

Lot No.: 10M

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1 high resolution for frequent alleles SSP

Product number: 101.221-12 – including Taq polymerase
Lot number: 10M
Expiry date: 2014-January-01
Number of tests: 12 tests
Number of wells per test: 47 + 1

Well specifications:

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|----------|----------------|
| 1 | 2011-850-01 | 17 | 2011-850-17 | 33 | 2011-850-33 |
| 2 | 2011-850-02 | 18 | 2011-850-18 | 34 | 2011-850-34 |
| 3 | 2011-850-03 | 19 | 2011-850-19 | 35 | 2011-850-35 |
| 4 | 2011-850-04 | 20 | 2011-850-20 | 36 | 2011-850-36 |
| 5 | 2011-850-05 | 21 | 2011-850-21 | 37 | 2011-850-37 |
| 6 | 2011-850-06 | 22 | 2011-850-22 | 38 | 2011-850-38 |
| 7 | 2011-850-07 | 23 | 2011-850-23 | 39 | 2011-850-39 |
| 8 | 2011-850-08 | 24 | 2011-850-24 | 40 | 2011-850-40 |
| | | | | | |
| 9 | 2011-850-09 | 25 | 2011-850-25 | 41 | 2011-850-41 |
| 10 | 2011-850-10 | 26 | 2011-850-26 | 42 | 2011-850-42 |
| 11 | 2011-850-11 | 27 | 2011-850-27 | 42 | 2011-850-43 |
| 12 | 2011-850-12 | 28 | 2011-850-28 | 43 | 2011-850-44 |
| 13 | 2011-850-13 | 29 | 2011-850-29 | 45 | 2011-850-45 |
| 14 | 2011-850-14 | 30 | 2011-850-30 | 46 | 2011-850-46 |
| 15 | 2011-850-15 | 31 | 2011-850-31 | 47 | 2011-850-47 |
| 16 | 2011-850-16 | 32 | 2011-850-32 | | |

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 2, 5, 12-14, 17, 18, 35, 38-43 and 45 were available.

The specificities of the primers in primer solutions 2, 5, 12, 14, 17, 18, 35, 38, 39, 41, 42 and 45 were tested by separately adding additional 5'-primers, respectively additional 3'-primers. In primer solution 13, 40 and 43 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 5, 18, 22, 34, 41 and 42 one, two or three 5'-primers were not possible to test. In primer solutions 4, 14, 15, 17, 18, 35, 38, 39, 41 and 45 one or three 3'-primer was not possible to test. Additional primers in primer solutions 4, 30, 37 and 46 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

The negative control primer pairs, **Production No. 2010-760-01**, can detect contamination with PCR products diluted 10^7 .



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

Date of approval: 2011-July-18

Approved by:



Quality Control, Supervisor

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Declaration of Conformity

Product name: *Olerup SSP*[®] DQB1High**Product number:** 101.221-12**Lot number:** 10M**Intended use:** DQB1 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 9001:2008 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*.

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-July-18



Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

