

KIR HLA Ligand
104.201-12 – including *Taq* polymerase
104.201-12u – without *Taq* polymerase

Certificates

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

Lot No.: 39Y

Lot-specific information

www.olerup-ssp.com

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: 39Y
Expiry date: 2017-November-01
Number of tests: 12
Number of wells per test: 6+1

Well specifications:

Well No.	Production No.
1	2015-520-01
2	2015-520-02
3	2012-063-03
4	2012-063-04
5	2012-063-05
6	2012-063-06

The negative control primer pairs, **Production No. 2015-499-01**, can detect contamination with PCR products diluted 10^{-7} .

Results of Quality Control: No false positive or false negative amplifications obtained.

Date of approval: 2015-05-27

Approved by:

Kevin Mattsson

Production Quality Control

Declaration of Conformity

Product name: Olerup SSP® KIR HLA Ligand
Product number: 104.201-12/12u
Lot number: 39Y

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

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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
2015-May-27



Daniel Malica
Head of QA and Regulatory Affairs

