Case Study

Complementary Nature of Dual Biomarkers for Kidney Transplant Patients

- 60-year-old male patient
- 3 years post-transplant
- Stable serum creatinine; no pre-transplant donor-specific anti-bodies (DSAs)
- Immunosuppression: everolimus and mycophenolate mofetil due to alopecia

Goal

Monitor patient on an unconventional immunosuppression regimen more closely.

Approach

Monitor immune status serially with OmniGraf.

Results

OmniGraf identified abnormal results and prompted a biopsy in a patient with normal serum creatinine and no other laboratory findings of rejection.

The Opportunity of a Dual Biomarker Panel

This patient was originally followed with TruGraf gene expression profile (GEP) testing, consistently providing a reassuring TX ("Transplant eXcellence") result. When patient was converted to OmniGraf dual-biomarker (TruGraf gene expression profiling (GEP) and Viracor TRAC donor-derived cell-free DNA (dd-cfDNA)) rejection panel testing, the dd-cfDNA values were high, indicating potential rejection.

With simultaneous gene expression profile and dd-cfDNA results, the clinician is provided the most comprehensive non-invasive information regarding rejection in their patient.

Case Study: 60-Year-Old Kidney Recipient, 3 Years Post-Transplant

This kidney transplant recipient is a 60-year-old male patient, who received his kidney graft 3 years ago from a living relative donation. His original immunosuppression regimen included tacrolimus and mycophenolate mofetil; tacrolimus was later converted to everolimus due to alopecia.

Months 18 and 24 post-transplant:

- TruGraf: Negative / TX ("Transplant eXcellence")
- No DSAs identified

Month 36 post-transplant: *patient transitioned to OmniGraf monitoring*

- TruGraf: Negative / TX: low risk of rejection
- Viracor TRAC: 4.45%: high risk of rejection

Month 37 post-transplant: *repeat OmniGraf*

- TruGraf: Negative / TX: low risk of rejection
- Viracor TRAC: 4.47%: high risk of rejection

Repeated positive Viracor TRAC results prompted a for-cause biopsy. The biopsy results confirmed acute subclinical antibody-mediated rejection. The patient was subsequently treated for rejection.

Dual Biomarkers Are Complementary and Informative

As evidenced by recent literature, gene expression profile (GEP) testing is more sensitive to acute cellular rejection while donor-derived cell-free DNA (dd-cfDNA) is more sensitive to antibody-mediated rejection (AMR). With a persistent elevated dd-cfDNA along with clinical background, the clinician was prompted to further evaluate the patient which led to a biomarker prompted biopsy. If the clinician only utilized the one biomarker more sensitive to AMR, they may have missed the presence of subclinical acute rejection.

In this case, subclinical AMR was identified before traditional monitoring, leading to earlier intervention and possibly improving long term graft survival.

OMNIGRAF™

The first and only non-invasive panel that combines genetic biomarker tests for the earliest and most accurate view of kidney transplant rejection.

	Combination Panel	Gene Expression	Donor-Derived Cell-Free DNA
	OmniGraf™	**TruGraf®**	**Viracor TRAC®**
Type of Biomarker	Blood gene expression (120 genes) & dd-cdDNA (~100,000 SNPs)	Blood gene expression (120 genes)	dd-cfDNA (~100,000 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 subclinical rejection in kidney transplant recipients with stable kidney function	Rules out acute rejection in kidney transplant recipients with suspicion of clinical acute rejection
Validation	Surveillance	Surveillance	For-cause biopsy
When to Start Testing	90 days post-transplant	90 days post-transplant	Suspicion of clinical rejection
Blood Draw Required	6ml / 1 tube	5ml / 2 tubes	10ml / 1 tube
Result Measurements	Gene Expression (***TruGraf***): TX (Transplant eXcellence) or Not-TX dd-cfDNA (***Viracor TRAC***): % of dd-cfDNA	TX or Not-TX	% of dd-cfDNA
Interpretation of Results	Negative / TX & <0.7 = low risk of rejection Positive / Not-TX & ≥0.7 = high risk of rejection	Negative / TX: low risk of rejection Positive / Not-TX: at risk of rejection	< 0.7% clinical rejection unlikely ≥ 0.7% clinical rejection should be considered
Negative Predictive Value (NPV)	94%	92%	92%
Positive Predictive Value (PPV)	89%	65%	40%
Suggested Testing Frequency	Quarterly monitoring	Quarterly monitoring	Clinical suspicion of rejection
Rejection Type Targeted	TCMR & ABMR	TCMR	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.

Learn more at
transplantgenomics.com/omnigraf-kidney

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