

101.613-12– including *Taq* polymerase, IFU-01
101.613-12u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **61R**

Lot-specific information

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*05 SSP

Product number: 101.613-12 – including *Taq* polymerase
101.613-12u – without *Taq* polymerase
Lot number: 61R
Expiry date: 2015-June-01
Number of tests: 12
Number of wells per test: 32

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-778-01	13	2010-778-13	25	2010-778-25
2	2010-778-02	14	2010-778-14	26	2010-778-26
3	2012-107-03	15	2010-778-15	27	2010-778-27
4	2010-778-04	16	2010-778-16	28	2010-778-28
5	2012-107-05	17	2010-778-17	29	2010-778-29
6	2010-778-06	18	2010-778-18	30	2012-984-30
7	2010-778-07	19	2010-778-19	31	2012-107-31
8	2012-984-08	20	2010-778-20	32	2012-984-32
9	2010-778-09	21	2012-107-21		
10	2010-778-10	22	2010-778-22		
11	2010-778-11	23	2010-778-23		
12	2010-778-12	24	2010-778-24		

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

No DNAs carrying the alleles to be amplified by primer solutions 4 to 6, 8 to 12, 14 to 16, 18, 20, 22 to 30 and 32 were available. The specificities of the primers in primer solutions 5, 6, 8, 10 to 12, 14, 15, 20, 22 to 24, 26, 27, 29 and 32 were tested by separately adding additional 5'-primers respectively 3'-primers. In primer solutions 4, 25, 28 and 30 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 9, 16 and 18 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solutions 3, 8, 10, 11, 14, 15, 20, 23, 29 and 32 one or two 3'-primers were not possible to test. In primer solutions 12, 15, 20, 26, 29 and 32 one 5'-primer was not possible to test. One additional 3'-primer in primer solution 3 was tested by separately adding one 5'-primer.

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

Date of approval: 2013-January-09

Approved by:



Production Quality Control



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Declaration of Conformity**Product name:** Olerup SSP® HLA-C*05**Product number:** 101.613-12/12u**Lot number:** 61R**Intended use:** HLA-C*05 high resolution 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 13485:2003, 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, Franzengatan 5, SE-112 51 Stockholm, Sweden.

Stockholm, Sweden
2013-January-09


Ann-Cathrin Jareman
Head of QA and Regulatory Affairs