

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*27 SSP

Product number: 101.521-24/04 – including *Taq* pol.
Lot number: 22L
Expiry date: 2013-September-01
Number of tests: 24 test – Product No. 101.521-24
4 tests – Product No. 101.521-04
Number of wells per test: 32

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2006-205-01	13	2009-661-13	25	2011-839-25
2	2011-839-02	14	2006-205-14	26	2011-839-26
3	2011-839-03	15	2011-839-15	27	2011-839-27
4	2006-205-04	16	2011-839-16	28	2011-839-28
5	2006-205-05	17	2009-661-17	29	2011-839-29
6	2006-205-06	18	2009-661-18	30	2011-839-30
7	2006-205-07	19	2009-661-19	31	2011-839-31
8	2006-205-08	20	2011-839-20	32	2011-839-32
9	2006-205-09	21	2011-839-21		
10	2011-839-10	22	2011-839-22		
11	2006-205-11	23	2006-205-23		
12	2008-511-12	24	2007-352-24		

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 12, 19 and 25 to 31 were available. The specificities of the primers in primer solutions 12, 19, 25, 26 and 28 to 31 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solution 27 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 10, 13, 14, 17, 18, 20 to 22 and 28 to 31 one of the 3'-primers was not possible to test. In primer solutions 12, 15, 16, 26, 28, 30 and 31 one or two of the 5'-primers were not possible to test.

Additional primers in primer solutions 10, 13 to 18 and 20 to 22 were tested by separately adding one additional 5'-primer and /or one additional 3'-primer.

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

Date of approval: 2011-April-01

Approved by:



Quality Control, Supervisor

Declaration of Conformity

Product name: Olerup SSP® HLA-B*27

Product number: 101.521-24/04

Lot number: 22L

Intended use: HLA-B*27 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

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

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-April-01



Olle Olerup
Managing Director