


Certificate of Analysis

LIFECODES LSA™ Class I LSA1
REF 265100


LOT 08101B



≤ -65°C LSA1B

2-8°C LSACJ
LSAPC1
LSANC1
LSAWB

(Storage Conditions)


 2012-08-31


EXP: 31-Aug-2012

LIFECODES LSA™ Class I is a bead-based immunoassay used to qualitatively detect HLA Class I IgG antibodies. Each kit consists of all reagents required for performing 24 assays. LIFECODES LSA™ Class I Beads are designed to detect IgG antibodies to HLA Class I glycoproteins. LSA Class I is composed of different Luminex® Beads to which purified recombinant Class I HLA glycoproteins are conjugated. 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 LSA Procedure prior to release.

CAUTION: LIFECODES LSA Class I Beads and Conjugate Concentrate are extremely light sensitive. Minimize exposure to light.

For Research Use Only

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

TEST	SPECIFICATION	LOT	
Components			
	265103 LSA1B LSA Class I Bead Mix (960µL)	08101B	2012-09-30
	265002 LSACJ LSA Conjugate Concentrate (120µL)	08271U	2012-08-31
	265001 LSAWB LSA Wash Buffer (25mL)	08161D	2012-11-30
	265101 LSAPC1 LSA Class I Positive Control (50µL)	09091A	2013-08-31
	265102 LSANC1 LSA Class I Negative Control (50µL)	09091B	2013-08-31
	Worksheet: LC980		N/A
	Plate Format Sheet: LC979	N/A	N/A
	Product Insert: LC976CE	N/A	N/A

Bead Count Minimum 60 events in 60 seconds

Photobleaching No photobleaching detected

 Specificity Expected results with known sera
 Refer to worksheet graph for expected reactivity with LSAPC1 (positive and negative reactivity to multiple antigens from at least two Class I loci).
 Less than or equal to 10% reactivity with LSANC1

 Other Testing This lot gave positive results when tested with sera from individuals known to be immunized against human HLA Class I antigens.

 This lot gave negative results when tested with the 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: Theresa Cuchelo

 Date: 1/24/2012

 QA Release: Stacy

 Date: 1/24/2012