

101.115-24/03 – including *Taq* polymerase, IFU-01
 101.115-24u/03u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **85S**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® DRB1*11 SSP

Product number: 101.115-24/03 – including *Taq* pol.
 101.115-24u/03u – without *Taq* pol.
Lot number: 85S
Expiry date: 2016-April-01
Number of tests: 24 tests – Product No. 101.115-24/24u
 3 tests – Product No. 101.115-03/03u
Number of wells per test: 43

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-751-01	17	2010-751-17	33	2012-048-33
2	2010-751-02	18	2012-048-18	34	2012-048-34
3	2013-246-03	19	2010-751-19	35	2012-048-35
4	2010-751-04	20	2012-048-20	36	2012-048-36
5	2010-751-05	21	2013-246-21	37	2012-048-37
6	2011-883-06	22	2012-048-22	38	2012-048-38
7	2010-751-07	23	2010-751-23	39	2012-048-39
8	2010-751-08	24	2010-751-24	40	2012-048-40
9	2010-751-09	25	2010-751-25	41	2013-246-41
10	2013-246-10	26	2013-246-26	42	2013-246-42
11	2012-048-11	27	2011-883-27	43	2013-246-43
12	2010-751-12	28	2010-751-28		
13	2011-883-13	29	2010-751-29		
14	2010-751-14	30	2013-246-30		
15	2013-246-15	31	2011-883-31		
16	2011-883-16	32	2010-751-32		

The specificity of each primer solution of the kit has been tested against 48 well characterized cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 12, 16, 21 to 23, 33 to 40, 42 and 43 were available. The specificities of the primers in primer solutions 12, 16, 21, 22, 33, 34, 36, 40 and 42 were tested by separately adding one or more additional 5'-primers, respectively one or more additional 3'-primers.

In primer solution 23, 35 and 38 the 3'-primer was tested by separately adding one 5'-primer, the 5'-primer was not possible test.

In primer solution 37, 39 and 43 the 5'-primer was tested by separately adding one 3'-primer, the 3'-primer was not possible test.

In primer solutions 3, 9 to 11, 16, 19, 22, 24, 30, 32, 33 and 36 one, two or three of the 3'-primers were not possible to test, and in primer solutions 12, 13, 15, 26 and 34 one or two of the 5'-primers were not possible to test.

Additional 3'-primers in primer solutions 5, 9, 10, 17 to 20 and 24 were tested by separately adding one or two 5'-primers.

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

Date of approval: 2013-October-24

Approved by:

Karin Muttsson

Production Quality Control

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Lot-specific information

Declaration of Conformity

Product name: Olerup SSP® DRB1*11
Product number: 101.115-24/24u, -03/03u
Lot number: 85S

Intended use: DRB1*11 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 13485:2012, 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, 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
2015-February-04



Daniel Malica
Head of QA and Regulatory Affairs