

101.621-12 – including *Taq* pol., IFU-01
101.621-12u – without *Taq* pol., IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **76S**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*01 SSP

Product number: 101.621-12 – including *Taq* polymerase
101.621-12u – without *Taq* polymerase
Lot number: 76S
Expiry date: 2016-January-01
Number of tests: 12
Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-707-01	9	2012-014-09	17	2012-014-17
2	2010-707-02	10	2012-014-10	18	2013-189-18
3	2010-707-03	11	2011-826-11	19	2011-826-19
4	2011-826-04	12	2010-707-12	20	2012-014-20
5	2012-014-05	13	2010-707-13	21	2013-189-21
6	2011-826-06	14	2013-189-14	22	2012-014-22
7	2013-189-07	15	2013-189-15	23	2012-014-23
8	2012-014-08	16	2011-826-16	24	2013-189-24

The specificity of each primer solution of the HLA-C*01 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 2 to 6, 8 to 12 and 14 to 24 were available. The specificity of the primers in primer solutions 2 to 5, 8 to 12, 14 to 18, 20 and 22 to 24 were tested by adding additional 5'-primers respectively 3'-primers. In primer solution 6, it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 19 and 21 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 11, 17, 20 and 24 one or two of the 5'-primers were not possible to test. In primer solutions 2, 4, 5, 7, 9, 10, 14, 15, 16, 18, 20 and 23 one or two of the 3'-primers were not possible to test. In primer solution 7 one additional 5'-primer was tested by separately adding one additional 3'-primer.

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

Date of approval: 2013-July-23

Approved by:



Production Quality Control

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Declaration of Conformity

Product name: Olerup SSP® HLA-C*01

Product number: 101.621-12/12u

Lot number: 76S

Intended use: HLA-C*01 high resolution histocompatibility 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 13485:2012, 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.

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

Stockholm, Sweden
2013-July-23



Åsa Olausson
Production Quality Control