



# The immune system is smart. VitaGraft Kidney is SMARTER.

VitaGraft Kidney is a blood-based transplant monitoring test that quantifies the concentration of donor-derived cell-free DNA (dd-cfDNA) following kidney transplantation using droplet-digital PCR (dd-PCR) technology.

## SMARTER Framework & Product Highlights

- S Specific**  
Confidently rule out injury with a 94% NPV\*1,2
- M Measurable**  
Quantify dd-cfDNA using both fractional abundance (%) & absolute quantification (cp/mL)
- A Actionable**  
dd-cfDNA has a short half life (20min - 2hrs), allowing almost immediate detection of injury & recovery<sup>3</sup>
- R Reimbursed**  
VitaGraft Kidney is covered by Medicare
- T Timely**  
Receive results typically within 48 hours\*\* to optimize patient management decisions
- E Easy to use**  
Seamlessly integrate into current workflows
- R Reliable**  
The only reimbursed test on the market that uses dd-PCR to quantify dd-cfDNA\*\*\*

**86%** of unnecessary biopsies triggered by elevated plasma creatinine in stable patients **may be avoided** using VitaGraft Kidney.<sup>1</sup>

## Fast & Accurate Results

- Step 1**  
Post-transplant patient blood sample drawn at transplant facility or local laboratory\*
- Step 2**  
Send samples to Oncocyte's CAP/CLIA certified laboratory
- Step 3**  
dd-cfDNA measured using dd-PCR
- Step 4**  
Risk for active rejection reported

\*Calculated at 25% prevalence using biopsy-proven samples from combined data from references 1,2.  
\*\* Upon sample receipt.  
\*\*\* dd-PCR is used to calibrate NGS, see references 3-5.

\*For the first test we require a one-time urine sample in addition to blood to set the assay for the patient. Thereafter, we require blood only for all subsequent tests.

# Validated in **459** kidney transplant patients with over **3,000** samples for up to five years post-transplant.<sup>1,2,6,7</sup>

## Test Performance

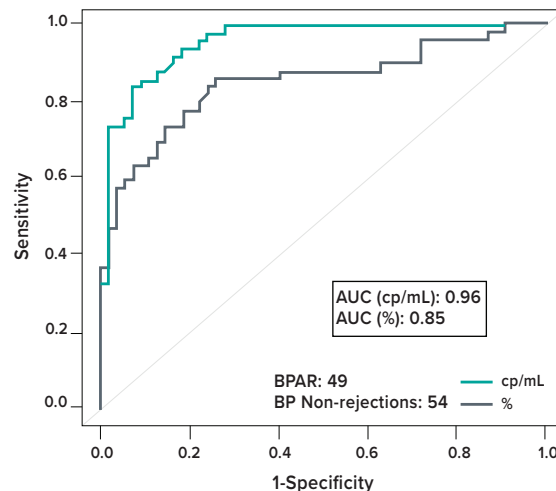
### Validated in two independent studies

VitaGraft Kidney has been shown to significantly discriminate between rejection and non-rejection using biopsy-proven samples.<sup>1,2</sup>

0.5% & 50cp/mL*	Sensitivity**	Specificity**	PPV (25%)	NPV (25%)
Both Above	63%	98%	92%	89%
One Above	86%	76%	54%	94%
cp/mL Above	76%	93%	77%	92%
% Above	73%	81%	57%	90%

\*Decision limits for % and cp/mL.

\*\*Calculated using biopsy-proven samples from combined data from references 1,2.

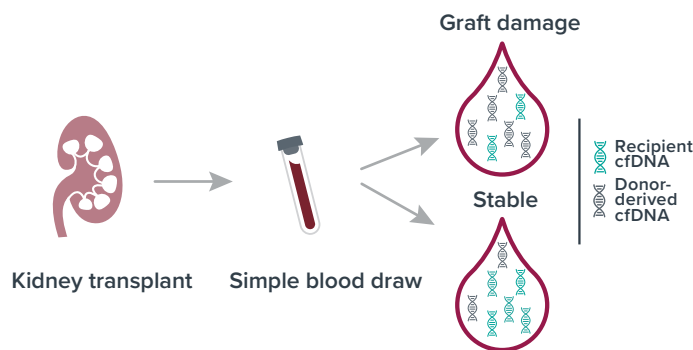


## Methodology

Through dd-PCR, VitaGraft Kidney determines a set of single-nucleotide polymorphisms (SNPs) specific to each patient.

A subset of SNPs are selected from commonly-shared SNPs across the global population. This allows for differentiation between the donor and recipient cfDNA and the creation of a personalized assay for the patient.

From this, dd-cfDNA may be quantified using VitaGraft Kidney. The SNP selection process occurs once per patient and is locked down for all future testing.



## Clear and Concise Results Delivered



### We're here to help

Oncocyte Customer Service can answer any questions you have. Please contact us at:

Phone: +1-844-621-8880  
customer.service@oncocyte.com

We do not want cost to be a barrier to testing, patients can call (844-679-6600), fax (949-271-4972), or visit our website (oncocyte.com/vitagraft-kidney) to see if they qualify for our financial assistance program.

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**REFERENCES** 1. Oellerich M, Shpikova M, Asendorf T, et al. (2019) Absolute quantification of donor-derived cell-free DNA as a marker of rejection and graft injury in kidney transplantation: Results from a prospective observational study. *Am J Transplant* 19(11):3087. 2. Akifova A, Budde K, Choi M, et al. (2023). Donor-Derived Cell-Free DNA in Biopsy-Proven Antibody-Mediated Rejection Versus Recurrent IgA Nephropathy After Kidney Transplantation. *Kidney International Reports* doi:10.1016/j.ekir.2023.07.011. 3. Oellerich M, Sherwood K, Keown P, et al. (2021). Liquid biopsies: donor-derived cell-free DNA for the detection of kidney allograft injury. *Nat Rev Nephrol* 17(9):591. 4. Altuğ Y, Liang N, Ram R, et al. (2019). Analytical Validation of a Single-nucleotide Polymorphism-based Donor-derived Cell-free DNA Assay for Detecting Rejection in Kidney Transplant Patients. *Transplantation* 103(12):2657. 5. Grskovic M, Hiller DJ, Eubank LA, et al. (2016) Validation of a Clinical-Grade Assay to Measure Donor-Derived Cell-Free DNA in Solid Organ Transplant Recipients. *J Mol Diagn* 18(6):890. 6. Schutz E, Asendorf T, Beck J, et al. (2020) Time-dependent apparent increase in dd-cfDNA percentage in clinically stable patients between one and five years following kidney transplantation. *Clin Chem* 66(10):1290. 7. Osmanodja B, Akifova A, Budde K, et al. (2021). Absolute or Relative Quantification of Donor-derived Cell-free DNA in Kidney Transplant Recipients: Case Series. *Transplant Direct* 7(11):e778.

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