vericiDx | Tutivia™ Validation Study

A prospective, blinded, observational, multicenter, international study designed to evaluate three different RNA signatures related to rejection and injury of transplanted kidneys. Each signature is unique and individually assessed with differing end points. Tutivia™ which identifies the post-transplant risk for acute rejection, has completed the 151 patient clinical validation. Clarava™ which assesses the pre-transplant risk for early acute rejection, will be completed in 2023, and Protega™ which reports a prognostic risk score for development of kidney fibrosis, will be finalized upon the completion of 24 month outcomes. The total study will include over five hundred patients for all time points.

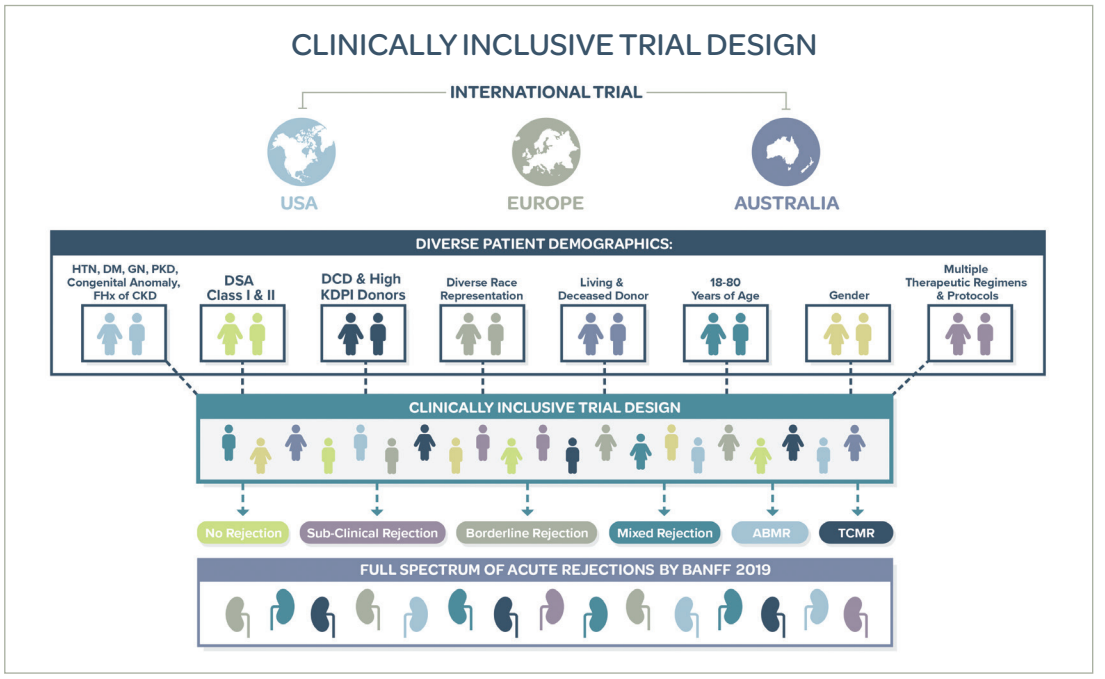


Figure 1. *Importance of Clinical Study Design on Translational Utility*

Tutivia™ Clinical Validation Study Demographics

151 Unique Study Participants	
Mean/Median Recipient Age	53/53 Years
Mean/Median Donor Age	47/46 Years
Male	97 (64%)
Female	54 (36%)
Race	
Asian	5
Black	31
Native American	0
Pacific Islander	3
White	108
Not Answered	4
Participation Location	**Number of Patients**
USA	84
Europe (Italy France, Spain)	57
Australia	10
Living Donor Recipient	**51 (33%) Total**
Living Related Donor	28
Living Unrelated Donor	23

Deceased Donor Recipient	**100 (66%) Total**
Standard Criteria Donor	51
Expanded Criteria Donor	17
Donors after Cardiac Death	31
Not Answered (Deceased)	1
Number of Previous Kidney Transplants/Patients	
0	120
1	18
2	3
Missing	10
ABO Incompatibility	**Number of Patients**
No	147
Yes	4
HLA Mis-matches (A, B, DRB1, DQB1)	**Number of Patients**
0-4	53
5-8	73
Missing	25

Table 1. *Study Population and Demographics*

tutivia™ DELIVERS.

- Thirteen centers in the US, Spain, France, Italy, and Australia are included in the results to date.
- Tutivia™ utilizes a proprietary RNA next generation sequencing profile, which assesses specific genes involved in the kidney injury spectrum identifying immunologic response, direct damage to kidney tissue, and expression that provides protection to the transplanted kidney.
- Tutivia™ utilizes a proprietary AI driven algorithm which produces a risk score from 0-100. Greater than 50 is interpreted as high risk for AR, while less than or equal to 50 is interpreted as low risk for AR.
- Verici Dx translates a patient's individual gene expression related to rejection to produce an overall patient risk score. This individualized risk score allows the clinician to shift focus to the single individual with that particular score at that particular encounter.
- A blinded central pathologist read all biopsies, with expertise in reading kidney transplant biopsies, and local pathologist readings were also collected.
- The study assesses risk of AR within first 6 months post-transplant. All participants are followed out to 24 months post-transplant. All patients in the validation study were independent from the patients that comprised the training set.
- One hundred and fifty-one patients studied to evaluate performance of Tutivia™ are included in the results presented here.

Tutivia™ Validation Study

tutivia™ DELIVERS.

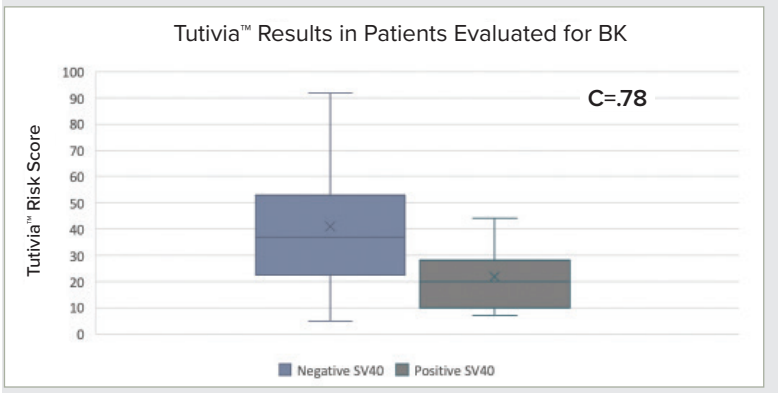
RESULTS

151 total patient biopsies. Indication biopsies N=44 protocol biopsies N=107

44 PATIENTS IN THE VALIDATION SET UNDERWENT INDICATION BIOPSY

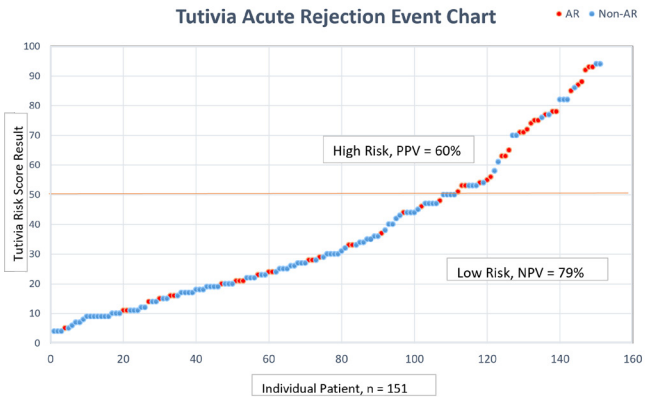
- **80%** of indication biopsies were performed in the first 60 days
- **69%** of these early biopsies showed acute rejection (AR)
- **83%** of early biopsies showing AR had a high Tutivia risk score

- Mean time for AR was 61 days. Median was 57. (Range of time to AR was 6 to 175 days)
- 26.5% of patients had a score >50
  - » 60% of those correlated with histologic reading of AR (PPV 60%)
- 73.5% of patients had score ≤50
  - » 79% of those had no evidence of AR (NPV 79%)



- BK can be difficult to differentiate from rejection in current biomarker testing.
- Of the 151 patients in the validation set, 6 biopsies were determined to be BK positive through central and/or local pathology, all had a Tutivia™ score ≤50.
- Patients with BK nephropathy (SV40+) were highly correlated with lower Tutivia™ results than those with negative SV40; C =.78.

[1] *Loupy A, Haas M, Roufosse C, et al. The Banff 2019 Kidney Meeting Report (I): Updates on and clarification of criteria for T cell– and antibody-mediated rejection. Am J Transplant. 2020;20:2318–2331. https://doi.org/10.1111/ajt.15898*



- When you receive a high-risk Tutivia™ result, the odds ratio of that patient having acute rejection (AR) is **5.74** over a low-risk result.
- This high odds ratio increases confidence in making informed treatment decisions.

Tutivia™ Delivers

1. Earlier insights for proactive care.
2. Personalization to dynamically inform treatment decisions.
3. Reliable testing for all your patients.

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