Olerup SSP™ HLA-C low resolution

Product number:	**101.601-24/12 – licensed for PCR** **101.601-24u/12u – not licensed for PCR**
Lot number:	**Y22**
Expiry date:	**2009-August-01**
Number of tests:	**24 tests – Product No. 101.601-24** **12 tests – Product No. 101.601-12**
Number of tubes per test:	**23 + 1**
Storage - pre-aliquoted primers:	**dark at -20°C**
- PCR Master Mix:	**-20°C**

This Product Description is only valid for Lot No. Y22.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP™ HLA-C LOW RESOLUTION LOT

The HLA-C low resolution specificity and interpretation tables have been updated for the HLA-Cw alleles described since the previous *Olerup* SSP™ HLA-C low resolution lot was made **(Lot No. V97)**.

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

Tube	5'-primer	3'-primer	rationale
3	-	-	Changed to the 800 bp internal positive control primer pair to decrease primer dimer formation tendency.
5	Added	Added	Primer added for the Cw*1214 allele.
8	-	Added	Primer added for the Cw*0603 allele.
11	Modified	-	Increased yield of specific PCR product.
16	Added	Added	Primer added for the Cw*0511 allele.
17	Added	-	Primer added for the Cw*1520 allele.
18	-	Added	Primer added for the Cw*0427 allele.
22	Added	Added	Primer added for the Cw*0511 allele.
23	Added	-	Primer added for the Cw*1610 allele.

Change in revision R01 compared to R00:

- Footnote that primer mix 22 may give rise to primer dimer formation added to the Specificity Table.

Change in revision R02 compared to R01:

- The Cw*0212. 0403 and 0406 alleles are amplified by primer mix 23. Information corrected in the Specificity and Interpretation Tables.

Well **24** 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*	**+**	**+**	**+**			
Cw*	**+**	**+**	**+**			
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 or the 2nd intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as in *Tissue Antigens* 1998, 51:II, 417-466. 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, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as in *Tissue Antigens* 1998, 51:II, 417-466. The sequence of the 3 terminal nucleotides of the primer is given.

PRODUCT DESCRIPTION

HLA-C low resolution SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for grouping the HLA-Cw*0102 to Cw*1802 alleles into the groups Cw*01xx to Cw*18xx.
The primer solutions are pre-aliquoted into 0.2 ml PCR tubes. Each tube in the set contains a dried primer solution consisting of a specific primer mix, i.e. allele- and group-specific primers as well as a ***control primer pair*** matching non-allelic sequences.
PCR Master Mix complete with Taq, *Taq* polymerase, nucleotides, buffer, glycerol and cresol red, as well as PCR lids are included in the licensed kit.
PCR Master Mix without Taq, nucleotides, buffer, glycerol and cresol red, as well as PCR lids are included in the unlicensed kit.
23 + 1 PCR reactions with a reaction volume of 10 µl are performed per sample.
Note: The pellets in the tubes may vary in form and colour. This does not affect the performance of the product.

STRIP LAYOUT

Each test consists of 24 PCR reactions in a 24 well cut 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**

Wells 1 to 23 – HLA-Cw low resolution primers.
Well 24 – Negative Control.
The 24 well cut PCR plate is marked with 'C low Y22'.
Well No. 1 is marked with '1'.
The PCR plates are covered with a PCR-compatible foil.
Please note: When removing each 24 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Only HLA-Cw alleles will be amplified by the HLA-C low resolution typing kit, except that primer mix 13 will amplify the B*6702 allele and primer mix 20 will amplify the B*1403 allele. Thus, the interpretation of HLA-C low resolution typings is only influenced by these HLA-B alleles and not by other HLA class I genes.

UNIQUELY IDENTIFIED ALLELES

All the HLA-Cw alleles, i.e. **Cw*0102 to Cw*1802**, recognized by the HLA Nomenclature Committee in October 2007[1] will be amplified by the primers in the HLA-C low resolution SSP kit. The HLA-Cw alleles will be grouped into the Cw*01xx to Cw*18xx groups.

[1]***Nomenclature for factors of the HLA system, 1998***. *Tissue Antigens* 1999: **53**: 407-446.
HLA-Cw alleles listed on the IMGT/HLA web page 2007-October-05, release 2.19.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The ambiguous HLA-Cw homo- and heterozygous combinations of allele groups based on the two first digits of the allele designation are available in the ScoreTM interpretation software. (In most cases these ambiguities can be resolved by the Olerup SSP™ HLA-Cw high resolution SSP sets.)

LICENSES

101.601-24/12 – licensed for PCR.
Notice to purchaser: Limited License.

The purchase price of this product includes limited, non-transferable rights under U.S. Patents 4,683,202, 4,683,195 and 4,965,188 and their foreign counterparts, owned by Roche Molecular Systems, Inc. and F. Hoffman-La Roche Ltd ("Roche"), to use only this amount of the product to practice the Polymerase Chain Reaction ("PCR") Process described in said patents solely for the HLA Typing applications of the purchaser solely for organ or tissue or bone marrow transplantation, and explicitly excludes analysis of forensic evidence or parentage determination. The rights to use this product to perform and to offer commercial service for HLA Typing for organ or tissue transplantation using PCR, including reporting the results of the purchaser's activities for a fee or other commercial consideration, is also hereby granted. Further information on purchasing licenses to practice PCR may be obtained by contacting in the United States, the Director of Licensing at Roche Molecular Systems, inc., 1145 Atlantic Avenue, Alameda, California 94501, and outside the United States, the PCR Licensing Manager, F. Hoffmann-La Roche Ltd, Grenzacherstr. 124, CH-4070 Basel, Switzerland.

101.601-24u/12u – not licensed for PCR.
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101.601-24/12 and 101.601-24u/12u

These products use ARMS™ technology and is sold under license from Zeneca Limited. ARMS is the subject of European Patent No. 0332435, US Patent No. 5595890 and corresponding world-wide patents. ARMS is a trademark of Zeneca Limited.

GUARANTEE

Olerup SSP AB guarantees that the primers in the HLA-C low resolution bulk typing kit have the specificities given in the Specificity and Interpretation Tables of the product insert and in the GenoVision version of the HELMBERG-SCORE™ software.

When stored at –20°C, the dried primers are stable for 22 months from the date of manufacture.

When stored at –20°C, the PCR Master Mix complete with *Taq* and the PCR Master Mix without *Taq* are stable for 24 months from the date of manufacture.

The kit is shipped at ambient temperature.

PROTOCOL

DNA EXTRACTION

Extracted, highly pure DNA is needed for SSP typings. We recommend isolation of DNA using GenoPrep B200 or GenoPrep B350 cartridges on the GenoM™-6 robotic workstation (GenoVision Europe *Tel:* +43 1 710 15 00 or GenoVision Inc. USA *Tel:* +1 610 430 88 41; http://www.genovision.com). Using GenoM™-6-extracted DNA ACD, EDTA and heparinised blood can be used as starting material. Because of its high purity, GenoM™-6-extracted DNA can be diluted when used in combination with *Olerup* SSP™ products. The recommended DNA concentration is 15 ng/ul.
Alternatively – BUT DO NOT USE HEPARINISED BLOOD WITH THESE METHODS - the DNA can be extracted using trimethylammoniumbromide salts (DTAB/CTAB) or by salting out. Dissolve the extracted DNA in dH_2O.

IMPORTANT:
Optimal DNA concentration using: GenoM™-6-extracted DNA, 15 ng/µl.
DNA extracted by other methods, 30 ng/µl.

Concentration exceeding 50 ng/µl will increase the risk for nonspecific amplifications and weak extra bands, especially for HLA Class I high resolution SSP typings.

PCR AMPLIFICATION

101.601-24/12 – licensed for PCR

For one HLA-Cw low resolution typing, begin by adding to well No. 24, i.e. the well with the negative control primer pairs:

7 µl dH_2O
3 µl PCR Master Mix complete with *Taq*,

then add at room temperature in a 0.5 ml tube:

27 x 2 µl = 54 µl DNA (30 ng/µl)
27 x 3 µl = 81 µl PCR Master Mix complete with *Taq* – mix well before taking your aliquot
27 x 5 µl = 135 µl dH_2O

Mix well, dispense 10 µl of the DNA-PCR Master Mix-H_2O mixture into each of the 23 wells of an HLA-Cw low resolution typing, i.e. wells 1 to 23. ***Well No. 1 of the 24 well PCR plate is marked with '1'.*** Close the 24 well PCR plate with the provided lids.

101.601-24u/12u – not licensed for PCR

For one HLA-Cw low resolution typing, begin by adding at room temperature in a 0.5 ml tube:

28 x 3 µl = 84 µl PCR Master Mix without *Taq* – mix well before taking your aliquot
2.2 µl *Taq* polymerase (5 units/µl)

Mix well, dispense 3 µl of the PCR Master Mix-*Taq* mixture from the 0.5 ml tube into well No. 24, i.e. the well with the negative control primer pairs. Then add 7 µl dH_2O to well 24.

Then add at room temperature to the 0.5 ml tube containing 84 + 2.2 - 3 = 83,2 µl PCR Master Mix-*Taq* mixture:

27 x 2 µl = 54 µl DNA (30 ng/µl)
27 x 5 µl – 2,2 µl = 132.8 µl dH_2O

Mix well, dispense 10 µl of the DNA-PCR Master Mix-*Taq*-H_2O mixture into each of the 23 wells of an HLA-Cw low resolution typing, i.e. wells 1 to 23. ***Well No. 1 of the 24 well PCR plate is marked with '1'.*** Close the 24 well PCR plate with the provided lids.

Use a 96 well thermal cycler with a heated lid. The temperature gradient across the heating block should be < 1°C.

PCR cycling parameters:

1. 1 cycle	94°C	2 min	denaturation
2. 10 cycles	94°C	10 sec.	denaturation
	65°C	60 sec.	annealing and extension
3. 20 cycles	94°C	10 sec.	denaturation
	61°C	50 sec.	annealing
	72°C	30 sec.	extension

The same PCR cycling parameters are used for all the *Olerup* SSP kits.

AGAROSE GEL ELECTROPHORESIS

Prepare a 2% (w/v) agarose gel in 0.5 x TBE buffer. Dissolve the agarose by boiling in a microwave oven. Let the gel solution cool to 60°C. Stain the gel prior to casting with ethidium bromide (10 mg/ml), 5 µl per 100 ml gel solution. For maximal ease of handling use our ethidium bromide dropper bottles (Product No. 103.301-10), 1 drop of ethidium bromide solution per 50-75 ml of gel. **Note: Ethidium bromide is a powerful carcinogen.**
Load the PCR products, preferably using an 8-channel pipette. Load a DNA size marker (100 base pair ladder, Product No. 103.201-100) in one well per row.
Run the gel in 0.5 x TBE buffer, without re-circulation of the buffer, for 15-20 minutes at 8-10 V/cm.

DOCUMENTATION AND INTERPRETATION

Put the gel on a UV transilluminator and document by photography.
Record the presence and absence of specific PCR products. The relative lengths of the specific PCR products are helpful in the interpretation of the results.
Record the presence and relative lengths of the internal positive control bands. The differently sized control bands will help in the correct orientation of the typing as well as in kit identification.
Lanes without either control band or specific PCR products should be repeated.

Interpret the typings with the ***lot-specific Interpretation and Specificity Tables***.

INTERPRETATION SOFTWARE

The interpretation software (Product No. 110.101) can be helpful in the interpretation of the typings.

PCR MASTER MIXES

The PCR Master Mix complete with *Taq* contains:

Taq polymerase	0.4 unit per 10 µl SSP reaction
nucleotides	final concentration of each dNTP is 200 µM
PCR buffer	final concentrations: 50 mM KCl, 1.5 mM $MgCl_2$, 10 mM Tris-HCl pH 8.3, 0.001% w/v gelatin
glycerol	final concentration of glycerol is 5%
cresol red	final concentration of cresol red is 100 µg/ml

The same PCR Master Mix complete with *Taq* is used for all the licensed *Olerup* SSP kits.

The PCR Master Mix without *Taq* contains:

nucleotides	final concentration of each dNTP is 200 µM
PCR buffer	final concentrations: 50 mM KCl, 1.5 mM $MgCl_2$, 10 mM Tris-HCl pH 8.3, 0.001% w/v gelatin
glycerol	final concentration of glycerol is 5%
cresol red	final concentration of cresol red is 100 µg/ml

The same PCR Master Mix without *Taq* is used for all the unlicensed *Olerup* SSP kits.

The PCR Master Mix complete with *Taq* and the PCR Master Mix without *Taq* can be shipped at ambient temperature.
When stored at –20°C, the PCR Master Mix complete with *Taq* and the PCR Master Mix without *Taq* are stable for 24 months from the date of manufacture.
Vials with the PCR Master Mixes can be kept at +4°C for 4 weeks, but the PCR Master Mixes are then no longer stable for 24 months.

SPECIFICITY TABLE

HLA-C low resolution SSP typing

Specificities and sizes of the PCR products of the 23 primer mixes used for HLA-C low resolution SSP typing

Primer Mix	Approx. size of spec. PCR product[1]	Size of control band[2]	Amplified HLA class I [3] alleles
1[4]	155, 370 bp	**800 bp**	010201-0119
2[5]	225, 270 bp	**800 bp**	0110, 020201-020203, 020205-0220, 0608, 0806[weakly], 0807, 1214, 1701-1704, 1803
3	280 bp	**800 bp**	020201-020203, 020205-0220, 030201-030203, 030401-0310, 0314-0317, 0319, 0323-0329, 0332-033802, 0340-0342, 0344-0346, 0403, 0406, 0416, 0603, 150201-1509, 151002, 1511, 1513, 1515-1521
4[6]	155 bp	1070 bp	030201-030406, 0305-0315, 0317-0340, 0342-0346
5[5]	225, 280 bp	**800 bp**	030301-030305, 031101-0313, 0320N-0322Q, 0330, 0331, 0343, 0807, 1214, 1512, 1701-1704
6	125 bp	1070 bp	020201-020203, 020205-0220, 04010101-040104, 0403-041502, 0417-0420, 0423-0431, 1511
7	165 bp	1070 bp	050101-050103, 0503-0517, 0605, 0810, 1221
8	130, 240, 355 bp	**800 bp**	0206, 0339, 06020101-0616N, 1215, 1216, 150201-1503, 1507, 1508, 151001-1513, 1515-1518, 1521
9[7]	245, 425 bp	1070 bp	070101-0733N, 0735-0753
10[6]	115, 175 bp	**800 bp**	080101-0812, 0814, 0815
11	340 bp	1070 bp	0114, 020201-020203, 020205-0211, 0213-0220, 0307, 0315, 0345, 04010101-040104, 0403-0410, 0412-0420, 0423-0428, 0430, 0431, 050101-0517, 06020101-0610, 0612-0616N, 0707, 0709, 0749, 0810, 120401-1205, 1209, 1221, 1404, 150201-1506, 1508-1513, 1515-1520,

			1602, 1609, 1701-1704, 1801-1803
12	150, 185, 220 bp	1070 bp	0104, 120201-12030102, 120303-120305, 120402-1208, 1210-1213, 1215-1221
13[6]	130, 160 bp	**800 bp**	0212, 04010101-040104, 0403-0409N, 0412-0420, 0423-0431, 0753, 0805, 120201-120303, 120305, 120402, 1206-1208, 1210-1220, 1503, 1516, 160101-1602, 1606-1610, **B*6702**
14[8]	220 bp	**800 bp**	0104, 0109, 0205, 0217, 06020101-0603, 0607-0613, 0615, 0616N, 12030101-1207, 1211-1213, 1215, 1219, 160401
15[6]	255 bp	**800 bp**	020201[weakly], 020202-020203, 020205-0213, 0215-0220, 0307, 0310, 0315, 0329, 0345, 0403, 0406, 0416, 050101-050103, 0503-0517, 0603, 0810, 120401-1205, 1209, 1221, 150201-1506, 1508-1513, 1515-1521, 1602, 1609, 1701-1704
16[6]	95, 255 bp	1070 bp	0411, 0429, 0511, 0517, 0804, 0813, 140201-1409
17[5,6]	110, 325 bp	1070 bp	0206, 1208, 1215, 150201-1513, 1515-1521
18[5]	190, 255 bp	1070 bp	0213, 0218, 04010101-040104, 0403-0410, 0412-0420, 0423-0431, 0517, 0605, 080101-080102, 0803, 0806, 0808-0811, 0814, 1214, 160101-1602, 160401, 1606-1610
19	240 bp	**800 bp**	1701-1704
20	220, 425 bp	**800 bp**	010201-0103, 0106-0108, 0110-0119, 0516, 0605, 0606, 0707, 0709, 0749, 0812, 1209, 140201-1405, 1407N, 1801-1803, **B*1403**
21	325, 380 bp	1070 bp	0103, 030301-030407, 0306-0312, 0314, 0318-0324, 0326, 0328-0332, 0334, 0337-0346, 04010101-040104, 0403-0420, 0424-0431, 050101-050103, 0503, 0505-0517, 0609, 0614, 0710, 0728, 0741, 0743, 080101-0808, 0810, 0812-0815, 150201-1513,

22[5]	95, 135 bp	1070 bp	1515-1521, 1701-1704, 1801-1803 030201-0317, 0319-033802, 0340-0346, 0511, 0517, 0603, 0804, 0813
23	160, 225 bp	1070 bp	0212, 0403, 0406, 06020101-060203, 0604, 0606-0616N, 070101-0725, 072701-0732N, 0735-0738, 0741-0753, 1216, 160101-1602, 1606-1610, 1801-1803

[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-C low resolution 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 bp or more. Size differences shorter than 20 bp are not given. For high resolution SSP kits the 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 band may sometimes be observed. Such bands can be disregarded and do not influence the interpretation of the SSP typings.
[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 tubes, or a band of 800 base pairs, for some tubes.
Tube 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-C low resolution typing.
In addition, tubes number 2, 3, 5, 8, 10, 13, 14, 15, 19 and 20 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

PLEASE NOTE: All the SSP kits, except the B*37, B*41, B*42, B*46, B*47, B*48, B*49, B*50, B*53, B*67, B*78, B*81 and B*82 kits and the Cw*01, Cw*02, Cw*08, Cw*12,Cw*14, Cw*15, Cw*16, Cw*17 and Cw*18 kits, from *Olerup* SSP AB can be uniquely identified by the number of tubes and the kit-specific pattern of the two differently sized control bands.

In the presence of a specific amplification the intensity of the control band often decreases.
[3]For several HLA-C alleles only partial 1st and 4th exon nucleotide sequences are available. In these instances it is not known whether some of the primers of the HLA-C low resolution SSP sets are completely matched with the target sequences or not. We assume that unknown sequences are conserved within allelic groups.
[4]Primer mix 1 will for most Cw*01 alleles give rise to two specific PCR fragments.
[5]Primer mixes 2, 5, 17, 18 and 22 have a tendency of giving rise to primer oligomer artifacts. Most pronounced for primer mixes 5 and 22.
[6]Primer mixes 4, 10, 13, 15, 16 and 17 yield somewhat less intense specific PCR fragments than the other HLA-C low resolution primer mixes.
[7]Primer mix 9 will for most Cw*07 alleles give rise to two specific PCR fragments.
[8]Primer mix 14 might faintly amplify the Cw*0102 to 0103, the Cw*0105 to Cw*0119 and the Cw*140201 to 1409 alleles.

INTERPRETATION TABLE

HLA-Cw low resolution SSP typing

Amplification patterns of the Cw*0102 to Cw*1802 alleles

	Tube											
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
Length of spec.	**155**	**225**	**280**	**155**	**225**	**125**	**165**	**130**	**245**	**115**	**340**	**150**
PCR product(s)	**370**	**270**			**280**			**240**	**425**	**175**		**185**
								355				**220**
Length of int.	**800**	**800**	**800**	**1070**	**800**	**1070**	**1070**	**800**	**1070**	**800**	**1070**	**1070**
pos. control[1]												
5'-primer(s)[2]	**89**	**2nd I**	**106**	**477**	**105**	**112**	**176**	**28**	**47**	**176**	**1st I**	**2nd I**
	5'-gAA3'	5'-CCA3'	5'-CTg3'	5'-gCC3'	5'-gCT3'	5'-CCT3'	5'-gCA3'	5'-TCA3'	5'-Agg3'	5'-gCA3'	5'-CgA3'	5'-CCA3'
	368				**2nd I**	**118**		**2nd I**	**648**	**527**		**361**
	5'-gTg3'				5'-CCA3'	5'-CCA3'		5'-CCA3'	5'-CAC3'	5'-TAC3'		5'-AgT3'
												369
												5'-TAC3'
3'-primer(s)[3]	**201**	**512**	**343**	**589**	**343**	**201**	**302**	**97**	**302**	**311**	**302**	**474**
	5'-CTC3'	5'-CCA3'	5'-ACC3'	5'-CTT3'	5'-ACT3'	5'-CTT3'	5'-ggT3'	5'-gTC3'	5'-ggC3'	5'-ggT3'	5'-ggT3'	5'-gCA3'
	3rd I	**559**			**512**			**213**	**853**	**601**		**477**
	5'-CTC3'	5'-CTC3'			5'-CCA3'			5'-Cgg3'	5'-CAT3'	5'-CTT3'		5'-gCA3'
								420				**538**
								5'-gCT3'				5'-gCA3'
Tube No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
HLA-Cw allele[4]												
***010201-010205, 0106-0108, 0111-0113, 0115-0119**	**+**											
***0103**	**+**											
***0104**	**+**											**+**
***0105**	**+**											
***0109**	**+**											
***0110**	**+**	**+**										
***0114**	**+**										**+**	
***020201**		**+**	**+**			**+**					**+**	
***020202-020203, 020205-0204, 0207-0211, 0215, 0216, 0219, 0220**		**+**	**+**			**+**					**+**	
***0205, 0217**		**+**	**+**			**+**					**+**	
***0206**		**+**	**+**			**+**		**+**			**+**	
***0212**		**+**	**+**			**+**						
***0213, 0218**		**+**	**+**			**+**					**+**	
Tube No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

INTERPRETATION TABLE

HLA-Cw low resolution SSP typing

Amplification patterns of the Cw*0102 to Cw*1802 alleles

Tube											
13	14	15	16	17	18	19	20	21	22	23	
130	220	255	95	110	190	240	220	325	95	160	Length of spec.
160			255	335	250		425	380	135	225	PCR product(s)
800	800	800	1070	1070	1070	800	800	1070	1070	1070	Length of int.
											pos. control[1]
201	361	98	98	201	201	499	47	355	105	97	5'-primer(s)[2]
5'-CCA3'	5'-AgT3'	5'-CTA3'	5'-CTC3'	5'-CCA3'	5'-CCA3'	5'-TCT3'	5'-Agg3'	5'-TCA3'	5'-gCT3'	5'-TCg3'	
419			485	409	2nd I		361	412	485	118	
5'-gTC3'			5'-CAA3'	5'-ggC3'	5'-CCA3'		5'-AgT3'	5'-ATA3'	5'-CAA3'	5'-CCA3'	
					361					418	
					5'-AgT3'					5'-Agg3'	
										419	
										5'-gTC3'	
289	538	312	311	270	341	3rd I	302	3rd I	201	289	3'-primer(s)[3]
5'-AgC3'	5'-CCA3'	5'-AgT3'	5'-ggT3'	5'-TAg3'	5'-CgT3'	5'-CTC3'	5'-ggT3'	5'-CTC3'	5'-CTC3'	5'-AgC3'	
539	538		539	3rd I	341		538		539	539	
5'-TCT3'	5'-gCA3'		5'-TCA3'	5'-CTC3'	5'-ggT3'		5'-CCg3'		5'-TCA3'	5'-TCT3'	
					527						
					5'-CCg3'						
13	14	15	16	17	18	19	20	21	22	23	Tube No.
											HLA-Cw allele[4]
							+				*010201-010205, 0106-0108, 0111-0113, 0115-0119
							+	+			*0103
	+										*0104
											*0105
	+										*0109
							+				*0110
							+				*0114
		W									*020201
		+									*020202-020203, 020205 0204, 0207-0211, 0215, 0216, 0219, 0220
	+	+									*0205, 0217
		+		+							*0206
+		+								+	*0212
		+			+						*0213, 0218
13	14	15	16	17	18	19	20	21	22	23	Tube No.

Length of spec.	155	225	280	155	225	125	165	130	245	115	340	150
PCR product(s)	370	270			280			240	425	175		185
								355				220
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12
*0214		+	+			+					+	
*030201-030203, 0305, 0317, 0325, 0327, 0333, 0335, 0336			+	+								
*030301-030305, 031101-031102, 0312, 0320N-0322Q, 0330, 0331, 0343				+	+							
*030401-030406, 0306, 0308, 0309, 0314, 0319, 0323, 0324, 0326, 0328, 0332, 0334, 0337-033802, 0340, 0342, 0344, 0346			+	+								
*030407, 0341			+									
*0307, 0345			+	+							+	
*0310, 0329			+	+								
*0313				+	+							
*0315			+	+							+	
*0316			+									
*0318				+								
*0339				+				+				
*04010101-040104, 040401-0405, 0407-0409N, 0412-041502, 0417-0420, 0424-0428, 0430, 0431						+					+	
*0403, 0406			+			+					+	
*0410						+					+	
*0411						+						
*0416			+								+	
*0423						+					+	
*0429						+						
*050101-0503, 0505-0510, 0512-0515							+				+	
*0504							+				+	
*0511							+				+	
*0516							+				+	
*0517							+				+	
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12

130	220	255	95	110	190	240	220	325	95	160	Length of spec.
160			255	335	250		425	380	135	225	PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	Tube No.
											*0214
									+		*030201-030203, 0305, 0317, 0325, 0327, 0333, 0335, 0336
								+	+		*030301-030305, 031101, 031102, 0312, 0320N-0322Q, 0330, 0331, 0343
								+	+		*030401-030406, 0306, 0308, 0309, 0314, 0319, 0323, 0324, 0326, 0328, 0332, 0334, 0337-033802, 0340, 0342, 0344, 0346
								+	+		*030407, 0341
		+						+	+		*0307, 0345
		+						+	+		*0310, 0329
									+		*0313
		+							+		*0315
									+		*0316
								+			*0318
								+			*0339
+					+			+			*04010101-040104, 040401-0405, 0407-0409N, 0412-041502, 0417-0420, 0424-0428, 0430, 0431
+		+			+			+		+	*0403, 0406
					+			+			*0410
			+					+			*0411
+		+			+			+			*0416
+					+						*0423
+			+		+			+			*0429
		+						+			*050101-0503, 0505-0510, 0512-0515
		+									*0504
		+	+					+	+		*0511
		+					+	+			*0516
		+	+		+			+	+		*0517
13	14	15	16	17	18	19	20	21	22	23	Tube No.

Length of spec.	155	225	280	155	225	125	165	130	245	115	340	150
PCR product(s)	370	270			280			240	425	175		185
								355				220
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12
*06020101-060203, 0607, 0610, 0612, 0613, 0615, 0616N								+			+	
*0603			+					+			+	
*0604								+			+	
*0605							+	+			+	
*0606								+			+	
*0608		+						+			+	
*0609								+			+	
*0611								+				
*0614								+			+	
*070101-0706, 0708, 0711-0725, 072701-072702, 0729-0732N, 0735-0738, 0742, 0744-0748, 0750-0752									+			
*0707, 0709, 0749									+		+	
*0710, 0728, 0741, 0743									+			
*0726, 0733N, 0739, 0740									+			
*0753									+			
*080101-080102, 0803, 0808, 0814										+		
*0802, 0815										+		
*0804										+		
*0805										+		
*0806		W								+		
*0807		+			+					+		
*0809, 0811										+		
*0810							+			+	+	
*0812										+		
*0813												
*120201-120203, 1210, 1217, 1218, 1220												+
*12030101-12030102, 120303, 120305, 1206, 1207, 1211-1213, 1219												+
*120302												
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12

130	220	255	95	110	190	240	220	325	95	160	Length of spec.
160			255	335	250		425	380	135	225	PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	Tube No.
	+									+	*06020101-060203, 0607, 0610, 0612, 0613, 0615, 0616N
	+	+							+		*0603
										+	*0604
					+		+				*0605
							+			+	*0606
	+									+	*0608
	+							+		+	*0609
	+									+	*0611
								+		+	*0614
										+	*070101-0706, 0708, 0711-0725, 072701-072702, 0729-0732N, 0735-0738, 0742, 0744-0748, 0750-0752
							+			+	*0707, 0709, 0749
								+		+	*0710, 0728, 0741, 0743
											*0726, 0733N, 0739, 0740
+										+	*0753
					+			+			*080101-080102, 0803, 0808, 0814
								+			*0802, 0815
			+					+	+		*0804
+								+			*0805
					+			+			*0806
								+			*0807
					+						*0809, 0811
		+			+			+			*0810
							+	+			*0812
			+					+	+		*0813
+											*120201-120203, 1210, 1217, 1218, 1220
+	+										*12030101-12030102, 120303, 120305, 1206, 1207, 1211-1213, 1219
+	+										*120302
13	14	15	16	17	18	19	20	21	22	23	Tube No.

Length of spec.	**155**	**225**	**280**	**155**	**225**	**125**	**165**	**130**	**245**	**115**	**340**	**150**
PCR product(s)	**370**	**270**			**280**			**240**	**425**	**175**		**185**
								355				**220**
Tube No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
***120304**												+
***120401**											+	
***120402**											+	+
***1205**											+	+
***1208**												+
***1209**											+	
***1214**		+			+							
***1215**								+				+
***1216**								+				+
***1221**							+				+	+
***140201-1403, 1405, 1407N**												
***1404**											+	
***1406, 1408, 1409**												
***150201-150203, 1508, 151002, 1513, 1515, 1517, 1518**			+					+			+	
***1503, 1516**			+					+			+	
***1504-1506, 1509, 1519, 1520**			+								+	
***1507**			+					+				
***151001**								+			+	
***1511**			+			+		+			+	
***1512**					+			+			+	
***1521**			+					+				
***160101-160103, 1606-1608, 1610**												
***1602, 1609**											+	
***160401**												
***1701-1704**		+			+						+	
***1801, 1802**											+	
***1803**		+									+	
HLA-Cw allele[4]												
Tube No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**
B*1403												
B*6702												
Tube No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**	**9**	**10**	**11**	**12**

130	220	255	95	110	190	240	220	325	95	160	Length of spec.
160			255	335	250		425	380	135	225	PCR product(s)
13	14	15	16	17	18	19	20	21	22	23	Tube No.
	+										*120304
	+	+									*120401
+	+	+									*120402
	+	+									*1205
+				+							*1208
		+					+				*1209
+					+						*1214
+	+			+							*1215
+										+	*1216
		+									*1221
			+				+				*140201-1403, 1405, 1407N
			+				+				*1404
			+								*1406, 1408, 1409
		+		+				+			*150201-150203, 1508, 151002, 1513, 1515, 1517, 1518
+		+		+				+			*1503, 1516
		+		+				+			*1504-1506, 1509, 1519, 1520
				+				+			*1507
		+		+				+			*151001
		+		+				+			*1511
		+		+				+			*1512
		+		+				+			*1521
+					+					+	*160101-160103, 1606-1608, 1610
+		+			+					+	*1602, 1609
	+				+						*160401
		+				+		+			*1701-1704
							+	+		+	*1801, 1802
							+	+		+	*1803
											HLA-Cw allele[4]
13	14	15	16	17	18	19	20	21	22	23	Tube No.
							+				B*1403
+											B*6702
13	14	15	16	17	18	19	20	21	22	23	Tube No.

[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 tubes, or a band of 800 base pairs, for some tubes.
Tube 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-C low resolution SSP typing.
In addition, tubes number 2, 3, 5, 8, 10, 13, 14, 15, 19 and 20 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

PLEASE NOTE: All the SSP kits, except the B*37, B*41, B*42, B*46, B*47, B*48, B*49, B*50, B*53, B*67, B*78 and B*82 kits and the Cw*01, Cw*02, Cw*08, Cw*12,Cw*14, Cw*15, Cw*16, Cw*17 and Cw*18 kits, from *Olerup* SSP AB can be uniquely identified by the number of tubes and the kit-specific pattern of the two differently sized control bands.

[2]The nucleotide position, in the 1st, 2nd, 3rd or 4th exon or the 1st or 2nd intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as in *Tissue Antigens* 1998, **51:II**, 417-466. The sequence of the 3 terminal nucleotides of the primer is given.
[3]The nucleotide position, in the 1st, 2nd, 3rd or 4th exon or the 3rd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as in *Tissue Antigens* 1998, **51:II**, 417-466. The sequence of the 3 terminal nucleotides of the primer is given.
[4]The sequence of the Cw*0101 allele has been shown to be identical to Cw*0102.
The sequence of the Cw*0201 allele has been shown to be identical to Cw*02022.
The sequence of the Cw*020204 allele has been shown to be identical to Cw*0210.
The sequence of the Cw*0301 allele has been shown to be identical to Cw*0304.
The sequence of the Cw*0402 allele has been shown to be identical to Cw*04011.
The sequence of the Cw*0422 allele has been shown to be identical to Cw*0421.
The sequence of the Cw*0601 allele has been shown to be identical to Cw*0602.
The sequence of the Cw*1101 allele has been shown to be in error.
The sequence of the Cw*1201 allele has been shown to be identical toCw*12022.
The nucleotide sequence of Cw*1301 has been shown to be in error.
The sequence of the Cw*1401 allele has been shown to be identical toCw*1402.
The sequence of the Cw*1501 allele has been shown to be identical toCw*1502.
The sequence of the Cw*1603 allele has been shown to be identical toCw*1403.
The sequence of the Cw*16042 allele has been shown to be identical toCw*16041.
The sequence of the Cw*1605 allele has been shown to be identical toCw*16041.

CELL LINE VALIDATION SHEET

HLA-C low resolution SSP primer set

					Tube														
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	200626101	200626102	200736503	200626104	200736505	200626106	200626107	200626108	200736509	200736510	200626111	200626112	200626113	200626114	200626115	200736516
		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	CTM395354	*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	*0102	*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	-	-	-	-	-	+	-	-	-	-	+	-	+	-	-	-

CELL LINE VALIDATION SHEET

HLA-C low resolution SSP primer set

					Tube						
					17	**18**	**19**	**20**	**21**	**22**	**23**
				Prod. No.:	200736517	2007-36518	200626119	200626120	200626121	2007-36522	2007-36523
	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	CTM395354	*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	*0102	*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-C low resolution SSP

Product number: **101.601-24/12 – licensed for PCR**
101.601-24u/12u – not licensed for PCR
Lot number: **Y22**
Expiry date: **2009-August-01**
Number of tests: **24 tests – Product No. 101.601-24**
12 tests – Product No. 101.601-12
Number of tubes per test: **23 + 1**

Tube specifications:

Tube No.	Production No.	Tube No.	Production No.	Tube No.	Production No.
1	2006-261-01	9	2007-365-09	17	2007-365-17
2	2006-261-02	10	2007-365-10	18	2007-365-18
3	2007-365-03	11	2006-261-11	19	2006-261-19
4	2006-261-04	12	2006-261-12	20	2006-261-20
5	2007-365-05	13	2006-261-13	21	2006-261-21
6	2006-261-06	14	2006-261-14	22	2007-365-22
7	2006-261-07	15	2006-261-15	23	2007-365-23
8	2006-261-08	16	2007-365-16		

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

The negative control primer pairs, **Production No. 2006-257-01**, can detect contamination with PCR products diluted 10^{-7}.

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

Date of approval: 2007-November-21

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: *Olerup* SSP™ HLA-C low resolution
Product number: 101.601-24/12, 101.601-24u/12u
Lot number: Y22

Intended use: HLA-C low 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 13485:2004, 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 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
2007-November-21

Olle Olerup
Managing Director

WARRANTY

Olerup SSP AB warrants its products to the original purchaser against defects in materials and workmanship under normal use and application. *Olerup* SSP AB's sole obligation under this warranty shall be to replace, at no charge, any product that does not meet the performance standards stated on the product specification sheet.

This warranty applies only to products that have been handled and stored in accordance with *Olerup* SSP AB's recommendations, and does not apply to products that have been the subject of alternation, misuse, or abuse.

All claims under this warranty must be directed to *Olerup* SSP AB in writing and must be accompanied by a copy of the purchaser's invoice. This warranty is in lieu of all other warranties, expressed or implied, including the warranties of merchantability and fitness for a particular purpose. In no case shall *Olerup* SSP AB be liable for incidental or consequential damages.

This product may not be reformulated, repacked or resold in any form without the written consent of *Olerup* SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

Handle all samples as if capable of transmitting disease. All work should be performed wearing gloves and appropriate protection.

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