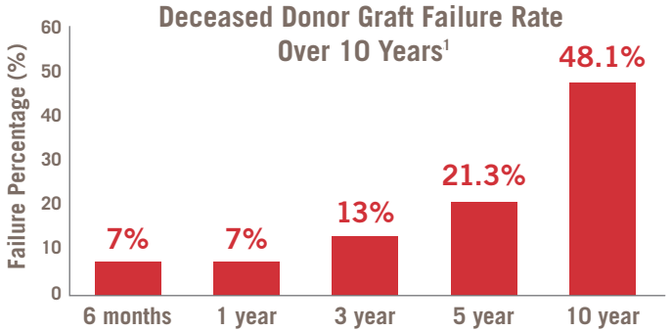
AlloSure® KIDNEY

Detect Subclinical Rejection with Surveillance Testing

Long Term Kidney Graft Failure Remains High

Kidney Transplant Outcomes

- Graft injury and rejection are the main reasons for transplant failures, excluding death. But conventional renal biomarkers are lagging indicators in transplant patients.
- Graft failure rates accelerate after the first year post-transplant.
- Effective surveillance beyond the first year is key.



Introducing ADMIRAL: An Independent Multicenter Analysis that Validated AlloSure for Surveillance Use

Assessing Dd-cfDNA Monitoring Insights of Renal Allografts with Longitudinal Surveillance

Robust Patient Cohort
1,092 Patients with 3,965 AlloSure Draws

Surveillance Testing
Median of 6 AlloSure Draws Per Patient

AlloSure Kidney: The ONLY dd-cfDNA Service Clinically Validated for Surveillance

219 Paired Biopsies

109 Paired Biopsies For Surveillance
35 confirmed ABMR Median AlloSure Score: 0.91%
10 confirmed cases of TCMR Median AlloSure Score: 0.52%

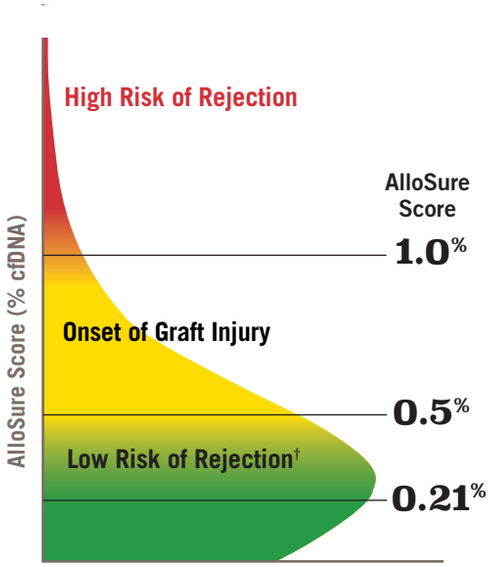
110 Paired Biopsies For Cause
40 confirmed ABMR Median AlloSure Score: 2.2%
28 confirmed cases of TCMR Median AlloSure Score: 1.3%

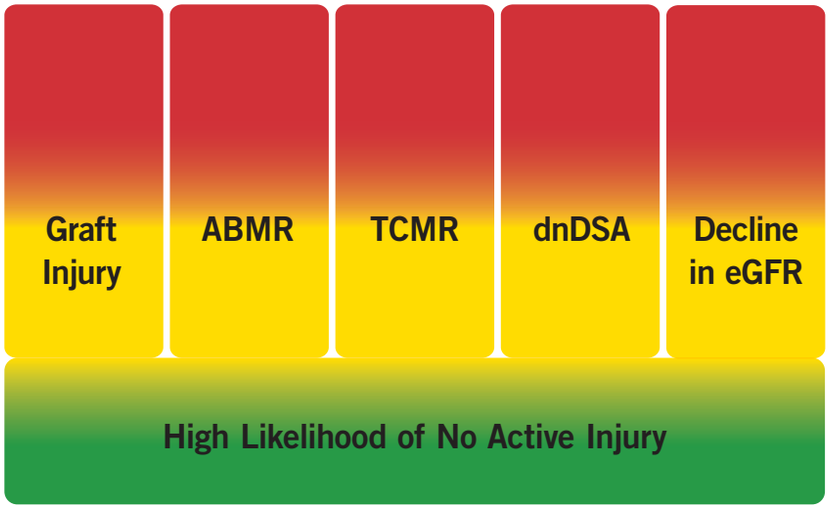
40% of biopsies in the surveillance cohort confirmed the presence of subclinical rejection that may have gone undetected by traditional tests

AlloSure KIDNEY®

Clinical Decision Support with AlloSure[2-4]

AlloSure Score provides meaningful, actionable information to your existing clinical paradigm



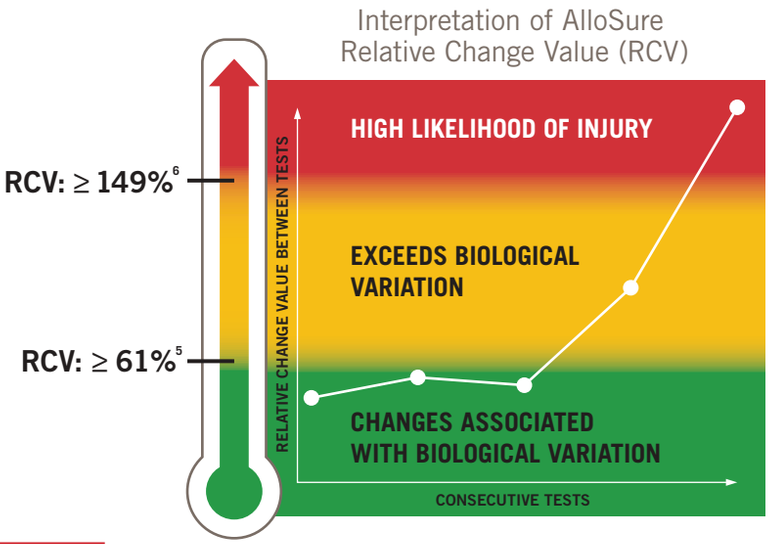


AlloSure is the ONLY Validated dd-cfDNA for Longitudinal Management Using Relative Change Value

Relative Change Value

In addition to the absolute value, the delta/RCV between results can be indicative of allograft injury:

- Increases in AlloSure results over 61% exceed biological variation[5]
- A median increase of 149% between serial results is indicative of graft injury (p=0.02)[6]



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1. Hart A et al. Am J Transplant 2019; 21 Suppl 2: p. 21–137.
2. Bu L, et al. Kidney Intl 2021
3. Bloom RD et al. J Am Soc Nephrol 2017; 28:2221–2232.
4. Stites E, et al. Am J Transplant 2020; 00:1–8.
5. Bromberg JS et al. J Appl Lab Med. 2017; 2:309–321.
6. Bu L. et. al. Kidney International. 2021.

20+ YEARS

Celebrating Thymoglobulin® and the evolution of kidney transplantation

FOR 20 YEARS AND BEYOND

Watch our video on the history of kidney transplantation and Thymoglobulin

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Thymoglobulin®
Anti-thymocyte Globulin (Rabbit)

Thymoglobulin® (anti-thymocyte globulin (rabbit)) is indicated for the prophylaxis and treatment of acute rejection in patients receiving a kidney transplant. Thymoglobulin is to be used in conjunction with concomitant immunosuppression.

IMPORTANT SAFETY INFORMATION

WARNING: IMMUNOSUPPRESSION.
Thymoglobulin should only be used by physicians experienced in immunosuppressive therapy in transplantation.

- **Contraindications.** Thymoglobulin is contraindicated in patients with a history of allergy or anaphylaxis to rabbit proteins or to any product excipients, or who have active acute or chronic infections which contraindicate any additional immunosuppression.
- **Management of Immunosuppression.** To prevent over-immunosuppression, physicians may wish to decrease the dose of the maintenance immunosuppression regimen during the period of Thymoglobulin use. Dosing for Thymoglobulin is different from dosing for other ATG products, because protein composition and concentrations vary depending on the source of ATG. Thymoglobulin should be used under strict medical supervision in a hospital setting, and patients should be carefully monitored during the infusion.
- **Immune Mediated Reactions.** Serious immune-mediated reactions, including anaphylaxis or severe cytokine release syndrome (CRS), have been reported with the use of Thymoglobulin. Fatal anaphylaxis has been reported. If an anaphylactic reaction occurs, the infusion should be terminated immediately.
- **Infusion-Associated Reactions.** Cases consistent with cytokine release syndrome (CRS) have been reported with rapid infusion rates. CRS is attributed to the release of cytokines by activated monocytes and lymphocytes. Severe acute CRS can cause serious cardiorespiratory events and/or death. Close compliance with the recommended dosage and infusion time may reduce the incidence and severity of infusion-associated reactions (IARs). Slowing the infusion rate may minimize many of these IARs. Reactions at the infusion site may include pain, swelling, and redness of the skin.
- **Hematologic Effects.** Low counts of platelets and white blood cells (including low counts of lymphocytes and neutrophils) have been identified and are reversible following dose adjustments. Total white blood cell and platelet counts should be monitored.
- **Infection and Malignancy.** Infections, reactivation of infection, febrile neutropenia, sepsis, malignancies including lymphoproliferative disorders (LPD) and other lymphomas as well as solid tumors have been reported after Thymoglobulin administration in combination with multiple immunosuppressive agents. These events can be fatal.
- **Immunization.** The safety of immunization with attenuated live vaccines following Thymoglobulin therapy has not been studied; therefore, immunization with attenuated live vaccines is not recommended for patients who have recently received Thymoglobulin.
- **Overdosage.** Thymoglobulin overdosage may result in leukopenia (including lymphopenia and neutropenia) and/ or thrombocytopenia, which can be managed with dose reduction.
- **Adverse Reactions.** The most common adverse reactions and laboratory abnormalities (incidence >5% higher than comparator) are urinary tract infection, abdominal pain, hypertension, nausea, shortness of breath, fever, headache, anxiety, chills, increased potassium levels in the blood, and low counts of platelets and white blood cells.
- During post-marketing surveillance, arthralgia/myalgia, lymphadenopathy, proteinuria, and decreased oxygen saturation tend to occur 5 to 15 days after Thymoglobulin infusion and are consistent with serum sickness. Symptoms are manageable with corticosteroid treatment.

Click here for full Prescribing Information, including Boxed WARNING.

MAT-US-2107295-v2.0-03/2022

Biomarkers for Kidney Transplant Recipients

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	Combination Panel	Gene Expression	Donor-Derived Cell-Free DNA		
	OmniGraf™	TruGraf®	Viracor TRAC®	AlloSure® Kidney	Prospera™
Type of Biomarker	Blood gene expression (120 genes) & dd-cdDNA (~100,000 SNPs)	Blood gene expression (120 genes)	dd-cfDNA (~100,000 SNPs)	dd-cfDNA (405 SNPs)	dd-cfDNA (13,392 SNPs)
Context of Use	Earliest[1] and most accurate[2] detection of subclinical and clinical rejection in transplant patients with stable kidney function	Rules out silent subclinical rejection in kidney transplant patients with stable kidney function	Rules out acute rejection in patients with suspicion of clinical acute rejection	Rules out acute rejection in patients with suspicion of clinical acute rejection	Rules out acute rejection in patients with suspicion of clinical acute rejection
Validation	Surveillance	Surveillance	For-cause biopsy	For-cause biopsy	For-cause biopsy
When to Start Testing	90 days post-transplant	90 days post-transplant	Suspicion of clinical rejection	Suspicion of clinical rejection	Suspicion of clinical rejection
Blood Draw Required	6ml / 1 tube	5ml / 2 tubes	10ml / 1 tube	10ml / 1 tube	10ml / 1 tube
Result Measurements	Gene Expression (TruGraf): TX or Not-TX dd-cfDNA (VIracor TRAC): % of dd-cfDNA	TX or Not-TX	% of dd-cfDNA	% of dd-cfDNA	% of dd-cfDNA
Interpretation of Results	TX + <0.7 = low risk for rejection Not-TX + ≥0.7 = high risk for rejection	TX: low risk for rejection Not-TX: at risk for rejection	< 0.7% clinical rejection unlikely ≥ 0.7% clinical rejection should be considered	≤ 1% reflect absence of active rejection > 1% probability of active rejection	≤ 1% wait and watch, no action > 1% use clinical findings to determine if biopsy is indicated
Sensitivity	77%	77%	58%	59%	89%
Specificity	94%	79%	85%	85%	73%
Negative Predictive Value (NPV)	94%	92%	92%	84%	95%
Positive Predictive Value (PPV)	89%	65%	40%	61%	52%
Suggested Testing Frequency	Quarterly monitoring	Quarterly monitoring	Clinical suspicion of rejection	Monthly 1-4 months; quarterly 6 months and beyond	Clinical suspicion of rejection
Rejection Type Targeted	TCMR & ABMR	TCMR	ABMR	ABMR	ABMR

[1]OmniGraf and TruGraf are the only tests that detect subclinical acute rejection, before the onset of clinical acute rejection.
[2] OmniGraf has the highest Positive Predictive Value of currently-available biomarker-based rejection tests.

OMNIGRAF™

One Powerful Panel
Two Targeted Biomarkers

OmniGraf™ is the first and only non-invasive test panel that combines novel genetic biomarkers for the earliest and most accurate view of kidney transplant rejection.

Combining gene expression profiling with donor-derived cell-free DNA for increased precision and accuracy, **OmniGraf** delivers clinically-actionable data on rejection status — empowering clinicians to provide the best possible long-term outcomes.

The Power of **One:**

One All-Inclusive Sample Collection Kit

One 6ml Routine Blood Draw

One Overnight Shipment

One Easy-to-Interpret Longitudinal Report

Learn more at transplantgenomics.com/

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100-03-002 v3 / Oct 2021

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