CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*14 SSP

Product number: **101.625-06 – including *Taq* polymerase**
101.625-06u – without *Taq* polymerase

Lot number: **12S**
Expiry date: **2015-October-01**
Number of tests: **6**
Number of wells per test: **24**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2013-162-01	9	2013-162-09	17	2013-162-17
2	2013-162-02	10	2013-162-10	18	2013-162-18
3	2013-162-03	11	2013-162-11	19	2013-162-19
4	2013-162-04	12	2013-162-12	20	2013-162-20
5	2013-162-05	13	2013-162-13	21	2013-162-21
6	2013-162-06	14	2013-162-14	22	2013-162-22
7	2013-162-07	15	2013-162-15	23	2013-162-23
8	2013-162-08	16	2013-162-16	24	2013-162-24

The specificity of each primer solution of the HLA-C*14 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer mixes 10 to 14 and 17 to 24 were available. The specificities of the primers in primer solutions 10, 12 to 14, 17 to 19, 21 and 23 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 11, it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 20, 22 and 24 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 1, 10, 12 to 14, 17, 19, 21 and 23 one or two of the 3'-primers was not possible to test, and in primer solution 12 one of the 5'-primers was not possible to test. Finally, one additional 5'-primer in primer solution 6 was tested by adding one additional 3'-primer.

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

Date of approval: 2013-May-17

Approved by:

Production Quality Control

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*14
Product number: 101.625-06/06u
Lot number: 12S

Intended use: HLA-C*14 high resolution histocompatibility 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.

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

Stockholm, Sweden
2013-May-17

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs