

Olerup SSP[®] HLA-Cw*05

| | |
|----------------------------------|--|
| Product number: | 101.613-12 – including <i>Taq</i> polymerase |
| Lot number: | 54E |
| Expiry date: | 2010-April-01 |
| Number of tests: | 12 |
| Number of wells per test: | 15 |
| 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. 54E.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-Cw*05 LOT

The HLA-Cw*05 specificity and interpretation tables have been updated for the HLA-Cw alleles described since the previous *Olerup SSP*[®] HLA-Cw*05 lot was made (**Lot No. X61**).

One well has been removed from the HLA-Cw*05 kit,
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 |
|------|-----------|-----------|---|
| 4 | - | Modified | Increased specificity of specific primer pair. |
| 8 | - | Modified | Increased specificity of specific primer pair. |
| 11 | Removed | Removed | Primer not necessary when the Cw*0502 allele has been deleted from the allele database. |

PRODUCT DESCRIPTION

HLA-Cw*05 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the Cw*0501 to Cw*0517 alleles.

PLATE LAYOUT

Each test consists of 16 PCR reactions in a 16 well PCR plate. Well 16 is empty.

| | | | | | | | |
|---|----|----|----|----|----|----|-------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | empty |

The 16 well cut PCR plate is marked with 'Cw*05'.

Well No. 1 is marked with the Lot No. '54E'.

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-Cw*05 SSP subtypings will be influenced by the Cw*0113, Cw*0605, six Cw*07, the Cw*08 and the Cw*1221 alleles when present on the other haplotype. In addition, the A*2910 allele will be amplified by primer mix 6 and the B*1533 allele will be amplified by primer mixes 3 and 10.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*05 alleles, i.e. **Cw*0501 to Cw*0517**, recognized by the HLA Nomenclature Committee in January 2008¹ will give rise to unique amplification patterns by the primers in the HLA-Cw*05 subtyping kit.

The HLA-Cw*05 subtyping kit cannot distinguish the Cw*050101 to Cw*050104 alleles.

¹HLA-Cw alleles listed on the IMGT/HLA web page 2008-January-11, release 2.20.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 16 HLA-Cw*05 alleles can be combined in 136 homozygous and heterozygous combinations. Seventy-one of these genotypes do not give rise to unique amplification patterns.

| | | |
|-----------|----------|--|
| +++----+- | ----+--- | 0501,0517 = 0509,0511 = 0511,0517 |
| +++--++- | ----- | 0503,0505 = 0503,0516 |
| +++--+- | ----+-- | 0503,0512 = 0503,0515 |
| +++--+- | ----- | 0501,0503 = 0503,0503 |
| +++--++- | ----- | 0504,0505 = 0504,0516 |
| +++--+- | ----+-- | 0504,0512 = 0504,0515 |
| +++--+- | ----- | 0501,0504 = 0504,0504 |
| +++--++- | ----- | 0505,0506 = 0506,0516 |
| +++--+- | +----- | 0505,0507N = 0507N,0516 |
| +++--+- | -+----- | 0505,0508 = 0508,0516 |
| +++--+- | --+----- | 0505,0510 = 0510,0516 |
| +++--+- | ----+--- | 0505,0511 = 0511,0516 |
| +++--+- | ----+--- | 0505,0512 = 0505,0515 = 0512,0516 = 0515,0516 |
| +++--+- | -----+- | 0505,0513 = 0513,0516 |
| +++--+- | -----+ | 0505,0514 = 0514,0516 |
| +++--+- | ----- | 0501,0505 = 0501,0516 = 0505,0516 = 0516,0516 |
| +++--++ | ----+--- | 0506,0512 = 0506,0515 |
| +++--++ | ----- | 0501,0506 = 0506,0506 |
| +++--+- | +----+-- | 0507N,0512 = 0507N,0515 |
| +++--+- | +----- | 0501,0507N = 0507N,0507N |
| +++--+- | -+--+- | 0508,0512 = 0508,0515 |
| +++--+- | -+----- | 0501,0508 = 0508,0508 |
| +++--+- | --+--+- | 0510,0512 = 0510,0515 |
| +++--+- | --+----- | 0501,0510 = 0510,0510 |
| +++--+- | ----+--- | 0511,0512 = 0511,0515 |
| +++--+- | ----+--- | 0501,0511 = 0511,0511 |
| +++--+- | ----+-- | 0512,0513 = 0513,0515 |
| +++--+- | ----+-- | 0512,0514 = 0514,0515 |
| +++--+- | ----+--- | 0501,0512 = 0501,0515 = 0512,0515 = 0515,0515 |
| +++--+- | -----+- | 0501,0513 = 0513,0513 |
| +++--+- | -----+ | 0501,0514 = 0514,0514 |
| -++----- | ----+--- | 0509,0517 = 0517,0517 |

SPECIFICITY TABLE

HLA-Cw*05 SSP subtyping

Specificities and sizes of the PCR products of the 15 primer mixes used for HLA-Cw*05 SSP subtyping

| Primer Mix | Size of spec. PCR product ¹ | Size of control band ² | Amplified HLA-Cw*05 alleles | Other amplified HLA Class I alleles ^{3,4} |
|-----------------|--|-----------------------------------|---|--|
| 1 | 155 bp | 800 bp | 050101-050104, 0503-0508, 0510, 0511, 0513-0516 | 0741, 0802, 0804, 0805, 0807, 0812, 0813 |
| 2 | 165 bp | 1070 bp | 050101-050104, 0503-0517 | 0605, 0810, 1221 |
| 3 | 155 bp | 1070 bp | 0509, 0517 | 0113, 0815, B*1533 |
| 4 ⁵ | 120 bp | 800 bp | 0503 | 0752 |
| 5 | 225 bp | 1070 bp | 0504 | 0809, 0811 |
| 6 | 270 bp | 1070 bp | 0505, 0516 | 0812, A*2910 |
| 7 | 265 bp | 1070 bp | 050101-050104, 0503, 0504, 0506-0508, 0510-0516 | 070401-070402, 0711, 0712, 0741, 080101-0814 |
| 8 ⁵ | 85 bp | 800 bp | 0506 | |
| 9 | 285 bp | 1070 bp | 0507N | |
| 10 ⁵ | 95 bp | 1070 bp | 0508 | B*1533 |
| 11 | 285 bp | 1070 bp | 0510 | |
| 12 ⁵ | 95 bp | 1070 bp | 0511, 0517 | 0804, 0813 |
| 13 ⁵ | 120 bp | 1070 bp | 0512, 0515 | |
| 14 | 240 bp | 1070 bp | 0513 | |
| 15 | 195 bp | 1070 bp | 0514 | |

¹Alleles 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-Cw*05 SSP subtypings.

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 length 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 inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low

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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.

²The 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-Cw*05 subtyping.

In addition, wells number 4 and 8 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.

³Due to the sharing of sequence motifs between HLA-Cw alleles non-HLA-Cw*05 alleles will be amplified by primer mixes 1, 2, 3, 5, 7 and 12.

⁴Due to the sharing of sequence motifs between HLA class I genes, the A*2910 allele by primer mix 6 and the B*1533 allele will be amplified by primer mixes 3, 10.

⁵Specific PCR fragments shorter than 125 base pairs have a lower intensity than longer PCR bands.

| INTERPRETATION TABLE | | | | | | | | |
|--|----------------------|----------------------|----------------------|-------------------------|----------------------|----------------------|----------------------|----------------------|
| HLA-Cw*05 subtyping | | | | | | | | |
| Amplification patterns of the Cw*0501 to 0517 alleles | | | | | | | | |
| | Well | | | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| Length of spec. | 155 | 165 | 155 | 120 | 225 | 270 | 265 | 85 |
| PCR product | | | | | | | | |
| Length of int. | 800 | 1070 | 1070 | 800 | 1070 | 1070 | 1070 | 800 |
| pos. control¹ | | | | | | | | |
| 5'-primer(s)² | 485 | 176 | 485 | 3rd I | 419 | 379 | 379 | 176 |
| | 5'-CAA ^{3'} | 5'-gCA ^{3'} | 5'-CAA ^{3'} | 5'-TgT ^{3'} | 5'-gTC ^{3'} | 5'-ACg ^{3'} | 5'-ACC ^{3'} | 5'-gCA ^{3'} |
| | | | | | | 361 | | |
| | | | | | | 5'-AgT ^{3'} | | |
| 3'-primer(s)³ | 601 | 302 | 601 | 668 | 601 | 601 | 601 | 221 |
| | 5'-CTT ^{3'} | 5'-ggT ^{3'} | 5'-CTC ^{3'} | 5'-TgA ^{3'} | 5'-CTT ^{3'} | 5'-CTC ^{3'} | 5'-CTC ^{3'} | 5'-ACC ^{3'} |
| | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| HLA-Cw allele⁴ | | | | | | | | |
| *050101-050104 | 1 | 2 | | | | | 7 | |
| *0503 | 1 | 2 | | 4 | | | 7 | |
| *0504 | 1 | 2 | | | 5 | | 7 | |
| *0505 | 1 | 2 | | | | 6 | | |
| *0506 | 1 | 2 | | | | | 7 | 8 |
| *0507N | 1 | 2 | | | | | 7 | |
| *0508 | 1 | 2 | | | | | 7 | |
| *0509 | | 2 | 3 | | | | | |
| *0510 | 1 | 2 | | | | | 7 | |
| *0511 | 1 | 2 | | | | | 7 | |
| *0512 | | 2 | | | | | 7 | |
| *0513 | 1 | 2 | | | | | 7 | |
| *0514 | 1 | 2 | | | | | 7 | |
| *0515 | 1 | 2 | | | | | 7 | |
| *0516 | 1 | 2 | | | | 6 | 7 | |
| *0517 | | 2 | 3 | | | | | |
| *0113, 0815 | | | 3 | | | | | |
| *0605, 1221 | | 2 | | | | | | |
| *070401-070402, 0711, 0712, 080101-080102, 0803, 0806, 0808, 0814 | | | | | | | 7 | |
| *0741, 0802, 0805, 0807 | 1 | | | | | | 7 | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

| INTERPRETATION TABLE | | | | | | | |
|--|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------------------|
| HLA-Cw*05 subtyping | | | | | | | |
| Amplification patterns of the Cw*0501 to 0517 alleles | | | | | | | |
| Well | | | | | | | |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | |
| 285 | 95 | 285 | 95 | 120 | 240 | 195 | Length of spec. |
| | | | | | | | PCR product |
| 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | Length of int. |
| | | | | | | | pos. control¹ |
| 355 | 485 | 355 | 485 | 176 | 115 | 446 | 5'-primer(s)² |
| 5'-CC ^{3'} | 5'-CAA ^{3'} | 5'-TCA ^{3'} | 5'-CAA ^{3'} | 5'-gCA ^{3'} | 5'-ggA ^{3'} | 5'-CgT ^{3'} | |
| | | | | 453 | | | |
| | | | | 5'-AAT ^{3'} | | | |
| 601 | 538 | 601 | 539 | 256 | 312 | 601 | 3'-primer(s)³ |
| 5'-CTT ^{3'} | 5'-CCA ^{3'} | 5'-CTT ^{3'} | 5'-TCA ^{3'} | 5'-CCA ^{3'} | 5'-AgT ^{3'} | 5'-CTT ^{3'} | |
| | | | | 527 | | | |
| | | | | 5'-CCA ^{3'} | | | |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |
| | | | | | | | HLA-Cw allele⁴ |
| | | | | | | | *050101-050104 |
| | | | | | | | *0503 |
| | | | | | | | *0504 |
| | | | | | | | *0505 |
| | | | | | | | *0506 |
| 9 | | | | | | | *0507N |
| | 10 | | | | | | *0508 |
| | | | | | | | *0509 |
| | | 11 | | | | | *0510 |
| | | | 12 | | | | *0511 |
| | | | | 13 | | | *0512 |
| | | | | | 14 | | *0513 |
| | | | | | | 15 | *0514 |
| | | | | 13 | | | *0515 |
| | | | | | | | *0516 |
| | | | 12 | | | | *0517 |
| | | | | | | | *0113, 0815 |
| | | | | | | | *0605, 1221 |
| | | | | | | | *070401-070402, 0711, |
| | | | | | | | 0712, 080101-080102, |
| | | | | | | | 0803, 0806, 0808, 0814 |
| | | | | | | | *0741, 0802, 0805, 0807 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |

| | | | | | | | | |
|----------------------------------|------------|------------|------------|------------|------------|------------|------------|-----------|
| Length of spec. | 155 | 165 | 155 | 120 | 225 | 270 | 265 | 85 |
| PCR product | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| *0752 | | | | 4 | | | | |
| *0804, 0813 | 1 | | | | | | 7 | |
| *0809, 0811 | | | | | 5 | | 7 | |
| *0810 | | 2 | | | | | 7 | |
| *0812 | 1 | | | | | 6 | 7 | |
| HLA-Cw allele⁴ | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| A*2910 | | | | | | 6 | | |
| B*1533 | | | 3 | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |

¹The 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-Cw*05 subtyping. In addition, wells number 4 and 8 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

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| 285 | 95 | 285 | 95 | 120 | 240 | 195 | Length of spec. PCR product |
|-----|----|-----|----|-----|-----|-----|--------------------------------|
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |
| | | | | | | | *0752 |
| | | | 12 | | | | *0804, 0813 |
| | | | | | | | *0809, 0811 |
| | | | | | | | *0810 |
| | | | | | | | *0812 |
| | | | | | | | HLA-Cw allele ⁴ |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |
| | | | | | | | A*2910 |
| | 10 | | | | | | B*1533 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | Well No. |

²The nucleotide position, in the 2nd or 3rd exon or the 3rd intron, 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.

³The nucleotide position, in the 2nd, 3rd or 4th exon, 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.

⁴The HLA-Cw*0502 nucleotide sequence has been deleted as it is identical to Cw*0509.

| CELL LINE VALIDATION SHEET | | | | | Well | | | | | | | | | | | | | | | |
|-----------------------------|----------------|--|-------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|---|
| HLA-Cw*05 SSP subtyping kit | | | | | | | | | | | | | | | | | | | | |
| | | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | |
| | | | | Prod. No.: | 200732201 | 200732202 | 200732203 | 200845804 | 200732205 | 200732206 | 200732207 | 200845808 | 200732209 | 200732210 | 200732212 | 200732213 | 200732214 | 200732215 | 200732216 | |
| | IHWC cell line | | Cw* | | | | | | | | | | | | | | | | | |
| 1 | 9001 SA | | *0702 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 2 | 9280 LK707 | | *0701 | *1505 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 3 | 9011 E4181324 | | *1202 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 4 | 9275 GU373 | | *0304 | *0401 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 5 | 9009 KAS011 | | *0602 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 6 | 9353 SM | | *0304 | *0702 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 7 | 9020 QBL | | *0501 | | + | + | - | - | - | - | + | - | - | - | - | - | - | - | - | - |
| 8 | 9007 DEM | | *0602 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 9 | 9026 YAR | | *1203 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 10 | 9107 LKT3 | | *0102 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 11 | 9051 PITOUT | | *1601 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 12 | 9052 DBB | | *0602 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 13 | 9067 BTB | | *0102 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 14 | 9071 OLG A | | *0102 | *0304 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 15 | 9075 DKB | | *0304 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 16 | 9037 SWEIG007 | | *0202 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 17 | 9008 WILJON | | *1203 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 18 | 9257 32367 | | *0102 | *0705 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 19 | 9038 BM16 | | *0701 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 20 | 9059 SLE005 | | *0304 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 21 | 9064 AMALA | | *0303 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 22 | 9056 KOSE | | *1203 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 23 | 9124 IHL | | *0102 | *1502 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 24 | 9035 JBUSH | | *1203 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 25 | 9049 IBW9 | | *0802 | | + | - | - | - | - | + | - | - | - | - | - | - | - | - | - | - |
| 26 | 9285 WT49 | | *0701 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 27 | 9191 CH1007 | | *0704 | *1505 | - | - | - | - | - | + | - | - | - | - | - | - | - | - | - | - |
| 28 | 9320 BEL5GB | | *0501 | *1601 | + | + | - | - | - | + | - | - | - | - | - | - | - | - | - | - |
| 29 | 9050 MOU | | *1601 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 30 | 9021 RSH | | *1701 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 31 | 9019 DUCAF | | *0501 | | + | + | - | - | - | + | - | - | - | - | - | - | - | - | - | - |
| 32 | 9297 HAG | | *1701 | *1703 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 33 | 9098 MT14B | | *0304 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 34 | 9104 DHIF | | *1203 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 35 | 9302 SSTO | | *0501 | | + | + | - | - | - | + | - | - | - | - | - | - | - | - | - | - |
| 36 | 9024 KT17 | | *0303 | *0401 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 37 | 9065 HHKB | | *0702 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 38 | 9099 LZL | | *0303 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 39 | 9315 CML | | *0202 | *0701 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 40 | 9134 WHONP199 | | *0602 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 41 | 9055 H0301 | | *0802 | | + | - | - | - | - | + | - | - | - | - | - | - | - | - | - | - |
| 42 | 9066 TAB089 | | *0102 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 43 | 9076 T7526 | | *0102 | *0801 | - | - | - | - | - | + | - | - | - | - | - | - | - | - | - | - |
| 44 | 9057 TEM | | *1203 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 45 | 9239 SHJO | | *0602 | *1701 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 46 | 9013 SCHU | | *0702 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 47 | 9045 TUBO | | *0704 | *1502 | - | - | - | - | - | + | - | - | - | - | - | - | - | - | - | - |
| 48 | 9303 TER-ND | | *0401 | *1601 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-Cw*05 SSP

Product number: 101.613-12 – including *Taq* polymerase
Lot number: 54E
Expiry date: 2010-April-01
Number of tests: 12
Number of wells per test: 15

Well specifications:

| Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|
| 1 | 2007-322-01 | 9 | 2007-322-09 |
| 2 | 2007-322-02 | 10 | 2007-322-10 |
| 3 | 2007-322-03 | 12 | 2007-322-12 |
| 4 | 2008-458-04 | 13 | 2007-322-13 |
| 5 | 2007-322-05 | 14 | 2007-322-14 |
| 6 | 2007-322-06 | 15 | 2007-322-15 |
| 7 | 2007-322-07 | 16 | 2007-322-16 |
| 8 | 2008-458-08 | | |

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 3, 4, 5, 6, 8, 9, 10, 11, 13, 14 and 15 were available. The specificities of the primers in primer solutions 3, 5, 6, 10, 11 and 13 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 4 and 8 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 9, 14 and 15 it was only possible to test the 3'-primer, the 5'-primer was not possible to test.

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

Date of approval: 2009-May-25

Approved by:

Quality Control, Supervisor

Lot No.: **54E**

Lot-specific information

www.olerup.com

Declaration of Conformity

Product name: *Olerup* SSP® HLA-Cw*05
Product number: 101.613-12
Lot number: 54E

Intended use: HLA-Cw*05 high resolution 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 9001:2000 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
2009-May-25

Olle Olerup
Managing Director

Lot No.: **54E**

Lot-specific information

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