

Lot No.: **75K**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C high resolution for frequent alleles SSP
Product number: 101.707-12u – without Taq polymerase
Lot number: 75K
Expiry date: 2013-April-01
Number of tests: 12
Number of wells per test: 95 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2008-497-01	33	2009-668-33	65	2009-668-65
2	2008-497-02	34	2008-497-34	66	2008-497-66
3	2008-497-03	35	2008-497-35	67	2008-497-67
4	2008-497-04	36	2009-668-36	68	2008-497-68
5	2008-497-05	37	2008-497-37	69	2008-497-69
6	2008-497-06	38	2008-497-38	70	2008-497-70
7	2008-497-07	39	2008-497-39	71	2009-668-71
8	2008-497-08	40	2008-497-40	72	2009-668-72
9	2008-497-09	41	2008-497-41	73	2008-497-73
10	2008-497-10	42	2009-668-42	74	2008-497-74
11	2009-668-11	43	2008-497-43	75	2008-497-75
12	2008-497-12	44	2009-668-44	78	2008-497-76
13	2008-497-13	45	2008-497-45	77	2008-497-77
14	2009-668-14	46	2008-497-46	78	2008-497-78
15	2008-497-15	47	2008-497-47	79	2008-497-79
16	2009-668-16	48	2008-497-48	80	2008-497-80
17	2008-497-17	49	2008-497-49	81	2008-497-81
18	2008-497-18	50	2008-497-50	82	2008-497-82
19	2009-668-19	51	2008-497-51	83	2008-497-83
20	2008-497-20	52	2008-497-52	84	2008-497-84
21	2008-497-21	53	2008-497-53	85	2008-497-85
22	2008-497-22	54	2008-497-54	86	2008-497-86
23	2008-497-23	55	2008-497-55	87	2008-497-87
24	2008-497-24	56	2008-497-56	88	2008-497-88
25	2008-497-25	57	2009-668-57	89	2008-497-89
26	2009-668-26	58	2008-497-58	90	2008-497-90
27	2008-497-27	59	2008-497-59	91	2008-497-91
28	2008-497-28	60	2008-497-60	92	2008-497-92
29	2008-497-29	61	2008-497-61	93	2009-668-93
30	2008-497-30	62	2008-497-62	94	2008-497-94
31	2008-497-31	63	2008-497-63	95	2008-497-95
32	2008-497-32	64	2008-497-64		

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The specificity of each primer solution of the HLA-C high resolution for frequent alleles primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer pairs in solutions 2, 4, 5, 8 to 10, 18, 19, 21, 32 to 34, 43, 44, 49, 51, 53, 55, 56, 58, 59, 65, 80, 81, 86, 88 and 91. The specificity of most of the primers in these solutions was tested by separately adding one or more additional 5'-primer, respectively one or more additional 3'-primer. In primer solutions 2 to 5, 8, 9, 18, 20, 21, 23, 31, 34, 36, 37, 44, 45, 49, 51, 56, 59, 65, 73, 76, 78, 80, 83, 91 and 92 one or more of the 5'-primers were not possible to test. In primer solutions 2, 3, 5, 6, 8, 10, 13, 15, 16, 21, 26, 27, 29, 32, 36, 43, 44, 51, 55, 58, 59, 61, 75, 79, 86 and 88 one or more of the 3'-primers were not possible to test. Additional 5'-primers or 3'-primers in primer solutions 3, 6, 11, 12, 13, 16, 17, 20, 26, 27, 31, 36, 37, 45, 46, 50, 71, 74, 75, 92 and 93 were tested by separately adding one or more additional 3'-primer, respectively one or more additional 5'-primer.

The negative control primer pairs, **Production No. 2010-760-01**, can detect contamination with PCR products diluted 10^{-7} .

Results: No false positive or false negative amplifications were obtained.

Date of approval: 2012-May-08

Approved by:



Production Quality Control

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Declaration of Conformity

Product name: Olerup SSP® HLA-C high resolution for frequent alleles
Product number: 101.707-12u
Lot number: 75K

Intended use: HLA-C high resolution for frequent alleles histo-compatibility testing

Manufacturer: Olerup SSP AB
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We, Olerup SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at Olerup SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

The Authorized Representative located within the Community is: Olerup SSP AB.

Stockholm, Sweden
2012-May-08



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs