KIR HLA Ligand Product Insert Page 15 of 20 104.201-12 – including *Taq* polymerase General "Instructions for Use"

104.201-12 – including *Taq* polymerase 104.201-12u – without *Taq* polymerase

Lot-specific information www.olerup-ssp.com

IFU-03 can be downloaded from

CERTIFICATE OF ANALYSIS

Olerup SSP® KIR HLA Ligand SSP

Product number: 104.201-12 – including *Taq* polymerase

104.201-12u -without Taq polymerase

Lot number: 665

Expiry date: 2015-December-01

Number of tests: 12 Number of wells per test: 6

Well specifications:

Lot No.: 66S

Well No.	Production No.
1	2012-063-01
2	2012-063-02
3	2012-063-03
4	2012-063-04
5	2012-063-05
6	2012-063-06

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

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

Date of approval: 2013-August-23

Approved by:

Production Quality Control

The Olouss

KIR HLA Ligand Product Insert Page 16 of 20

104.201-12 – including *Taq* polymerase 104.201-12u – without *Taq* polymerase

General "Instructions for Use" IFU-03 can be downloaded from

Lot No.: 66S Lot-specific information www.olerup-ssp.com

Declaration of Conformity

Product name: Olerup SSP® KIR HLA Ligand

Product number: 104.201-12/12u

Lot number: 66S

Intended use: Determination of HLA-C, HLA-B^{Bw4+} and HLA-A^{Bw4+} KIR

ligand sequence motifs.

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-August-23

Ann-Cathrin Jareman

Head of QA and Regulatory Affairs

Une - Castonia Ineman