CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*13 SSP

Product number: 101.116-24/03 – including *Taq* pol.
Lot number: 03G
Expiry date: 2011-July-01
Number of tests: 24 tests – Product No. 101.116-24
3 tests – Product No. 101.116-03
Number of wells per test: 32

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2006-224-01	13	2006-224-13	25	2006-224-25
2	2009-612-02	14	2009-612-14	26	2008-486-26
3	2006-224-03	15	2005-224-15	27	2009-612-27
4	2006-224-04	16	2009-612-16	28	2006-224-28
5	2006-224-05	17	2008-486-17	29	2006-224-29
6	2006-224-06	18	2009-612-18	30	2006-224-30
7	2006-224-07	19	2009-612-19	31	2009-612-31
8	2006-224-08	20	2007-347-20	32	2006-224-32
9	2006-224-09	21	2007-347-21		
10	2006-224-10	22	2006-224-22		
11	2008-486-11	23	2007-347-23		
12	2006-224-12	24	2006-224-24		

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 11, 17 to 21, 24, 31 and 32 were available. The specificities of the primers in primer solution 11, 17, 18, 20, 21, 24 and 31 were tested by separately adding one additional 5'-primer or one additional 3'-primer, respectively. In primer solution 19 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solution 7, 26 and 31 one of the 5'-primers was not possible to test. One or more of the 3'-primers in primer solutions 17, 18, 22, 23, 24 and 27 were not possible to test.
Additional 3'-primers in primer solutions 2, 5, 6, 12 and 32 were tested by separately adding one 5'-primer. One additional 5'-primer in primer solution 14 was tested by separately adding one 3'-primer.

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

Date of approval: 2011-October-24

Approved by:
Åsa Olausson
Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP® DRB1*13
Product number: 101.116-24/03
Lot number: 03G

Intended use: DRB1*13 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 9001:2000 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.)

Saltsjöbaden, Sweden
2011-October-24

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs