

### Certificate of Analysis


**LIFECODES LSA™ Class II** LSA2
**REF** 265200

LOT 09191D

  
 (Storage Conditions)

 ≤ -65°C LSA2B
LSACJ  
LSAPC2  
LSANC2  
LSAWB

2-8°C

 2012-10-31

**EXP:** 31-OCT-2012


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

			<span style="border: 1px solid black; padding: 2px;">LOT</span>	
265203	<span style="border: 1px solid black; padding: 2px;">LSA2B</span>	LSA Class II Bead Mix (960µL)	09191D	2012-11-30
265002	<span style="border: 1px solid black; padding: 2px;">LSACJ</span>	LSA Conjugate Concentrate (120µL)	10211A	2012-10-31
265001	<span style="border: 1px solid black; padding: 2px;">LSAWB</span>	LSA Wash Buffer (25mL)	11101D	2013-02-28
265201	<span style="border: 1px solid black; padding: 2px;">LSAPC2</span>	LSA Class II Positive Control (50µL)	10061E	2013-10-31
265202	<span style="border: 1px solid black; padding: 2px;">LSANC2</span>	LSA Class II Negative Control (50µL)	10061D	2013-10-31
		Worksheet: LC981		N/A
		Plate Format Sheet: LC979	N/A	N/A
		Direction Insert: LC976 O	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 LSAPC2 (positive and negative reactivity to multiple antigens from at least two Class II loci).  
 Less than or equal to 10% reactivity in LSANC2

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

This lot gave negative results when tested with the 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:** Shelley Cuchelo
**Date:** 12/20/11
**QA Release:** Bona Casserly
**Date:** 12/20/11