

**TACROLIMUS (FK-506), WHOLE BLOOD  
(LC-MS / MS)**

**ug/L**

### Interpretation

KIDNEY TRANSPLANT	POST TRANSPLANT	THERAPEUTIC RANGE in ug/L
PEDIATRIC	0-3 months	10-12
	3 -6 months	8-10
	6-12 months	6-8
	>12 months	4-7
ADULT	0-6 months	8-10
	6-12 months	6-8
	>12 months	4-6
	>5 years	3-5
	Toxic range	>20

LIVER TRANSPLANT	POST TRANSPLANT	THERAPEUTIC RANGE in ug/L
PEDIATRIC	0-3 months	10-12
	3 -6 months	8-10
	>6 months	6-8
ADULT	0-3 months	10-12
	3-6 months	8-10
	>6 months	6-8
	Toxic range	>20

**Note:** 1. Therapeutic range is based on whole blood specimen drawn 12 hrs post dose or prior to next dose (trough)

2. Factors affecting Tacrolimus concentration in blood are:

- Nature of transplant
- Age and general health of the patient
- Co-administration of drugs
- Intake of drug with meal
- Time post transplant

3. Tacrolimus Whole blood concentrations can be measured by either chromatographic (LC-MS/MS) or immunoassay (CLIA) methodologies. These two techniques are not directly interchangeable and the measured drug level depends on the methodology used. Reference ranges are different for the two methodologies. Generally CLIA has a positive bias as compared with LC-MS/MS due to cross reacting antibodies with the drug metabolites.

## Comments

LC-MS/MS is considered the most sensitive, specific and precise technology for monitoring immunosuppressants. Therapeutic drug monitoring (TDM) is commonly used to help maintain drug levels within the concentration range in which the drug exerts its clinical effect with minimal adverse reactions. Tacrolimus is a potent immunosuppressant approved for prophylaxis of organ rejection in patients receiving allogeneic liver transplants. It has also been used effectively in other solid organ transplant patients like kidney transplant for prevention of graft versus host disease as well as in pancreatic islet transplantation. It exerts immunosuppressive effect following the formation of a complex with immunophilins. Its absorption from small intestine is highly variable ranging from 4-93% and changes with time following transplant surgery. Even the elimination half life of Tacrolimus is variable being 12 hours in liver transplant patients and 19 hours in renal transplant patients.

## Indications for testing

- Immunosuppressant dose optimization
- Failure to respond to immunosuppressants
- Signs or Symptoms consistent with inadequate or excessive immunosuppression
- Changes to concomitant medications or other variables that affect pharmacokinetics