CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*08 SSP

Product number: 101.513-24u/04u – without *Taq* pol.
Lot number: 07K
Expiry date: 2012-June-01
Number of tests: 24 tests – Product No. 101.513-24u
4 tests – Product No. 101.513-04u
Number of wells per test: 40

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-716-01	17	2010-716-17	33	2010-716-33
2	2010-716-02	18	2010-716-18	34	2010-716-34
3	2010-716-03	19	2010-716-19	35	2010-716-35
4	2010-716-04	20	2010-716-20	36	2010-716-36
5	2010-716-05	21	2010-716-21	37	2010-716-37
6	2010-716-06	22	2010-716-22	38	2010-716-38
7	2010-716-07	23	2010-716-23	39	2010-716-39
8	2010-716-08	24	2010-716-24	40	2010-716-40
9	2010-716-09	25	2010-716-25		
10	2010-716-10	26	2010-716-26		
11	2010-716-11	27	2010-716-27		
12	2010-716-12	28	2010-716-28		
13	2010-716-13	29	2010-716-29		
14	2010-716-14	30	2010-716-30		
15	2010-716-15	31	2010-716-31		
16	2010-716-16	32	2010-716-32		

The specificity of each primer solution of the kit has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 5 to 7, 9, 10, 12 to 14, 16, 17, 19, 20, 23, 25 to 31 and 33 to 40 were available. The specificities of the primers in primer solutions 5 to 7, 9, 10, 13, 14, 16, 17, 19, 20, 23, 25, 29, 36 and 40 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. The specificity of the 5'-primers in primer solutions 12, 27, 34 and 39 were tested by adding one additional 3'-primer, the 3'-primers were not possible to test. In primer solutions 26, 28, 30, 31, 35, 37 and 38 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 6, 19, 20, 29 and 33 one of the 3'-primers was not possible to test, and in primer solutions 10, 13 and 14one of the 5'-primers was not possible to test. Additional primers in primer solutions 11 and 18 were tested by separately adding one additional 3'-primer respective one additional 5'-primer.

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

Date of approval: 2012-June -29

Approved by:

Åsa Olausson

Production Quality Control

Declaration of Conformity

Product name: *Olerup* SSP® HLA-B*08
Product number: 101.513-24u/04u
Lot number: 07K

Intended use: HLA-B*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 II List B, conformity assessed using Annex IV, 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.

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Stockholm, Sweden
2012-June-29

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs