101.707-12 – including *Taq* polymerase, IFU-01
101.707-12u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 24S **Lot-specific information** **www.olerup-ssp.com**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C high resolution for frequent alleles SSP

Product number: **101.707-12 – including *Taq* polymerase**
101.707-12u – without *Taq* polymerase

Lot number: **24S**
Expiry date: **2015-December-01**
Number of tests: **12**
Number of wells per test: **95 + 1**
Storage - pre-aliquoted primers: **dark at -20°C**
- PCR Master Mix: **-20°C**
- Adhesive PCR seals **RT**
- Product Insert **RT**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2013-175-01	33	2011-934-33	65	2011-934-65
2	2013-175-02	34	2008-497-34	66	2008-497-66
3	2013-175-03	35	2008-497-35	67	2008-497-67
4	2013-175-04	36	2009-668-36	68	2008-497-68
5	2013-175-05	37	2008-497-37	69	2008-497-69
6	2008-497-06	38	2008-497-38	70	2013-175-70
7	2013-175-07	39	2008-497-39	71	2009-668-71
8	2013-175-08	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	2013-175-81
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	2013-175-20	52	2013-175-52	84	2008-497-84
21	2013-175-21	53	2013-175-53	85	2008-497-85
22	2008-497-22	54	2008-497-54	86	2013-175-86
23	2013-175-23	55	2013-175-55	87	2013-175-87
24	2008-497-24	56	2013-175-56	88	2008-497-88
25	2008-497-25	57	2009-668-57	89	2008-497-89
26	2009-668-26	58	2013-175-58	90	2008-497-90
27	2008-497-27	59	2008-497-59	91	2013-175-91
28	2013-175-28	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		

CE

For *In Vitro* Diagnostic Use.

Lot No.: 24S **Lot-specific information** **www.olerup-ssp.com**

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 and 88. 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, 33, 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, 91, 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. 2013-165-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2013-July-18

Approved by:

Åsa Olausson

Production Quality Control

Lot No.: 24S **Lot-specific information** **www.olerup-ssp.com**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C high resolution for frequent alleles
Product number: 101.707-12/12u
Lot number: 24S

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

Manufacturer:
Olerup SSP AB
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

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 13485:2012, 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.

Stockholm, Sweden
2013-July-18

Åsa Olausson
Production Quality Control