportunity	Greenfield opportunity and full R&D pipeline fuel rapid growth over the next decade
Strategic credibility	Merging established science with leading diagnostics partner, Bio-Rad Laboratories
Compelling value proposition	Attractive reimbursement drives potential attractive margin, recurring revenue stream for transplant centers & iMDx [1]
IP portfolio	Attractive to partners and enables value protection
Science-driven team	Experienced in molecular diagnostics and managing rapid growth

1. Tied to MolDX LCD on surveillance testing and the fact that transplant hospitals have well-established kidney transplant programs

Experienced Leadership Pioneering Molecular Diagnostics & Disruptive Growth



Josh Riggs

President & Chief Executive Officer

Bethesda group

life technologies

IT



Ekkehard Schütz, MD, PHD, FADLM

Chief Science Officer

GEORG-AUGUST-UNIVERSITÄT GÖTTINGEN

CHRONIX BIOMEDICAL



Yuh-Min (Johnson) Chiang, PHD

Chief Technology Officer

ALVEO TECHNOLOGIES, Inc.

ThermoFisher SCIENTIFIC

Cepheid A better way.

FOUNDATION MEDICINE



Andrea James

Chief Financial Officer

AXON

Colliers Securities

TESLA



Donnie Purto

SVP Sales

natera

PerkinElmer Science with Purpose

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Innovative science meets simple business model

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

Diagnostics has a history of moving closer to the patient

Familiar test	1. Specialized laboratory	2. Local / point-of-care testing	3. Testing at home
Pregnancy	**1920s–1930s:** Animal-based laboratory tests	**1960s–1970s:** Faster immunoassays and professional test kits	**1978:** Home pregnancy tests reach U.S. consumers
Blood sugar	**1910s–1920s**: Laboratory blood glucose measurement	**1960s–1970s:** Blood test strips and early meters	**1980s:** Portable home glucose meters
COVID-19	**Early 2020:** Laboratory PCR testing	**March 2020:** First FDA-authorized point-of-care test	**December 2020:** First FDA-authorized OTC home test

We are driving this trend in the molecular testing category, and our first strategic market is transplanted organ health.

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Diagnostics has a history of moving closer to the patient

Familiar test	1. Specialized laboratory	2. Local / point-of-care testing	3. Testing at home
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COVID-19	**Early 2020:** Laboratory PCR testing	**March 2020:** First FDA-authorized point-of-care test	**December 2020:** First FDA-authorized OTC home test

Next step for transplant molecular diagnostics: bring the test to the local lab.

Transplant dd-cfDNA (molecular biomarker)	Still relies on a send-out model	iMDx seeks to enable testing by local laboratories with GraftAssure technology	

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Building a kitted product engine: Why transplant?

High Clinical Demand

Will doctors order it?

Strong Reimbursement

Can we get paid?

IP Protected

Do we have a right to sell it?

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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.

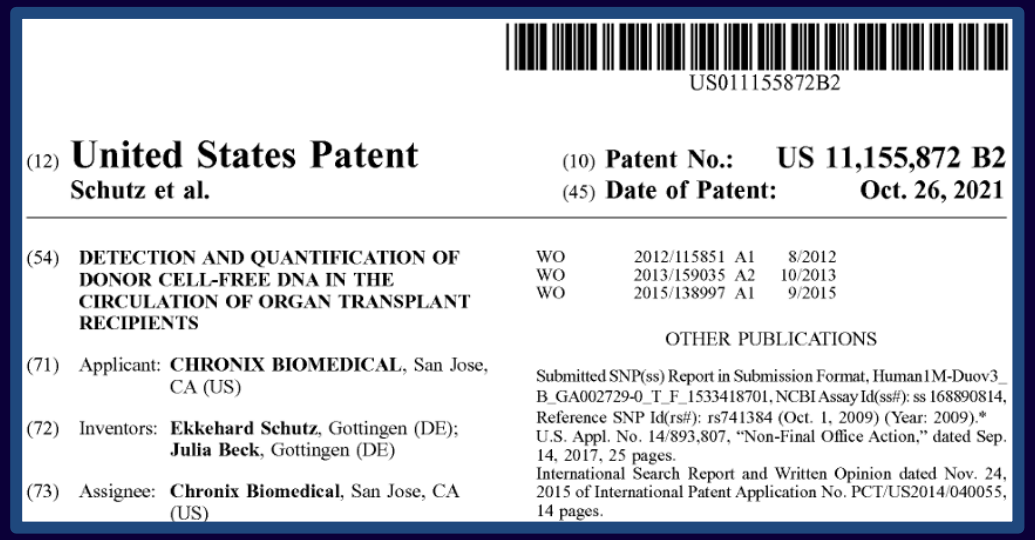
Valenzuela NM, Lan J, Hitchman KMK, Amstutz U, Bloom RD, Levine DJ, Mengel M, Mannon RB. 2025 Report of the Sensitization in Transplantation: Assessment of Risk Working Group on donor-derived cell-free DNA: establishing analytical validity as the basis for appropriate and effective clinical utilization. Am J Transplant. 2026;26(1):20-31. doi:10.1016/j.ajt.2025.08.036

Strong Reimbursement

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

– MolDX (Palmetto GBA) set GraftAssureCore's Medicare rate at $2,753 per result in May 2025,(iMDx press release, May 19, 2025). This matches the CMS national Medicare rate of $2,753.25 per dd-cfDNA test (CMS 2026 Clinical Laboratory Fee Schedule, CY 2026 Q4 release, HCPCS 0118U, 0493U and 0540U). GraftAssure bills under PLA code 0690U from October 1, 2026; MolDX does not publish test-level prices.

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)

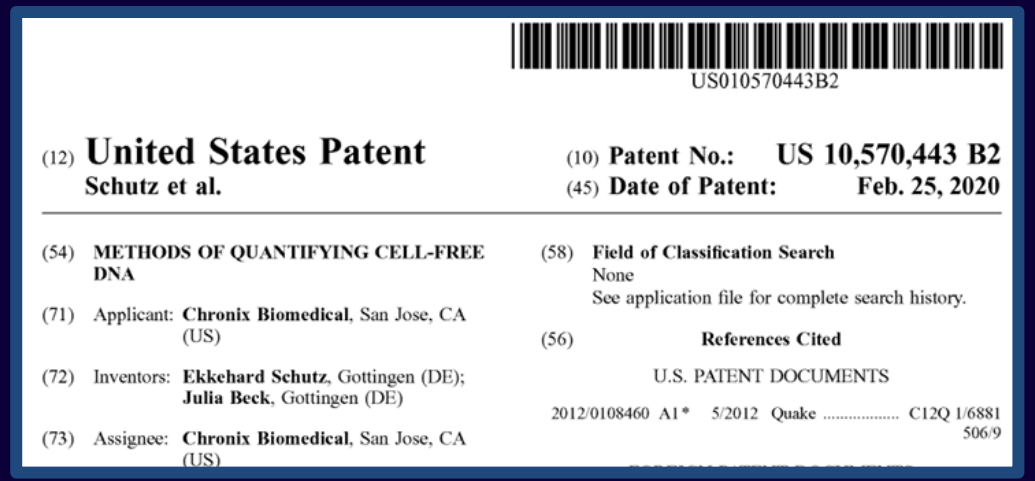
(72) Inventors: **Ekkehard Schutz**, Gottingen (DE); **Julia Beck**, Gottingen (DE)

(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)

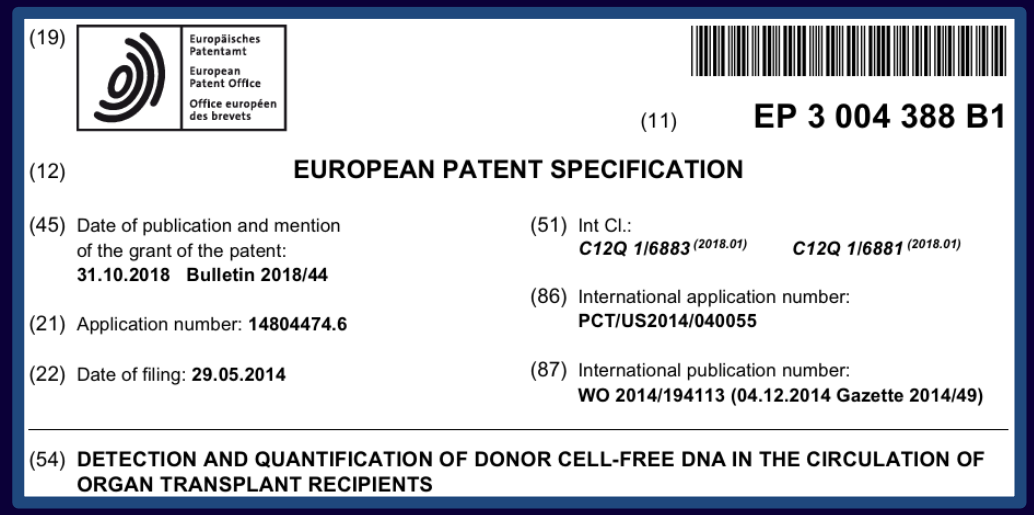
(73) Assignee: **Chronix Biomedical**, San Jose, CA (US)

(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**

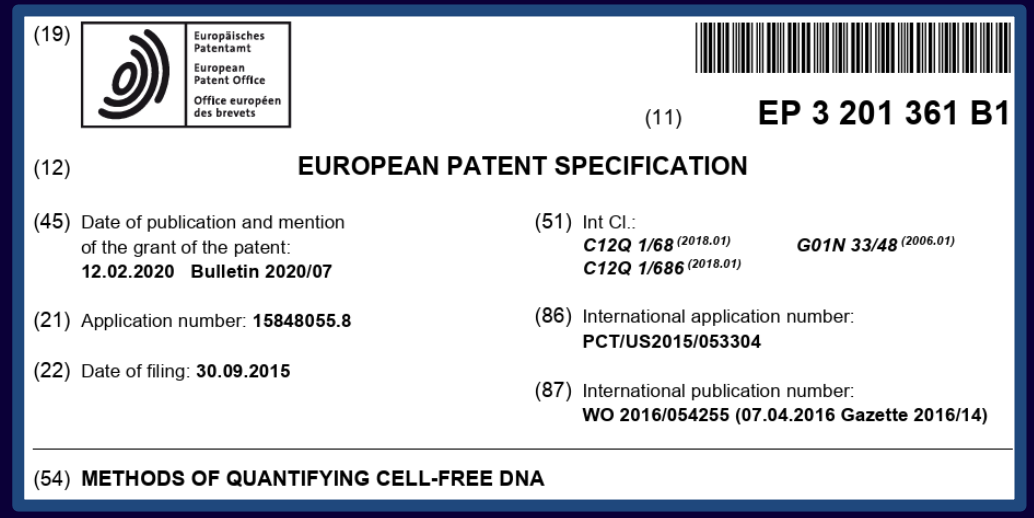
(22) Date of filing: **29.05.2014**

(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**

Our products and pipeline

Transplant Products and Candidates		
Kidney	**Type of test**	**Availability and where run**
GraftAssure Dx™	IVD: Kitted *in vitro* diagnostic test	Submitted for FDA review March 2026
GraftAssure CORE™	LDT: Laboratory-developed test	Available as a send-out test via iMDx CLIA lab
GraftAssure IQ™	RUO: Kitted research-use-only test	Introduced summer 2024

Transplant product pipeline

Heart

Lung

Urine testing

Oncology pipeline

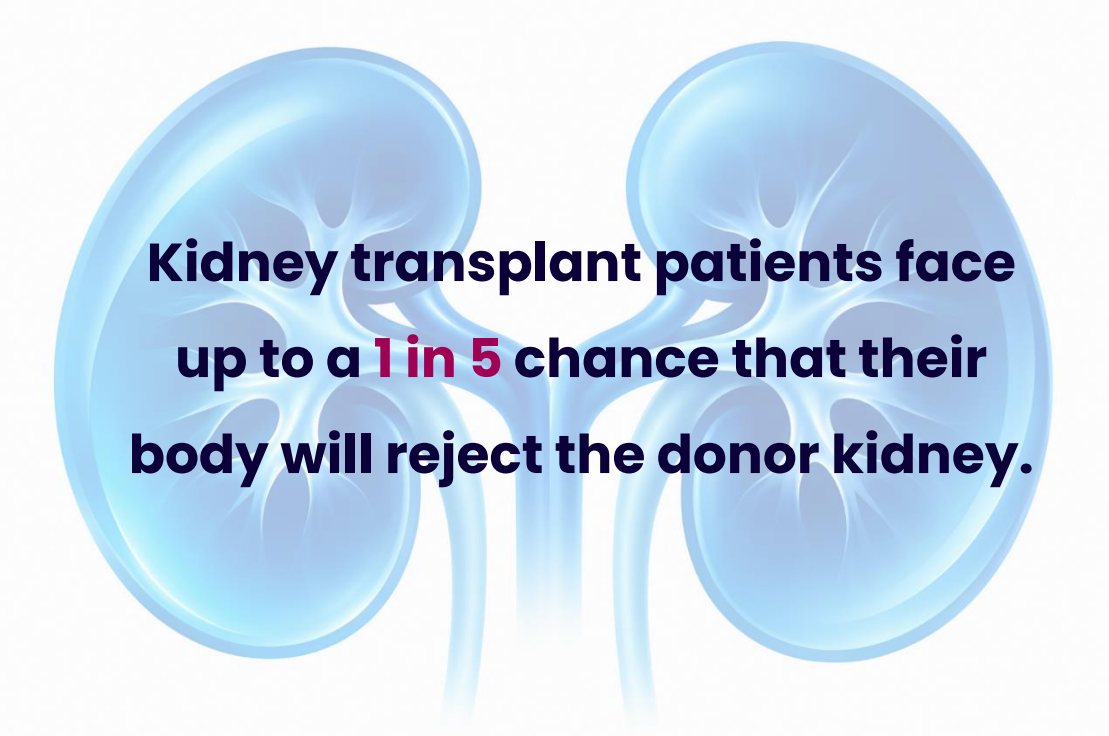
DETERMA IO™

DETERMA CNI™

OncoTIME™

iMDx™

Transplant testing matters



iMDx's test is designed to find 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

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Diagnostic journey of a transplant patient [1]

			BEFORE SURGERY	SURGERY	TRANSPLANTED ORGAN HEALTH MONITORING			
	TEST	WHERE RUN	Waitlist Months to years	Surgery and stay Days 0 to 7	Recovery Weeks 2 to 12	Back to routine Months 4 to 12	Settling in Years 2 and 3	Long term Years 4 to 10
ORGAN MATCHING	ABO blood type	In-house	Once					
	HLA tissue typing	In-house	Once					
	HLA antibody screen	In-house	Every 3 months					
	APOL1 risk gene	Send out	If indicated					
	Crossmatch	In-house		At organ availability				
ORGAN HEALTH MONITORING	Tacrolimus level	In-house		Daily	1 to 3 a week	Every 2 to 4 weeks	Every 2 to 3 months	Every 2 to 3 months
	Kidney function (CMP)	In-house		Daily	1 to 3 a week	Every 2 to 4 weeks	Every 2 to 3 months	Every 2 to 3 months
	Blood count (CBC)	In-house		Daily	1 to 3 a week	Monthly	Yearly	Yearly
	BK virus PCR	In-house			Monthly	Monthly to quarterly	Quarterly, year 2	
	Donor antibodies (DSA)	In-house			Month 3	Month 12	Yearly	Yearly
	dd-cfDNA, today	Send out			6 tests		8 tests (4 per year)	For cause / no limit
	GraftAssure dd-cfDNA	In-house			6 tests		8 tests (4 per year)	For cause / no limit

Transplant hospitals perform *most* tests in-house. GraftAssure is designed to enable in-house dd-cfDNA testing, a natural fit.

KEY: ABO: blood group system, HLA: human leukocyte antigen, APOL1: apolipoprotein L1, CMP: comprehensive metabolic panel, CBC: complete blood count, DSA: donor-specific antibodies

1. Typical schedule; timing and where tests run vary by center. dd-cfDNA follows the final MolDX LCD: 6 tests in year 1, 4 in year 2 and 4 in year 3, then for cause. Lab timing: KDIGO 2009; AST 2019 (BK virus); ESOT 2023 (DSA).

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National average reimbursement rates [1]

	TEST	Average Reimbursement	BEFORE SURGERY Waitlist Months to years	SURGERY Surgery and stay Days 0 to 7	TRANSPLANTED ORGAN HEALTH MONITORING Recovery Weeks 2 to 12	Back to routine Months 4 to 12	Settling in Years 2 and 3	Long term Years 4 to 10
ORGAN MATCHING	ABO blood type	$3	Once					
	HLA tissue typing	$405	Once					
	HLA antibody screen	$64	Every 3 months					
	APOL1 risk gene	$137	If indicated					
	Crossmatch	$109		At organ availability				
ORGAN HEALTH MONITORING	Tacrolimus level	$14		Daily	1 to 3 a week	Every 2 to 4 weeks	Every 2 to 3 months	Every 2 to 3 months
	Kidney function (CMP)	$11		Daily	1 to 3 a week	Every 2 to 4 weeks	Every 2 to 3 months	Every 2 to 3 months
	Blood count (CBC)	$8		Daily	1 to 3 a week	Monthly	Yearly	Yearly
	BK virus PCR	$43			Monthly	Monthly to quarterly	Quarterly, year 2	
	Donor antibodies (DSA)	$650			Month 3	Month 12	Yearly	Yearly
	dd-cfDNA, today	$2,753			6 tests		8 tests (4 per year)	For cause / no limit
	GraftAssure dd-cfDNA	$2,753			6 tests		8 tests (4 per year)	For cause / no limit

Transplant hospitals perform *most* tests in-house. GraftAssure is designed to enable in-house dd-cfDNA testing, a natural fit.

KEY: ABO: blood group system, HLA: human leukocyte antigen, APOL1: apolipoprotein L1, CMP: comprehensive metabolic panel, CBC: complete blood count, DSA: donor-specific antibodies

1. CMS 2026 Clinical Laboratory Fee Schedule, national payment rate per test (CY 2026 Q4 release).

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Hospital billing journey of a transplant patient[1]

		BEFORE SURGERY	SURGERY	TRANSPLANTED ORGAN HEALTH MONITORING			
TEST	Average Reimbursement	Waitlist Months to years	Surgery and stay Days 0 to 7	Recovery Weeks 2 to 12	Back to routine Months 4 to 12	Settling in Years 2 and 3	Long term Years 4 to 10
ORGAN MATCHING							
ABO blood type	$3	$3					
HLA tissue typing	$405	$405					
HLA antibody screen	$64						
APOL1 risk gene	$137	$0					
Crossmatch	$109		$109				
ORGAN HEALTH MONITORING							
Tacrolimus level	$14		$98	$462	$280	$168	$588
Kidney function (CMP)	$11		$77	$363	$220	$132	$462
Blood count (CBC)	$8		$56	$264	$72	$16	$56
BK virus PCR	$43			$129	$387	$172	
Donor antibodies (DSA)	$650			$650	$650	$1,300	$4,550
dd-cfDNA, today	$2,753			$0		$0	$0
GraftAssure dd-cfDNA	$2,753			$16,518		$22,024	For cause / no limit

Transplant hospitals perform *most* tests in-house. GraftAssure is designed to enable in-house dd-cfDNA testing, a natural fit.

KEY: ABO: blood group system, HLA: human leukocyte antigen, APOL1: apolipoprotein L1, CMP: comprehensive metabolic panel, CBC: complete blood count, DSA: donor-specific antibodies

1. Values: tests per period x CMS 2026 Clinical Laboratory Fee Schedule national rate (CY 2026 Q4 release), at the high end of each testing range.

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Hospital billing journey of a transplant patient [1]

		BEFORE SURGERY	SURGERY	TRANSPLANTED ORGAN HEALTH MONITORING			
TEST	Average Reimbursement	Waitlist Months to years	Surgery and stay Days 0 to 7	Recovery Weeks 2 to 12	Back to routine Months 4 to 12	Settling in Years 2 and 3	Long term Years 4 to 10
ORGAN MATCHING							
ABO blood type	$3	$3					
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Crossmatch	$109		$109				
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BK virus PCR	$43			$129	$387	$172	
Donor antibodies (DSA)	$650			$650	$650	$1,300	$4,550
dd-cfDNA, today	$2,753			$0		$0	$0
GraftAssure dd-cfDNA	$2,753			$38,542			For cause / no limit

Transplant hospitals perform *most* tests in-house. GraftAssure is designed to enable in-house dd-cfDNA testing, a natural fit.

KEY: ABO: blood group system, HLA: human leukocyte antigen, APOL1: apolipoprotein L1, CMP: comprehensive metabolic panel, CBC: complete blood count, DSA: donor-specific antibodies

1. Values: tests per period x CMS 2026 Clinical Laboratory Fee Schedule national rate (CY 2026 Q4 release), at the high end of each testing range.

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Hospital billing scales with transplant volume

Worked example: 50 transplants per year[1]

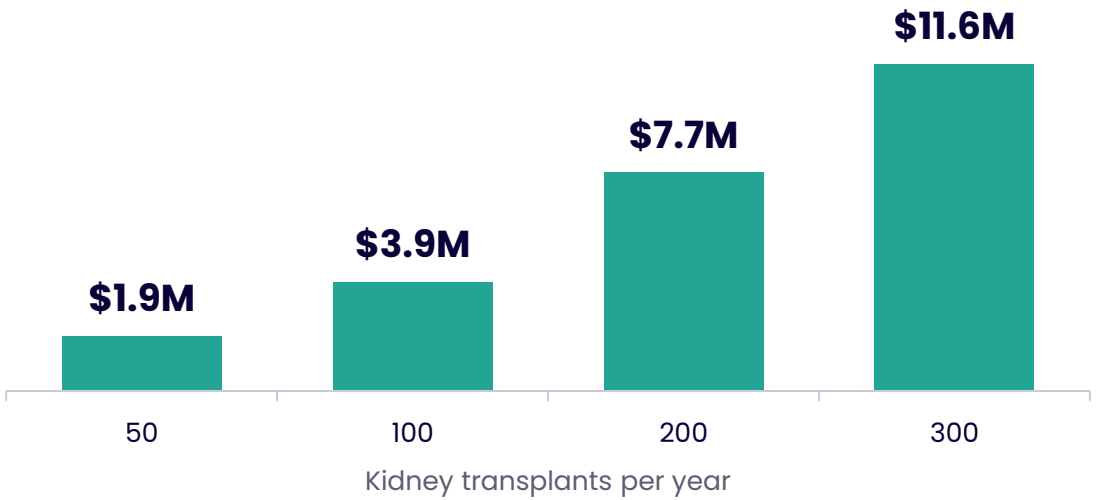
150 × **$12.8k** = **~$1.9M**

patients under management[2] | average annual billing per patient[3] | annual billing potential[4]

How it builds after go-live[4]

Year 1	Year 2	Year 3 onward
$0.8M	**$1.4M**	**$1.9M**
50 patients	100 patients	150 patients

Target annual billing potential at steady state, by center size[1,4]



Hospitals bill $0 for dd-cfDNA today because the test is sent out. GraftAssure is designed to bring that billing in-house.[5]

1. This target is solely illustrative and is not a projection or guidance, and actual results may vary significantly based on conditions related to the Company's business or industry that are out of its control. Target is based on kidney recipients only.
2. Patients under management equals transplants performed in the three most recent years (50 per year x 3). Assumes every recipient remains in the center's care and is tested on the full schedule.
3. 14 GraftAssure tests in the first three years post-transplant (6 in year one, 4 in each of years two and three) at $2,753 per test, the CMS 2026 Clinical Laboratory Fee Schedule national rate (CY 2026 Q4 release): $38,542 per patient, or about $12.8k per year. Assumes all tests are paid at that rate; actual payer mix and payment vary.
4. Steady state is reached in the third year after go-live, once three annual transplant cohorts overlap. Excludes testing beyond year three and patients transplanted before go-live.
5. dd-cfDNA testing is performed today by commercial send-out laboratories, which bill for the test. GraftAssure is designed to enable in-house testing.

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GraftAssureDx: Advancing since 2012; Under FDA review for commercial use

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

KEY

(for this and forthcoming slides):

CMS: Centers for Medicare & Medicaid Services

LDT: Lab Developed Test

RUO: Research Use Only

FDA: US Food and Drug Administration

IVD: *In Vitro* Diagnostic

GODT: Global Observatory on Donation and Transplantation

ISHLT: International Society for Heart & Lung Transplantation

SRTR: Scientific Registry of Transplant Recipients

MolDx: Program run by Medicare to prioritize reimbursement

LCD: Local Coverage Determination

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

Regulated (kitted) transplant testing is a ~$3B greenfield opportunity

Sources:
2024 GODT data (https://graphics.tts.org/2024-data-global-report.pdf) 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.

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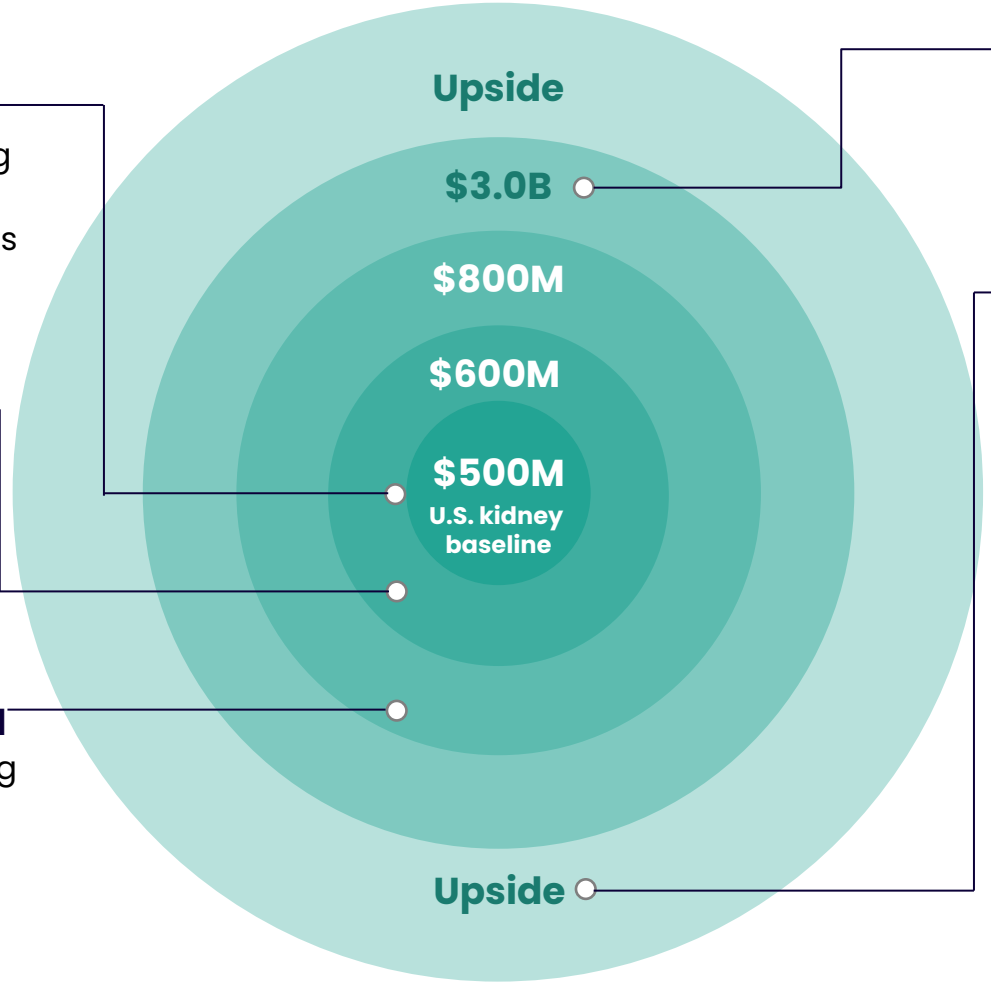
Large, growing opportunity

Tiered growth driven by product expansion & new era of surveillance

$500M U.S. KIDNEY, BASELINE
Living kidney transplant patients receiving an average of ~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 could 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.* We believe this could enable a new era of surveillance, prophylaxis and therapy monitoring: Clinicians will be trying to catch organ rejection as early as possible so that transplanted organs express less damage *and* stay in patients longer. Urine testing, which is in early development, could expand the TAM.

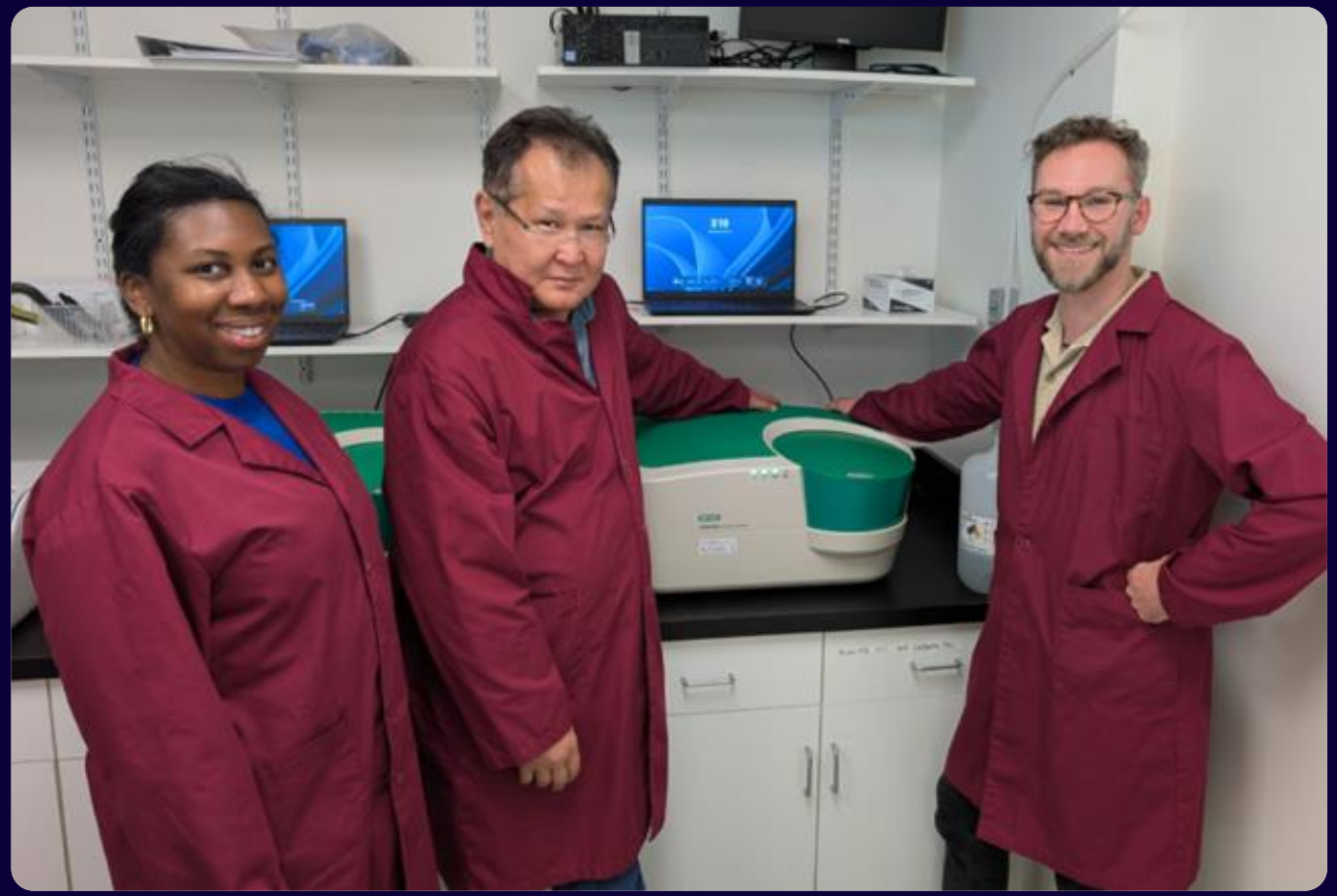
Same sources and assumptions as the global TAM slide. U.S. TAM based on 2025 OPTN U.S. transplant volumes (27,574 kidney, 4,587 heart, 3,490 lung).

iMDx™
Insight Molecular Diagnostics

Strategic Partner



We are not building this alone



iMDx product development team members receiving a Bio-Rad QX600Dx ddPCR System (IUO).

iMDx + Bio-Rad

Our GraftAssure family of assays run on Bio-Rad instruments (QX600Dx)

Bio-Rad (NYSE: BIO) is a top five shareholder and has made **four equity investments** in iMDx

Opportunity for partnership expansion, milestone-based investments

26

GraftAssure deployments

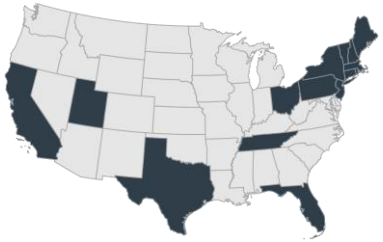
22 Sites

8 Countries

3 Continents

Benefits of pre-revenue deployments:

- ✓ Institutes publishing favorable abstracts
- ✓ Favorable independent head-to-head data
- ✓ FDA-submitted assay was improved after field-testing on research-use-only mode





Transplant Center Laboratory	Location	Pilot	FDA Trial
Vanderbilt University Medical Center	Nashville, Tennessee		✓
Tampa General Hospital	Tampa, Florida	✓	✓
Mayo Clinic in Florida	Jacksonville, Florida		✓
Baylor Scott & White Health	Dallas, Texas		✓
Cleveland Clinic	Cleveland, Ohio		✓
Intermountain Medical Center	Murray, Utah		✓
Univ. of South. Calif. Keck School of Medicine	Los Angeles, California		✓
DCI Laboratory	Nashville, Tennessee		✓
Ivy League University Lab	Northeast, US	✓	
University Hospital Lab	Singapore	✓	
University Hospital Lab	UK	✓	
University Hospital Lab	Austria	✓	
University Hospital Lab	UK	✓	
University Hospital Lab	Texas	✓	
The Charité, Humboldt University of Berlin	Berlin, Germany	✓	✓
Heidelberg University Hospital	Heidelberg, Germany	✓	✓
Major transplant hospital laboratory	Czech Republic	✓	
University Hospital Lab	Norway	✓	
University Hospital Lab	San Diego, California	✓	
California Hospital Lab	Los Angeles, California	✓	
University Hospital Lab	Mountain West, US	✓	
Large Hospital Lab	Bern, Switzerland	✓	

Pipeline includes several more in U.S., Canada and France

Some customer names redacted for competitive sensitivity

iMDx™

Large, highly concentrated market

ANNUAL TRANSPLANTS

27,000[1]

U.S. adult kidney recipients in 2025

110,467 kidney transplants globally in 2024[2]. U.S. market roughly a quarter of 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[1]



Top 50 centers do **54%** of transplants[1]



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

MEDICARE COVERAGE

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

$2,753 per test

Final MolDX LCD L40058 covers 6 tests in year 1 post transplant and up to 4 annual tests in years 2 and 3. Years 4+: surveillance testing based on published literature & societal guidelines. In addition, for cause testing at *any time* post-transplant is also covered.

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

1. U.S. kidney transplants and center-level volume: OPTN National Data, 2025 (hrsa.gov/optn/data)
2. https://graphics.tts.org/2024-data-global-report.pdf.

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GraftAssure pipeline: 7 centers in validation

Pre-launch U.S. kidney pipeline, presented on a no-names basis

7
U.S. transplant centers in validation[1]

~7%
of annual U.S. kidney transplant volume[2]

>25,000
tests per year at MolDX baseline testing frequency[3]

>$15M
annual revenue target at steady state[4]

Pipeline centers All in validation, go-lives expected 2027[5]

1. **Academic medical center** Northeast
2. **Academic medical center** Texas
3. **Academic medical center** California · **MolDX**[6]
4. **Academic medical center** California · **MolDX**[6]
5. **Academic medical center** Mountain West · **MolDX**[6]
6. **Academic medical center** Southeast · **MolDX**[6]
7. **High-volume center** Florida

Centers are investing their own resources in head-to-head validations and preparing to launch. iMDx is in active discussions with national reference laboratories.[7]

1. Company data as of November 2026. "In validation" means the center is evaluating GraftAssure in its own laboratory, including head-to-head comparison with send-out testing. Center names withheld; descriptors are general.
2. Combined annual kidney transplant volume of the pipeline centers (SRTR 2025) divided by 27,573 U.S. kidney transplants in 2025 (OPTN/UNOS).
3. Illustrative. Assumes every kidney transplant recipient at the pipeline centers is tested 14 times in the first three years post-transplant (6 in year one, 4 in each of years two and three), the Company's MolDX baseline, once three annual cohorts overlap.
4. This target is solely illustrative and is not a projection or guidance, and actual results may vary significantly based on conditions related to the Company's business or industry that are out of its control. Target is based on aforementioned test volume in note 3 multiplied by the Company's assumed revenue per test and reflects kidney only and full utilization at all centers in the third year after go-live.
5. Company expectation based on center-reported timelines; go-live dates are not assured.
6. Center located in a Medicare jurisdiction that participates in the MolDX program.
7. No agreement has been signed and there is no assurance that one will be reached.

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ASHI 2026: momentum for in-house testing

In-house dd-cfDNA testing is moving from interest toward adoption

Independent clinical data

98%+

concordance with send-out testing[1]

- **Third public head-to-head** of GraftAssure against send-out dd-cfDNA testing[1]
- **Independently presented** by a U.S. academic transplant center running GraftAssure in-house
- **6.5-hour STAT turnaround** reported for an in-house sample[2]

Reimbursement

0690U

new GraftAssure PLA code[3]

- **Effective October 1, 2026**, giving laboratories a dedicated code for billing GraftAssureDX[3]
- **Cited in the ASHI reimbursement session**, putting the code in front of HLA laboratory directors[4]

Laboratory standards

PT

proficiency testing for dd-cfDNA[5]

- **ASHI announced continued development** of proficiency testing for dd-cfDNA[5]
- **Establishes a framework for broad adoption** of in-house dd-cfDNA testing in the HLA community

1. Head-to-head comparison of in-house GraftAssure results with commercial send-out dd-cfDNA testing, presented by an independent U.S. academic transplant center at the ASHI 2026 Annual Meeting. Third publicly presented head-to-head to date.
2. Single STAT sample at one center; not representative of routine turnaround time.
3. Proprietary Laboratory Analyses (PLA) code 0690U, American Medical Association, effective October 1, 2026. A PLA code does not by itself establish coverage or payment.
4. ASHI 2026 Annual Meeting reimbursement session.
5. As communicated by ASHI at its 2026 Annual Meeting. The program is in development and is not yet offered; timing and scope are determined by ASHI.

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Winning Strategy: 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

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iMDx Investment Summary Recap

Science-driven team, experienced in molecular diagnostics and rapid **growth**

Full R&D pipeline intended to fuel growth and portfolio expansion over the next decade

IP portfolio supports market position and is attractive to potential partners

Disruptive approach to molecular diagnostic testing

- Empower local labs with kits
- Differentiated business model
- Proven, more affordable, faster tests

Growing credibility in first strategic market: Kidney transplant

- U.S. Medicare (CMS) reimbursement for GraftAssureCore received 2023, reimbursement amount increased in May 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
- Potential opportunities for future milestone-based investments

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Insight Molecular Diagnostics

THANK YOU

IMDXINC.COM

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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.

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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=40058

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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]

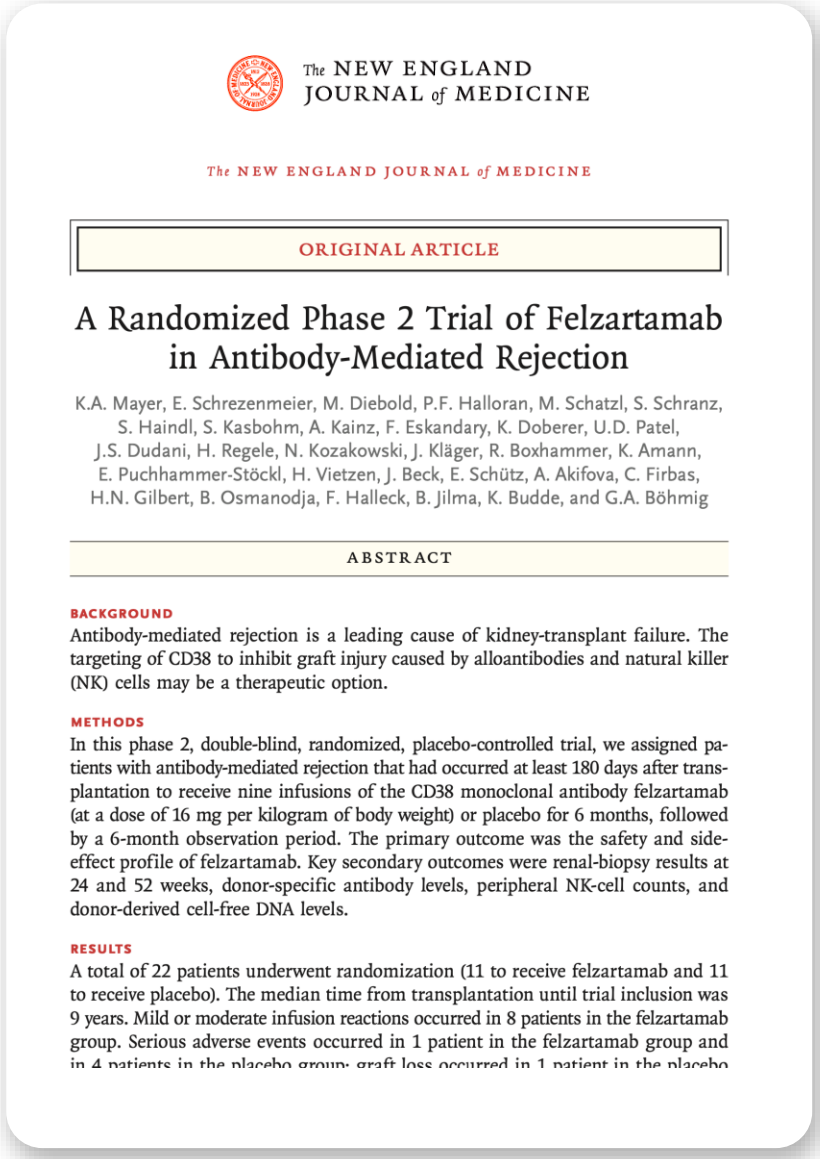
87 Heart Recipients

Transplantation (2022)[18]

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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

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High Concordance between ddPCR (GraftAssure™) and NGS (AlloSeq™) for dd-cfDNA Quantification in Kidney Transplantation

PEER-REVIEWED PUBLICATION

Reineke et al. | Clinical Chemistry | 2026 | Heidelberg University Hospital

PATIENT COHORT

141

- Kidney transplant recipients
- 254 paired plasma samples
- 97 biopsy + 44 stable patients

STUDY OBJECTIVES

- Compare ddPCR (GraftAssure) vs. NGS (AlloSeq) for dd-cfDNA % quantification
- Assess analytical concordance, biological variability, and clinical equivalency

ASSAY CONCORDANCE AT 0.5% THRESHOLD

r=0.96	99.2%	κ=0.97	0%
Pearson Correlation	Diagnostic Agreement	Cohen's Kappa	Mean Bias (Bland-Altman)

dd-cfDNA BY CLINICAL CLASSIFICATION (Mean %)

Clinical Group	AlloSeq (NGS)	GraftAssure (ddPCR)	P value
ABMR (Rejection)	1.96 ± 1.06%	2.08 ± 1.07%	0.99
TCMR	0.43 ± 0.40%	0.49 ± 0.51%	NS
Stable Graft Function	0.18 ± 0.11%	0.17 ± 0.13%	NS

Biological Variability (GraftAssure, stable patients): CV_I = 9.7% | RCV = 40.9% | Lower than all published AlloSure-based studies (61–70%)

KEY TAKEAWAYS

1. First head-to-head comparison of NGS vs. ddPCR for dd-cfDNA: results are clinically interchangeable (99.2% agreement)
2. GraftAssure's lower LLoQ (0.04% vs. 0.23%) and lower RCV enable more granular longitudinal monitoring
3. Assay equivalence supports flexible implementation: potential to reduce cost and increase testing access

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Comparison of Two Different dd-cfDNA Assays to Identify Kidney Allograft Rejection Risk: GraftAssureIQ™ RUO and Prospera™

INDUSTRY POSTER

Soares et al. | ATC 2026 | Tampa General Hospital, Tampa, FL

PATIENT COHORT

147

- Kidney transplant recipients enrolled
- 141 paired samples analyzed

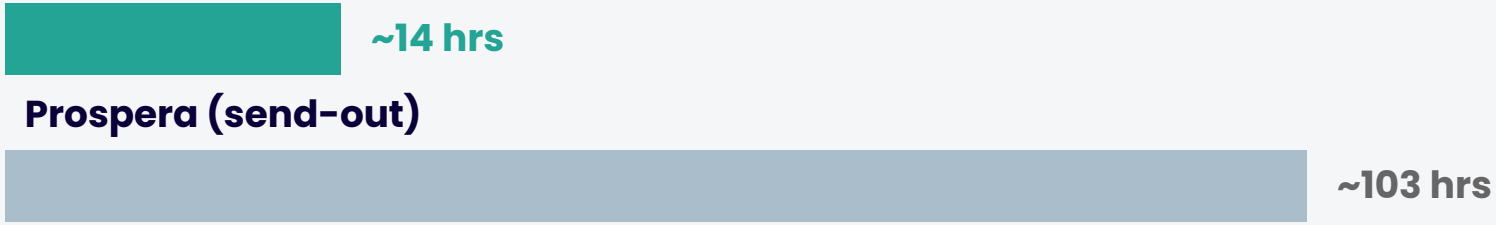
STUDY OBJECTIVES

- Compare clinical performance of GraftAssureIQ RUO vs. Prospera dd-cfDNA test
- Assess turnaround time of in-house vs. send-out testing

KEY PERFORMANCE DATA

R^2=0.93	98.6%	ρ=0.96	κ=0.95
Linearity (FA)	Diagnostic Agreement	Spearman Correlation	Cohen's Kappa

TURNAROUND TIME COMPARISON



KEY TAKEAWAYS

1. Clinical agreement was excellent — results support interchangeability for fractional dd-cfDNA assessment
2. High accuracy at both 0.5% and 1.0% cutoffs with strong agreement metrics (Accuracy 98.6%, κ=0.95)
3. GraftAssureIQ RUO delivers ~7× faster TAT than Prospera (~14 hrs vs. ~103 hrs), potentially enabling same-day clinical decisions

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Reimbursed

+ Clinically Useful

= Potential Rapid Adoption

iMDx's product appeal

Transplant centers want a test that is

easy to use and designed to return a **same day answer** that is **clinically actionable** and **cost effective**

IP attractive to industry partners

Multiple strategic partnership opportunities

IP Category	Products	Product Partner	Lab Partner
Organ Transplant	GraftAssure Dx™ Decentralized Transplant Monitoring GraftAssure IQ™ For Research Use Only GraftAssure CORE™ Personalized Transplant Monitoring	Bio-Rad signed Q2 2024, potential for expansion	In discussions with potential national lab partners
Oncology Therapy Selection	DETERMA IO™	Non-binding development letter of intent with major instrument maker signed Q2 2025	
Oncology Therapy Monitoring	OncoTIME™ DETERMA CNI™		

iMDx™

A pure play on major industry tailwinds…



Digital PCR-based precision

Digital PCR is simple, fast, and easy to use *and* yields **precise** DNA quantification



Point-of-care

Decentralized testing trends toward the patient and point-of-care testing.

Additionally, may provide economic benefits to the transplant centers



Less Invasive

Simple blood draw versus allograft biopsy..

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What's Ahead.
Next heart.

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

>$100
million estimated TAM in the United States

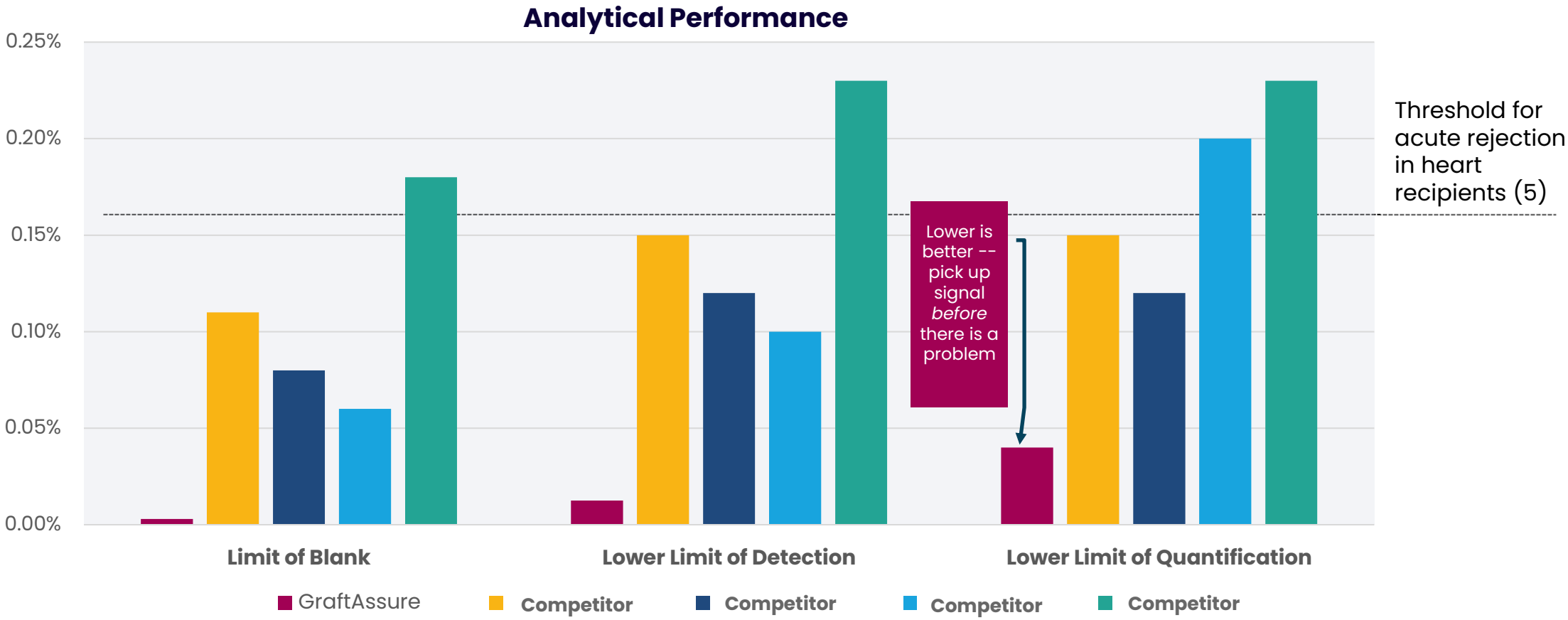
>$250
million estimated TAM globally

- Development: GraftAssure is designed to be organ-agnostic
- Goal to showcase the digital PCR advantage in heart transplant management
- Higher testing frequency per patient
- Higher clinical stakes
- Further adoption incentive for hospitals

Same sources and assumptions as the global TAM slide. U.S. TAM based on 4,587 annual U.S. heart transplants per 2025 OPTN data.

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Heart: The Digital PCR Advantage



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.

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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.