101.628-06– including *Taq* polymerase, IFU-01
101.628-06u – without *Taq* polymerase, IFU-02

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

Lot No.: 50R **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*17 SSP

Product number: **101.628-06 – including *Taq* polymerase**
101.628-06u – without *Taq* polymerase

Lot number: **50R**
Expiry date: **2015-May-01**
Number of tests: **6**
Number of wells per test: **14**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-786-01	7	2010-786-07	13	2012-097-13
2	2008-473-02	8	2012-097-08	14	2012-097-14
3	2012-097-03	9	2011-954-09		
4	2008-473-04	10	2011-954-10		
5	2008-473-05	11	2011-954-11		
6	2009-637-06	12	2011-954-12		

The specificity of each primer solution of the HLA-C*17 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 and 5 to 14 were available. The specificity of the primers in primer solutions 2, 6, 8, 12 and 13 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 5 and 7 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 9 to 11 and 14 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. One additional 3'-primer in primer solution 1 was tested by separately adding one 5'-primer.

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

Date of approval: 2012-December-07

Approved by:

Production Quality Control

CE

101.628-06– including *Taq* polymerase, IFU-01
101.628-06u – without *Taq* polymerase, IFU-02

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Lot No.: 50R **Lot-specific information**

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*17
Product number: 101.628-06/06u
Lot number: 50R

Intended use: HLA-C*17 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-07

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs