Patient Information

Patient Name:	Doe Jane
Date of Birth:	01/01/1980
Patient ID:	P99457
Medical Record #:	LP1234567
Transplant Date:	02/12/2021
Collection Kit #:	123456-2-T
Accessioning ID:	101029098
Case File ID:	101

Test information

Ordering Physician:	Dr. Matthew Smith, M.D. (G123456)
Clinic:	Natera, Inc.
Report Date:	09/19/2022
Transplanted Organ:	Kidney
Samples Collected:	09/14/2022
Samples Received:	09/15/2022

Prospera™
Transplant assessment

Prospera assesses transplanted organ injury by reporting **donor-derived cell-free DNA (dd-cfDNA)** in a recipient's blood.

CURRENT TEST RESULT AND INTERPRETATION

dd-cfDNA %

1.75%

Percentage of dd-cfDNA in the sample

dd-cfDNA Score *

44 cp/ml

* see methodology and limitations

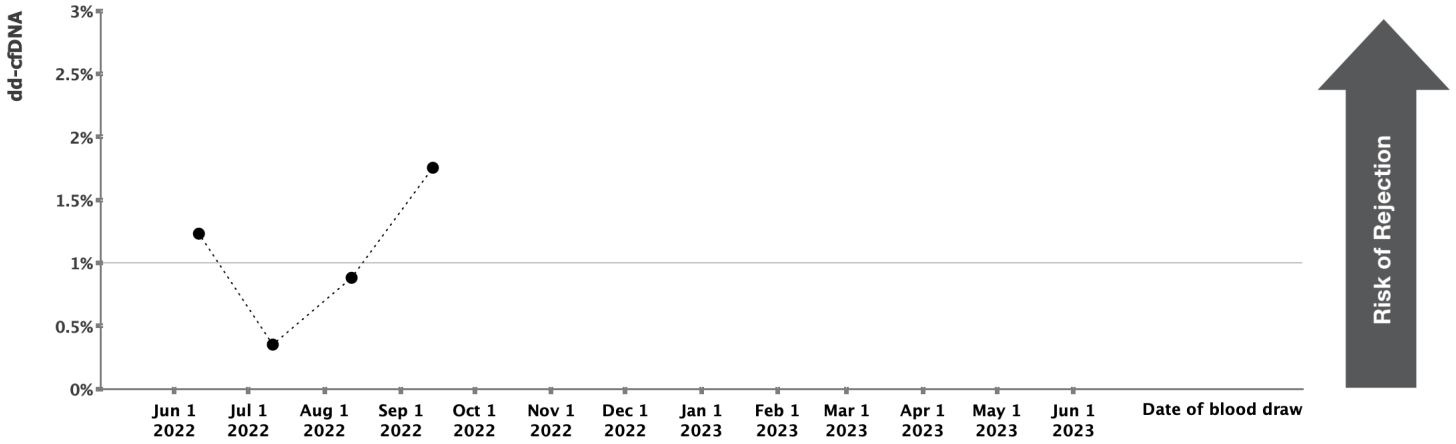
Increased risk for rejection

Reference range

Increased risk for rejection
dd-cfDNA% ≥ 1% **or** dd-cfDNA score ≥ 78 cp/ml

Decreased risk for rejection
dd-cfDNA% < 1% **and** dd-cfDNA score < 78 cp/ml

PATIENT TESTS SUMMARY



Blood Draw Date	dd-cfDNA%	dd-cfDNA change	dd-cfDNA Score*	Interpretation
06/11/2022	1.23%	-	98 cp/ml	Increased Risk
07/11/2022	0.35%	-0.88%	52 cp/ml	Decreased Risk
08/12/2022	0.88%	0.53%	50 cp/ml	Decreased Risk
09/14/2022	1.75%	0.87%	44 cp/ml	Increased Risk

METHODOLOGY AND TECHNICAL DETAILS

Prospera is a screening test that measures cfDNA derived from the donor organ to evaluate the risk of Active Rejection (AR) in a patient. AR includes antibody-mediated rejection, T-cell-mediated rejection, or mixed rejection, in both subclinical and clinical presentations. Cell-free DNA is extracted from the transplant recipient's blood and is sequenced using next generation sequencing (NGS) to collect genotypes specific to the patient and the donor organ. Percentage of dd-cfDNA (dd-cfDNA%) in the specimen is quantified by a proprietary algorithm that does not require prior analysis of donor or recipient DNA. The dd-cfDNA score is a score derived from an estimate of the amount of dd-cfDNA present in the specimen. Patients with ≥1% dd-cfDNA% or ≥78 cp/ml dd-cfDNA score have an increased risk of AR compared to patients with <1% dd-cfDNA% and <78 cp/ml dd-cfDNA score. If dd-cfDNA score did not meet established performance criteria or could not be determined, rejection risk assessments are based solely on dd-cfDNA%.

LIMITATIONS

Prospera is a screening test intended to monitor AR over time and is not designed to diagnose disease. It is not intended for use by clinicians as a stand-alone test for detecting AR. Results should be interpreted by a clinician in the context of patient history and other clinical factors to aid patient biopsy management, rejection event monitoring, and immunosuppressant dosing. Prospera is not indicated for use in patients who are pregnant, less than two weeks post-transplant, recipients of an allograft from an identical twin, recipients of an allogeneic cell transplant, recipients with active somatic disease, or recipients with multiple organ transplants except for simultaneous pancreas-kidney (SPK) transplants. Results do not exclude the possibility of other organ injuries and may require diagnostic confirmation of AR status by alternative testing methods. False positive or false negative results may occur, including due to laboratory error. Laboratory error, including misidentification of samples, during any phase of testing cannot be completely excluded.

DISCLAIMERS

Reviewed by: Jing Xie, PhD, FACMG, Laboratory Director

CLIA Laboratory Director: J. Dianne Keen-Kim, PhD, FACMG, HCLD(ABB)