CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*11 SSP

Product number: 101.115-24u/03u – without *Taq* pol.
Lot number: 42M
Expiry date: 2014-January-01
Number of tests: 24 tests – Product No. 101.115-24u
3 tests – Product No. 101.115-03u
Number of wells per test: 32

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-751-01	13	2011-883-13	25	2010-751-25
2	2010-751-02	14	2010-751-14	26	2010-751-26
3	2010-751-03	15	2010-751-15	27	2011-883-27
4	2010-751-04	16	2011-883-16	28	2010-751-28
5	2010-751-05	17	2010-751-17	29	2010-751-29
6	2011-883-06	18	2010-751-18	30	2010-751-30
7	2010-751-07	19	2010-751-19	31	2011-883-31
8	2010-751-08	20	2010-751-20	32	2010-751-32
9	2010-751-09	21	2010-751-21		
10	2010-751-10	22	2011-883-22		
11	2011-883-11	23	2010-751-23		
12	2010-751-12	24	2010-751-24		

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

No DNAs carrying the alleles to be amplified by primer solutions 12, 16 and 21 to 23 were available. The specificities of the primers in primer solutions 12, 16, 21 and 22 were tested by separately adding one or several additional 5'-primer(s), respectively, one or several additional 3'-primer(s).
In primer solution 23 the 3'-primer was tested by separately adding one 5'-primer, the 5'-primer was not possible test.
In primer solutions 9 to 11, 16, 19, 22, 24 and 32 one, two or three of the 3'-primers were not possible to test, and in primer solutions 12, 13, 15 and 26 one or two of the 5'-primers were not possible to test. Additional 3'-primers in primer solutions 5, 9, 10, 17 to 20 and 24 were tested by separately adding one or two 5'-primers.

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

Date of approval: 2011-October-05

Approved by:

Åsa Claesson

Quality Control, Supervisor

CE
0088

For *In Vitro* Diagnostic Use.

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*11
Product number: 101.115-24u/03u
Lot number: 42M

Intended use: DRB1*11 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
2011-October-05

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs