# *Olerup* SSP® HLA-B*57:01

| | |
|---|---|
| **Product number:** | **101.572-12u – without *Taq* polymerase** |
| **Lot number:** | **12K** |
| **Expiry date:** | **2012-June-01** |
| **Number of tests:** | **12** |
| **Number of wells per test:** | **11** |
| **Storage - pre-aliquoted primers:** | **dark at -20°C** |
| **- PCR Master Mix:** | **-20°C** |
| **- Adhesive PCR seals** | **RT** |
| **- Product Insert** | **RT** |

## This Product Description is only valid for Lot No. 12K.

## CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® HLA-B*57:01 LOT.

The HLA-B*57:01 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup* SSP® HLA-B*57:01 lot was made **(Lot No. 44G)**.

Three wells have been added to the HLA-B*57:01 kit,
wells **9 to 11.**
A negative control has been included as well **11.**

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot.

| Well | 5'-primer | 3'-primer | rationale |
|---|---|---|---|
| 3 | - | Added | Primer added for the B*57:27 allele. |
| 4 | Added | Added | Primer pairs added for the B*57:20 and 57:29 alleles. |
| 5 | Added | Added | Primers added for the B*57:23 and 57:26 alleles. |
| 9 | New | New | New primer pair for the B*57:21 allele. |
| 10 | New | New | New primer pair for the B*57:13 and 57:22 alleles. |
| 11 | New | New | Negative control. |

Well **11** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup* SSP® HLA Class I, DRB, DQB1 and DPB1 amplicons as well as the amplicons generated by control primer pairs.

PCR product sizes range from 75 to 430 base pairs.
The PCR product generated by the control primer pair is 430 base pairs.

| **Length of PCR product** | **105** | **200** | **105** | **80** | **75** | **80** |
|---|---|---|---|---|---|---|
| **5'-primer[1]** | **164** | **340** | **440** | **45** | **45** | **43** |
| | **5'-CAC3'** | **5'-Agg3'** | **5'-TTA3'** | **5'-Tg g3'** | **5'-Tg g3'** | **5'-Tg g3'** |
| **3'-primer[2]** | **231** | **2nd I** | **507** | **59** | **58** | **57** |
| | **5'-TgC3'** | **5'-AAA3'** | **5'-TTg3'** | **5'-CTC3'** | **5'-ggC3'** | **5'-CTC3'** |
| **A*** | **+** | **+** | **+** | | | |
| **B*** | **+** | **+** | **+** | | | |
| **C*** | **+** | **+** | **+** | | | |
| **DRB1** | | | | **+** | **+** | |
| **DRB3** | | | | **+** | **+** | |
| **DRB5** | | | | **+** | | |
| **DQB1** | | | | | **+** | |
| **DPB1** | | | | | | **+** |

[1]The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.
[2]The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

# PRODUCT DESCRIPTION

## HLA-B*57:01 SSP subtyping

### CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*57:01:01 to 57:01:07 alleles.

### PLATE LAYOUT

Each test consists of 11 PCR reactions in a 16 well cut PCR plate. Wells 12 to 16 are empty.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** |
| **9** | **10** | **11** | **empty** | **empty** | **empty** | **empty** | **empty** |

The 16 well cut PCR plate is marked with 'B*57:01' in silver/gray ink.
Well No. 1 is marked with the Lot No. '12K'.
A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.
The PCR plates are heat-sealed with a PCR-compatible foil.
**Please note:** When removing each 16 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

### INTERPRETATION

The interpretation of HLA-B*57:01 SSP subtypings will influence by the other B*57 alleles and also by the B*40:30, 40:34, 55:14 and 58:14 alleles.

### UNIQUELY IDENTIFIED ALLELES

HLA-B*57:01 will give rise to a unique amplification pattern by the primers in the HLA-B*57:01 kit[1].
The HLA-B*57:01 typing kit cannot distinguish the B*57:01:01 to B*57:01:07alleles.

[1]HLA-B alleles listed on the IMGT/HLA web page 2010-April-01, release 3.0.0, www.ebi.ac.uk/imgt/hla.

# SPECIFICITY TABLE

## HLA-B*57:01 SSP subtyping

### Specificities and sizes of the PCR products of the 11 primer mixes used for HLA-B*57:01 SSP subtyping

| Primer Mix | Size of spec. PCR product[1] | Size of control band[2] | Amplified HLA-B*57:01 alleles | Other amplified HLA-B alleles[3] |
|---|---|---|---|---|
| **1**[4] | 90 bp | **800 bp** | 57:01:01-57:01:07 | *57:02:01-57:15, 57:17-57:19, 57:21-57:31 |
| **2** | 220 bp | **800 bp** | 57:01:01-57:01:07 | *57:03:01-57:03:02, 57:06-57:08, 57:10, 57:14-57:18, 57:20-57:23, 57:25-57:27, 57:29, 57:31, **40:30, 40:34, 55:14, 58:14** |
| **3**[4,6] | 95 bp, 170 bp, 215 bp | **800 bp** | | *57:04, 57:06, 57:18, 57:27 |
| **4**[4,5] | 100 bp | 1070 bp | | *57:15, 57:20, 57:29 |
| **5**[4,7] | 90 bp, 165 bp, 245 bp | **800 bp** | | *57:07, 57:16, 57:23, 57:26, **55:14** |
| **6**[4,8] | 90 bp, 210 bp | 1070 bp | | *57:02:01-57:03:02, 57:07-57:09, 57:12, 57:17, **40:30, 40:34** |
| **7**[9] | 140 bp, 165 bp, 215 bp, 240 bp | 1070 bp | | *57:09, 57:13-57:14, 57:24-57:25, 57:31, **40:30, 40:34, 55:14, 58:14** |
| **8** | 195 bp | 1070 bp | | *57:10 |
| | | | | |
| **9** | 150 bp | **800 bp** | | *57:21 |
| **10** | 205 bp | 1070 bp | | *57:13, 57:22, **55:14** |
| **11**[10] | - | - | | **Negative control** |

[1]Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-B*57:01 SSP typings.
When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.
Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.
PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.
PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.
Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherit feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

[2]The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.
Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*57:01 subtyping.
In addition, wells number 2, 3, 5 and 9 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.
In the presence of a specific amplification the intensity of the control band often decreases.
[3]Due to the sharing of sequence motifs between HLA-B alleles some non-HLA-B*57 alleles will be amplified by primer mixes 2, 5 to 7 and 10.
[4]Short specific PCR fragments are less intense and not as sharp as longer specific bands.
[5]Primer mix 4 has a tendency of giving rise to nonspecific amplifications.
[6]Primer mix 3: Specific PCR fragment of 95 bp in the B*57:04 allele. Specific PCR fragment of 170 bp in the B*57:06 and B*57:18 alleles. Specific PCR fragment of 215 bp in the B*57:27 allele.
[7]Primer mix 5: Specific PCR fragment of 90 bp in the B*57:16 allele. Specific PCR fragment of 165 bp in the B*57:23 allele. Specific PCR fragment of 245 bp in the B*57:07 and 57:26 and in the B*55:14, alleles.
[8]Primer mix 6: Specific PCR fragment of 90 bp in the B*57:02:01-57:03:02, 57:07, 57:09, 57:12 and 57:17 and in the B*40:30 and 40:34 alleles. Specific PCR fragment of 210 bp in the B*57:08 allele.
[9]Primer mix 7: Specific PCR fragment of 140 bp in the B* 57:31 allele. Specific PCR fragment of 165 bp in the B*57:14 and B*55:14 and 58:14 alleles. Specific PCR fragment of 215 bp in the B*57:09 and 57:24 alleles. Specific PCR fragment of 240 bp in the B*57:25 allele. Specific PCR fragment of 140 and 240bp in the B*57:13 and in the B*40:30 and 40:34 alleles.
[10]Primer mix 11 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

# INTERPRETATION TABLE

## HLA-B*57:01 SSP typing

| | Well[4] | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** |
| **Length of spec.** | 90 | 220 | 95 | 100 | 90 | 90 | 140 | 195 | 150 | 205 | |
| **PCR product** | | | 170 | | 165 | 210 | 165 | | | | |
| | | | 215 | | 245 | | 215 | | | | |
| | | | | | | | 240 | | | | |
| **Length of int.** | 800 | 800 | 800 | 1070 | 800 | 1070 | 1070 | 1070 | 800 | 1070 | |
| **pos. control[1]** | | | | | | | | | | | |
| **5'-primer(s)[2]** | 209 | 362 | 362 | 209 | 130 | 320 | 362 | 103 | 352 | 362 | Negative Control |
| | 5' -ggC 3' | 5' -ggT 3' | 5' -ggT 3' | 5' -ggC 3' | 5' -AgT 3' | 5' -CCC 3' | 5' -ggT 3' | 5' -CCT 3' | 5' -ACg 3' | 5' -ggT 3' | |
| | | | | 704 | 209 | 362 | | | | | |
| | | | | 5' -TgT 3' | 5' -ggA 3' | 5' -ggT 3' | | | | | |
| | | | | | 362 | | | | | | |
| | | | | | 5' -ggT 3' | | | | | | |
| **3'-primer(s)[3]** | 256 | 539 | 418 | 259 | 256 | 2nd I | 463 | 256 | 463 | 527 | |
| | 5' -CCC 3' | 5' -TCA 3' | 5' -gTC 3' | 5' -CTT 3' | 5' -CCC 3' | 5' -TCg 3' | 5' -gCg 3' | 5' -CCC 3' | 5' -gCT 3' | 5' -CCT 3' | |
| | | | 481 | 271 | 559 | 412 | 486 | | | | |
| | | | 5' -gTA 3' | 5' -CAC 3' | 5' -CgT 3' | 5' -gTT 3' | 5' -gCg 3' | | | | |
| | | | 500 | 774 | 572 | | 538 | | | | |
| | | | 5' -ggA 3' | 5' -ggT 3' | 5' -gCg 3' | | 5' -gTC 3' | | | | |
| | | | 537 | | | | 559 | | | | |
| | | | 5' -Agg 3' | | | | 5' -CTC 3' | | | | |
| **Well No.** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
| **HLA-B allele** | | | | | | | | | | | |
| ***57:01:01-57:01:07** | 1 | 2 | | | | | | | | | Negative Control |
| ***57:02:01-57:02:02, 57:12** | 1 | | | | | 6 | | | | | |
| ***57:03:01-57:03:02, 57:08, 57:17** | 1 | 2 | | | | 6 | | | | | |
| ***57:04** | 1 | | 3 | | | | | | | | |
| ***57:05, 57:11, 57:19, 57:28N, 57:30** | 1 | | | | | | | | | | |
| ***57:06, 57:18, 57:27** | 1 | 2 | 3 | | | | | | | | |
| ***57:07** | 1 | 2 | | | 5 | 6 | | | | | |
| ***57:09** | 1 | | | | | 6 | 7 | | | | |
| ***57:10** | 1 | 2 | | | | | | 8 | | | |
| ***57:13** | 1 | | | | | | 7 | | | 10 | |
| ***57:14, 57:25, 57:31** | 1 | 2 | | | | | 7 | | | | |
| ***57:15, 57:29** | 1 | 2 | | 4 | | | | | | | |
| ***57:16** | | 2 | | | 5 | | | | | | |
| ***57:20** | | 2 | | 4 | | | | | | | |
| ***57:21** | 1 | 2 | | | | | | | 9 | | |
| ***57:22** | 1 | 2 | | | | | | | | 10 | |
| ***57:23, 57:26** | 1 | 2 | | | 5 | | | | | | |
| ***57:24** | 1 | | | | | | 7 | | | | |
| ***40:30, 40:34** | | 2 | | | | 6 | 7 | | | | |
| ***55:14** | | 2 | | | 5 | | 7 | | | 10 | |
| ***58:14** | | 2 | | | | | 7 | | | | |
| **HLA-B allele** | | | | | | | | | | | |
| **Well No.** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |

[1]The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.
Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*57:01 subtyping.
In addition, wells number 2, 3, 5 and 9 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.
[2]The nucleotide position, in the 2nd, 3rd or 4th exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.
[3]The nucleotide position, in the 2nd, 3rd or 4th exon or the 2nd intron matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.
[4]Primer mix 3: Specific PCR fragment of 95 bp in the B*57:04 allele. Specific PCR fragment of 170 bp in the B*57:06 and B*57:18 alleles. Specific PCR fragment of 215 bp in the B*57:27 allele.
Primer mix 5: Specific PCR fragment of 90 bp in the B*57:16 allele. Specific PCR fragment of 165 bp in the B*57:23 allele. Specific PCR fragment of 245 bp in the B*57:07 and 57:26 and in the B*55:14, alleles.
Primer mix 6: Specific PCR fragment of 90 bp in the B*57:02:01-57:03:02, 57:07, 57:09, 57:12 and 57:17 and in the B*40:30 and 40:34 alleles. Specific PCR fragment of 210 bp in the B*57:08 allele.
Primer mix 7: Specific PCR fragment of 140 bp in the B*57:31 allele. Specific PCR fragment of 165 bp in the B*57:14 and B*55:14 and 58:14 alleles. Specific PCR fragment of 215 bp in the B*57:09 and 57:24 alleles. Specific PCR fragment of 240 bp in the B* 57:25 allele. Specific PCR fragment of 140 and 240bp in the B*57:13 and in the B*40:30 and 40:34 alleles.
Primer mix 11 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by control primer pairs. PCR product sizes range from 75 to 200 base pairs. The PCR product generated by the control primer pair is 430 base pairs.

# CELL LINE VALIDATION SHEET

## HLA-B*57:01 SSP typing kit

| | | | | | Well | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 |
| | | | | Prod. No.: | 200959801 | 200848702 | 201072603 | 201072604 | 201072605 | 200959806 | 201072607 | 200959808 | 201072609 | 201072610 |
| | IHWC cell line | | B* | | | | | | | | | | | |
| 1 | 9001 | SA | *07:02 | | - | - | - | - | - | - | - | - | - | - |
| 2 | 9280 | LK707 | *52:01 | *73:01 | - | - | - | - | - | - | - | - | - | - |
| 3 | 9011 | E4181324 | *52:01 | | - | - | - | - | - | - | - | - | - | - |
| 4 | 9275 | GU373 | *15:10 | *53:01 | - | - | - | - | - | - | - | - | - | - |
| 5 | 9009 | KAS011 | *37:01 | | - | - | - | - | - | - | - | - | - | - |
| 6 | 9353 | SM | *39:01 | *51:01 | - | - | - | - | - | - | - | - | - | - |
| 7 | 9020 | QBL | *18:01 | | - | - | - | - | - | - | - | - | - | - |
| 8 | 9025 | DEU | *35:01 | | - | - | - | - | - | - | - | - | - | - |
| 9 | 9026 | YAR | *38:01 | | - | - | - | - | - | - | - | - | - | - |
| 10 | 9107 | LKT3 | *54:01 | | - | - | - | - | - | - | - | - | - | - |
| 11 | 9051 | PITOUT | *44:03 | | - | - | - | - | - | - | - | - | - | - |
| 12 | 9052 | DBB | *57:01 | | + | + | - | - | - | - | - | - | - | - |
| 13 | 9025 | JESTHOM | *27:05 | | - | - | - | - | - | - | - | - | - | - |
| 14 | 9071 | OLGA | *15:01 | *15:20 | - | - | - | - | - | - | - | - | - | - |
| 15 | 9075 | DKB | *40:01 | | - | - | - | - | - | - | - | - | - | - |
| 16 | 9037 | SWEIG007 | *40:02 | | - | - | - | - | - | - | - | - | - | - |
| 17 | 9282 | CTM3953540 | *08:01 | *55:01 | - | - | - | - | - | - | - | - | - | - |
| 18 | 9257 | 32367 | *14:01 | *56:01 | - | - | - | - | - | - | - | - | - | - |
| 19 | 9038 | BM16 | *18:01 | | - | - | - | - | - | - | - | - | - | - |
| 20 | 9059 | SLE005 | *40:01 | | - | - | - | - | - | - | - | - | - | - |
| 21 | 9064 | AMALA | *15:01 | | - | - | - | - | - | - | - | - | - | - |
| 22 | 9056 | KOSE | *35:03 | | - | - | - | - | - | - | - | - | - | - |
| 23 | 9124 | IHL | *40:02 | *56:02 | - | - | - | - | - | - | - | - | - | - |
| 24 | 9035 | JBUSH | *38:01 | | - | - | - | - | - | - | - | - | - | - |
| 25 | 9049 | IBW9 | *14:02 | | - | - | - | - | - | - | - | - | - | - |
| 26 | 9285 | WT49 | *58:01 | | - | - | - | - | - | - | - | - | - | - |
| 27 | 9191 | CH1007 | *07:05 | *51:01 | - | - | - | - | - | - | - | - | - | - |
| 28 | 9320 | BEL5GB | *44:02 | *44:03 | - | - | - | - | - | - | - | - | - | - |
| 29 | 9050 | MOU | *44:03 | | - | - | - | - | - | - | - | - | - | - |
| 30 | 9021 | RSH | *42:01 | | - | - | - | - | - | - | - | - | - | - |
| 31 | 9019 | DUCAF | *18:01 | | - | - | - | - | - | - | - | - | - | - |
| 32 | 9297 | HAG | *41:02 | | - | - | - | - | - | - | - | - | - | - |
| 33 | 9098 | MT14B | *40:01 | | - | - | - | - | - | - | - | - | - | - |
| 34 | 9104 | DHIF | *38:01 | | - | - | - | - | - | - | - | - | - | - |
| 35 | 9302 | SSTO | *44:02 | | - | - | - | - | - | - | - | - | - | - |
| 36 | 9024 | KT17 | *15:01 | *35:01 | - | - | - | - | - | - | - | - | - | - |
| 37 | 9065 | HHKB | *07:02 | | - | - | - | - | - | - | - | - | - | - |
| 38 | 9099 | LZL | *15:01 | | - | - | - | - | - | - | - | - | - | - |
| 39 | 9315 | CML | *08:01 | *27:05 | - | - | - | - | - | - | - | - | - | - |
| 40 | 9134 | WHONP199 | *13:02 | *46:01 | - | - | - | - | - | - | - | - | - | - |
| 41 | 9055 | H0301 | *14:02 | | - | - | - | - | - | - | - | - | - | - |
| 42 | 9066 | TAB089 | *46:01 | | - | - | - | - | - | - | - | - | - | - |
| 43 | 9076 | T7526 | *46:01 | | - | - | - | - | - | - | - | - | - | - |
| 44 | 9057 | TEM | *38:01 | | - | - | - | - | - | - | - | - | - | - |
| 45 | 9239 | SHJO | *42:01 | *50:01 | - | - | - | - | - | - | - | - | - | - |
| 46 | 9013 | SCHU | *07:02 | | - | - | - | - | - | - | - | - | - | - |
| 47 | 9045 | TUBO | *51:01 | | - | - | - | - | - | - | - | - | - | - |
| 48 | 9303 | TER-ND | *35:01 | *44:03 | - | - | - | - | - | - | - | - | - | - |

# CERTIFICATE OF ANALYSIS

## *Olerup* SSP® HLA-B*57:01 SSP

**Product number:** **101.572-12u – without *Taq* polymerase**
**Lot number:** **12K**
**Expiry date:** **2012-June-01**
**Number of tests:** **12**
**Number of wells per test:** **11**

**Well specifications:**

| Well No. | Production No. |
|---|---|
| 1 | 2009-598-01 |
| 2 | 2008-487-02 |
| 3 | 2010-726-03 |
| 4 | 2010-726-04 |
| 5 | 2010-726-05 |
| 6 | 2009-598-06 |
| 7 | 2010-726-07 |
| 8 | 2009-598-08 |
| 9 | 2010-726-09 |
| 10 | 2010-726-10 |

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

No DNAs carrying the alleles to be amplified by primer solutions 3 to 5 and 7 to 10 were available. The specificities of the primers in primer solutions 3 to 5, 7, 8 and 10 were tested by separately adding one or two additional 5'-primer(s), respectively one or two additional 3'-primer(s). In primer solution 9 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.
In primer solution 3 three 3'-primers were not possible to test, in primer solution 4 one 5'-primer and two 3'-primers were not possible to test and in primer solution 5 two 5'-primers were not possible to test.
The negative control primer pairs, **Production No. 2009-614-01**, can detect contamination with PCR products diluted $10^{-7}$.

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

***Date of approval:*** 2010-June-10

***Approved by:***

**Quality Control, Supervisor**

# Declaration of Conformity

**Product name:** *Olerup* SSP® HLA-B*57:01
**Product number:** 101.572-12u
**Lot number:** 12K

**Intended use:** HLA-B*57:01 histocompatibility testing

**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 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 *Olerup* SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

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

Notified Body: Lloyd's Register Quality Assurance Limited, Hiramford, Middlemarch Office Village, Siskin Drive, Coventry CV3 4FJ, United Kingdom. (Notified Body number: 0088.)

Saltsjöbaden, Sweden
2010-June-10

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