

Case Study

The Value of Long-Term Monitoring of Graft Health



- 30-year-old male patient
- 10 years post-transplant
- Stable serum creatinine (1.1-1.3 baseline)
- Immunosuppression: tacrolimus and mycophenolate mofetil
- History of acute cellular rejection at 2 years post-transplant

Goal

Continue to monitor patients who are many years post-transplant but have historical factors that increase their risk for rejection.

Approach

Monitor immune status at baseline and follow serially with OmniGraf.

Results

OmniGraf identified likely subclinical rejection 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

Serum creatinine is a late marker of graft injury with low sensitivity and specificity for rejection. With the OmniGraf rejection panel (combining TruGraf gene expression profiling (GEP) and Viracor TRAC donor-derived cell-free DNA (dd-cfDNA) performed simultaneously), the clinician is provided with the most comprehensive non-invasive information regarding rejection in their patient.

Case Study: 30-Year-Old Kidney Recipient, 10 Years Post-Transplant

This kidney transplant recipient is a 30-year-old male patient, who received his kidney graft 10 years ago. His original immunosuppression regimen included tacrolimus and mycophenolate mofetil. The patient has a history of acute cellular rejection at 2 years post-transplant, and was successfully treated.

Laboratory Test Results:

- Serum Creatinine: 1.1mg/dl
- Urine Protein: Negative

OmniGraf Results:

- TruGraf: Positive / Not-TX (Not "Transplant eXcellence"): at risk of rejection
- Viracor TRAC: 4.05%, at risk of rejection

The OmniGraf result prompted a for-cause biopsy; results indicated chronic active antibody-mediated rejection. The patient received treatment and was followed up 3 months post-treatment with a new OmniGraf panel.

OmniGraf Results:

- TruGraf: Negative / TX ("Transplant eXcellence"): low risk of rejection
- Viracor TRAC: 3.6%, at risk of rejection

OmniGraf Results Validated Need for Biopsy

In this case, OmniGraf was able to identify a patient at high risk for silent subclinical rejection, allowing for early intervention. OmniGraf provided the clinician with the ability to continually monitor the patient non-invasively through their post-rejection therapy. With two positive biomarker results, OmniGraf has a positive predictive value (PPV) of 89% to suggest histological findings of rejection.

OmniGraf results in post-rejection treatment may offer insight into the trajectory of the immune system's response and aid in personalizing immunosuppression therapies.

	Combination Panel	Gene Expression	Donor-Derived Cell-Free DNA
	OmniGraf™	TruGraf®	Viracor TRAC®
Type of Biomarker	Blood gene expression (120 genes) & dd-cfDNA (~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 (<i>TruGraf</i>): TX (Transplant eXcellence) or Not-TX dd-cfDNA (<i>Viracor TRAC</i>): % 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

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

