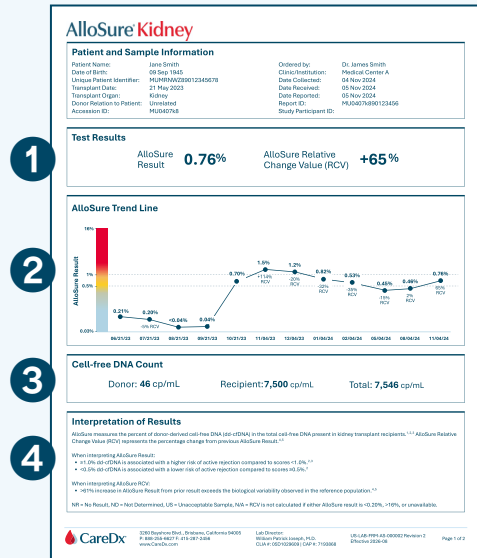


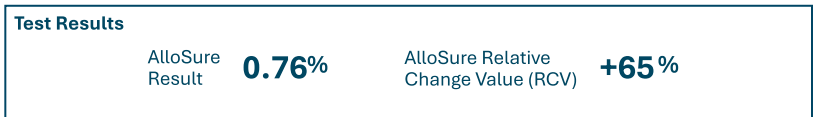
This guide is designed for clinicians and should be used as a supplement to the AlloSure results report.

AlloSure results and allograft rejection status should always be considered in the context of other clinical factors and a clinician's judgement.



1 Test Results

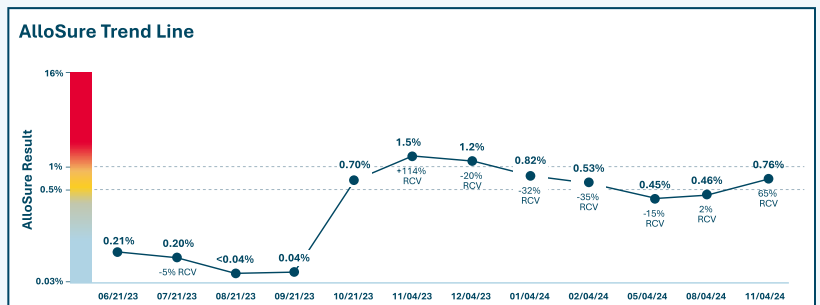
The Test Results section reports the dd-cfDNA level obtained from the most recent AlloSure draw and the Relative Change Value (RCV), which represents the percentage change from previous AlloSure result.



2 AlloSure Trend Line

The AlloSure Trend Line depicts a patient's AlloSure results over time. For optimized clinical care, establishing a patient's baseline AlloSure level may be beneficial.

The X-axis highlights the date of blood draw; the Y-axis represents the % dd-cfDNA level. A solid line connects dd-cfDNA levels over time and reflects the RCV between results.*



*RCV is not calculated if either AlloSure result is <0.20%, >16%, or unavailable.
NR = No Result, ND = Not Determined, US = Unacceptable Sample.

3 Cell-free DNA Count

The Cell-free DNA Count values describe the number of cell-free DNA (cfDNA) copies in 1 mL (cp/mL) of plasma sample.

Cell-free DNA Count

Donor: **46** cp/mL

Recipient: **7,500** cp/mL

Total: **7,546** cp/mL

Total cfDNA Count is the amount of cfDNA from both the donor and the recipient. Donor cfDNA Count is the amount of donor-derived cfDNA. Recipient cfDNA Count is the amount of recipient-derived cfDNA.

Please Note: This portion of the test result is optional and needs to be turned on for interested accounts.

4 Interpretation of Results

≥1.0% AlloSure is associated with a high risk of active rejection

For AlloSure dd-cfDNA at 1.0%, there is a positive predictive value (PPV) of 54% and a negative predictive value (NPV) of 84% for active rejection.¹⁻³

0.5-1.0% AlloSure is associated with an intermediate risk of active rejection

0.5% AlloSure dd-cfDNA has a PPV for all rejection of 50% and an NPV of 90%.¹⁻³

<0.5% AlloSure dd-cfDNA is associated with a low risk of active rejection

AlloSure dd-cfDNA levels below 0.5% are associated with a lower risk of active rejection compared to scores ≥0.5%.

>61% increase in AlloSure from prior result (RCV) exceeds normal biological variability⁴

Considerations for Simultaneous Pancreas-Kidney (SPK) Patients

- AlloSure levels in stable patients were between 0.18% to 0.29%^{5,6}
- 97% of patients without rejection had AlloSure levels <0.5%⁵
- Patients with rejection had AlloSure levels elevated from their baseline^{5,6}
- The RCV in Section 1 and thresholds in Section 4 have not been validated in SPK

Contraindications and Limitations

- AlloSure is not intended for use in kidney transplant recipients who are pregnant, recipients of a transplant from a monozygotic twin, recipients of allogeneic bone marrow transplant, or the recipients of multiple transplanted organs other than SPK transplant
- Transfusion of blood components containing white blood cells in the 30 days prior to blood draw may lead to aberrant results. Renal biopsies performed 24 hours prior to AlloSure specimen collection may elevate dd-cfDNA

References: 1. Bu, L et al. *Kidney International* 2021; 2. Bloom RD et al. *J Am Soc Nephrol*. 2017; 28:2221-2232; 3. Stites E, et al. *Am J Transplant*. 2020; 00:1-8; 4. Bromberg JS et al. *J Appl Lab Med*. 2017; 2:309-321; 5. Williams MD, et al. *Transplantation Direct* 2022; 8:e1321. doi: 10.1097/TXD.0000000000001321.; 6. Yoo A, et al. *Transplantation Direct* 2023; 9:e1459. doi:10.1097/TXD.0000000000001459