104.201-12 - including Taq polymerase 104.201-12u - without Tag polymerase

Lot No.: 10L

Lot-specific information

www.olerup-ssp.com

## CERTIFICATE OF ANALYSIS

Olerup SSP® KIR HLA Ligand SSP

Product number:

104.201-12 - including Tag polymerase

104.201-12u -without Tag polymerase

Lot number:

10L

Expiry date:

2013-July-01

Number of tests:

12

Number of wells per test:

5

Well specifications:

Well No.	Production No.
1	2011-827-01
2	2011-827-02
3	2011-827-03
4	2011-827-04
5	2011-827-05

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: 2011-February-04

Approved by:

Quality Control, Supervisor

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

Lot No.: 10L

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:

10L

Intended use:

Determination of HLA-C, HLA-BBw4+ and HLA-ABw4+ KIR

ligand sequence motifs.

Manufacturer:

Olerup SSP AB Hasselstigen 1

SE-133 33 Saltsjöbaden, 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: Olerup SSP AB.

Saltsjöbaden, Sweden 2011-February-04

Olle Olerup

Managing Director