

101.432-12 – including *Taq* polymerase, IFU-01 Rev. No. 03
101.432-12u – without *Taq* polymerase, IFU-02 Rev. No. 03

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

Lot No.: 42N

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*33 SSP

Product number: 101.432-12 – including *Taq* polymerase
101.432-12u – without *Taq* polymerase
Lot number: 42N
Expiry date: 2014-September-01
Number of tests: 12
Number of wells per test: 24

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2012-983-01	9	2009-640-09	17	2012-983-17
2	2012-983-02	10	2009-640-10	18	2010-804-18
3	2012-983-03	11	2012-983-11	19	2012-983-19
4	2009-640-04	12	2012-983-12	20	2012-983-20
5	2012-983-05	13	2009-640-13	21	2012-983-21
6	2009-640-06	14	2012-983-14	22	2012-983-22
7	2012-983-07	15	2009-640-15	23	2010-804-23
8	2009-640-08	16	2012-983-16	24	2012-983-24

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 5, 7 to 13, 15, 16 and 18 to 24 were available. The specificities of the primers in primer solutions 5, 7 to 13, 19, 23 and 24 were tested by separately adding additional 5'-primers respectively 3'-primers. In primer solutions 16 and 22 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solution 15, 18, 20 and 21 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 7, 13 and 17, one 5'-primer was not possible to test, and in primer solutions 6, 8, 9, 11 to 14 and 24 one 3'-primer was not possible to test. Additional primers in primer solutions 6, 14 and 17 were tested by separately adding one additional 5'-primer and/or one additional 3'-primer.

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

Date of approval: 2012-April-05

Approved by:

Isa Clauss

Production Quality Control

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Declaration of Conformity

Product name: Olerup SSP® HLA-A*33

Product number: 101.432-12/12u

Lot number: 42N

Intended use: HLA-A*33 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 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, Middlesbrough Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom.
(Notified Body number: 0088.)

Stockholm, Sweden
2012-April-05

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs