ClearPoint DIAGNOSTIC LABORATORIES

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LAB ALERT – NEW TEST

NOTIFICATION DATE: 2/10/2014
EFFECTIVE DATE: 2/11/2014

TACROLIMUS BY IMMUNOASSAY

NEW TEST CODE: TACRIA

INTERFACE CODE: 1004635

OLD TEST CODES TO BE DEACTIVATED: None

OLD INTERFACE CODES TO BE DEACTIVATED: None

METHODOLOGY: Chemiluminescent Microparticle Immunoassay (CMIA)

CLINICAL UTILITY: Tacrolimus, an immunosuppressive drug has been shown to be effective for treatment of organ rejection following liver and kidney transplantation. Quantitative determination of Tacrolimus in Human Whole Blood is used as an aid in the management of Liver and Kidney allograft patients receiving Tacrolimus therapy. Clinical studies are in progress regarding its use in other indications.

In blood, Tacrolimus is bound to proteins, mainly albumin and alpha-1-acid glycoprotein, and is highly bound to erythrocytes. Pharmacokinetics studies indicated that whole blood serves as the more appropriate medium to describe the pharmacokinetic properties of Tacrolimus. Tacrolimus is extensively metabolized in the liver and small intestine and nine of its metabolites have been identified. The use of Tacrolimus is associated with serious toxic side effects e.g. nephrotoxicity. Other side effects include neurotoxicity, insomnia and nausea.

Note:
Numerous factors contribute to variable requirements for optimal blood levels of Tacrolimus e.g. the complexity of the clinical state, individual differences in sensitivity to immunosuppressive and nephrotoxic effects of Tacrolimus, co-administration of other immunosuppressants, type of transplant, and time after transplant. Therefore, no firm therapeutic range exists for Tacrolimus in whole

	blood. Since the therapeutic ranges also vary according to the commercial test used, therefore, it is recommend that one assay be consistently used for monitoring individual patients.
PERFORMED:	Sunday – Saturday **Note:** The test will be performed at 12 noon daily; therefore, the cut-off time to receive specimens in the lab will be 11:00 a.m.
COLLECTION:	Only lavender top tube (EDTA) specimen is acceptable.
SPECIMEN PREPARATION:	Label specimens with both the time of collection and the last drug administration.
STABILITY (FROM COLLECTION TO INITIATION OF TESTING):	Ambient: 24 hours; Refrigerated (2 – 8°C): 7 days; Frozen (-20°C): 6 months.
TRANSPORT:	Refrigerated
REFERENCE RANGE:	Variable
RESULTS REPORTED:	1 day
CPT CODE(S):	80197
PERFORMING LAB:	ClearPoint Diagnostic Laboratories
ORDER / CONTACT INFORMATION:	ClearPoint Client Services: 972-966-7700 | Fax: 972-966-7799 Thomas P. Lohmann, MD: 972-966-7135

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