

Olerup SSP[®] HLA-Cw*04

| | |
|----------------------------------|--|
| Product number: | 101.612-12 – including <i>Taq</i> polymerase |
| Lot number: | 72F |
| Expiry date: | 2011-April-01 |
| Number of tests: | 12 |
| Number of wells per test: | 24 |
| 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. 72F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-Cw*04 LOT

The HLA-Cw*04 specificity and interpretation tables have been updated for the HLA-Cw alleles described since the previous *Olerup SSP*[®] HLA-Cw*04 lot was made (**Lot No. 56E**).

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

| Well | 5'-primer | 3'-primer | rationale |
|------|-----------|-----------------|--|
| 5 | Added | - | Increased yield of specific PCR product. |
| 8 | Added | - | Increased yield of specific PCR product. |
| 9 | Added | Added | Primer pair added for the Cw*0435 allele. |
| 12 | Moved | Moved, added | Primer pair moved to well 24, primer added for the Cw*0433 allele. |
| 16 | Added | - | Primer added for the Cw*0437 allele. |
| 17 | Added | - | Increased yield of specific PCR product. |
| 19 | Added | Added | Primer pair added for the Cw*0435 and Cw*0437 alleles. |
| 24 | Added | Added | Primer pair from well 12. |

PRODUCT DESCRIPTION

HLA-Cw*04 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-Cw*0401 to HLA-Cw*0437 alleles.

PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well PCR plate.

| | | | | | | | |
|----|----|----|----|----|----|----|----|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |

The 24 well cut PCR plate is marked with 'HLA-Cw*04' in silver/gray ink.

Well No. 1 is marked with the Lot No. '72F'.

The PCR plates are heat-sealed with a PCR-compatible foil.

Please note: When removing each 24 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*04 SSP subtypings will be influenced by other HLA-Cw alleles, as primer mixes 1, 4, 5, 7, 8, 11, 14 and 16 amplify non-HLA-Cw*04 alleles. In addition, the B*5802 allele will be amplified by primer mixes 5 and 8.

UNIQUELY IDENTIFIED ALLELES

All the HLA-C*04 alleles, i.e. **Cw*0401 to Cw*0437**, recognized by the HLA Nomenclature Committee in January 2009¹ will give rise to unique amplification patterns by the primers in the HLA-Cw*04 subtyping kit.

The HLA-Cw*04 subtyping kit cannot distinguish the Cw*04010101 to Cw*040106 alleles and the Cw*040401 and Cw*040402 alleles.

¹HLA-Cw alleles listed on the IMGT/HLA web page 2009-January-16, release 2.24.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 34 HLA-Cw*04 alleles give rise to 35 different amplification patterns that can be combined in 630 homozygous and heterozygous combinations. 412 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR product generated by primer mix 9, 10, 12, 14, 15 and 19 were not considered in these calculations.

+++++---+ ---+----- ----- 0403,0434 = 0406,0408
+++++---+ ---+----- ----- 0406,0429 = 0406,0433
+++++---+ ---+----- ----- 0403,0413 = 0406,0418
+++++---+ ---+----- ----- 0401,0406 = 0403,0404
+++++---+ ---+----- ----- 0403,0429 = 0403,0433

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| | | | |
|-----------|-----------|-----------|--|
| ++++----- | --+----- | ----- | 0403,0414 = 0403,0428 |
| +++-+---+ | --+----- | ----- | 0407,0434 = 0427,0434 = 0432,0434 |
| +++-+--- | --+----- | ----- | 0407,0413 = 0413,0427 = 0413,0432 |
| +++-+--- | --+----- | ----- | 0404,0407 = 0404,0427 = 0404,0432 |
| +++-+---+ | -+++----- | ----- | 0411,0434 = 0434,0436 |
| +++-+---+ | -+++----- | ----- | 0410,0434 = 0431,0434 |
| +++-+---+ | -+++----- | ----- | 0429,0434 = 0433,0434 |
| +++-+---+ | --+----- | ----- | 0408,0413 = 0416,0434 = 0418,0434 |
| +++-+---+ | --+----- | ----- | 0401,0434 = 0404,0408 = 0408,0434 |
| +++-+--- | -+++----- | ----- | 0411,0413 = 0413,0436 |
| +++-+--- | -+++----- | ----- | 0404,0411 = 0404,0436 |
| +++-+--- | -+++----- | ----- | 0410,0413 = 0413,0431 |
| +++-+--- | -+++----- | ----- | 0404,0410 = 0404,0431 |
| +++-+--- | --++----- | ----- | 0413,0429 = 0413,0433 |
| +++-+--- | --++----- | ----- | 0404,0429 = 0404,0433 |
| +++-+--- | --+----- | ----- | 0401,0413 = 0404,0416 = 0404,0418 = 0413,0416 = 0413,0418 |
| +++-----+ | --+----- | ----- | 0405,0407 = 0405,0427 = 0405,0432 |
| +++----- | -+++----- | ----- | 0405,0411 = 0405,0436 |
| +++----- | -+++----- | ----- | 0405,0410 = 0405,0431 |
| +++----- | -+++----- | ----- | 0405,0429 = 0405,0433 |
| +++----- | --+----- | ----- | 0405,0416 = 0405,0418 |
| +++----- | --+----- | ----- | 0405,0414 = 0405,0428 |
| +++----- | --+----- | ----- | 0401,0405 = 0405,0405 |
| +++-----+ | --+----- | ----- | 0407,0408 = 0408,0427 = 0408,0432 |
| +++----- | +--+----- | --+----- | 0407,0435 = 0427,0435 = 0432,0435 |
| +++----- | +--+----- | -----+ | 0407,0430 = 0427,0430 = 0430,0432 |
| +++----- | +--+----- | ----- | 0407,0409N = 0409N,0427 = 0409N,0432 |
| +++----- | -+++----- | ----- | 0407,0411 = 0407,0436 = 0411,0432 = 0427,0436 = 0432,0436 |
| +++----- | -+++----- | ----- | 0407,0410 = 0407,0431 = 0410,0427 = 0410,0432 = 0427,0431 = 0431,0432 |
| +++----- | --++----- | ----- | 0407,0429 = 0407,0433 = 0427,0429 = 0429,0432 = 0432,0433 |
| +++----- | --+----- | ----- | 0407,0412 = 0412,0427 = 0412,0432 |
| +++----- | --+----- | ----- | 0407,0418 = 0416,0432 = 0418,0427 = 0418,0432 |
| +++----- | --+----- | ----- | 0407,0414 = 0407,0428 = 0414,0427 = 0414,0432 = 0427,0428 = 0428,0432 |
| +++----- | --+----- | --+----- | 0407,0437 = 0427,0437 = 0432,0437 |
| +++----- | --+----- | ----- | 0407,041501 = 041501,0427 = 041501,0432 |
| +++----- | --+----- | +--+----- | 0407,0417 = 0417,0427 = 0417,0432 |
| +++----- | --+----- | +--+----- | 0407,0419 = 0419,0427 = 0419,0432 |
| +++----- | --+----- | --+----- | 0407,0420 = 0420,0427 = 0420,0432 |
| +++----- | --+----- | --+----- | 0407,041502 = 041502,0427 = 041502,0432 |
| +++----- | --+----- | -----+ | 0407,0423 = 0423,0427 = 0423,0432 |
| +++----- | --+----- | -----+ | 0407,0424 = 0424,0427 = 0424,0432 |
| +++----- | --+----- | -----+ | 0407,0425 = 0425,0427 = 0425,0432 |
| +++----- | --+----- | -----+ | 0407,0426 = 0426,0427 = 0426,0432 |
| +++----- | --+----- | ----- | 0401,0407 = 0401,0427 = 0401,0432 = 0407,0432 = 0427,0432 = 0432,0432 |

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| | | |
|---------------------|-------|-----------------------|
| +++-----+ -+++----- | ----- | 0408,0411 = 0408,0436 |
| +++-----+ -++----- | ----- | 0408,0410 = 0408,0431 |
| +++-----+ --++----- | ----- | 0408,0429 = 0408,0433 |
| +++-----+ --+---+- | ----- | 0408,0416 = 0408,0418 |
| +++-----+ --+---+- | ----- | 0408,0414 = 0408,0428 |
| +++-----+ --+----- | ----- | 0401,0408 = 0408,0408 |

0401 = 040101-040106

0404 = 040401-040402

SPECIFICITY TABLE

HLA-Cw*04 SSP subtyping

Specificities and sizes of the PCR products of the 24 primer mixes used for HLA-Cw*04 SSP subtyping

| Primer Mix | Size of spec. PCR product ¹ | Size of control band ² | Amplified HLA-Cw*04 alleles | Other amplified HLA Class I alleles ³ |
|----------------------|--|-----------------------------------|--|--|
| 1 | 250 bp | 800 bp | 04010101-040106, 0403, 0405, 0407-0412, 041501-0418, 0419 ^{weakly} , 0420, 0423-0433, 0435-0437 | 010201-0121, 020201-020203, 020205-020206, 0204-0215, 0217, 0219-0223, 050101-050104, 0503-0510, 0512-0516, 0518-0523, 06020101-06020102, 060203, 0603, 0605-0619, 0802, 0805, 0807, 0812, 0815, 0817-0819, 120201-1213, 1215-1217, 1221, 140201-1405, 1407N-1411, 1508, 160401, 1801-1803 |
| 2 | 220 bp | 1070 bp | 04010101-040106, 040401-0405, 0407-0409N, 0412 ^{weakly} , 0413-041502, 0417-0420, 0423-0435, 0437 | 0764 |
| 3⁴ | 145 bp | 1070 bp | 04010101-040106, 040401-0405, 0408-041502, 0417-0420, 0423-0426, 0428-0437 | |
| 4 | 210 bp | 1070 bp | 0403, 0406 | 0212 |
| 5⁵ | 250 bp | 1070 bp | 040401-040402, 0406, 0413, 0434 | 0122, 0203, 0216, 0218, 0511, 0517, 0604, 080101-080102, 0803, |

| | | | | |
|--------------------------|------------------|---------------|--|--|
| | | | | 0804, 0806, 0808-0811, 0813, 0814, 0816, 1214, 1218, 1220, 1406, 150201-1507, 1509-1513, 1515-1521, 1701-1705, B*5802 |
| 6⁴ | 95 bp | 1070 bp | 0405 | |
| 7⁴ | 145 bp | 1070 bp | 0407, 0427, 0432 | 0334, 0764, 1803 |
| 8⁵ | 270 bp | 1070 bp | 0408, 0434 | 1515, B*5802 |
| 9^{4,5,6} | 110, 180, 220 bp | 1070 bp | 0409N, 0430, 0435 | |
| 10⁷ | 195, 220 bp | 1070 bp | 0410, 0411, 0431, 0436 | |
| 11 | 180 bp | 1070 bp | 04010101-040106, 0403-0410, 0412-0420, 0423-0426, 0428-0432, 0434-0437 | 0605 |
| 12^{4,8} | 125, 180 bp | 1070 bp | 0411, 0429, 0433, 0436 | |
| 13 | 225 bp | 1070 bp | 0412 | |
| 14⁹ | 155, 190 bp | 1070 bp | 0413, 0416, 0418 | 0708 |
| 15^{6,10} | 170, 190 bp | 1070 bp | 0414, 0428 | |
| 16⁴ | 130 bp | 1070 bp | 041501, 0437 | 0305, 0325, 0327, 1409 |
| 17^{4,6} | 90 bp | 800 bp | 0417 | |
| 18 | 225 bp | 1070 bp | 0419 | |
| 19^{4,11} | 120, 155 bp | 1070 bp | 0420, 0435, 0437 | |
| 20 | 540 bp | 1070 bp | 041502, 0417 | |
| 21⁴ | 85 bp | 1070 bp | 0423 | |
| 22⁴ | 130 bp | 1070 bp | 0424 | |
| 23⁴ | 85 bp | 1070 bp | 0425 | |
| 24 | 180 bp | 1070 bp | 0426, 0430 | |

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*04 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 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.

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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 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*04 subtyping.

In addition, well number 17 contains 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 some non-HLA-Cw*04 alleles will be amplified by primer mixes 1, 2, 4, 5, 7, 8, 11, 14 and 16. In addition, HLA-B*5802 will be amplified by primer mixes 5 and 8.

⁴Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁵The primers in primer mix 5, 8 and 9 may have a tendency of giving rise to nonspecific amplifications. The specific PCR product in primer mix 9 may also be less intense than the other Cw*04 specific PCR products.

⁶Primer mix 9: Specific PCR fragment of 110 bp in the Cw*0435 allele. Specific PCR fragment of 180 bp in the Cw*0430 allele. Specific PCR fragment of 220 bp in the Cw*0409N allele.

⁷Primer mix 10: Specific PCR fragment of 195 bp in the Cw*0431 allele. Specific PCR fragment of 220 bp in the Cw*0410, Cw*0411 and Cw*0436 alleles.

⁸Primer mix 12: Specific PCR fragment of 125 bp in the Cw*0429 and Cw*0436 alleles. Specific PCR fragment of 180 bp in the Cw*0433 allele. Specific PCR fragment of 125 and 180 bp in the Cw*0411 allele.

⁹Primer mix 14: Specific PCR fragment of 155 bp in the Cw*0416 allele. Specific PCR fragment of 190 bp in the Cw*0413, Cw*0418 and Cw*0708 alleles.

¹⁰Primer mix 15: Specific PCR fragment of 170 bp in the Cw*0414 allele. Specific PCR fragment of 190 bp in the Cw*0428 allele.

¹¹Primer mix 19: Specific PCR fragment of 120 bp in the Cw*0435 and Cw*0437 alleles. Specific PCR fragment of 155 bp in the Cw*0420 allele.

INTERPRETATION TABLE

HLA-Cw*04 SSP subtyping

Amplification patterns of the Cw*0401 to Cw*0437 alleles

| | Well ⁵ | | | | | | | | | | | |
|----------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| Length of spec. | 250 | 220 | 145 | 210 | 250 | 95 | 145 | 270 | 110 | 195 | 180 | 125 |
| PCR product | | | | | | | | | 180 | 220 | | 180 |
| | | | | | | | | | 220 | | | |
| Length of int. | 800 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 |
| pos. control ¹ | | | | | | | | | | | | |
| 5'-primer(s) ² | 2 nd | 112 | 112 | 118 | 2 nd | 98 | 112 | 2 nd | 391 | 112 | 201 | 218 |
| | 5'-CCA ^{3'} | 5'-CCT ^{3'} | 5'-CCT ^{3'} | 5'-CCA ^{3'} | 5'-CCA ^{3'} | 5'-CTC ^{3'} | 5'-CCT ^{3'} | 5'-CCA ^{3'} | 5'-ACC ^{3'} | 5'-CCT ^{3'} | 5'-CCA ^{3'} | 5'-ggA ^{3'} |
| | | | | | | | 459 | | 1018 | 368 | | |
| | | | | | | | 5'-gAT ^{3'} | | 5'-gTg ^{3'} | 5'-gTT ^{3'} | | |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | |
| 3'-primer(s) ³ | 539 | 289 | 218 | 289 | 539 | 154 | 218 | 559 | 459 | 289 | 341 | 302 |
| | 5'-TCC ^{3'} | 5'-AgC ^{3'} | 5'-gCT ^{3'} | 5'-AgC ^{3'} | 5'-TCA ^{3'} | 5'-CAg ^{3'} | 5'-gCg ^{3'} | 5'-CAg ^{3'} | 5'-AgA ^{3'} | 5'-AgT ^{3'} | 5'-CgT ^{3'} | 5'-ggC ^{3'} |
| | | | | | | | 559 | | 1052 | 521 | | 341 |
| | | | | | | | 5'-CTC ^{3'} | | 5'-Tgg ^{3'} | 5'-ggA ^{3'} | | 5'-Cgg ^{3'} |
| | | | | | | | | | 1092 | | | |
| | | | | | | | | | 5'-TTA ^{3'} | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| HLA-Cw allele ⁴ | | | | | | | | | | | | |
| *04010101-040106 | 1 | 2 | 3 | | | | | | | | 11 | |
| *0403 | 1 | | | 4 | | | | | | | 11 | |
| *040401-040402 | | 2 | 3 | | 5 | | | | | | 11 | |
| *0405 | 1 | 2 | 3 | | | 6 | | | | | 11 | |
| *0406 | | | | 4 | 5 | | | | | | 11 | |
| *0407 | 1 | 2 | | | | | 7 | | | | 11 | |
| *0408 | 1 | 2 | 3 | | | | | 8 | | | 11 | |
| *0409N | 1 | 2 | 3 | | | | | | 9 | | 11 | |
| *0410 | 1 | | 3 | | | | | | | 10 | 11 | |
| *0411 | 1 | | 3 | | | | | | | 10 | | 12 |
| *0412 | 1 | w | 3 | | | | | | | | 11 | |
| *0413 | | 2 | 3 | | 5 | | | | | | 11 | |
| *0414 | | 2 | 3 | | | | | | | | 11 | |
| *041501 | 1 | 2 | 3 | | | | | | | | 11 | |
| *041502 | 1 | 2 | 3 | | | | | | | | 11 | |
| *0416 | 1 | | | | | | | | | | 11 | |
| *0417 | 1 | 2 | 3 | | | | | | | | 11 | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

| INTERPRETATION TABLE | | | | | | | | | | | | |
|--|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|---|
| HLA-Cw*04 SSP subtyping | | | | | | | | | | | | |
| Amplification patterns of the Cw*0401 to Cw*0437 alleles | | | | | | | | | | | | |
| Well ⁵ | | | | | | | | | | | | |
| 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | |
| 225 | 155 | 170 | 130 | 90 | 225 | 120 | 540 | 85 | 130 | 85 | 170 | Length of spec. PCR product |
| | 190 | 190 | | | | 155 | | | | | | |
| 1070 | 1070 | 1070 | 1070 | 800 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | Length of int. pos. control ¹ |
| 112 | 105 | 412 | 368 | 2 nd I | 368 | 347 | 112 | 368 | 127 | 172 | 89 | |
| 5'-CCT ^{3'} | 5'-gCT ^{3'} | 5'-ATA ^{3'} | 5'-gTg ^{3'} | 5'-CCA ^{3'} | 5'-gTT ^{3'} | 5'-gTA ^{3'} | 5'-CCT ^{3'} | 5'-gTT ^{3'} | 5'-ggA ^{3'} | 5'-TCC ^{3'} | 5'-gAT ^{3'} | |
| | 368 | 697 | 369 | | | 368 | | | | | 1018 | |
| | 5'-gTT ^{3'} | 5'-TCC ^{3'} | 5'-TAC ^{3'} | | | 5'-gTg ^{3'} | | | | | 5'-gTg ^{3'} | |
| | | | | | | 391 | | | | | | |
| | | | | | | 5'-ACC ^{3'} | | | | | | |
| 295 | 218 | 539 | 459 | 379 | 550 | 459 | 368 | 412 | 218 | 218 | 218 | 3'-primer(s) ³ |
| 5'-TCC ^{3'} | 5'-gCT ^{3'} | 5'-TCT ^{3'} | 5'-AgA ^{3'} | 5'-CAC ^{3'} | 5'-CAT ^{3'} | 5'-AgA ^{3'} | 5'-CAT ^{3'} | 5'-gTC ^{3'} | 5'-gCT ^{3'} | 5'-gCT ^{3'} | 5'-gCT ^{3'} | |
| | 514 | 846 | | | | | | | | | 1052 | |
| | 5'-CTT ^{3'} | 5'-CAC ^{3'} | | | | | | | | | 5'-Tgg ^{3'} | |
| | 527 | | | | | | | | | | | |
| | 5'-CCg ^{3'} | | | | | | | | | | | |
| 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | Well No. HLA-Cw allele ⁴ |
| | | | | | | | | | | | | |
| | | | | | | | | | | | | *04010101-040106 |
| | | | | | | | | | | | | *0403 |
| | | | | | | | | | | | | *040401-040402 |
| | | | | | | | | | | | | *0405 |
| | | | | | | | | | | | | *0406 |
| | | | | | | | | | | | | *0407 |
| | | | | | | | | | | | | *0408 |
| | | | | | | | | | | | | *0409N |
| | | | | | | | | | | | | *0410 |
| | | | | | | | | | | | | *0411 |
| 13 | | | | | | | | | | | | *0412 |
| | 14 | | | | | | | | | | | *0413 |
| | | 15 | | | | | | | | | | *0414 |
| | | | 16 | | | | | | | | | *041501 |
| | | | | | | | 20 | | | | | *041502 |
| | 14 | | | | | | | | | | | *0416 |
| | | | | 17 | | | 20 | | | | | *0417 |
| 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | Well No. |

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| Length of spec. | 250 | 220 | 145 | 210 | 250 | 95 | 145 | 270 | 110 | 195 | 180 | 125 |
|--|-----|-----|-----|-----|-----|----|-----|-----|-----|-----|-----|-----|
| PCR product | | | | | | | | | 180 | 220 | | 180 |
| | | | | | | | | | 220 | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| *0418 | 1 | 2 | 3 | | | | | | | | 11 | |
| *0419 | w | 2 | 3 | | | | | | | | 11 | |
| *0420 | 1 | 2 | 3 | | | | | | | | 11 | |
| *0423 | 1 | 2 | 3 | | | | | | | | 11 | |
| *0424 | 1 | 2 | 3 | | | | | | | | 11 | |
| *0425 | 1 | 2 | 3 | | | | | | | | 11 | |
| *0426 | 1 | 2 | 3 | | | | | | | | 11 | |
| *0427 | 1 | 2 | | | | | 7 | | | | | |
| *0428 | 1 | 2 | 3 | | | | | | | | 11 | |
| *0429 | 1 | 2 | 3 | | | | | | | | 11 | 12 |
| *0430 | 1 | 2 | 3 | | | | | | 9 | | 11 | |
| *0431 | 1 | 2 | 3 | | | | | | | 10 | 11 | |
| *0432 | 1 | 2 | 3 | | | | 7 | | | | 11 | |
| *0433 | 1 | 2 | 3 | | | | | | | | | 12 |
| *0434 | | 2 | 3 | | 5 | | | 8 | | | 11 | |
| *0435 | 1 | 2 | 3 | | | | | | 9 | | 11 | |
| *0436 | 1 | | 3 | | | | | | | 10 | 11 | 12 |
| *0437 | 1 | 2 | 3 | | | | | | | | 11 | |
| *010201-0121, 020201-020203, 020205-020206, 0204-0211, 0213-0215, 0217, 0219-0223, 05010101-050104, 0503-0510, 0512-0516, 0518-0523, 06020101-06020102, 060203, 0603, 0606-0619, 0802, 0805, 0807, 0812, 0815, 0817-0819, 120201-1213, 1215-1217, 1221, 140201-1405, 1407N, 1408, 1410, 1411, 1508, 160401, 1801, 1802 | 1 | | | | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

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| 225 | 155 | 170 | 130 | 90 | 225 | 120 | 540 | 85 | 130 | 85 | 170 | Length of spec. PCR product |
|---|-----|-----|-----|----|-----|-----|-----|----|-----|----|-----|--------------------------------|
| | 190 | 190 | | | | 155 | | | | | | |
| 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | Well No. |
| | 14 | | | | | | | | | | | *0418 |
| | | | | | 18 | | | | | | | *0419 |
| | | | | | | 19 | | | | | | *0420 |
| | | | | | | | | 21 | | | | *0423 |
| | | | | | | | | | 22 | | | *0424 |
| | | | | | | | | | | 23 | | *0425 |
| | | | | | | | | | | | 24 | *0426 |
| | | | | | | | | | | | | *0427 |
| | 15 | | | | | | | | | | | *0428 |
| | | | | | | | | | | | | *0429 |
| | | | | | | | | | | | 24 | *0430 |
| | | | | | | | | | | | | *0431 |
| | | | | | | | | | | | | *0432 |
| | | | | | | | | | | | | *0433 |
| | | | | | | | | | | | | *0434 |
| | | | | | | 19 | | | | | | *0435 |
| | | | | | | | | | | | | *0436 |
| | | | 16 | | | 19 | | | | | | *0437 |
| <p>*010201-0121, 020201-020203, 020205-020206, 0204-0211, 0213-0215, 0217, 0219-0223, 05010101-050104, 0503-0510, 0512-0516, 0518-0523, 06020101-06020102, 060203, 0603, 0606-0619, 0802, 0805, 0807, 0812, 0815, 0817-0819, 120201-1213, 1215-1217, 1221, 140201-1405, 1407N, 1408, 1410, 1411, 1508, 160401, 1801, 1802</p> | | | | | | | | | | | | |
| 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | Well No. |

| Length of spec. | 250 | 220 | 145 | 210 | 250 | 95 | 145 | 270 | 110 | 195 | 180 | 125 |
|---|-----|-----|-----|-----|-----|----|-----|-----|-----|-----|-----|-----|
| PCR product | | | | | | | | | 180 | 220 | | 180 |
| | | | | | | | | | 220 | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| *0122, 0203, 0216, 0218, 0511, 0517, 0604, 080101-080102, 0803, 0804, 0806, 0808-0811, 0813, 0814, 0816, 1214, 1218, 1220, 1406, 150201-1507, 1509- 1513, 1516-1521, 1701- 1705 | | | | | 5 | | | | | | | |
| *0212 | 1 | | | 4 | | | | | | | | |
| *0305, 0325, 0327 | | | | | | | | | | | | |
| *0334 | | | | | | | 7 | | | | | |
| *0605 | 1 | | | | | | | | | | 11 | |
| *0708 | | | | | | | | | | | | |
| *0764 | | 2 | | | | | 7 | | | | | |
| *1409 | 1 | | | | | | | | | | | |
| *1515 | | | | | 5 | | | 8 | | | | |
| *1803 | 1 | | | | | | 7 | | | | | |
| HLA-Cw allele ⁴ | | | | | | | | | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |
| B*5802 | | | | | 5 | | | 8 | | | | |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 |

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*04 subtyping. .

In addition, well number 17 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

²The nucleotide position, in the 2nd, 3rd or 6th, exon or in the 2nd 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 7th 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.

Lot No.: **72F**

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| 225 | 155 | 170 | 130 | 90 | 225 | 120 | 540 | 85 | 130 | 85 | 170 | Length of spec. PCR product |
|-----|-----|-----|-----|----|-----|-----|-----|----|-----|----|-----|---|
| | 190 | 190 | | | | 155 | | | | | | |
| 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | Well No. |
| | | | | | | | | | | | | *0122, 0203, 0216, 0218, 0511, 0517, 0604, 080101-080102, 0803, 0804, 0806, 0808-0811, 0813, 0814, 0816, 1214, 1218, 1220, 1406, 150201-1507, 1509- 1513, 1516-1521, 1701- 1705 |
| | | | | | | | | | | | | *0212 |
| | | | 16 | | | | | | | | | *0305, 0325, 0327 |
| | | | | | | | | | | | | *0334 |
| | | | | | | | | | | | | *0605 |
| | 14 | | | | | | | | | | | *0708 |
| | | | 16 | | | | | | | | | *0764 |
| | | | | | | | | | | | | *1409 |
| | | | | | | | | | | | | *1515 |
| | | | | | | | | | | | | *1803 |
| | | | | | | | | | | | | HLA-Cw allele ⁴ |
| 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | Well No. |
| | | | | | | | | | | | | B*5802 |
| 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | Well No. |

⁴The nucleotide sequence of the Cw*0402 allele has been shown to be identical to Cw*04010101. The nucleotide sequence of the Cw*0421 allele has been renamed to Cw*041502.

The nucleotide sequence of the Cw*0422 allele has been shown to be identical to Cw*0421.

⁵Primer mix 9: Specific PCR fragment of 110 bp in the Cw*0435 allele. Specific PCR fragment of 180 bp in the Cw*0430 allele. Specific PCR fragment of 220 bp in the Cw*0409N allele.

Primer mix 10: Specific PCR fragment of 195 bp in the Cw*0431 allele. Specific PCR fragment of 220 bp in the Cw*0410, Cw*0411 and Cw*0436 alleles.

Primer mix 12: Specific PCR fragment of 125 bp in the Cw*0429 and Cw*0436 alleles. Specific PCR fragment of 180 bp in the Cw*0433 allele. Specific PCR fragment of 125 and 180 bp in the Cw*0411 allele.

Primer mix 14: Specific PCR fragment of 155 bp in the Cw*0416 allele. Specific PCR fragment of 190 bp in the Cw*0413, Cw*0418 and Cw*0708 alleles.

Primer mix 15: Specific PCR fragment of 170 bp in the Cw*0414 allele. Specific PCR fragment of 190 bp in the Cw*0428 allele.

Primer mix 19: Specific PCR fragment of 120 bp in the Cw*0435 and Cw*0437 alleles. Specific PCR fragment of 155 bp in the Cw*0420 allele.

'w', may be weakly amplified.

| CELL LINE VALIDATION SHEET | | | | | HLA-Cw*04 SSP subtyping kit | | | | | | | | | | | | | | | | |
|----------------------------|------|------------|-------|-------|-----------------------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| | | | | | Well | | | | | | | | | | | | | | | | |
| | | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | |
| | | | | | Prod. No.: | 200618401 | 200957902 | 200618403 | 200846004 | 200957905 | 200618406 | 200846007 | 200957908 | 200957909 | 200846010 | 200618411 | 200957912 | 200733713 | 200733714 | 200846015 | 200957916 |
| IHCW 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 | 9004 | JESTHOM | *0102 | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 14 | 9071 | OLGA | *0102 | *0304 | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 15 | 9075 | DKB | *0304 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 16 | 9037 | SWEIG007 | *0202 | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 17 | 9282 | CTM3953540 | *0303 | *0701 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 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 | + | + | + | - | - | - | - | - | - | - | + | - | - | - | - | - | - |



Lot No.: 72F

Lot-specific information

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| CELL LINE VALIDATION SHEET | | | | | Well | | | | | | | |
|-----------------------------|-----------------|--|-------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| HLA-Cw*04 SSP subtyping kit | | | | | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| | | | | Prod. No.: | 200957917 | 200733718 | 200957919 | 200846020 | 200733721 | 200957922 | 200733723 | 200957924 |
| | 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 | 9004 JESTHOM | | *0102 | | - | - | - | - | - | - | - | - |
| 14 | 9071 OLGA | | *0102 | *0304 | - | - | - | - | - | - | - | - |
| 15 | 9075 DKB | | *0304 | | - | - | - | - | - | - | - | - |
| 16 | 9037 SWEIG007 | | *0202 | | - | - | - | - | - | - | - | - |
| 17 | 9282 CTM3953540 | | *0303 | *0701 | - | - | - | - | - | - | - | - |
| 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*04 SSP

Product number: 101.612-12 – including *Taq* polymerase
Lot number: 72F
Expiry date: 2011-April-01
Number of tests: 12
Number of wells per test: 24

Well specifications:

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|----------|----------------|----------|----------------|----------|----------------|
| 1 | 2006-184-01 | 9 | 2009-539-09 | 17 | 2009-539-17 |
| 2 | 2009-539-02 | 10 | 2008-460-10 | 18 | 2007-337-18 |
| 3 | 2006-184-03 | 11 | 2006-184-11 | 19 | 2009-539-19 |
| 4 | 2008-460-04 | 12 | 2009-539-12 | 20 | 2008-460-20 |
| 5 | 2009-539-05 | 13 | 2007-337-13 | 21 | 2007-337-21 |
| 6 | 2006-184-06 | 14 | 2007-337-14 | 22 | 2009-539-22 |
| 7 | 2008-460-07 | 15 | 2008-460-15 | 23 | 2007-337-23 |
| 8 | 2009-539-08 | 16 | 2009-539-16 | 24 | 2009-539-24 |

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 6, 8, 10, 12, 13, 15 and 17 to 24 were available. The specificity of the primers in primer solutions 8, 10, 12, 15, 17, 20, 21 and 24 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 6, 13 and 18 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 22 and 24 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 15 and 19 one of the 5'-primers was not possible to test, and in primer solutions 10 and 14 one of the 3'-primers was not possible to test. In primer solutions 9 and 24 one 5'-primer and one 3'-primer was not possible to test. Additional primers in primer solutions 7, 9, 14 and 16 were tested by separately adding one 5'-primer and/or one 3'-primer.

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

Date of approval: 2009-May-25

Approved by:

Quality Control, Supervisor

Lot No.: **72F**

Lot-specific information

www.olerup.com

Declaration of Conformity

Product name: *Olerup* SSP[®] HLA-Cw*04
Product number: 101.612-12
Lot number: 72F

Intended use: HLA-Cw*04 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 9001:2003, ISO 17025:1999 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III.

The Technical Construction 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-April-25

Olle Olerup
Managing Director

Lot No.: **72F**

Lot-specific information

www.olerup.com

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Fax: 610-344-7989

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Web page: <http://www.olerup.com>

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