

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.: **95V**

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: 95V
Expiry date: 2017-February-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	2014-373-01	33	2014-373-33	65	2014-373-65
2	2014-373-02	34	2014-373-34	66	2014-373-66
3	2014-373-03	35	2014-373-35	67	2014-373-67
4	2014-373-04	36	2014-373-36	68	2014-373-68
5	2014-373-05	37	2014-373-37	69	2014-373-69
6	2014-373-06	38	2014-373-38	70	2014-373-70
7	2014-373-07	39	2014-373-39	71	2014-373-71
8	2014-373-08	40	2014-373-40	72	2014-373-72
9	2014-373-09	41	2014-373-41	73	2014-373-73
10	2014-373-10	42	2014-373-42	74	2014-373-74
11	2014-373-11	43	2014-373-43	75	2014-373-75
12	2014-373-12	44	2014-373-44	76	2014-373-76
13	2014-373-13	45	2014-373-45	77	2014-373-77
14	2014-373-14	46	2014-373-46	78	2014-373-78
15	2014-373-15	47	2014-373-47	79	2014-373-79
16	2014-373-16	48	2014-373-48	80	2014-373-80
17	2014-373-17	49	2014-373-49	81	2014-373-81
18	2014-373-18	50	2014-373-50	82	2014-373-82
19	2014-373-19	51	2014-373-51	83	2014-373-83
20	2014-373-20	52	2014-373-52	84	2014-373-84
21	2014-373-21	53	2014-373-53	85	2014-373-85
22	2014-373-22	54	2014-373-54	86	2014-373-86
23	2014-373-23	55	2014-373-55	87	2014-373-87
24	2014-373-24	56	2014-373-56	88	2014-373-88
25	2014-373-25	57	2014-373-57	89	2014-373-89
26	2014-373-26	58	2014-373-58	90	2014-373-90
27	2014-373-27	59	2014-373-59	91	2014-373-91
28	2014-373-28	60	2014-373-60	92	2014-373-92
29	2014-373-29	61	2014-373-61	93	2014-373-93
30	2014-373-30	62	2014-373-62	94	2014-373-94
31	2014-373-31	63	2014-373-63	95	2014-373-95
32	2014-373-32	64	2014-373-64		

The negative control primer pairs, **Production No. 2013-307-01**, can detect contamination with PCR products diluted 10^{-7} .



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Results of Quality Control: No false positive or false negative amplifications
obtained.

Date of approval: 2014-September-09

Approved by:

Karin Olsson

Production Quality Control

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Declaration of Conformity

Product name: Olerup SSP® HLA-C high resolution for frequent alleles
Product number: 101.707-12/12u
Lot number: 95V

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

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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 13485:2012, 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

2014 - September - 12



Daniel Malica
Head of QA and Regulatory Affairs