101.615-24/04 – including *Taq* pol., IFU-01
101.615-24u/04u – without *Taq* pol., IFU-02

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"Instructions for Use" (IFU)

Lot No.: 38R **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*07 SSP

Product number: **101.615-24/04 – including *Taq* pol.**
101.615-24u/04u – without *Taq* pol.

Lot number: **38R**

Expiry date: **2015-June-01**

Number of tests: **24 tests – Product No. 101.615-24/24u**
4 tests – Product No. 101.615-04/04u

Number of wells per test: **64**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-698-01	25	2010-698-25	49	2012-005-49
2	2011-895-02	26	2010-698-26	50	2012-005-50
3	2011-895-03	27	2012-081-27	51	2012-081-51
4	2010-698-04	28	2011-895-28	52	2012-081-52
5	2012-081-05	29	2011-895-29	53	2012-081-53
6	2010-698-06	30	2012-081-30	54	2012-081-54
7	2010-698-07	31	2012-005-31	55	2012-081-55
8	2010-698-08	32	2010-698-32	56	2012-081-56
9	2010-698-09	33	2011-895-33	57	2012-081-57
10	2010-698-10	34	2012-081-34	58	2012-081-58
11	2012-005-11	35	2012-081-35	59	2012-081-59
12	2010-698-12	36	2012-08136	60	2012-081-60
13	2010-698-13	37	2012-081-37	61	2012-081-61
14	2012-081-14	38	2012-081-38	62	2012-081-62
15	2012-081-15	39	2010-698-39	63	2012-081-63
16	2012-081-16	40	2012-081-40	64	2012-081-64
17	2010-698-17	41	2010-698-41		
18	2012-081-18	42	2012-081-42		
19	2012-081-19	43	2012-081-43		
20	2012-081-20	44	2012-081-44		
21	2010-698-21	45	2012-081-45		
22	2010-698-22	46	2012-005-46		
23	2012-081-23	47	2012-005-47		
24	2011-895-24	48	2012-081-48		

The specificity of each primer solution of the kit has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 5, 10, 11, 13 to 15, 18, 19, 23 to 31, 34 to 36, 38, 39, 41 to 44 and 46 to 64 were available.
The specificities of the primers in primer solutions 5, 10, 11, 13 to 15, 18, 19, 24 to 27, 31, 36, 38, 42 to 44, 46 to 50, 53, 54, 56 to 60, 63 and 64 were tested by separately adding one 5'-primer, respectively one 3'-primer.

Lot No.: 38R **Lot-specific information**

In primer solutions 35, 51 and 61 it was only possible to test the 5'-primer, the 3'-primer were not possible to test.
In primer solutions 23, 28 to 30, 34, 39, 41, 52, 55 and 62 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.
In primer solutions 8, 11, 20, 22, 26, 33, 38, 42, 44, 46 to 49, 53, 56, 57, 59 and 63 one or two 5'-primers were not possible to test, and in primer solutions 5, 9, 13, 15, 18, 19, 21, 25, 32, 36, 38, 40, 43, 46 to 48, 50, 54, 58, 60, 63 and 64 one or two 3'-primers were not possible to test.
Additional primers in primer solutions 2, 8, 9, 18, 20, 21, 33, 37, 40 and 45 were tested by separately adding either one 5'-primer or one 3'-primer.

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

Date of approval: 2012-December-12

Approved by:

Production Quality Control

101.615-24/04 – including *Taq* pol., IFU-01
101.615-24u/04u – without *Taq* pol., IFU-02

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Lot No.: 38R **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*07
Product number: 101.615-24/24u, -04/04u
Lot number: 38R

Intended use: HLA-C*07 high resolution histocompatibility 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 13485:2003, 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.

Stockholm, Sweden
2012-December-12

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs