

How To Order Pleximark[™] Tx

Web: Check ordering information under – http://www.plexision.com Phone: 1.855.753.9474 or 1.855.PLEXISION

Fax: 1.412.224.2776

Mailing Address:

Plexision, Inc. 4424 Penn Avenue, # 202, Medical Building, Pittsburg, PA, 15224-1338.

Insurance Coverage

Plexision will bill the patient's insurance plan and work directly with the insurer for payment.

Patient Assistance Program

Plexision will assist with the cost of $Pleximark^{TM}Tx$, if there is no insurance coverage. For additional information, call 1.855.753.9474 or email info@plexision.com.

References

- 1. US Patent 8759016
- 2. Am J Transplant. 2009; 9(1): 179-913
- 3. Surgery. 2009; 146(2): 166-73
- 4. Pediatr Transplant, 2012; 16(0): 83-91
- 5. CLIA ID: 39D2042664
- 6. Transplantation, 2011. 92(4): 433-8





Assessing the likelihood of renal transplant rejection



Description

Pleximark[™]Tx is a patented¹ blood test to assess the likelihood of acute cellular rejection after renal transplantation.*

Purpose

Knowledge about rejection can be combined with available clinical data to plan additional treatment for your patient.

Rationale

- § Renal transplant rejection is usually suspected because of elevated serum creatinine. Elevated creatinine is also seen with infection and mechanical blockage. A "for cause" biopsy is needed to confirm rejection. Roughly half of "for cause" biopsies do not show rejection.
- S Rejection can also occur without affecting serum creatinine, especially if immunosuppression is suboptimal. Surveillance biopsies are performed at predetermined intervals to detect 'silent' rejection and assess immunosuppression.
- **§** The Pleximark blood test measures the likelihood of rejection. This knowledge can be combined with clinical information to develop a treatment plan. Benefits include:
 - improving long-term management with serial monitoring,
 - enhancing the diagnostic yield of "for cause' biopsies,
 - optimizing the frequency of surveillance biopsies.



Intended Use

To assess the likelihood of acute cellular rejection after renal transplantation.

Procedure

- S Pleximark™Tx is a functional cell-based blood test, which measures the immune response of recipient lymphocytes to donor lymphocytes in cell culture.
- S The test requires whole blood in sodium heparin tubes to be shipped at ambient temperature for overnight delivery to Plexision's laboratory. Seven-10 ml whole blood are needed from adults, and 3-5 ml are needed from children.
- § Recipient T-cytotoxic memory cells, which express the inflammatory marker, CD40 ligand or CD154 are measured with flow cytometry.
- **S** Results are expressed as an index of rejection, which is a measure of the likelihood of rejection.
- S Results are reported the day after the blood sample is received at the laboratory, and within two days of obtaining the blood sample from the patient.
- S The technology underlying the Pleximark[™]Tx test has been evaluated in over 200 children with liver or intestine transplantation and adults with renal transplantation.²⁻⁴

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* Pleximark[™]Tx is a laboratory developed test which has been developed by Plexision. It is not FDA-approved.





Performance

- The Pleximark ${}^{\rm T}\!{\rm X}$ test is performed in Plexision's CLIA-approved ${}^{\rm 5}$ laboratory, and
- Has been developed in relationship to "for cause" biopsies in renal transplant recipients. Identifies renal transplant recipients experiencing rejection with sensitivity of 88% and specificity of 86%⁶.
- Identifies renal transplant recipients experiencing rejection with sensitivity of 88% and specificity of 86%⁶.
- Requires whole blood shipped at ambient temperature
 3-5ml for children and 7-10 ml in adults

This knowledge can be combined with other clinical information to develop a treatment plan.