

### Test Name

TruGraf® Blood Gene Expression Test

### CPT Code

81479

### Test Ordering Code

30929

### Clinical Utility

The TruGraf® test is intended for use in kidney transplant recipients with stable renal function as an alternative to surveillance biopsies.

### Application

TruGraf® is indicated for use in renal transplant patients who are 18 years of age or older and at least 90 days post-transplant with stable serum creatinine values. Clinical validity of the TruGraf® test was established in kidney transplant recipients (First et al, 2017).

### Eligible Patients (must meet all of the following criteria):

- Renal transplant recipients at least 18 years of age.
- Recipient of a primary or subsequent deceased-donor or living-donor kidney transplantation.
- Stable serum creatinine; current serum creatinine <2.3 mg/dl, <20% increase compared to the average of the previous 3 serum creatinine levels
- Kidney transplant patients who are more than 90 days post-transplant

### TruGraf® Testing Process

Transplant Genomics supplies TruGraf® Blood Draw collection kits that can be obtained directly from the patient's transplant center or mailed to the patient's home where the patient can then go to any Quest blood draw center, or distributed in bulk to enable ease of testing in Tx center centralized laboratories. When

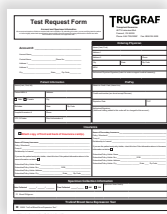
presenting the TruGraf® kit and completed TruGraf® Test Requisition form, the Quest or transplant center laboratory phlebotomist will draw the patient's blood, complete the test requisition and mail the completed test requisition and TruGraf® blood collection kit to our CLIA lab for processing. The TruGraf® blood collection kit contains 2-PAXGene tubes (PreAnalytix/BD) which will stabilize the sample and prevent RNA degradation prior to analysis.

A TruGraf® blood collection kit and complete TruGraf® test requisition form is received by our CLIA certified laboratory. Results are returned to the appropriate clinician within 7 days of receipt of sample. The pattern of gene expression in a patient's blood sample is determined to correspond more closely to one of two classes, "TX" (for Transplant eXcellence), ruling out subclinical rejection with high confidence and indicating that a patient is likely to be adequately immunosuppressed. If a patient's sample is determined to more closely resemble the other class, "not-TX", then subclinical rejection cannot be ruled out with high confidence, and the patient may not be adequately immunosuppressed.

### Ordering TruGraf

There are multiple ways to order TruGraf. For a single test, multiple "bulk order" testing for laboratory automation, and up to 24 month standing orders.

- **Paper Requisition:** TruGraf testing can be ordered manually by requesting an editable Test Requisition Form (TRF) via email at: [info@trugraf.com](mailto:info@trugraf.com).
- **By Phone:** Contact us at 1.844.TruGraf
- **Online Order:** TruGraf can be ordered and results accessed through our online portal, Retriever
- **Interface:** TruGraf can be interfaced through a bidirectional HL7 interface, set up of which can be arranged by contacting us at 1-844-TruGraf or [info@trugraf.com](mailto:info@trugraf.com)



Physician Completes  
Test Requisition Form



Medical Personnel  
Draws Patient's Blood



Ship Sample in our Kit  
to our CLIA Lab



Physician Receives  
Patient Report

For sample collection questions, contact us: 1.844.TruGraf Fax: 888.2243499 Email: [info@TruGraf.com](mailto:info@TruGraf.com)