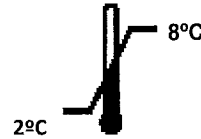


Certificate of Analysis

LIFECODES Class II IDv2 Kit **LM2Q**
REF 628223
LOT 102411-LM2QR


Store at 2 - 8°C

 2012-10-14




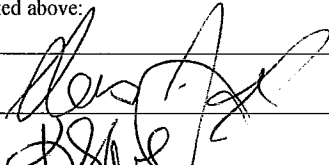
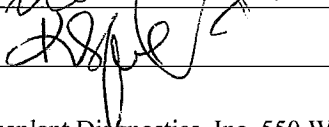
EXP: 14-OCT-2012

LIFECODES Class II IDv2 is a bead-based immunoassay used to qualitatively detect Panel Reactive HLA Class II IgG antibodies (PRA). Each kit consists of all reagents required for performing 24 assays. LIFECODES Class II IDv2 is composed of affinity purified Class II HLA glycoproteins from different individuals conjugated to different x-MAP® 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 Class II IDv2 Kit Procedure prior to release.

CAUTION: LIFECODES Class II IDv2 Beads and Conjugate Concentrate are extremely light sensitive. Minimize exposure to light. Store in light tight packaging provided.

x-MAP® Microspheres is a registered Trademark of Luminex Corporation, Austin, TX.

RUO

TEST	SPECIFICATION																											
Components	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 20%; text-align: center;">LOT</th> <th style="width: 20%; text-align: center;"></th> </tr> </thead> <tbody> <tr> <td>LM2B HLA II Beads (120uL)</td> <td style="text-align: center;">LM2Q102411</td> <td style="text-align: center;">2012-10-24</td> </tr> <tr> <td>LMCJ Conjugate Concentrate (170uL)</td> <td style="text-align: center;">LMCJ101411</td> <td style="text-align: center;">2012-10-14</td> </tr> <tr> <td>LMWB Wash Buffer (30mL)</td> <td style="text-align: center;">LMWB3-081211</td> <td style="text-align: center;">2013-08-12</td> </tr> <tr> <td>LMPC Positive Control Sera (80uL)</td> <td style="text-align: center;">LMPC062911</td> <td style="text-align: center;">2013-06-29</td> </tr> <tr> <td>LMNC Negative Control Sera (80uL)</td> <td style="text-align: center;">LMNC063011</td> <td style="text-align: center;">2013-06-30</td> </tr> <tr> <td>Recording Sheet (1 each)</td> <td style="text-align: center;">LC1060.3 (08/10)</td> <td style="text-align: center;">N/A</td> </tr> <tr> <td>Plate Format Sheet (1 each)</td> <td style="text-align: center;">Rev. 12 October 2009</td> <td style="text-align: center;">N/A</td> </tr> <tr> <td>Product Insert LC1038</td> <td style="text-align: center;">LC1038RUO.1 (11/09)</td> <td style="text-align: center;">N/A</td> </tr> </tbody> </table>		LOT		LM2B HLA II Beads (120uL)	LM2Q102411	2012-10-24	LMCJ Conjugate Concentrate (170uL)	LMCJ101411	2012-10-14	LMWB Wash Buffer (30mL)	LMWB3-081211	2013-08-12	LMPC Positive Control Sera (80uL)	LMPC062911	2013-06-29	LMNC Negative Control Sera (80uL)	LMNC063011	2013-06-30	Recording Sheet (1 each)	LC1060.3 (08/10)	N/A	Plate Format Sheet (1 each)	Rev. 12 October 2009	N/A	Product Insert LC1038	LC1038RUO.1 (11/09)	N/A
	LOT																											
LM2B HLA II Beads (120uL)	LM2Q102411	2012-10-24																										
LMCJ Conjugate Concentrate (170uL)	LMCJ101411	2012-10-14																										
LMWB Wash Buffer (30mL)	LMWB3-081211	2013-08-12																										
LMPC Positive Control Sera (80uL)	LMPC062911	2013-06-29																										
LMNC Negative Control Sera (80uL)	LMNC063011	2013-06-30																										
Recording Sheet (1 each)	LC1060.3 (08/10)	N/A																										
Plate Format Sheet (1 each)	Rev. 12 October 2009	N/A																										
Product Insert LC1038	LC1038RUO.1 (11/09)	N/A																										
Bead Count	Minimum 60 events in 60 seconds on Luminex 2.3 Instrument																											
Photobleaching	No Photobleaching detected																											
PRA/Specificity	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td colspan="2">Expected results with known sera</td> </tr> <tr> <td style="width: 50%;">Greater than or equal to 85% PRA on LMPC</td> <td style="width: 50%;">Average PRA of LMPC = 100%</td> </tr> <tr> <td>Less than or equal to 10% PRA on LMNC</td> <td>Average PRA of LMNC = 0%</td> </tr> </table>	Expected results with known sera		Greater than or equal to 85% PRA on LMPC	Average PRA of LMPC = 100%	Less than or equal to 10% PRA on LMNC	Average PRA of LMNC = 0%																					
Expected results with known sera																												
Greater than or equal to 85% PRA on LMPC	Average PRA of LMPC = 100%																											
Less than or equal to 10% PRA on LMNC	Average PRA of LMNC = 0%																											
Other Testing	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 20%;">Value</th> <th style="width: 20%;">Range</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Mean MFI value of the Positive Control bead was:</td> <td style="text-align: center;">19499</td> <td style="text-align: center;">17549 - 20681</td> </tr> <tr> <td rowspan="3" style="text-align: center;">Mean MFI value of the Negative Control beads were:</td> <td style="text-align: center;">CON1</td> <td style="text-align: center;">20 - 309</td> </tr> <tr> <td style="text-align: center;">CON2</td> <td style="text-align: center;">10 - 117</td> </tr> <tr> <td style="text-align: center;">CON3</td> <td style="text-align: center;">20 - 608</td> </tr> <tr> <td colspan="3">Positive Control bead gave mean average MFI value that was an average of 378 times the mean MFI value of the Negative Control beads.</td> </tr> <tr> <td colspan="3">This lot gave positive results when tested with sera from at least 20 individuals known to be immunized against human HLA Class II antigens</td> </tr> <tr> <td colspan="3">This lot gave negative results when tested with sera of individuals known to have no immunization against human HLA Class II antigens</td> </tr> <tr> <td colspan="3">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.</td> </tr> </tbody> </table>		Value	Range	Mean MFI value of the Positive Control bead was:	19499	17549 - 20681	Mean MFI value of the Negative Control beads were:	CON1	20 - 309	CON2	10 - 117	CON3	20 - 608	Positive Control bead gave mean average MFI value that was an average of 378 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 II antigens			This lot gave negative results when tested with sera of individuals known to have no immunization against human HLA Class II 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.				
	Value	Range																										
Mean MFI value of the Positive Control bead was:	19499	17549 - 20681																										
Mean MFI value of the Negative Control beads were:	CON1	20 - 309																										
	CON2	10 - 117																										
	CON3	20 - 608																										
Positive Control bead gave mean average MFI value that was an average of 378 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 II antigens																												
This lot gave negative results when tested with sera of individuals known to have no immunization against human HLA Class II 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: 11-21-11																										
Quality Assurance Release:		Date: 11-21-11																										