AlloSeq® cfDNA

The cutting edge solution to detect donor-derived cell-free DNA for transplant surveillance

This transplant focused innovation in organ transplant surveillance can drive better outcomes for your patients

AlloSeq cfDNA is a kit* or service** based solution that enables measurement of dd-cfDNA through a blood test

Derrick C., kidney transplant recipient

* AlloSeq cfDNA kit is CE-IVD in EU and the UK. In the rest of the world, AlloSeq cfDNA kit is for Research Use Only. Not to be used for diagnostic procedures.

** AlloSeq cfDNA Service is for Research Use Only. Not to be used for diagnostic procedures.

AlloSeq cfDNA is only available outside of the United States.

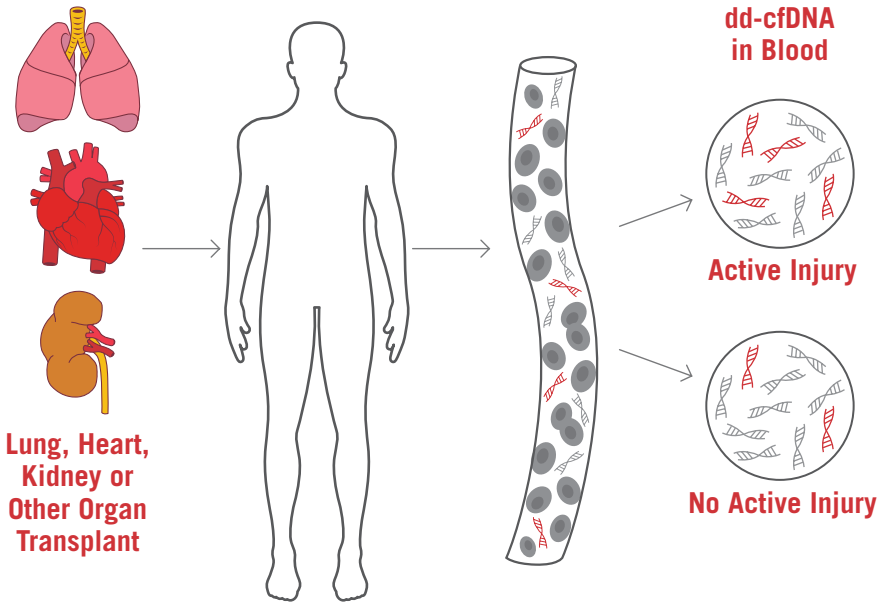
CareDx®

Cell-free DNA: a clear biomarker for organ injury

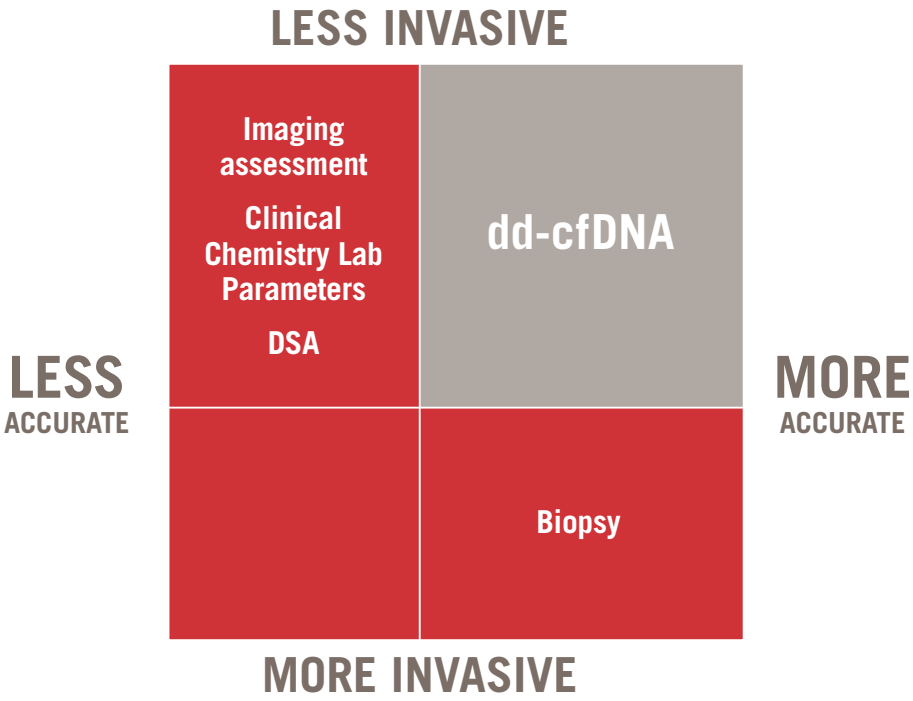
Cell-free (cfDNA) is fragmented DNA in the bloodstream that originates from cells undergoing cell injury and death

When graft injury occurs, donor-derived cell-free DNA (dd-cfDNA) increases in the blood

dd-cfDNA is a powerful, minimally invasive tool for organ transplant surveillance



AlloSeq cfDNA, innovation in action

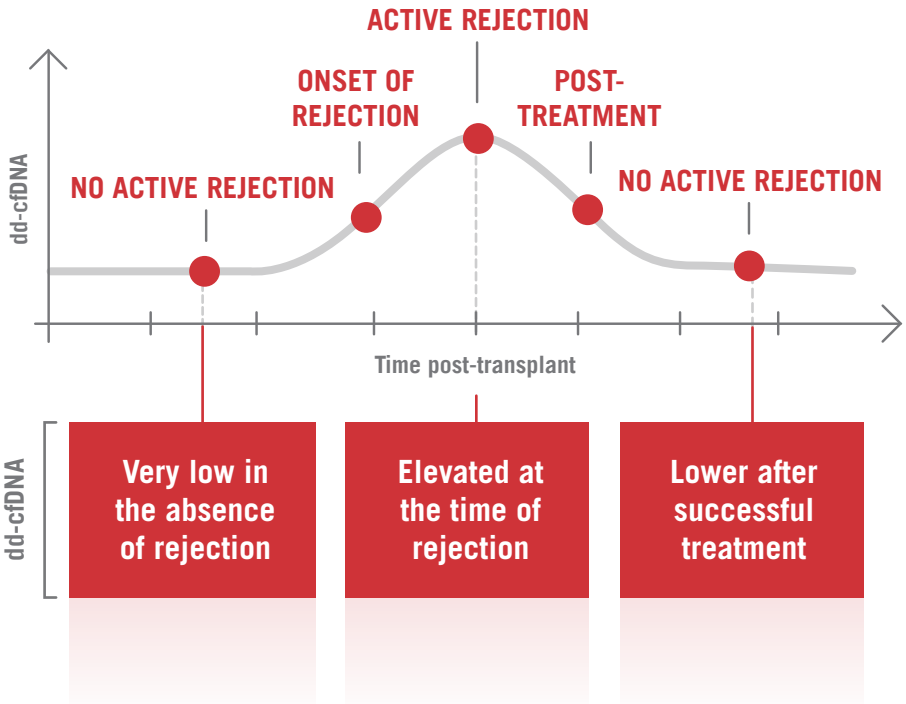


What is AlloSeq cfDNA?

+ A minimally invasive blood test that measures dd-cfDNA

+ AlloSeq cfDNA kit* is an NGS based test to run in your own lab and does not require prior genotyping
  – A simple workflow with sample to report solution within 24 hrs

+ AlloSeq cfDNA Service** is an alternate way to send your samples into CareDx lab to validate or use AlloSeq cfDNA without needing NGS equipment
  – Simple sample collection process with an easy-to-interpret report delivered directly to you



AlloSeq cfDNA can be added to to these current protocols with ease:

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AlloSeq cfDNA was developed after the successful clinical validation of AlloSure

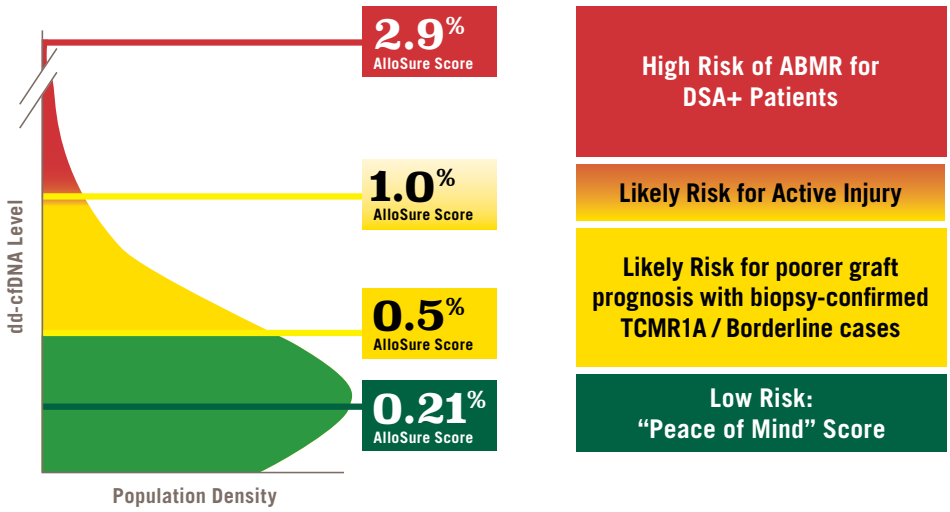
AlloSure is the dd-cfDNA surveillance service that has been clinically and analytically validated for identifying kidney, heart and lung injury.[1-6]

AlloSure is the most published dd-cfDNA test in transplantation with over 35+ peer reviewed journal publications.

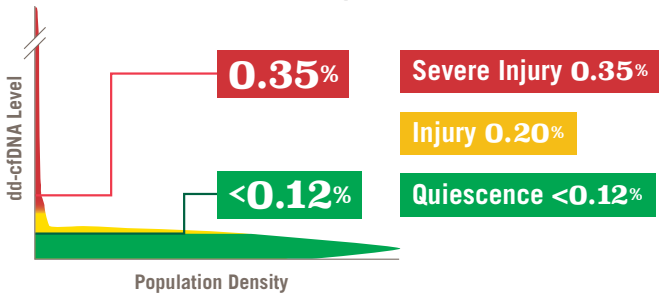
Clinical Decision Support with AlloSure

AlloSure at varying levels provides meaningful, actionable information to your existing clinical paradigm

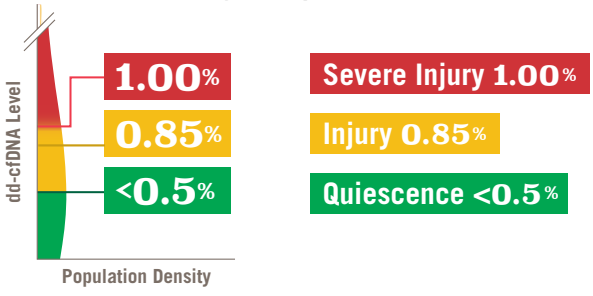
Interpretation of AlloSure dd-cfDNA in Kidney Transplantation[1-4]



Interpretation of AlloSure dd-cfDNA in Heart Transplantation[5]*



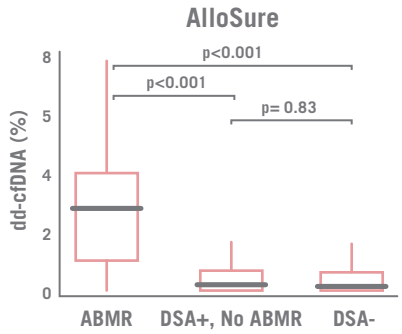
Interpretation of AlloSure dd-cfDNA in Lung Transplantation[6]*



*The severe injury category indicates a higher risk of allograft rejection, while DSA formation, infection, and other allograft injury can be identified at lower levels

AlloSure Kidney: Data Driven Insights

AlloSure is highly sensitive in distinguishing ABMR from no ABMR

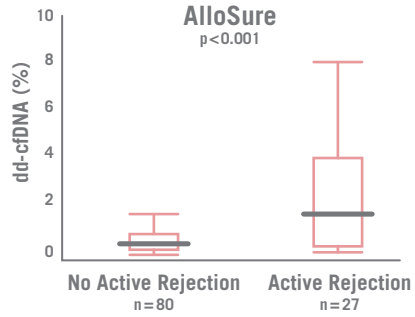


AlloSure > 2.9%
89% PPV for ABMR
in DSA+ Patients[1]

Sensitivity: 50%
Specificity: 94%
Prevalence: 40%
} At 2.9% dd-cfDNA

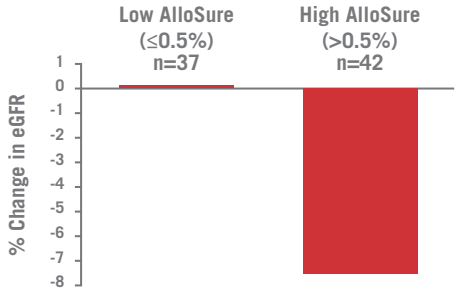
2.9% is the median from DART patients with ABMR in DSA+ Patients

AlloSure detects active rejection



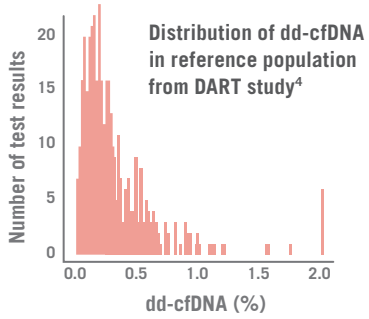
AlloSure >1.0% threshold
for Active Rejection*[2]

AlloSure differentiates biopsy confirmed TCMR1A / Borderline rejection patients



AlloSure >0.5% for eGFR Decline
in TCMR1A/Borderline Patients[3]

Reassurance with a low AlloSure score



AlloSure < 0.21% has 95% NPV
for Active Rejection*[4]

Sensitivity: 85%
Specificity: 33%
Prevalence: 10%
} At 0.21% dd-cfDNA

0.21% is the median from DART healthy stable recipients

*Active Rejection = acute/active ABMR; chronic, active ABMR; and TCMR IA and greater

dd-cfDNA surveillance testing can be added to previously established protocols

Example - For a Kidney Transplant:

Months 1, 2 post-transplant

+ Baseline to be established during this time
+ dd-cfDNA is associated with changes immediately post-transplant (ischemia reperfusion injury, DGF or medication dose changes) and may be a potential surrogate marker for these changes
+ Results may contribute to treatment decisions

Months 3, 4 post-transplant

+ dd-cfDNA changes can be used as an associated surrogate marker to monitor the waning of induction immunosuppressants
+ Continue to monitor changes from baseline
+ Maintain continuity in surveillance for patients who transition to a general nephrologist

		Time post-transplant	
Biomarker	**Condition Tested**	**1 week**	**1 Month**
Creatinine	Indirect graft function	Daily	2-3 per Week
BK Virus	Viral infection	Monthly	
DSA	Donor Specific Antibody formation	Weekly	Monthly
dd-cfDNA	**Active allograft injury**	**Monthly**	

Months 6, 9, 12 post-transplant

+ Monitor for acute rejection
+ Test along with DSA to improve the positive predictive value for antibody mediated rejection[1]

Year 2 Onward: quarterly testing through life of transplant

+ Monitor for changes in dd-cfDNA results that may occur before the onset of symptoms
+ Rejection due to ABMR increases over time and monitoring may provide an early warning of rejection[1]
+ A significant increase in dd-cfDNA may provide early insight into medication non-adherence

2-3 Months	4-6 Months	7-12 Months	12+ Months
Weekly	Every 2 Weeks	Monthly	Every 2-3 Months
	Every 3 Months		–
–	Every 6 Months		
	Every 2 Months	**Every 3 Months**	

ORDERING INFORMATION

Product	No. RXNs	Product Code
AlloSeq cfDNA - IVD	24	ASCF.1(24)-IVD
AlloSeq cfDNA - RUO	24	ASCF.1(24)
AlloSeq cfDNA Software	N/A	ASCFS1.0
AlloSeq cfDNA Service	N/A	N/A

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References

1. Jordan SC et al. *Transplant Direct.* 2018; 4:e379
2. Bloom RD et al. *J Am Soc Nephrol.* 2017; 28:2221–2232
3. Stites E, et al. *Am J Transplant.* 2020; 00:1–8
4. Bromberg JS et al. *J Appl Lab Med.* 2017; 2:309–321
5. Khush KK, et al. *Am J Transplant.* 2019 Oct;19(10):2889-2899; D-OAR is a sub-study of the Outcomes AlloMap Registry (OAR)
6. Keller, M.B et al; The Jornal of Heart and Lung Transplantation, 40(4), S148

CareDx®
Your Partner in Transplant Care™

AlloSeq® cfDNA

The cutting edge solution to detect donor-derived cell-free DNA for transplant surveillance

www.caredx.com/alloseq-cfdna

Want to order AlloSeq cfDNA surveillance tests?

- **AlloSeq cfDNA Services:** Send in samples to CareDx central lab in Stockholm, Sweden, Email: servicetesting@caredx.com or call +46-8-50893900

- **AlloSeq cfDNA Kit:** To learn more about how to bring AlloSeq cfDNA to your own lab, contact your CareDx representative or reach out to us:

Americas	orders-US@caredx.com
EMEA	orders-se@caredx.com
APAC	orders-aus@caredx.com

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