

Lot No.: **74N**

Lot-specific information

**CERTIFICATE OF ANALYSIS****Olerup SSP® HLA-C\*15 SSP**

Product number: 101.626-12 – including *Taq* polymerase  
101.626-12u – without *Taq* polymerase

Lot number: 74N

Expiry date: 2014-November-01

Number of tests: 12

Number of wells per test: 27

**Well specifications:**

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-718-01	11	2010-718-11	21	2011-848-21
2	2010-718-02	12	2010-718-12	22	2011-848-22
3	2010-718-03	13	2012-013-13	23	2011-848-23
4	2010-718-04	14	2010-718-14	24	2011-848-24
5	2010-718-05	15	2010-718-15	25	2012-013-25
6	2010-718-06	16	2011-848-16	26	2012-013-26
7	2010-718-07	17	2011-848-17	27	2012-013-27
8	2010-718-08	18	2011-848-18		
9	2010-718-09	19	2012-013-19		
10	2010-718-10	20	2011-848-20		

The specificity of each primer solution of the HLA-C\*15 primer set has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 6, 8, 13, 14, 16 to 22 and 24 to 27 were available. The specificity of the primers in primer solutions 6, 8, 13, 14 and 16 to 19 were tested by separately adding one 5'-primer, respectively one 3'-primer.

In primer solutions 20, 25 and 26 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solutions 21, 22, 24 and 27 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

In primer mixes 8, 9 and 14 one of the 5'-primers could not be tested, and in primer mixes 3, 7, 12, 17, 18 and 23 one or two of the 3'-primers could not be tested. Additional primers in primer solutions 9 and 23 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-May-10

**Approved by:**

*Asa Olsson*

**Production Quality Control**



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## Declaration of Conformity

**Product name:** Olerup SSP® HLA-C\*15**Product number:** 101.626-12/12u**Lot number:** 74N**Intended use:** HLA-C\*15 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-May-10

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs