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

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 8H1 **Lot-specific information**

CERTIFICATE OF ANALYSIS

Olerup SSP® KIR HLA Ligand

Product number:	**104.201-12 – including *Taq* polymerase** **104.201-12u – without *Taq* polymerase**
Lot number:	**8H1**
Expiry date:	**2023-12-01**
Number of tests:	**12**
Number of wells per test:	**7+1**

Well specifications:

Well No.	Production No.
1	2018-962-01
2	2018-962-02
3	2018-962-03
4	2018-962-04
5	2018-962-05
6	2018-962-06
7	2018-962-07

The negative control primer pairs, **Production No. 2019-109-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2020-01-09

Approved by: Rebecka Salmé

Production Quality Control

CE

104.201-12 – including *Taq* polymerase
104.201-12u – without *Taq* polymerase
Lot No.: 8H1

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot-specific information

Declaration of Conformity

Product name:	*Olerup* SSP® KIR HLA Ligand
Product number:	104.201-12/12u
Lot number:	8H1
Intended use:	Determination of HLA-A^{Bw4+}, HLA-B^{Bw4+}, HLA-B^{Bw6+} and HLA-C KIR ligand sequence motifs.
Manufacturer:	CareDx SSP AB Franzengatan 5 SE-112 51 Stockholm, Sweden ***Phone:*** +46-8-508 939 00 ***Fax:*** +46-8-717 88 18

We, CareDx 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) EN ISO 13485:2016, 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 *CareDx* AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

The Authorized Representative located within the Community is: *CareDx* AB.

In U.S.: For Research Use Only. Not For Use in Diagnostic Procedures.

Stockholm, Sweden
Date: 2020-01-09

Quality Assurance

CE