101.623-12 – including *Taq* pol., IFU-01
101.623-12u– without *Taq* pol., IFU-02

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

Lot No.: 13S

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*08 SSP

Product number:	**101.623-12 – including *Taq* polymerase** **101.623-12u – without *Taq* polymerase**
Lot number:	**13S**
Expiry date:	**2015-October-01**
Number of tests:	**12**
Number of wells per test:	**32**

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-758-01	13	2010-758-13	25	2013-165-25
2	2010-758-02	14	2010-758-14	26	2011-898-26
3	2010-758-03	15	2013-165-15	27	2011-898-27
4	2010-758-04	16	2013-165-16	28	2012-025-28
5	2010-758-05	17	2010-758-17	29	2012-025-29
6	2010-758-06	18	2010-758-18	30	2012-025-30
7	2010-758-07	19	2010-758-19	31	2012-025-31
8	2010-758-08	20	2010-758-20	32	2012-025-32
9	2011-898-09	21	2010-758-21		
10	2010-758-10	22	2011-898-22		
11	2012-025-11	23	2010-758-23		
12	2010-758-12	24	2012-025-24		

The specificity of each primer solution of the HLA-C*08 primer set has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 5 to 11, 14, 15, 17 to 20, 23 to 26 and 28 to 32 were available.
The specificity of the primers in primer solutions 5, 7 to 9, 11, 14, 15, 17 to 20, 24, 25, 28 to 32 were tested by adding additional 5'-primers respectively 3'-primers. In primer solutions 6, 10 and 26 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 23 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 8, 9, 14, 18, 19, 29 and 30, one or two 5'-primers were not possible to test. In primer solution 24 and 32, one or two 3'-primers were not possible to test.
In primer solution 16, one additional 5'-primer and one additional 3'-primer were tested by separately adding one 3'-primer respective one 5'-primer. In primer solution 22, one additional 5'-primer was tested by separately adding one 3'-primer.

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

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Lot No.: 13S **Lot-specific information**

Date of approval: 2013-May-22

Approved by:

Åsa Olausson
Production Quality Control

101.623-12 – including *Taq* pol., IFU-01
101.623-12u– without *Taq* pol., IFU-02

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Lot No.: 13S

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*08
Product number: 101.623-12/12u
Lot number: 13S

Intended use: HLA-C*08 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 13485:2012, 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-22

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs