

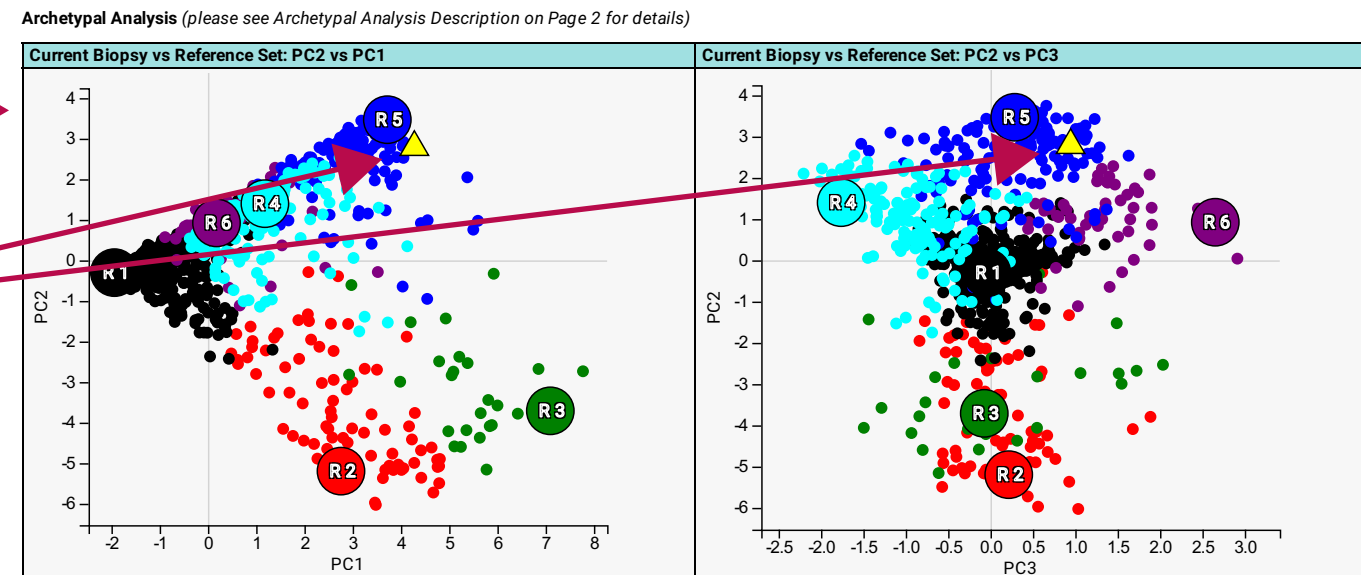
How to Interpret the Assessment Report

Molecular Microscope[®] Diagnostic Report for Kidney (MMDx-Kidney)

Patient and Institution Information		CLINICAL INFORMATION	
Patient Name or ID		Lab ID Number	
Patient DOB		Ordering Physician	
Patient MRN		Ordering Institution	
Testing and Clinical Information		CLINICAL INFORMATION	
Test Date		Time from Transplant to Biopsy	9 years
Report Date		Transplant Type	DD (Deceased)
Transplant Date		Biopsy Indication	Deterioration in renal function (slow)
Biopsy Date		Primary Disease	Hypertension, biopsy proven

Pure Molecular Interpretation (Results Summary)		Percent cortex ¹
Very active ABMR, with ptc, g, and cg molecular features. No TCMR. Moderate inflammation. Moderate AKI and atrophy-fibrosis. Note: the Molecular Microscope [®] Diagnostic System cannot exclude primary glomerular diseases.		79%

Result Details					
Biopsy Rejection and Injury Scores					
	Classifier / Gene Sets	Biopsy Score	Range of Values ²	Upper Limit of Normal ³	Interpretation
Injury Scores	Global Disturbance Score	2.63	-3.8 – 5.8	0.03	Moderate
	Acute Kidney Injury (AKI) Score	0.65	-0.6 – 1.6	0.39	Mild
	Atrophy-Fibrosis Score	0.47	0 – 1	0.76	Mild
Rejection Scores	Rejection Score	0.95	0 – 1	0.30	Severe
	T Cell-Mediated Rejection (TCMR) Score	0.02	0 – 1	0.10	Normal
	Antibody-Mediated Rejection (ABMR) Score	0.96	0 – 1	0.20	Severe



Rejection phenotype ⁴ (six scores, R1-R6, adding up to 1.0)			
● R1 Non-rejecting	0.00	● R4 Early-Stage ABMR (EABMR)	0.00
● R2 TCMR	0.00	● R5 Fully-Developed ABMR (FABMR)	0.87
● R3 Mixed Rejection	0.09	● R6 Late-Stage ABMR (LABMR)	0.03
▲ Current Sample 171005004MM		All ABMR (Sum of R4, R5, and R6)	0.91

1. Percent cortex is a quality control measure. 2. The 2.5th to 97.5th percentiles in the entire Reference Set. 3. 90th percentile in relevant Reference Set biopsies. 4. Scores from archetypal analysis.

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Survival in patients with similar biopsies in the Reference Set			
1 Year	71%	3 Year	55%

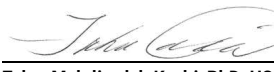
Additional Biopsy Scores					
	Classifier / Gene Sets	Biopsy Score	Range of Values ¹	Upper Limit of Normal ²	Interpretation
TCMR Related	TCMR-1	0.02	0 – 1	0.10	Normal
	TCMR-2	0.02	0 – 1	0.10	Normal
	Mean of 2 TCMR Classifiers	0.02	0 – 1	0.10	Normal
Rejection Related	Rejection	0.95	0 – 1	0.30	Severe
	AKI Score	0.65	-0.6 – 1.6	0.39	Mild
Injury-Scarring Related	Atrophy-Fibrosis Score	0.47	0 – 1	0.76	Mild
	ABMR-1	0.96	0 – 1	0.20	Severe
ABMR Related	ABMR-2	0.91	0 – 1	0.20	Severe
	ABMR-3	0.97	0 – 1	0.20	Severe
	Mean of 3 ABMR Classifiers	0.95	0 – 1	0.20	Severe
Classifiers based on Histologic Lesions	Glomerulitis (g) > 0 probability	0.85	0 – 1	0.34	Severe
	Transplant Glomerulopathy (cg) > 0 Probability	0.94	0 – 1	0.24	Severe
	Peritubular capillaritis (ptc) > 0	0.87	0 – 1	0.26	Severe
	DSA-positive probability	0.83	0 – 1	0.48	Severe
	Interstitial inflammation (i) > 1 probability	0.38	0 – 1	0.08	Moderate
	Tubulitis (t) > 1 probability	0.12	0 – 1	0.12	Normal
	Tubular atrophy (ct) > 1 probability	0.33	0 – 1	0.87	Normal
	Arterial hyalinosis (ah) > 0 probability	0.70	0 – 1	0.91	Normal

For Classifiers: TCMR-1 TCMR vs everything else. ABMR-1 ABMR vs everything else. ABMR-2 TCMR vs everything else, with BK/Borderline/Mixed withheld. ABMR-3 ABMR vs everything else, with TG/ABMR suspicious withheld.

Nearest Neighbor Analysis	
Rank order of the most common histologic diagnoses in the 50 nearest molecular neighbors.	
ABMR	70%
NOMOA	8%
Mixed	8%
TG	4%
GN	4%

Mean molecular scores in the 50 nearest molecular neighbors.	
ABMR	0.9
Rej	0.88
Acute Kidney Injury	0.53
Atrophy-Fibrosis	0.52
TCMR	0.03

Archetypal Analysis Description
Archetypal analysis was used to define a set of pure rejection phenotypes or archetypes (non-rejection, TCMR, stages of ABMR, and Mixed) within the reference biopsy data set. A visualization of the same data set, produced by principal component analysis, is shown. The axes represent molecular continua: PC1 is non-rejection to rejection (left to right); PC2 is ABMR to TCMR (top to bottom); and PC3 is early to late-stage ABMR (left to right). PC3 can be thought of as the view down the x axis of the PC2 vs PC1 figure. Scores for the probability of each archetype for the current biopsy are given below the plots.


Zahra Mehdizadeh Kashi, PhD, HCLD
CEO and Laboratory Director

The Molecular Microscope[®] Diagnostic System is a set of RNA classifiers that are derived via gene expression profiling analysis using GeneChip[™] 3' Expression Arrays. The performance characteristics of this test were determined by Kashi Clinical Laboratories under the accreditation guidelines of the College of American Pathologists. It has not been cleared or approved by the U.S. Food and Drug Administration.

1. The 2.5th to 97.5th percentiles in the entire Reference Set. 2. 90th percentile in relevant Reference Set biopsies.

Patient Information

Clinical Interpretation

Summary of molecular changes (Injury, Rejection Scores)

Visualization Relationship of biopsy to others in reference set

Indicates this biopsy

Proportions Rejection-related molecular changes)

Survival of Similar Biopsy

Rejection, injury-related binary classifies and AKI transcript set

Comparison to normal Scores of this biopsy interpreted vs. relatively normal biopsies