AlloSure®

Joyann Ferrara, kidney transplant recipient

AVAILABLE NOW

A clear path forward

THE LATEST INNOVATION IN KIDNEY TRANSPLANT SURVEILLANCE CAN DRIVE BETTER OUTCOMES FOR YOUR PATIENTS

AlloSure is the first non-invasive test that assesses organ health by directly measuring allograft injury, enabling better management of your kidney transplant recipients.

+ CLINICALLY & ANALYTICALLY VALIDATED **+ PRECISE, ACTIONABLE RESULTS** **+ COVERED BY MEDICARE**

It’s time for innovation

KIDNEY TRANSPLANT PATIENTS DESERVE A BETTER WAY

DETECTION OF ALLOGRAFT INJURY IS OF THE UTMOST IMPORTANCE

20%
Of kidney transplants fail within 5 years[1]

500%
A study of over 110,000 patients from the United States Renal Data System (USRDS) showed a 500% increase in cost burden for patients with renal transplant failure[2]

CURRENT TRANSPLANT SURVEILLANCE OPTIONS HAVE LIMITATIONS[3,4]

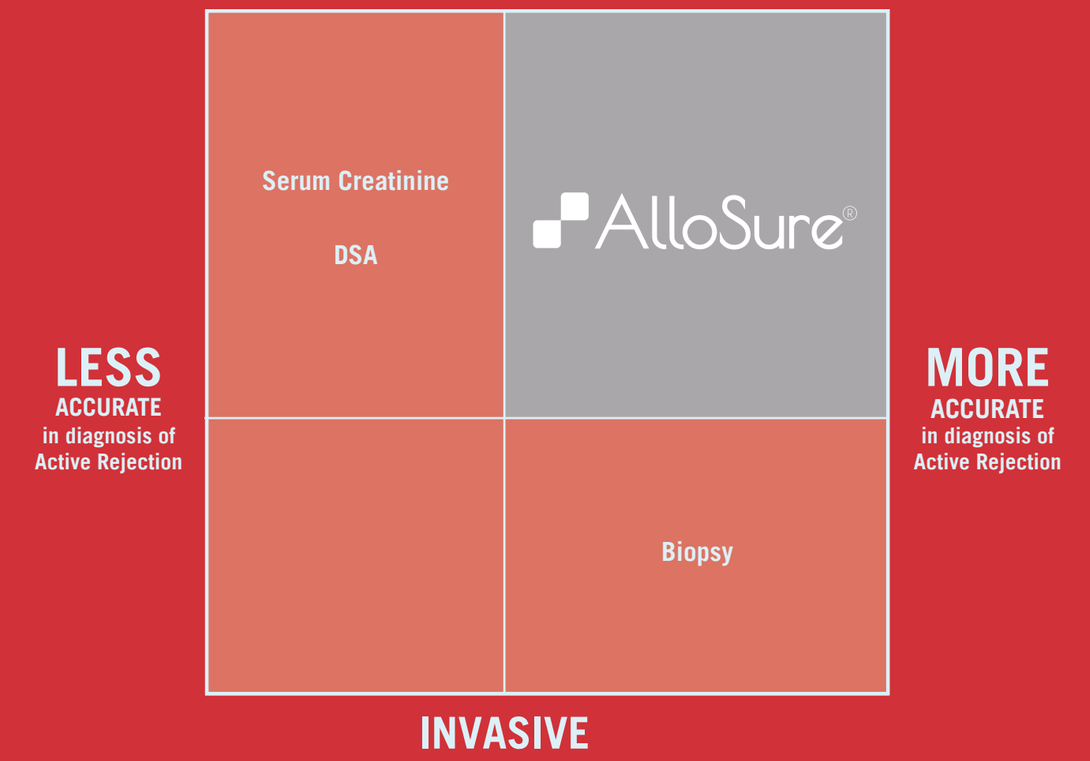
Two examples:

SERUM CREATININE: non-specific, not sensitive, risk of late signal

BIOPSY: high cost, sampling errors, inconvenient, potential for complications, interpretation challenges

AlloSure, innovation in action

AlloSure is clinically and analytically validated, non-invasive donor-derived cell-free DNA (dd-cfDNA) test for identifying kidney injury.



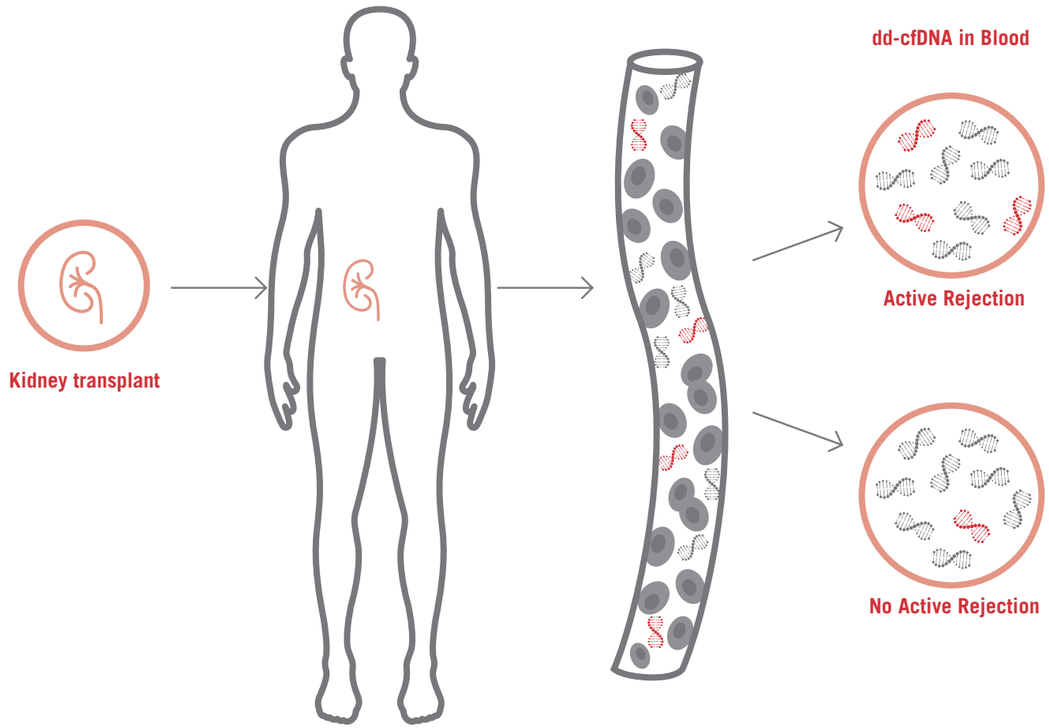
AlloSure is covered by Medicare

Cell-free DNA: a clear biomarker

CELL-FREE (cfDNA) IS FRAGMENTED DNA IN THE BLOODSTREAM THAT ORIGINATES FROM CELLS UNDERGOING CELL INJURY AND DEATH

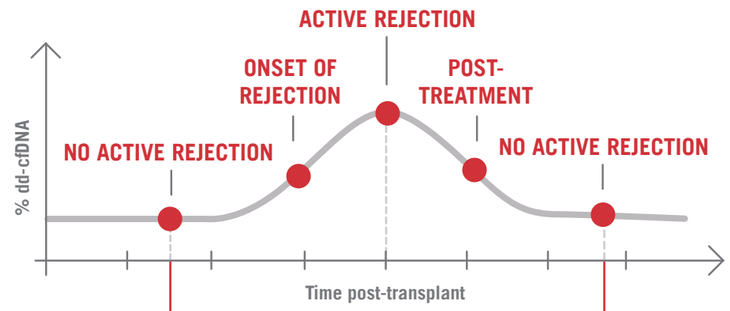
WHEN GRAFT INJURY OCCURS, DONOR-DERIVED CELL-FREE DNA (dd-cfDNA) INCREASES IN THE BLOOD

dd-cfDNA IS A POWERFUL, NON-INVASIVE TOOL FOR KIDNEY TRANSPLANT SURVEILLANCE



What is AlloSure?

+ A sensitive, accurate, and precise measure of organ health
+ A non-invasive blood test that does not require prior genotyping of the donor or recipient
+ A rejection rule-out test that has high specificity



dd-cfDNA			
	VERY LOW IN STABLE RECIPIENTS	ELEVATED AT THE TIME OF REJECTION	LOWER AFTER SUCCESSFUL TREATMENT

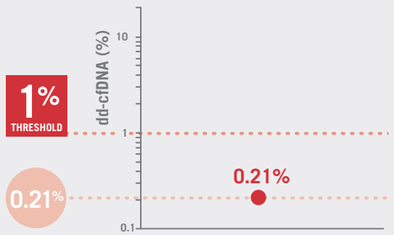
AlloSure is recommended in an all-comers patient population. Add AlloSure to these current protocols with ease:

Rejection surveillance	Clinically indicated for cause	Rejection treatment follow up

AlloSure performance characteristics

96% of AlloSure results for samples from DART healthy stable recipients are below the 1% threshold
50% of AlloSure results for samples from DART healthy stable recipients are below 0.21%

ALLOSURE CAN RULE OUT REJECTION

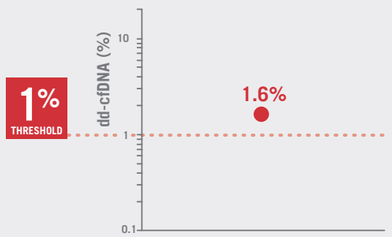


95% NPV for Active Rejection*

Sensitivity: 85%
Specificity: 33%
Prevalence: 10%[3†]
} at 0.21% dd-cfDNA

0.21% is the median from DART healthy stable recipients

ALLOSURE HAS HIGH SPECIFICITY FOR REJECTION DETECTION

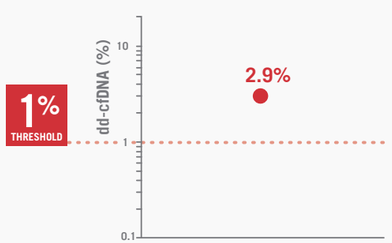


44% PPV for Active Rejection*

Sensitivity: 52%
Specificity: 93%
Prevalence: 10%[3†]
} at 1.6% dd-cfDNA

1.6% is the median from DART active rejection

ALLOSURE HAS HIGH PPV FOR ABMR IN DSA POSITIVE PATIENTS



85% PPV for ABMR in DSA+ Patients

Sensitivity: 50%
Specificity: 94%
Prevalence: 40%[4⊕]
} at 2.9% dd-cfDNA

2.9% is the median from DART ABMR

*Active Rejection = acute/active ABMR; chronic, active ABMR; and TCMR IA and greater
† Prevalence of rejection within the first year post-transplant
⊕ Prevalence of ABMR in DSA positive patients

What you should know about using AlloSure

PROCESS

ALLOSURE KITS FOR BLOOD SPECIMEN COLLECTION:

+ Provided at no charge by CareDx
+ Self-contained and include Streck tubes, tube labels, shipping materials, and shipping labels

ONCE BLOOD IS DRAWN:

+ No additional processing or preparation of the sample required before shipping
+ Stable for 7 days
+ Samples are tested in-house at CareDx's CLIA-certified and CAP-accredited clinical laboratory‡
+ Results reported within 72 hours of blood draw*
+ The CareDx laboratory runs 7 days a week

ALLOSURE SHOULD NOT BE ORDERED FOR PATIENTS WHO ARE:

+ The recipient of multiple transplanted organs (exception: specimens from kidney retransplant recipients are acceptable for testing)
+ The recipient of a transplant from a monozygotic (identical) twin
+ The recipient of allogeneic bone marrow transplant
+ Pregnant
+ Under the age of 18
+ Less than 2 weeks post-transplant

Intended Use:
The AlloSure test is intended to assess the probability of allograft rejection in kidney transplant recipients with clinical suspicion of rejection and to inform clinical decision making about the necessity of renal biopsy in such patients at least 2 weeks post-transplant in conjunction with standard clinical assessment.

*For those specimens shipped same day collected.

‡CLIA – Clinical Laboratory Improvement Amendments; CAP – College of American Pathologists

The DART study: Proven data. Clear detection.

The Circulating Donor-Derived Cell-Free DNA in Blood for Diagnosing Acute Rejection in Kidney Transplant Recipients (DART) study is the clinical validation study for AlloSure.

D DNA in Blood for Diagnosing

A Acute

R Rejection in Kidney

T Transplant Recipients

14 DART study centers nationwide in the US

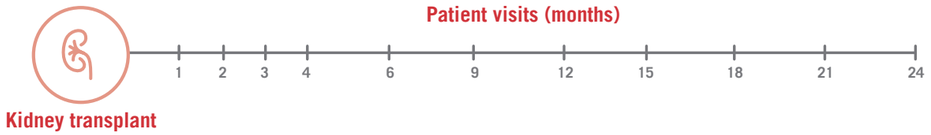
US Renal demographic represented

384 Patients were enrolled

102 & 27 For cause biopsy cohort: 102 patients (107 samples with both biopsy and AlloSure), 27 with active rejection

TWO DART STUDY PROTOCOLS:

Surveillance - newly transplanted recipients with AlloSure tests at 11 surveillance visits

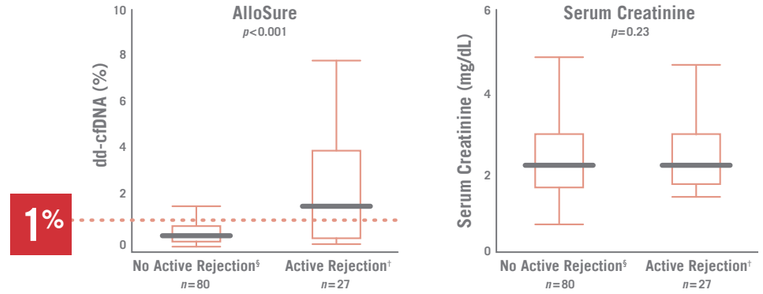


Clinically Indicated For Cause biopsy* - with AlloSure tests at time of biopsy and 1-2 follow-ups

*An elevated level of serum creatinine was the most common clinical indication for the biopsy

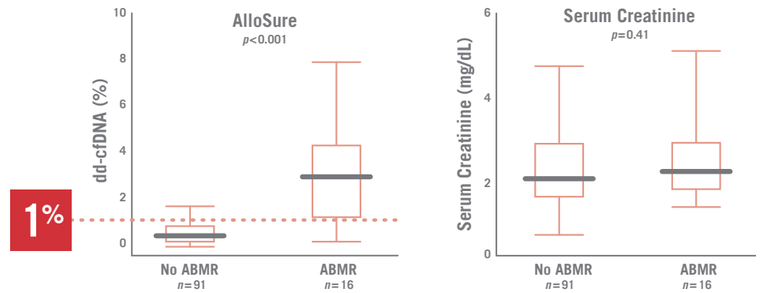
The DART study conclusions are clear.

ALLOSURE OUTPERFORMS SERUM CREATININE FOR DETECTING ACTIVE REJECTION∂

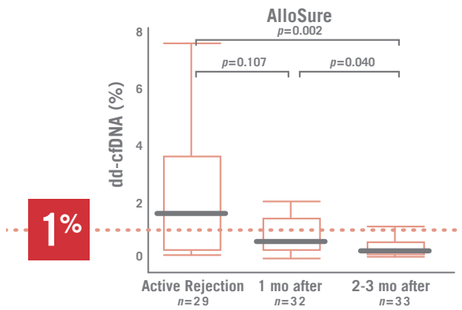


§ No active Rejection, n=80 samples from 75 patients
† Active Rejection = acute/active ABMR; chronic, active ABMR; and TCMR IA and greater, n=27 samples from 27 patients.

ALLOSURE IS HIGHLY SENSITIVE IN DISTINGUISHING ABMR FROM NO ABMR∂



ALLOSURE LEVELS DECREASE FOLLOWING REJECTION TREATMENT



∂ In patients with clinical suspicion of active rejection, the most common cause for the clinical suspicion of active rejection was elevated serum creatinine. The horizontal line is the median, and the top and bottom of the box represent the 75th and 25th percentile. Applicable to all 5 charts.

AlloSure is recommended in an all-comers patient population. Add AlloSure to these current protocols with ease:

Rejection Surveillance Using the AlloSure Routine Testing Schedule:
The AlloSure Routine Testing Schedule is based on the DART Study Protocol

AlloSure Routine Testing Schedule:
Year 1 schedule for AlloSure: Months 1, 2, 3, 4, 6, 9, and 12
Year 2+ schedule for AlloSure: Quarterly
Add AlloSure testing to current schedules for routine screening, such as DSAs, BKV

TIME POST-TRANSPLANT

Biomarker	Condition Tested	1 week	1 Month	2-3 Months	4-6 Months	7-12 Months	12+ Months
Creatinine[5]	Indirect graft function	Daily	2-3 per Week	Weekly	Every 2 Weeks	Monthly	Every 2-3 Months
BK Virus[5]	Viral infection	Monthly			Every 3 Months		–
DSA (Anti-HLA Antibodies)*	Donor Specific HLA Antibody formation	Weekly	Monthly	–	Every 6 Months		
AlloSure	**Active allograft injury**	**Monthly**			**Every 2 Months**	**Every 3 Months**	

*Site specific protocol, varies by center.

Clinically Indicated For Cause:
Use AlloSure as a step before the decision to perform a clinically indicated biopsy
Examples of Clinical Indications: High Creatinine, Proteinuria, DSA, BKV, DGF

Rejection Treatment Follow Up:
A monthly AlloSure for the first 3 months post-rejection treatment

Put your patients on a clear path forward with AlloSure

FEATURES

+ Measures dd-cfDNA, a direct indicator of kidney injury
+ Clinically and analytically validated
+ More accurate than serum creatinine in diagnosis of active rejection
+ Does not require donor or recipient genotyping
+ Appropriate for a wide array of patients who are greater than 2 weeks post-transplant and 18+ years of age
+ Covered by Medicare

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REFERENCES

1. Rao PS et al. Am J Kidney Dis 49:294-300, 2007.
2. GAO report. GAO-07-1117, 2007.
3. Matas et al. Am J Transplant 14:S11-S44, 2014.
4. Jordan et al. J Am Soc Nephrol 28:Suppl, 2017.
5. KDIGO Transplant Work Group. Am J Transplant 9:S1–S157, 2009.
6. Grskovic M et al. J Mol Diagn 18:890-902, 2016.
7. Bloom RD et al. J Am Soc Nephrol 28, 2017.
8. Bromberg JS et al. J Appl Lab Med 2, 2017.

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