

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.: **85N**

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: 85N

Expiry date: 2014-December-01

Number of tests: 12 tests

Number of wells per test: 59 + 1

Well specifications:

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

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, 58 and 59 were available.

The specificities of the primers in primer solutions 2, 12, 14, 17, 18, 37-39, 41, 42, 45, 50, 51, 53 and 58 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.

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

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



Product Insert

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In primer solutions 4, 14, 15, 17, 18, 35, 38, 39, 41, 45 and 51 one or three 3'-primer was not possible to test.

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

The negative control primer pairs, **Production No. 2012-002-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2012-July-06

Approved by:



Production Quality Control

101.221.12 – including *Taq* pol., IFU-01
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www.olerup-ssp.com**Declaration of Conformity**

Product name: Olerup SSP® DQB1High
Product number: 101.221-12/12u
Lot number: 85N

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.

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
2012-July-06

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs