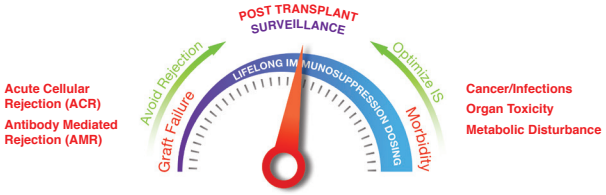
IMMUCOR | DX

kSORT™ TECHNICAL BRIEF

PS
POST-TRANSPLANT SURVEILLANCE

kSORT™ (kidney Solid Organ Response Test)

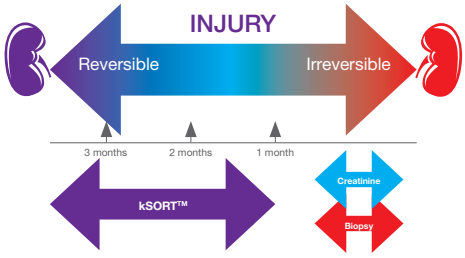
is a non-invasive, whole blood derived, molecular expression assay that can establish an immune risk index for enhanced post-transplant surveillance of graft health and immune quiescence in immunosuppressed, renal transplant patients. In conjunction with standard clinical care guidelines, kSORT™ assists in assessing the overall dynamic immune risk profile of post-renal transplant patients thereby improving risk stratification and patient management.



Background

The field of renal transplantation has progressed considerably in the past half-century largely due to an improved understanding of the role of the immune system in allograft rejection, the interpretation of the molecular mechanisms underlying graft failure, and better management of immunosuppression. However, due to the dynamic immune response of transplant patients, events such as acute rejection (AR) remains an obstacle occurring in approximately 15%–20% of patients using the current standard of care.

The current gold standard for detection of graft injury is an invasive biopsy following an increase in serum creatinine. However, biopsy histology is subject to sampling error and increased creatinine is insensitive, occurring only after graft damage has occurred. Immune activation can lead to chronic graft injury and requires cost-intensive care, reduce the quality of life of patients, and may ultimately result in total graft loss. A sensitive, specific, and noninvasive test for assessing the immune risk of post-transplant patients is a critical and currently unmet need.



Methods

kSORT™ is a quantitative, real-time PCR (qPCR) method analyzing the relative expression of a specific, proprietary gene set in peripheral blood, which has been shown to play a role in the immune response.

Gene expression of each of the target genes is measured using TaqMan primer/probes sets normalized to the expression of 18S ribosomal RNA.

The raw ddCT data generated by kSORT™ is analyzed using a proprietary centroid-based algorithm (kSAS), providing a qualitative Immune Risk Index Score of HIGH, LOW or INDETERMINATE that can be reported to clinicians.

Validation of kSORT™ performance included an evaluation of accuracy, precision, sensitivity and specificity. Analytical accuracy analysis demonstrated substantial correlation, yielding a Cohen's Kappa of 0.79 (Table 1a) for correlation between ImmucorDx and The Sarwal lab and 87% agreement between ImmucorDx results and biopsy results (Table 1b).

Table 1a.

Immucor DX	The Sarwal Lab			
	HIGH	IND	LOW	*Total*
HIGH	33	4	0	*37*
IND	0	4	6	*10*
LOW	0	2	51	*53*
Total	*33*	*10*	*57*	*100*

Table 1b.

Immucor DX	The Sarwal Lab		
	AR	NO AR	*Total*
HIGH	26	2	*28*
IND	2	7	*9*
LOW	0	47	*47*
Total	*28*	*56*	*84*

The assay gives an indeterminate rate of 11%; sensitivity and specificity are 100% and 96% respectively after excluding indeterminate samples.

Table 2.

Agreegment Rate	87%
IND Rate	11%
Sensitivity	100%
Specificity	96%

301 Michigan St NE, Suite 580
Grand Rapids, MI 49503
800.363.5915

www.immucor.com/DX

Ordering and Shipping Instructions

Peripheral blood specimens for kSORT™ are collected in PAXgene Blood RNA Tubes and sent to IMMUCOR DX, Grand Rapids, MI, USA along with the appropriate test requisition, patient and billing information. The PAXgene tube protects RNA from degradation thereby allowing for prolonged storage and transportation of the specimen. A PAXgene specimen is stable for 3 days at 15-25oC, 5 days at 2-8oC, and up to 8 years at <-20oC. The standard return shipping for kSORTTM kits is 2 business days. Contact IMMUCOR DX for ordering supplies and customer support at 1-800-363-5915.

Turnaround time and Reporting

Turnaround time (TAT) is 3 business days from receipt at IMMUCOR DX.

Reports will
be sent by fax to the ordering physician.

CPT Codes and Description

CPT 81599 Unlisted multianalyte assay with algorithmic analysis
CPT 86849 Unlisted immunology procedure

The CPT codes provided are for general informational purposes only. CPT coding is the sole responsibility of the billing party. Questions regarding coding should be addressed to your local Medicare carrier. Immucor assumes no responsibility for billing errors due to reliance on the CPT codes illustrated in this material.

Analytical Performance of the Kidney Solid Organ Response Test (kSORT™)
Namrata Bhatia (MPH)[1], Jody Thurston MT(ASCP)[2], Tiffany Roberts, PhD[2. 1] 953 Indiana St, San Francisco, CA 94107; 2301 Michigan St. NE STE 580, Grand Rapids, MI 49503

301 Michigan St NE, Suite 580
Grand Rapids, MI 49503
800.363.5915

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