ARUP Physician Services 004070
321 TESTING ANSR EXTRACT
Salt Lake City NY 84108

Date of Birth: 27-Sep-90
Gender: Male
ARUP ID: 554768
Requisition #:
Client Supplied ID:
Physician: Test, Test
Printed: 01-Jun-20 15:15:53

Procedure	Result	Units	Ref Interval	Accession	Collected	Received	Reported/ Verified
dd-cfDNA	1.1% @			20-150-900128	29-May-20 15:12:00	29-May-20 15:18:00	01-Jun-20 11:55:23
Donor Relationship	Bio Parent @			20-150-900128	29-May-20 15:12:00	29-May-20 15:18:00	01-Jun-20 11:55:23
Date of Transplant	12/22/2019 @			20-150-900128	29-May-20 15:12:00	29-May-20 15:18:00	01-Jun-20 11:55:24

29-May-20 15:12:00 Date of Transplant,Donor Relationship,dd-cfDNA:
Performed at: Natera, Inc., 201 Industrial Road, Suite 410 San Carlos, CA 94070

29-May-20 15:12:00 Date of Transplant:
INTERPRETIVE DATA: Prospera Transplant Assessment

REFERENCE RANGE
>= 1 %: Increased Risk for Active Rejection
< 1 %: Decreased Risk for Active Rejection

TECHNICAL DETAILS AND LIMITATIONS
Prospera measures DNA derived from donor kidneys to identify active rejection (AR). AR includes patients whose biopsy reveals antibody-mediated rejection, T-cell-mediated rejection, or mixed rejection in both subclinical and clinical presentation. Patients with dd-cfDNA levels of >/= 1 percent have a higher risk of AR than patients with dd-cfDNA levels of <1 percent. Prospera's negative predictive value is 95% and the positive predictive value is 52 percet (25 percent prevalence). Sensitivity is 89 percent and specificity is 73 percent (Sigdel TK et. al. J. Clin. Med. 2019, 8(1), 19). Prospera is not indicated for use in patients who are pregnant, less than two weeks posttransplant, recipients of an allograft from an identical twin, recipients of an allogeneic stem cell transplant, or recipients of a nonkidney organ transplant. Results should be interpreted in light of patient history and other clinical factors.

TESTING METHODOLOGY
Cell-free DNA is extracted from the transplant recipient's blood and is sequenced using next generation sequencing (NGS) to collect SNP data specificity to the patient and the donor organ. The dd-cfDNA fraction is determined using a proprietary algorithm that does not require prior analysis of either donor or recipient DNA. When samples do not meet the necessary quality metrics, a test result is not provided, and the clinician is advised to perform a second draw.

DISCLAIMERS
False positives and false negatives can occur. High dd-cfDNA fraction, associated with increased risk of AR, may require diagnostic confirmation of AR by alternative testing methods. Low dd-cfDNA fraction results do not fully exclude the diagnosis of AR nor do they exclude the possibility of other kidney injuries. The dd-cfDNA analysis provides analytical information to aid in the determination of the patient's rejection status; however, there are many potential sources of diagnostic errors, including misidentification of samples. Patients should understand that rare diagnostic errors may occur. Test results should always be interpreted by a clinician in the context of clinical data. This test was developed and its performance characteristics were

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determined by Natera (CLIA ID: 05D1082992). This test has not been cleared or approved by the U.S. Food and Drug Administration (FDA).