101.901-24 – including *Taq* polymerase, IFU-01
101.901-24u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for **"Instructions for Use" (IFU)**

Lot No.: 33S **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*06:02,DQA1*01:02 - SSP

Product number: **101.901-24 – including *Taq* polymerase**
101.901-24u- without *Taq* polymerase
Lot number: **33S**
Expiry date: **2015-October-01**
Number of tests: **24**
Number of wells per test: **11+1**

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2011-901-03	9	2013-184-06
2	2011-901-04	10	2013-184-07
3	2011-901-05	11	2013-184-08
4	2013-184-09		
5	2013-184-10		
6	2013-184-11		
7	2011-901-01		
8	2011-901-02		

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 3, 5, 6 and 10 were available. The specificities of the primers in primer solution 10 were tested by separately adding one additional 5'-primer, respectively, one additional 3'-primer. In primer solution 3 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solution 5 and 6 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 9 and 11 two 3'-primer was not possible to test, and in primer solutions 5 and 10 two respective three 5'-primers were not possible to test.
One additional 3'-primer in primer mix 9 and one additional 5'-primer in primer mix 11 were tested by separately adding one 3'-primer respective one 5'-primer.

The negative control primer pairs, **Production No. 2013-165-01**, can detect contamination with PCR products diluted 10^{-7}.

Lot No.: 33S **Lot-specific information**

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

Date of approval: 2013-May-23

Approved by:

Åsa Olausson

Production Quality Control

Lot No.: 33S

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*06:02,DQA1*01:02
Product number: 101.901-24/24u
Lot number: 33S

Intended use: DQB1*06:02,DQA1*01:02 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 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.

Stockholm, Sweden
2013-May-23

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs