

## Certificate of Analysis

**LIFECODES LifeScreen Deluxe Kit** LMX
**REF** 628215

LOT 091911-LMX


Store at 2 - 8°C



2012-05-19




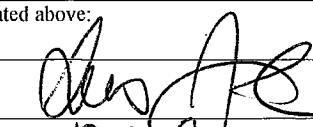
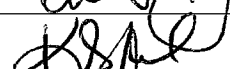
**EXP:** 19-MAY-2012

LIFECODES LifeScreen Deluxe is a qualitative bead-based immunoassay used to detect IgG antibodies to HLA Class I and Class II molecules. Each kit consists of all reagents required for performing 96 assays. LifeScreen is composed of affinity purified Class I and Class II HLA glycoproteins conjugated to 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 LifeScreen Deluxe Kit Procedure prior to release.

**CAUTION: LifeScreen Deluxe 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.

IVD

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;"><span style="border: 1px solid black; padding: 2px;">LOT</span></th> <th style="width: 20%; text-align: center;"></th> </tr> </thead> <tbody> <tr> <td><span style="border: 1px solid black; padding: 2px;">LMXB</span> LifeScreen Deluxe Beads (480uL)</td> <td style="text-align: center;">LMX-091911</td> <td style="text-align: center;">2012-05-19</td> </tr> <tr> <td><span style="border: 1px solid black; padding: 2px;">LMCJS</span> Conjugate Concentrate (550µL)</td> <td style="text-align: center;">LMCJS-091211</td> <td style="text-align: center;">2012-09-12</td> </tr> <tr> <td><span style="border: 1px solid black; padding: 2px;">LMWB</span> Wash Buffer (150mL)</td> <td style="text-align: center;">LMWB15-083111</td> <td style="text-align: center;">2013-08-31</td> </tr> <tr> <td><span style="border: 1px solid black; padding: 2px;">LMPC</span> Positive Control Sera (80µL)</td> <td style="text-align: center;">LMPC-051711</td> <td style="text-align: center;">2013-05-17</td> </tr> <tr> <td><span style="border: 1px solid black; padding: 2px;">LMNC</span> Negative Control Sera (80µL)</td> <td style="text-align: center;">LMNC-051611</td> <td style="text-align: center;">2013-05-16</td> </tr> <tr> <td>Recording Sheet (1 each)</td> <td style="text-align: center;">LC1004.4 (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 LC1003IVD</td> <td style="text-align: center;">LC1003IVD.8 (10/09)</td> <td style="text-align: center;">N/A</td> </tr> </tbody> </table>		<span style="border: 1px solid black; padding: 2px;">LOT</span>		<span style="border: 1px solid black; padding: 2px;">LMXB</span> LifeScreen Deluxe Beads (480uL)	LMX-091911	2012-05-19	<span style="border: 1px solid black; padding: 2px;">LMCJS</span> Conjugate Concentrate (550µL)	LMCJS-091211	2012-09-12	<span style="border: 1px solid black; padding: 2px;">LMWB</span> Wash Buffer (150mL)	LMWB15-083111	2013-08-31	<span style="border: 1px solid black; padding: 2px;">LMPC</span> Positive Control Sera (80µL)	LMPC-051711	2013-05-17	<span style="border: 1px solid black; padding: 2px;">LMNC</span> Negative Control Sera (80µL)	LMNC-051611	2013-05-16	Recording Sheet (1 each)	LC1004.4 (08/10)	N/A	Plate Format Sheet (1 each)	Rev. 12 October 2009	N/A	Product Insert LC1003IVD	LC1003IVD.8 (10/09)	N/A
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Bead Count	Minimum 60 events in 60 seconds on Luminex 2.3 Instrument																											
Photobleaching	No Photobleaching detected																											
Other Testing	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 20%; text-align: center;">Value</th> <th style="width: 20%; text-align: center;">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;">20271</td> <td style="text-align: center;">17547 - 21554</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;">72</td> </tr> <tr> <td style="text-align: center;">CON2</td> <td style="text-align: center;">80</td> </tr> <tr> <td style="text-align: center;">CON3</td> <td style="text-align: center;">201</td> </tr> <tr> <td colspan="3">Positive Control bead gave mean average MFI value that was an average of 271 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 I and/or Class II antigens</td> </tr> <tr> <td colspan="3">This lot gave negative results when tested with sera of at least 10 individuals known to have no immunization against human HLA Class I and/or 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:	20271	17547 - 21554	Mean MFI value of the Negative Control beads were:	CON1	72	CON2	80	CON3	201	Positive Control bead gave mean average MFI value that was an average of 271 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 and/or Class II antigens			This lot gave negative results when tested with sera of at least 10 individuals known to have no immunization against human HLA Class I and/or 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.				
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Quality Control Review:	 Date: 10-14-11																											
Quality Assurance Release:	 Date: 10-18-11																											