omixon
WE IMPROVE TRANSPLANT OUTCOMES

HOLOGRAFT™

Monitor cfDNA in your own laboratory

Cell-free DNA (cfDNA) refers to circulating DNA in the blood stream originating from the natural apoptosis or necrosis of cells in the body. In transplant patients, graft-derived, cfDNA represents a small, but detectable fraction of the patient's circulating cfDNA, and can be used as a surrogate biomarker of organ health, agnostic from the organ type.

Why measure cfDNA?

Bloom et al demonstrated that graft-fraction of 1% cfDNA can distinguish-antibody-mediated rejection (ABMR) from no-AMBR with high (96%) negative predictive value.[1]

Why measure absolute quantity of cfDNA?

A recent peer-reviewed paper published in JASN by Bunnapradist S, et al. showed that the absolute quantity of graft-derived cfDNA improved the sensitivity of test from 7/9 to 9/9 compared to using graft fraction alone, in cases of active rejection. [2]

How do we measure cfDNA?

HoloGRAFT™ uses digital PCR (dPCR) technology. dPCR involves partitioning the PCR solution into tens of thousands sub-nanoliter reactions, wherein a separate PCR takes place. After the PCR is completed, each partition is analyzed and scored as positive or negative. Using Poisson distribution statistics, the number of positive reactions can be used to calculate the concentration of target molecules, with an exceptional sensitivity of 10 copies/mL plasma.

Benefits of HOLOGRAFT™

- Monitoring of absolute quantity of donor derived cfDNA over time
- Short turnaround time - from DNA to results in **3 hours**
- 1-24 samples per run and up to **72 samples per day** (3 runs)
- Software assists protocol design and collects longitudinal data
- All major dPCR platform supported

Join Our Clinical Study

HOLOGRAFT™

HOLOGRAFT™ workflows

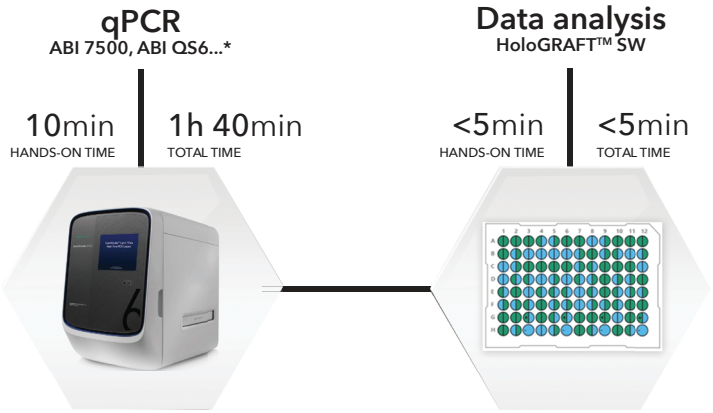

Fig 1: **Initial Screening** *assay to identify donor informative assays (One time only)*

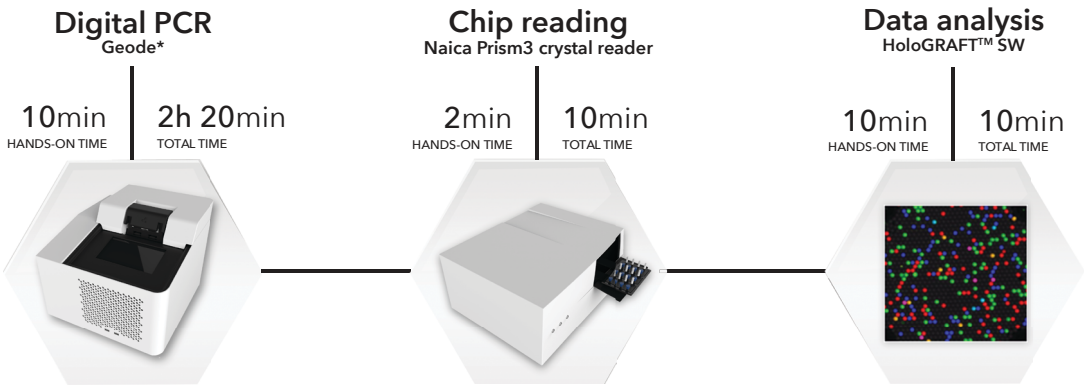

Fig 2: **dPCR monitoring test** *using two or more informative assays to determine the cfDNA concentrations of the donor and recipient cfDNA in Copies/mL, as well as the % of dd cfDNA.*

Analytical Performance of absolute quantitaiton of gd-cfDNA using the genetic markers in HoloGRAFT™ and measured by dPCR[3]

	Negative Predictive Value (NPV)	Positive Predictive Value (PPV)
Acute AMR	**0.98**	**0.60**
ABMR	**0.95**	**0.52**

The correlation of the dPCR assays used in HoloGRAFT™ were tested in connection with biopsy-verified antibody-mediated rejection by Whitlam et al. They also compared the correlation of graft fraction and absolute graft-derived cfDNA quantity with rejection. They found that absolute quantitation improved correlation with antibody-mediated rejection.

Reference

1 *Bloom, R. D. et al. Cell-Free DNA and Active Rejection in Kidney Allografts. J Am Soc Nephrol 28, 2221-2232, (2017).*

2 *Bunnapradist S, et al. Using both the fraction and quantity of donor-derived cell-free DNA to detect kidney allograft rejection, J Amer Soc Nephrology 2021*

3 *Whitlam, J. B. et al. Diagnostic application of kidney allograft-derived absolute cell-free DNA levels during transplant dysfunction. Am J Transplant, (2018).*

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