

Product Insert

101.221-12 – including *Taq* pol., IFU-01101.221-12u – without *Taq* pol., IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **55R**

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
101.221-12u – without *Taq* polymerase

Lot number: 55R

Expiry date: 2015-June-01

Number of tests: 12 tests

Number of wells per test: 63+ 1

Well specifications:

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|----------|----------------|
| 1 | 2011-850-01 | 25 | 2011-850-25 | 49 | 2012-026-49 |
| 2 | 2011-850-02 | 26 | 2012-102-26 | 50 | 2012-026-50 |
| 3 | 2011-850-03 | 27 | 2011-850-27 | 51 | 2012-026-51 |
| 4 | 2011-850-04 | 28 | 2011-850-28 | 52 | 2012-102-52 |
| 5 | 2012-102-05 | 29 | 2011-850-29 | 53 | 2012-026-53 |
| 6 | 2012-102-06 | 30 | 2011-850-30 | 54 | 2012-026-54 |
| 7 | 2011-850-07 | 31 | 2011-850-31 | 55 | 2012-102-55 |
| 8 | 2011-850-08 | 32 | 2011-850-32 | 56 | 2012-026-56 |
| 9 | 2011-850-09 | 33 | 2011-850-33 | 57 | 2012-102-57 |
| 10 | 2011-850-10 | 34 | 2011-850-34 | 58 | 2012-102-58 |
| 11 | 2012-102-11 | 35 | 2012-026-35 | 59 | 2012-102-59 |
| 12 | 2012-102-12 | 36 | 2011-850-36 | 60 | 2012-102-60 |
| | | | | | |
| 13 | 2011-850-13 | 37 | 2012-102-37 | 61 | 2012-102-61 |
| 14 | 2011-850-14 | 38 | 2011-850-38 | 62 | 2012-102-62 |
| 15 | 2011-850-15 | 39 | 2012-102-39 | 63 | 2012-102-63 |
| 16 | 2011-850-16 | 40 | 2011-850-40 | | |
| 17 | 2011-850-17 | 41 | 2012-102-41 | | |
| 18 | 2012-026-18 | 42 | 2012-102-42 | | |
| 19 | 2011-850-19 | 43 | 2011-850-43 | | |
| 20 | 2011-850-20 | 44 | 2012-102-44 | | |
| 21 | 2012-026-21 | 45 | 2011-850-45 | | |
| 22 | 2011-850-22 | 46 | 2011-850-46 | | |
| 23 | 2011-850-23 | 47 | 2012-102-47 | | |
| 24 | 2011-850-24 | 48 | 2012-102-48 | | |

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 2, 5, 12-14, 17, 18, 37-43, 45, 48-51, 53, 54, 56 and 58 to 63 were available.

The specificities of the primers in primer solutions 2, 12, 14, 17, 18, 37-39, 41, 42, 45, 50, 51, 53, 58 and 62 were tested by separately adding additional 5'-primers, respectively additional 3'-primers.

In primer solution 5, 13, 40, 43, 48 and 49 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

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In primer solution 54, 56, 59 to 61 and 63 it was only possible to test the 5'-primers, the 3'-primers were not possible to test.

In primer solutions 11, 18, 22, 34, 41, 42, 50, 51 and 52 one to three 5'-primers were not possible to test.

In primer solutions 4, 12, 14, 15, 17, 18, 35, 38, 39, 41, 42, 44, 45, 47, 51 and 57 one to three 3'-primers were not possible to test.

Additional primers in primer solutions 4, 30, 35, 44, 46, 47, 52 and 57 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer.

The negative control primer pairs, **Production No. 2012-085-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2012-December-17

Approved by:



Production Quality Control

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www.olerup-ssp.com**Declaration of Conformity****Product name:** Olerup SSP® DQB1High**Product number:** 101.221-12/12u**Lot number:** 55R**Intended use:** DQB1 high resolution histocompatibility testing**Manufacturer:** Olerup SSP AB
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SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
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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.

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
2014-September-02



Daniel Malica
Head of QA and Regulatory Affairs