

Lot No.: 57K

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-C*05 SSP

Product number: 101.613-12 – including Taq polymerase
Lot number: 57K
Expiry date: 2013-April-01
Number of tests: 12
Number of wells per test: 30

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 | 2010-778-03 | 15 | 2010-778-15 | 27 | 2010-778-27 |
| 4 | 2010-778-04 | 16 | 2010-778-16 | 28 | 2010-778-28 |
| 5 | 2010-778-05 | 17 | 2010-778-17 | 29 | 2010-778-29 |
| 6 | 2010-778-06 | 18 | 2010-778-18 | 30 | 2010-778-30 |
| 7 | 2010-778-07 | 19 | 2010-778-19 | | |
| 8 | 2010-778-08 | 20 | 2010-778-20 | | |
| 9 | 2010-778-09 | 21 | 2010-778-21 | | |
| 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 and 22 to 30 were available. The specificities of the primers in primer solutions 5, 6, 10 to 12, 14, 15, 20, 22 to 24, 26, 27 and 29 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4, 8, 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 10, 11, 14, 15, 20, 23 and 29, one or two 3'-primers were not possible to test. In primer solutions 12, 15, 20, 26 and 29, 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: 2010-November-24

Approved by:



Quality Control, Supervisor

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Declaration of Conformity

Product name: *Olerup* SSP® HLA-C*05
Product number: 101.613-12
Lot number: 57K

Intended use: HLA-C*05 high resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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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 13485:2003, 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
2010-November-24



Olle Olerup
Managing Director