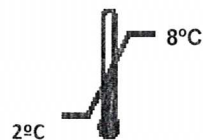


Certificate of Analysis

LIFECODES Class I ID Kit **LM1**
REF 628200

LOT 090111-LMI


Store at 2 - 8°C



2012-08-22


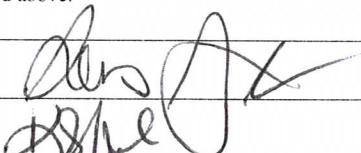
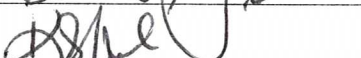
EXP: 22-AUG-2012

LIFECODES Class I ID is a bead-based immunoassay used to qualitatively detect Panel Reactive HLA Class I IgG antibodies (PRA). Each kit consists of all reagents required for performing 24 assays. LIFECODES Class I ID is composed of affinity purified Class I HLA glycoproteins from different individuals conjugated to different xMAP® Microspheres. Any retained IgG is detected by adding an anti-human IgG antibody conjugated to phycoerythrin and analyzed on the Luminex instrument. Each lot is tested following LIFECODES ID Kit Procedure prior to release.

CAUTION: LIFECODES Class I ID Beads and Conjugate Concentrate are extremely light sensitive. Minimize exposure to light. Store in light tight packaging provided.

IVD

xMAP® Microspheres is a registered Trademark of Luminex Corporation, Austin, TX.

TEST	SPECIFICATION		
Components		LOT	
	LM1B HLA I Beads (120uL)	LM1-090111	2012-09-01
	LMCJ Conjugate Concentrate (170µL)	LMCJ082211	2012-08-22
	LMWB Wash Buffer (30mL)	LMWB3-081211	2013-08-12
	LMPC Positive Control Sera (80µL)	LMPC032411	2013-03-24
	LMNC Negative Control Sera (80µL)	LMNC063011	2013-06-30
	Recording Sheet (1 each)	LC817.9 (08/10)	N/A
	Plate Format Sheet (1 each)	Rev. 12 OCT 2009	N/A
	Product Insert LC807IVD	LC807IVD.10 (10/09)	N/A
Bead Count	Minimum 60 events in 60 seconds on Luminex 2.3 Instrument		
Photobleaching	No Photobleaching detected		
PRA/Specificity	Expected results with known sera		
	Greater than or equal to 85% PRA on LMPC	Average PRA of LMPC = 100%	
Other Testing	Less than or equal to 10% PRA on LMNC	Average PRA of LMNC = 0%	
		Value	Range
	Mean MFI value of the Positive Control bead was:	20377	17589 - 21799
	Mean MFI value of the Negative Control beads were:	CON1 182	45 - 2869
	CON2 91	39 - 529	
	CON3 267	46 - 2023	
	Positive Control bead gave mean average MFI value that was an average of 134 times the mean MFI value of the Negative Control beads.		
	This lot gave positive results when tested with sera from at least 20 individuals known to be immunized against human HLA Class I antigens		
	This lot gave negative results when tested with sera of individuals known to have no immunization against human HLA Class I antigens		
	All human source material used in the preparation of this kit has been tested and found negative for antibody to HIV, HCV, and HBsAg by FDA approved methods. No test method, however, can offer complete assurance that HIV, Hepatitis C virus, Hepatitis B virus, or other infectious agents are absent. Therefore, the product should be handled in the same manner as potentially infectious material.		
This product conforms to the specifications indicated above:			
Quality Control Review:			Date: 10-4-11
Quality Assurance Release:			Date: 10-12-11