

CERTIFICATE OF ANALYSIS

Olerup SSP® DPB1 SSP

Product number: 101.311-24/04 – including *Taq* pol.
Lot number: 09M
Expiry date: 2013-November-01
Number of tests: 24 tests – Product No. 101.311-24
4 tests – Product No. 101.311-04
Number of wells per test: 48

Well specifications:

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|----------|----------------|
| 1 | 2011-849-01 | 17 | 2011-849-17 | 33 | 2011-849-33 |
| 2 | 2011-849-02 | 18 | 2011-849-18 | 34 | 2011-849-34 |
| 3 | 2011-849-03 | 19 | 2011-849-19 | 35 | 2011-849-35 |
| 4 | 2011-849-04 | 20 | 2011-849-20 | 36 | 2011-849-36 |
| 5 | 2011-849-05 | 21 | 2011-849-21 | 37 | 2011-849-37 |
| 6 | 2011-849-06 | 22 | 2011-849-22 | 38 | 2011-849-38 |
| 7 | 2011-849-07 | 23 | 2011-849-23 | 39 | 2011-849-39 |
| 8 | 2011-849-08 | 24 | 2011-849-24 | 40 | 2011-849-40 |
| | | | | | |
| 9 | 2011-849-09 | 25 | 2011-849-25 | 41 | 2011-849-41 |
| 10 | 2011-849-10 | 26 | 2011-849-26 | 42 | 2011-849-42 |
| 11 | 2011-849-11 | 27 | 2011-849-27 | 43 | 2011-849-43 |
| 12 | 2011-849-12 | 28 | 2011-849-28 | 44 | 2011-849-44 |
| 13 | 2011-849-13 | 29 | 2011-849-29 | 45 | 2011-849-45 |
| 14 | 2011-849-14 | 30 | 2011-849-30 | 46 | 2011-849-46 |
| 15 | 2011-849-15 | 31 | 2011-849-31 | 47 | 2011-849-47 |
| 16 | 2011-849-16 | 32 | 2011-849-32 | 48 | 2011-849-48 |

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 41, 42, 44 and 46 were available. In primer solutions 41, 42 and 46 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solution 44 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 15, 16, 23, 25, 26, 32, 33 and 38 one or two 5'-primers were not possible to test. In primer solutions 8, 11, 24, 28 and 48 one 3'-primer was not possible to test. Additional primers in primer solutions 14, 38, 40, 43, 47 and 48 were tested by separately adding one 5'-primers or one 3'-primer.

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

Date of approval: 2011-December-09

Approved by:

Isa Claussan

Production Quality Control



Declaration of Conformity

Product name: Olerup SSP® DPB1
Product number: 101.311-24/04
Lot number: 09M

Intended use: DPB1 high resolution histocompatibility testing

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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-December-09



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs