

Lot No.: **55M**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*08 SSP

Product number: 101.623-12 – including Taq polymerase
Lot number: 55M
Expiry date: 2014-February-01
Number of tests: 12
Number of wells per test: 29

Well specifications:

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

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 and 23 to 29 were available. The specificity of the primers in primer solutions 5, 7 to 9, 11, 14, 15, 17 to 20, 24, 25, 28 and 29 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 6, 10, 26 and 27 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, 11, 14, 18 and 19, one or two 5'-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.

Date of approval: 2011-September-16

Approved by:



Quality Control, Supervisor

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Declaration of Conformity

Product name: *Olerup SSP*[®] HLA-C*08
Product number: 101.623-12
Lot number: 55M

Intended use: HLA-C*08 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 13485:2003, 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.

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

Stockholm, Sweden
2011-September-16



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs