

HLA-B*39
101.566-12/04 – licensed for PCR
101.566-12u/04u – not licensed for PCR
Lot No.: **Y49**

1

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Olerup SSP™ HLA-B*39

Product number: 101.566-12/04 – licensed for PCR
101.566-12u/04u – not licensed for PCR
Lot number: Y49
Expiry date: 2009-October-01
Number of tests: 12 tests – Product No. 101.566-12
4 tests – Product No. 101.566-04
Number of tubes per test: 32
Storage - pre-aliquoted primers: dark at -20°C
- PCR Master Mix: -20°C

This Product Description is only valid for Lot No. Y49.

CHANGES COMPARED TO THE PREVIOUS OLERUP SSP™ HLA-B*39 LOT

The HLA-B*39 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP™* HLA-B*39 lot was made (**Lot No. V90**).

The primers of the tubes detailed below have been exchanged, added or modified compared to the previous lot of the HLA-B*39 kit.

Tube	5'-primer	3'-primer	rationale
3	Added	Added	Primer pair added for the B*3943 allele.
11	Exchanged	-	Increased resolution.
32	Added	Added	Primer pair added for the B*3942 allele.

PRODUCT DESCRIPTION

HLA-B*39 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*3901 to B*3943 alleles.

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.

32 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.

PLATE LAYOUT

Each test consists of 32 PCR reactions in a 32 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
25	26	27	28	29	30	31	32

The 32 well cut PCR plate is marked with 'B*39 Y49'.

Well No. 1 is marked with '1'.

The PCR plates are covered with a PCR-compatible foil.

Please note: When removing each 32 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

The interpretation of HLA-B*39 SSP subtypings will be influenced by the B*07, the B*08, the B*13, the B*14, most B*15, the B*18, the B*27, B*35, the B*37, the B*38, many B*40, several B*41, the B*42, several B*44, the B*45, two B*46, the B*47, the B*48, the B*49, the B*50, several B*51, two B*52, the B*53, the B*54, the B*55, the B*56, the B*57, most B*58, the B*59, the B*67, the B*7301, two B*78, the B*81, the B*82 and the B*8301 alleles when present on the other haplotype. In addition, the Cw*1515 allele will be amplified by primer mix 28.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*39 alleles, i.e. **B*3901 to B*3943**, recognized by the HLA Nomenclature Committee in October 2007¹ will give rise to unique amplification patterns by the primers in the HLA-B*39 subtyping kit².

The HLA-B*39 subtyping kit cannot distinguish the B*39010101 and B*390103 alleles or the B*390601 and B*390602 alleles or the B*391301 and B*391302.

¹*Nomenclature for factors of the HLA system, 1998. Tissue Antigens 1999; 53: 407-446.*

HLA-B alleles listed on the IMGT/HLA web page 2007-October-05, release 2.19.0, www.ebi.ac.uk/imgt/hla.

²The B*3910 and B*670102 alleles will give rise to identical amplification patterns with the HLA-B*39 subtyping kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*67 kits.

RESOLUTION IN HOMO- AND HETEROZYGOTES

The 42 HLA-B*39 alleles give rise to 45 different amplification patterns; B*390104 have a different amplification pattern than B*39010101/390103 and B*39010102L, B*390201 and B*390202 have different amplification patterns, and these 45 different amplification patterns can be combined in 1 035 homozygous and heterozygous combinations. 379 of these genotypes do not give rise to unique amplification patterns. In these calculations the different sizes of the specific PCR products in lanes 7, 10, 13, 16 and 27 were not considered.

+++---+--	-----	-++-+---	-----	390201, 3937 = 3903, 3913
+++---+--	-----	-++-+---	-----	390202, 3937 = 3913, 3937
+++---+--	-----	-++-+---	-----	3908, 3912 = 3908, 3931
+++---+--	-----	-++-+---	-----	3908, 3918 = 3913, 3918
+++---+--	-----	-++-+---	-----	3908, 3933 = 3908, 3940N = 3913, 3933
+++---+--	-----	-++-+---	-----	3908, 3941 = 3908, 3942
+++---+--	-----	-++-+---	-----	3901, 3908 = 390201, 3911 = 3908, 3936 = 3913, 3936
+++---+--	-----	-++-+---	-----	390104, 3908 = 390202, 3911 = 3905, 3908 = 3908, 3911 = 3911, 3913
+++---+--	-----	-++-+---	-----	3913, 3941 = 3913, 3942
+++---+--	-----	-++-+---	-----	3901, 3913 = 390201, 3905
+++---+--	-----	-++-+---	-----	390104, 3913 = 390202, 3905 = 3905, 3913
+++---+--	-----	-++-+---	-----	390201, 3943 = 390202, 3943 = 3913, 3943
+++---+--	-----	-++-+---	-----	3905, 3917 = 3910, 3937 = 3917, 3937 = 3920, 3937
+++---+--	-----	-++-+---	-----	3912, 3937 = 3931, 3937
+++---+--	-----	-++-+---	-----	3905, 3924 = 3937, 3941
+++---+--	-----	-++-+---	-----	3901, 3937 = 3903, 3905
+++---+--	-----	-++-+---	-----	390104, 3937 = 3905, 3937
+++---+--	-----	-++-+---	-----	3903, 3943 = 3930, 3937 = 3937, 3943
+++---+--	-----	-++-+---	-----	3924, 3937 = 3937, 3942
+++---+--	-----	-++-+---	-----	3910, 3911 = 3911, 3920
+++---+--	-----	-++-+---	-----	3911, 3912 = 3911, 3931
+++---+--	-----	-++-+---	-----	3905, 3918 = 3911, 3918
+++---+--	-----	-++-+---	-----	3905, 3933 = 3911, 3933 = 3911, 3940N
+++---+--	-----	-++-+---	-----	3911, 3930 = 3911, 3943
+++---+--	-----	-++-+---	-----	3911, 3941 = 3911, 3942
+++---+--	-----	-++-+---	-----	3901, 3911 = 3905, 3936 = 3911, 3936
+++---+--	-----	-++-+---	-----	390104, 3911 = 3905, 3911 = 3911, 3911
+++---+--	-----	-++-+---	-----	3910, 3943 = 3920, 3930 = 3920, 3943
+++---+--	-----	-++-+---	-----	3920, 3941 = 3920, 3942

+++----- +-----+-- --+--+--+ ----- 390104,3920 = 3905,3910 = 3905,3920
+++----- +-----+-- --+--+--+ -----+ 3912,3943 = 3931,3943
+++----- +-----+-- --+--+--+ ----- 3905,3912 = 3905,3931
+++----- +-----+-- --+--+--+ -----+ 3901,3943 = 390104,3943 = 3905,3930 =
3905,3943
+++----- +-----+-- --+--+--+ -----+ 3905,3941 = 3905,3942
+++----- +-----+-- --+--+--+ ----- 390104,3905 = 3905,3905
++-----+-- +-----+-- --+--+--+ ----- 390201,3926 = 390202,3926
++-----+-- +-----+-- --+--+--+ ----- 3912,3926 = 3926,3931
++-----+-- +-----+-- --+--+--+ -----+ 3926,3941 = 3926,3942
++-----+-- +-----+-- --+--+--+ ----- 3901,3926 = 390104,3926 = 3926,3926
++-----+-- +-----+-- --+--+--+ ----- 390201,3929 = 390202,3929
++-----+-- +-----+-- --+--+--+ ----- 390201,3914 = 390202,3914
++-----+-- +-----+-- --+--+--+ -----+ 390201,3924 = 390202,3924
++-----+-- +-----+-- --+--+--+ ----- 390201,3903 = 390202,3903
++-----+-- +-----+-- --+--+--+ -----+ 390201,3906 = 390202,3906
++-----+-- +-----+-- --+--+--+ -----+ 390201,3918 = 390202,3918
++-----+-- +-----+-- --+--+--+ -----+ 390201,3933 = 390202,3933
++-----+-- +-----+-- --+--+--+ ----- 390201,3936 = 390202,3936
++-----+-- +-----+-- --+--+--+ ----- 390201,3915 = 390202,3915
++-----+-- +-----+-- --+--+--+ -----+ 3923,3941 = 3923,3942
++-----+-- +-----+-- --+--+--+ ----- 3901,3923 = 390201,3909 = 390202,3909 =
3909,3923
++-----+-- +-----+-- --+--+--+ ----- 390201,3912 = 390201,3931 = 390202,3931
++-----+-- +-----+-- --+--+--+ ----- 3912,3939 = 3931,3939
++-----+-- +-----+-- ++--+--+--+ ----- 390201,3925N = 390202,3925N
++-----+-- +-----+-- ++--+--+--+ ----- 390201,3927 = 390202,3927
++-----+-- +-----+-- ++--+--+--+ ----- 390201,3928 = 390202,3928
++-----+-- +-----+-- ++--+--+--+ +-----+ 39010102L,390201 = 39010102L,390202
++-----+-- +-----+-- ++--+--+--+ ----- 390201,3932 = 390202,3932
++-----+-- +-----+-- ++--+--+--+ -----+ 390201,3938Q = 390202,3938Q
++-----+-- +-----+-- ++--+--+--+ -----+ 390201,3940N = 390202,3940N
++-----+-- +-----+-- ++--+--+--+ -----+ 390201,3934 = 390202,3934
++-----+-- +-----+-- ++--+--+--+ -----+ 390201,3935 = 390202,3935
++-----+-- +-----+-- ++--+--+--+ -----+ 390201,3930 = 390202,3930
++-----+-- +-----+-- ++--+--+--+ -----+ 390201,3941 = 390201,3942 = 390202,3941
= 390202,3942
++-----+-- +-----+-- ++--+--+--+ ----- 3901,390201 = 3901,390202 =
390104,390201 = 3922,3939
++-----+-- +-----+-- ++--+--+--+ ----- 390201,3922 = 390202,3922
++-----+-- +-----+-- ++--+--+--+ -----+ 3939,3941 = 3939,3942
++-----+-- +-----+-- ++--+--+--+ ----- 3901,3939 = 390104,3939
++-----+-- +-----+-- ++--+--+--+ ----- 3907,3914 = 3907,3929
++-----+-- +-----+-- ++--+--+--+ ----- 3910,3929 = 3917,3929
++-----+-- +-----+-- ++--+--+--+ ----- 3912,3929 = 3929,3931
++-----+-- +-----+-- ++--+--+--+ ----- 3901,3929 = 390104,3929 = 3914,3915 =
3915,3929
++-----+-- +-----+-- ++--+--+--+ -----+ 3924,3929 = 3929,3942
++-----+-- +-----+-- ++--+--+--+ ----- 3903,3929 = 3914,3929 = 3929,3929
++-----+-- +-----+-- ++--+--+--+ ----- 3910,3914 = 3914,3917
++-----+-- +-----+-- ++--+--+--+ ----- 3903,3916 = 3914,3916
++-----+-- +-----+-- ++--+--+--+ -----+ 3910,3924 = 3917,3924 = 3917,3941 =
3917,3942
++-----+-- +-----+-- ++--+--+--+ ----- 3901,3917 = 3903,3910 = 3903,3917
++-----+-- +-----+-- ++--+--+--+ ----- 3912,3914 = 3914,3931
++-----+-- +-----+-- ++--+--+--+ -----+ 3912,3924 = 3924,3931
++-----+-- +-----+-- ++--+--+--+ ----- 3903,3912 = 3903,3931
++-----+-- +-----+-- ++--+--+--+ ----- 3901,3914 = 390104,3914
++-----+-- +-----+-- ++--+--+--+ -----+ 3914,3924 = 3914,3942

+++-+-+ - - - - - + - - + - - + + - - - - - 3903,3914 = 3914,3914
 +++-+-+ - - - - - - - - - - - - - - - + 3901,3924 = 390104,3924 = 3903,3941 =
 3924,3941
 +++-+-+ - - - - - - - - - - - - - - - 3901,3903 = 390104,3903
 +++-+-+ - - - - - - - - - - - - - - - + 3903,3924 = 3903,3942 = 3924,3924 =
 3924,3942
 +++-+-+ - + - + - + - - - - - + - - - - - 3907,3912 = 3907,3931
 +++-+-+ - + - + - - - - - - - - - - + 3907,3941 = 3907,3942
 +++-+-+ - + - + - - - - - - - - - - 3901,3907 = 3904,3907 = 3907,3915
 +++-+-+ - + - + - - - - - - - - - - 390104,3907 = 3907,3907 = 3907,3919
 +++-+-+ - - - - - - - - - - - - - - - + 3904,3941 = 3904,3942
 +++-+-+ - - - - - - - - - - - - - - - 3901,3904 = 390104,3904
 +++-+-+ + - - - - + - - - - + - - - - - 3906,3912 = 3906,3931
 +++-+-+ + - - - - - - - - - - - - - - - 3901,3906 = 390104,3906
 +++-+-+ - + - - - - - - - - - - - - - + 3919,3941 = 3919,3942
 +++-+-+ - - + - - + - - - + - + - + - - 3912,3918 = 3918,3931
 +++-+-+ - - + - - + - - - + - + - + - - 3912,3933 = 3931,3933
 +++-+-+ - - + - - + - - - + - + - + - - 3912,3936 = 3931,3936
 +++-+-+ - - + - - - - - - + - + - + - - 3918,3933 = 3918,3940N
 +++-+-+ - - + - - - - - - + - + - + - - 3918,3941 = 3918,3942
 +++-+-+ - - + - - - - - - + - + - + - - 3901,3918 = 390104,3918 = 3918,3918 =
 3918,3927 = 3918,3935 = 3918,3936
 +++-+-+ - - + - - - - - - + - + - + - - 3901,3933 = 390104,3933 = 3933,3940N =
 3936,3940N
 +++-+-+ - - + - - - - - - + - + - + - - 3901,3936 = 390104,3936
 +++-+-+ - - - + - + - - - + - + - + - - 3912,3915 = 3915,3931
 +++-+-+ - - - + - - - - - + - + - + - - 3915,3941 = 3915,3942
 +++-+-+ - - - + - - - - - - - - - - 3901,3915 = 390104,3915 = 3915,3915
 +++-+-+ - - - + - + - - - + - + - + - - 3909,3912 = 3909,3931
 +++-+-+ - - - + - - - - - - - - - - + 3909,3941 = 3909,3942
 +++-+-+ - - - + - - - - - - - - - - 3901,3909 = 390104,3909 = 3909,3909
 +++-+-+ - - - - + - - - - + - + - + - - 3910,3941 = 3910,3942
 +++-+-+ - - - - + - - - - + - + - + - - 3912,3925N = 3925N,3931
 +++-+-+ - - - - + - - - - - - + - + - + - - 3912,3922 = 3922,3931
 +++-+-+ - - - - + - - - - - - + - + - + - - 3912,3927 = 3927,3931
 +++-+-+ - - - - + - - - - - - + - + - + - - 3912,3928 = 3928,3931
 +++-+-+ - - - - + - - - - - - + - - - - 39010102L,3912 = 39010102L,3931
 +++-+-+ - - - - + - - - - - - + - + - - 3912,3932 = 3931,3932
 +++-+-+ - - - - + - - - - - - + - - - - 3912,3938Q = 3931,3938Q
 +++-+-+ - - - - + - - - - - - + - - - - 3912,3940N = 3931,3940N
 +++-+-+ - - - - + - - - - - - + - + - + - 3912,3934 = 3931,3934
 +++-+-+ - - - - + - - - - - - + - - - - 3912,3935 = 3931,3935
 +++-+-+ - - - - + - - - - - - + - - - - 3912,3930 = 3930,3931
 +++-+-+ - - - - + - - - - - - + - - - - 3912,3941 = 3912,3942 = 3931,3941 =
 3931,3942
 +++-+-+ - - - - + - - - - - - + - - - - 3901,3912 = 3901,3931 = 390104,3912 =
 390104,3931 = 3912,3931 = 3931,3931
 +++-+-+ - - - - - - - - - + - + - + - - 3925N,3941 = 3925N,3942
 +++-+-+ - - - - - - - - - + - + - + - - 3901,3925N = 390104,3925N = 3925N,3925N
 +++-+-+ - - - - - - - - - - - + - + - - 3922,3941 = 3922,3942
 +++-+-+ - - - - - - - - - - - + - + - - 3901,3922 = 390104,3922
 +++-+-+ - - - - - - - - - - - + - + - - 3927,3941 = 3927,3942
 +++-+-+ - - - - - - - - - - - + - + - - 3901,3927 = 390104,3927 = 3927,3927
 +++-+-+ - - - - - - - - - - - + - + - - 3901,3928 = 390104,3928
 +++-+-+ - - - - - - - - - - - + - - - + 39010102L,3941 = 39010102L,3942
 +++-+-+ - - - - - - - - - - - + - - - - 3901,39010102L = 39010102L,39010102L =
 39010102L,390104
 +++-+-+ - - - - - - - - - - - + - - - - 3901,3932 = 390104,3932 = 3932,3938Q =
 3932,3940N = 3938Q,3940N

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++---+--- ----- --+--+--+ --+-----+ 3938Q,3941 = 3938Q,3942
++---+--- ----- --+--+--+ --+-----+ 3901,3938Q = 390104,3938Q = 3938Q,3938Q
++---+--- ----- --+--+--+ --+-----+ 3940N,3941 = 3940N,3942
++---+--- ----- --+--+--+ --+-----+ 3901,3940N = 390104,3940N = 3940N,3940N
++---+--- ----- --+--+--+ --+-----+ 3901,3934 = 390104,3934
++---+--- ----- --+--+--+ --+-----+ 3935,3941 = 3935,3942
++---+--- ----- --+--+--+ --+-----+ 3901,3935 = 390104,3935 = 3935,3935
++---+--- ----- --+--+--+ --+-----+ 3901,3930 = 390104,3930
++---+--- ----- --+--+--+ --+-----+ 3901,3941 = 3901,3942 = 390104,3941 =
390104,3942 = 3941,3941 = 3941,3942
++---+--- ----- --+--+--+ -----+ 3901,3901 = 3901,390104
++---+--- ----- --+--+--+ -----+ 3908,3910 = 3908,3920
++---+--- ----- --+--+--+ -----+ 390202,3908 = 3908,3908 = 3908,3913
++---+--- ----- --+--+--+ -----+ 390202,3920 = 3910,3913 = 3913,3920
++---+--- ----- --+--+--+ -----+ 390202,3913 = 3913,3913
++---+--- ----- --+--+--+ -----+ 3910,3920 = 3920,3920
+---++--- ----- -+--+--+ -----+ 390201,3939 = 390202,3939
+---++--- ----- -+--+--+ -----+ 390201,390201 = 390201,390202
+---++--- ----- -+--+--+ -----+ 390202,3923 = 3923,3923
+-----+-----+----- --+--+--+ -----+ 3910,3917 = 3917,3917
-+---+--- +----- --+--+--+ -----+ 3906,3930 = 3906,3934
-+---+--- --+----- --+--+--+ --+-----+ 3932,3933 = 3932,3936
-+---+--- --+----- --+--+--+ --+-----+ 3933,3933 = 3933,3936
-+---+--- ----- --+--+--+ -----+ 3930,3934 = 3934,3934

(3901 = 39010101 and 390103)

LICENSES

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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.

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101.566-12/04 and 101.566-12u/04u

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-B*39 subtyping kit have 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/μl.

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 dH₂O.

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

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For one HLA-B*39 subtyping, add at room temperature in a 0.5 ml tube:

38 x 2 μl = 76 μl DNA (30 ng/μl)

38 x 3 μl = 114 μl PCR Master Mix complete with *Taq* – mix well before taking your aliquot

38 x 5 μl = 190 μl dH₂O

Mix well, dispense 10 μl of the DNA-PCR Master Mix-H₂O mixture into each of the 32 wells of an HLA-B*39 subtyping. **Well No. 1 of the 32 well PCR plate is marked with '1'**. Close the 32 well PCR plate with the provided lids.

101.566-12u/04u – not licensed for PCR

For one HLA-B*39 subtyping, add at room temperature in a 0.5 ml tube:

38 x 2 μl = 76 μl DNA (30 ng/μl)

38 x 3 μl = 114 μl PCR Master Mix without *Taq* – mix well before taking your aliquot

3.0 μl *Taq* polymerase (5 units/μl)

38 x 5 μl – 3.0 μl = 187 μl dH₂O

Mix well, dispense 10 μl of the DNA-PCR Master Mix-*Taq*-H₂O mixture into each of the 32 wells of an HLA-B*39 subtyping. **Well No. 1 of the 32 well PCR plate is marked with '1'**. Close the 32 well PCR plate with the provided lids.

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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:

<i>Taq</i> polymerase	0.4 unit per 10 μ l SSP reaction
nucleotides	final concentration of each dNTP is 200 μ M
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 μ g/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 μ M
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 μ g/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 $+4^{\circ}\text{C}$ for 4 weeks, but the PCR Master Mixes are then no longer stable for 24 months.

SPECIFICITY TABLE

HLA-B*39 SSP subtyping

Specificities and sizes of the PCR products of the 32 primer mixes used for HLA-B*39 SSP subtyping

Primer Mix	Approx. size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*39 alleles ³	Other amplified HLA-Class I alleles ⁴
1 ⁵	230 bp	800 bp	39010101- 39010102L, 390103-3905, 3907-3920, 3922-3929, 3931, 3935, 3937-3941	1569, 380101-3807, 3808 ^{weakly} , 3809, 3811- 3817, 670101-6702
2 ⁵	170 bp	1070 bp	39010101- 39010102L, 390103-390104, 3903-390602, 3907 [?] , 3909, 3911, 3912, 3914, 3915, 3918, 3919, 3922, 3924- 3938Q, 3940N- 3943	1401-1407N, 1509, 1510, 1518, 1523, 1537, 1551, 1552, 1572, 1580, 1590, 1593, 1599, 9508, 9514, 9515, 9519, 9524, 9533, 9534, 380101- 380202, 3804, 3805, 3808-3815, 3817
3	200 bp	1070 bp	3905, 3908, 3911, 391301- 391302, 3920, 3937, 3943	0716, 0727, 0737, 0738, 0750, 0803, 0823, 1503, 1509, 1510, 1518, 1523, 1529, 1537, 1538, 1547, 1549, 1551, 1552, 1554, 1562, 1564, 1568, 1569, 1572, 1574, 1580, 1590, 1591, 1593, 1598, 1599, 9503, 9508, 9514, 9515, 9519, 9523, 9524, 9527, 9531-9534, 180101- 1815, 1817N-1827, 3521, 3524, 3525, 370101-3713, 380101- 380202, 3804-3812, 3815, 3817, 4012, 480101-4819, 5137, 5145, 5302, 5306, 5714,

				5809, 5812
4⁶	145 bp	1070 bp	3926	
5⁶	105 bp	800 bp	39010101- 39010102L, 390103-390201, 3903-3909, 3911, 3912, 3914, 3915, 3918, 3922, 3924-3943	1401-1407N, 3526, 670101
6^{5,7}	170 bp	800 bp	390201-390202, 3908, 391301- 391302, 3923, 3939	0727, 0750, 0804, 0817, 1503, 1547, 1554, 1561, 1562, 1564, 1568, 1569, 1591, 1598, 9503, 9523, 9527, 9531, 9532, 180101-1803, 1805, 1806, 1808-1815, 1817N-1827, 370101- 3713, 3803, 4012, 480101-4805, 4807- 4819
7⁸	165, 220 bp	1070 bp	3903, 3914, 3917, 3924, 3929, 3937	
8	180 bp	1070 bp	3904, 3907 [?]	3526
9⁵	230 bp	800 bp	390601-390602	
10^{5,6,9}	105, 165 bp	800 bp	3907, 3919	1569, 3535, 3582, 5122, 7803
11^{5,6}	160 bp	1070 bp	3908, 3911, 3918, 3933, 3936	1318, 1558, 1573, 5410, 5509, 5521
12	175 bp	800 bp	3907, 3915, 3929	1569, 3535
13^{5,6,10}	80, 215 bp	1070 bp	3909, 3923	
14⁶	80 bp	1070 bp	3910, 3916, 3917, 3920	070201-0707, 0709, 0711, 0712, 0714-0726, 0728-0731, 0733-0735, 0737, 0739-0749N, 0751-0760, 151101- 151103, 1576, 9501, 3576, 4061, 4201, 4202, 4204-4209, 4506, 5401- 5411, 5413, 550101- 5505, 5507-5517, 5519- 5528, 5601-5606, 5609- 5613, 5615-5620,

				670101-670102, 8101-8103, 8201, 8202, 8301
15	190 bp	800 bp	3912, 3931	
16¹¹	165, 225 bp	800 bp	3914, 3916, 3929	
17	180 bp	800 bp	3925N	
18	160 bp	800 bp	390201-390202, 3908, 391301-391302, 3922, 3923	0817, 1503, 1547, 1549, 1554, 1561, 1562, 1568, 1569, 1574, 1591, 1598, 9503, 9523, 9527, 9531, 9532, 1812, 370101-3707, 3709-3713, 3803, 3804, 4012, 480101-4805, 4807-4815, 4817-4819
19¹²	385 bp	1070 bp	39010101-39010102L, 390103-390104, 3903-3907, 3909-3912, 3914-3920, 3924-3942	070201-0712, 0714-0753, 0755-0760, 080101-0809, 0811-0816, 0818-0834, 1401-1407N, 380101-380202, 3805-3817, 4025 [?] , 4068 [?] , 4201, 4202, 4204-4209, 4806, 670101-670102, 7301, 8102
20⁶	100 bp	800 bp	3918, 3927	1569
21	220 bp	800 bp	39010101-39010102L, 390103-390202, 3904, 3905, 3907-391302, 3915, 3917-3920, 3922, 3923, 3925N-3927, 3931, 3935, 3938Q-3941	1569, 380101-3807, 3808 ^{weakly} , 3809, 3811-3817, 670101-6702
22	225 bp	800 bp	3928	
23^{6,7}	85 bp	800 bp	39010101-39010102L, 390103, 390201, 3903, 3904, 390601-390602, 3909, 3912, 3914, 3915, 3918, 3922, 3924-3936,	1401-1407N, 670101

24 ¹²	185 bp	1070 bp	3938Q-3943 39010101- 39010102L, 390103-390201, 3903, 3905- 390602, 3907 [?] , 3908, 3909, 3911, 3914, 3915, 3918, 3922, 3924- 3943	1401, 1407N, 380101- 3803, 3807- 3817, 670101
25	230 bp	1070 bp	39010102L	
26	265 bp	800 bp		1401-1404, 1407N
27 ^{6,13}	80, 185 bp	800 bp	3932, 3938Q	1315, 511301-511302, 5119
28	180 bp	1070 bp	3932, 3933, 3940N	1303, 1558, 1573, 9533, 9537, 3503, 3506, 3513, 3536, 3538, 3555, 3556, 3559, 3570, 3574, 3575, 4071, 4410, 4611, 511301-511302, 5115, 5304, 5403, 5601, 5602, 5604, 5607, 5608, 5611, 5613, 5614, 5616, 5617, 5619N, 5620, 8201, 8202, Cw*1515
29	245 bp	800 bp	390601-390602, 3934	0809, 1542, 1583, 3560, 4101, 4105-4107, 4204, 5121, 5136, 5401, 5402, 5404, 5405N, 5407, 5408N, 5410-5413, 550101-5503, 5505, 5507, 5510-5513, 5515- 5521, 5523, 5525-5528, 5901, 5902
30 ⁶	60 bp	800 bp	3918, 3935	1569
31 ¹²	150 bp	800 bp	3930, 3934, 3943	0748, 0813, 0825, 1301- 1304, 1306-1315, 1317, 1319, 1321, 1505, 1520, 1531, 1552, 1555, 1586, 1591, 9507, 9514, 9523, 9524, 180101-1812, 1814, 1817N, 1818, 1820, 1822-1827, 2701- 2703, 270502-270510, 2707-2709, 2711-2714,

				2716, 2717, 2719, 2723, 2726-2738, 350101- 3507, 350901-3510, 3512, 3513, 3515-3517, 3519-352002, 3522- 3534, 3536, 3537, 3539- 3542, 3546-3557, 3559, 3560, 3563-3565Q, 3568-3572, 3574-3578, 3582, 3583, 3702, 400101-4004, 40060101-401403, 4018-4022N, 4024, 4025, 4027, 4029-4031, 4033-4040, 4042-4050, 4052-4066, 4068-4078, 440301-440303, 4407, 4410, 4413, 4426, 4430- 4432, 4436-4440, 4443, 4445-4447, 4450, 4454, 4457, 4606, 4611, 47010101-4705, 480101-4804, 4806, 4807, 4809-4814, 4816- 4818, 510901-5110, 5115, 5131, 5140, 5142, 5203, 5210, 530101- 5305, 5307, 5309, 5310, 5312, 5313, 5401- 5405N, 5407-5409, 5411-5413, 550201- 550202, 5504, 5507, 5508, 5510, 5512, 5513, 5516, 5518, 5519, 5522, 5523, 5526, 5527, 5601, 5602, 5604, 5607- 5612, 5614-5620, 570101-570103, 570301-570302, 5706- 5708, 5710, 5711, 5714, 5801, 5802, 5804, 5807, 5809-5815, 5901, 5902, 7301, 7804, 8101-8103 3535
32	230 bp	800 bp	3924, 3941, 3942	

¹ Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-B*39 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 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.

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 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-B*39 subtyping.

In addition, tubes number 5, 6, 9, 10, 12, 15 to 18, 20 to 23, 26, 27, 29 to 32 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.

³For many HLA-B alleles complete 4th exon nucleotide sequences are not available. In these instances it is not known whether some of the primers of the SSP sets are completely matched with the target sequences or not. We assume that unknown sequences in the 4th exon are conserved within allelic groups.

The B*3910 and B*670102 alleles will give rise to identical amplification patterns with the HLA-B*39 subtyping kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*67 kits.

⁴Due to the sharing of sequence motifs between HLA-B alleles, non-HLA-B*39 alleles will be amplified by primer mixes 1 to 3, 5 to 8, 10 to 12, 14, 18 to 21, 23, 24, 26 to 32. In addition, the Cw*1515 allele will be amplified by primer mix 28.

⁵The primer pairs in primer mixes 1, 2, 6, 9, 10, 11 and 13 may give rise to a primer oligomer artifact.

⁶Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁷Primer solutions 6 and 23 may yield less specific PCR product than the other HLA-B*39 primer mixes.

⁸Primer solution 7: Specific PCR fragment of 165 bp in the B*3917 allele. Specific PCR fragment of 220 bp in the B*3903, B*3914, B*3924, B*3929 and B*3937 alleles.

⁹Primer solution 10: Specific PCR fragment of 105 bp in the B*3919, B*5122 and B*7803 alleles. Specific PCR fragment of 165 bp in the B*3907, B*1569, B*3535 and B*3582 alleles.

¹⁰Primer solution 13: Specific PCR fragment of 80 bp in the B*3923 allele. Specific PCR fragment of 215 bp in the B*3909 allele.

¹¹Primer solution 16: Specific PCR fragment of 165 bp in the B*3914 and B*3929 alleles. Specific PCR fragment of 225 bp in the B*3916 allele.

¹²Primer mixes 19, 24 and 31 have a tendency of giving rise to non-specific amplifications.

¹³Primer mix 27: Specific PCR fragment of 80 bp in the B*3932 and B*5119 alleles. Specific PCR fragment of 185 bp in the B*3938Q and B*1315 and B*511301-511302 alleles.

'?', nucleotide sequence information not available for the primer matching sequence.

HLA-B*39
101.566-12/04 – licensed for PCR
101.566-12u/04u – not licensed for PCR
Lot No.: **Y49**

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INTERPRETATION TABLE

HLA-B*39 SSP subtyping

Amplification patterns of the B*3901 to 3943 alleles

	Tube ⁵															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec.	230	170	200	145	105	170	165	180	230	105	160	175	80	80	190	165
PCR product							220			165			215			225
Length of int.	800	1070	1070	1070	800	800	1070	1070	800	800	1070	800	1070	1070	800	800
pos. control ¹	800	1070	1070	1070	800	800	1070	1070	800	800	1070	800	1070	1070	800	800
5'-primer(s) ²	355	142	142	419	246	142	363	106	357	206	419	412	368	272	97	360
	5'-CCC ³	5'-TCT ³	5'-TCT ³	5'-gTT ³	5'-gAA ³	5'-TCT ³	5'-AgC ³	5'-CCA ³	5'-Tgg ³	5'-gAC ³	5'-gTT ³	5'-ATg ³	5'-gTC ³	5'-CTA ³	5'-TCg ³	5'-CAC ³
			419		246		420			419			503		97	419
			5'-gTC ³		5'-gAA ³		5'-TTA ³			5'-gTC ³			5'-CCg ³		5'-TCC ³	5'-gTA ³
3'-primer(s) ³	544	272	292	524	311	272	544	246	544	272	539	544	544	311	246	544
	5'-ggT ³	5'-TgC ³	5'-gTA ³	5'-CAA ³	5'-ggT ³	5'-Tgg ³	5'-ggT ³	5'-TAT ³	5'-ggT ³	5'-TgC ³	5'-TCC ³	5'-ggT ³	5'-ggT ³	5'-ggT ³	5'-TAT ³	5'-ggT ³
			292							544						
			5'-gTA ³							5'-ggT ³						
			292													
			5'-gTA ³													
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-B allele ⁴																
*39010101, 390103	+	+			+											
*39010102L	+	+			+											
*390104	+	+			+											
*390201	+				+	+										
*390202	+					+										
*3903	+	+			+		+									
*3904	+	+			+			+								
*3905	+	+	+		+											
*390601-390602		+			+				+							
*3907	+	?			+			?		+		+				
*3908	+		+		+	+					+					
*3909	+	+			+								+			
*3910, 670102 ⁶	+														+	
*3911	+	+	+		+						+					
*3912	+	+			+											+
*391301-391302	+		+			+										
*3914	+	+			+		+									+
*3915	+	+			+							+				
*3916	+													+		+
*3917	+						+							+		
*3918	+	+			+						+					
*3919	+	+								+						
*3920	+		+											+		
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

INTERPRETATION TABLE															
HLA-B*39 SSP subtyping															
Amplification patterns of the B*3901 to 3943 alleles															
Tube⁵															
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
180	160	385	100	220	225	85	185	230	265	80	180	245	60	150	230
800	800	1070	800	800	800	800	1070	1070	800	800	1070	800	800	800	800
407	142	44	246	363	362	246	103	-149	361	419	419	357	527	544	44
5'-ggg ³	5'-TCT ³	5'-ggc ³	5'-gAA ³	5'-Agg ³	5'-gAC ³	5'-gAA ³	5'-CCT ³	5'-ggg ³	5'-AgT ³	5'-gTT ³	5'-gTT ³	5'-Tgg ³	5'-TgA ³	5'-gAg ³	5'-ggC ³
			486							544					355
			5'-ACg ³							5'-gAA ³					5'-TCA ³
															365
															5'-CAC ³
544	259	259	299	544	544	292	246	44	583	563	559	559	544	3 rd	112
5'-ggT ³	5'-CTC ³	5'-gTT ³	5'-TCA ³	5'-ggT ³	5'-ggT ³	5'-gTC ³	5'-TAT ³	5'-CCg ³	5'-gTg ³	5'-CgA ³	5'-CAg ³	5'-CgT ³	5'-ggT ³	5'-TAT ³	5'-CCA ³
			544							583	564				544
			5'-ggT ³							5'-gTg ³	5'-ACT ³				5'-ggT ³
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
Tube No.															
HLA-B allele⁴															
		+		+		+	+								
		+		+		+	+	+							
		+		+		+	+								
	+			+		+	+								
	+			+		+	+								
		+		+		+	+								
		+		+		+	+								
		+		+		+	+								
		+		+		+	+								
		+		+		+	+								
		+		+		+	+								
		+		+		+	+								
		+		+		+	+								
		+	+	+		+	+							+	
		+		+		+	+								
		+		+		+	+								
		+		+		+	+								
		+		+		+	+								
		+		+		+	+								
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
Tube No.															

Length of spec.	230	170	200	145	105	170	165	180	230	105	160	175	80	80	190	165
PCR product							220			165			215			225
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*3922	+	+			+											
*3923	+					+							+			
*3924	+	+			+		+									
*3925N	+	+			+											
*3926	+	+		+	+											
*3927	+	+			+											
*3928	+	+			+											
*3929	+	+			+		+					+				+
*3930		+			+											
*3931	+	+			+										+	
*3932		+			+											
*3933		+			+						+					
*3934		+			+											
*3935	+	+			+											
*3936		+			+						+					
*3937	+	+	+		+		+									
*3938Q	+	+			+											
*3939	+				+	+										
*3940N	+	+			+											
*3941	+	+			+											
*3942		+			+											
*3943		+	+		+											
*070201-0707, 0709, 0711, 0712, 0714, 0715, 0717-0726, 0728-0731, 0733-0735, 0739-0747, 0749N, 0751-0753, 0755-0760, 4201, 4202, 420501-4209															+	
*0708, 0710, 0732, 0736, 080101-0802, 0805-0808N, 0811, 0812, 0814-0816, 0818-0822, 0824, 0826-0834																
*0716			+												+	
*0727, 0750			+			+										
*0737			+												+	
*0738, 0803, 0823			+													
*0748															+	
*0754, 151101-151103, 1576, 9501, 5406, 5603															+	
*0804						+										
*0809																
*0813, 0825, 7301																
*0817, 1561						+										
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

180	160	385	100	220	225	85	185	230	265	80	180	245	60	150	230	Length of spec.
										185						PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.
	+			+		+	+									*3922
	+			+												*3923
		+				+	+								+	*3924
+		+		+		+	+									*3925N
		+		+		+	+									*3926
		+	+	+		+	+									*3927
		+			+	+	+									*3928
		+				+	+									*3929
		+				+	+							+		*3930
		+		+		+	+									*3931
		+				+	+			+	+					*3932
		+				+	+				+					*3933
		+				+	+					+		+		*3934
		+		+		+	+							+		*3935
		+				+	+									*3936
		+				+	+									*3937
		+		+		+	+			+						*3938Q
		+		+		+	+									*3939
		+		+		+	+				+					*3940N
		+		+		+	+								+	*3941
		+				+	+								+	*3942
						+	+							+		*3943
		+														*070201-0707, 0709, 0711, 0712, 0714, 0715, 0717-0726, 0728-0731, 0733-0735, 0739-0747, 0749N, 0751-0753, 0755-0760, 4201, 4202, 420501-4209
		+														*0708, 0710, 0732, 0736, 080101-0802, 0805-0808N, 0811, 0812, 0814-0816, 0818-0822, 0824, 0826-0834
		+														*0716
		+														*0727, 0750
		+														*0737
		+														*0738, 0803, 0823
		+												+		*0748
																*0754, 151101-151103, 1576, 9501, 5406, 5603
		+														*0804
		+										+				*0809
		+												+		*0813, 0825, 7301
	+															*0817, 1561
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.

Length of spec.	230	170	200	145	105	170	165	180	230	105	160	175	80	80	190	165
PCR product							220			165			215			225
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*1301-130204, 1304, 1306-1314, 1317, 1319, 1321, 1505, 1520, 1531, 1555, 1586, 9507, 2701-2703, 270502-270510, 2707-2709, 2711-2714, 2716, 2717, 2719, 2723, 2726-2738, 350101-350202, 350401-3505, 3507, 350901-3510, 3512, 3515-3517, 3519-352002, 3522, 3523, 3527-3534, 3537, 3539-3542, 3546-3554, 3557, 3563-3565Q, 3568, 3569, 3571, 3572, 3577, 3578, 3583, 400101-4004, 40060101-4011, 4013-401403, 4018-4022N, 4024, 4027, 4029-4031, 4033-4040, 4042-4050, 4052-4060, 4062-4066, 4069, 4070, 4072-4078																
*440301-440303, 4407, 4413, 4426, 4430-4432, 4436-4440, 4443, 4445-4447, 4450, 4454, 4457, 4606, 47010101-4705, 510901-5110, 5131, 5140, 5142, 5203, 5210, 530101-530104, 5303, 5305, 5307, 5309, 5310, 5312, 5313, 570101-570103, 570301-570302, 5706-5708, 5710, 5711, 5801, 5802, 5804, 5807, 5810N, 5811, 5813-5815, 7804																
*1303, 3503, 3506, 3513, 3536, 3555, 3556, 3559, 3570, 3574, 3575, 4071, 4410, 4611, 5115, 5304, 5607, 5608, 5614																
*1315																
*1318											+					
*1401, 1407N		+			+											
*140201-1404		+			+											
*1405-140602		+			+											
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

180	160	385	100	220	225	85	185	230	265	80	180	245	60	150	230	Length of spec.
										185						PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.
														+		*1301-130204, 1304, 1306-1314, 1317, 1319, 1321, 1505, 1520, 1531, 1555, 1586, 9507, 2701-2703, 270502-270510, 2707-2709, 2711-2714, 2716, 2717, 2719, 2723, 2726-2738, 350101-350202, 350401-3505, 3507, 350901-3510, 3512, 3515-3517, 3519-352002, 3522, 3523, 3527-3534, 3537, 3539-3542, 3546-3554, 3557, 3563-3565Q, 3568, 3569, 3571, 3572, 3577, 3578, 3583, 400101-4004, 40060101-4011, 4013-401403, 4018-4022N, 4024, 4027, 4029-4031, 4033-4040, 4042-4050, 4052-4060, 4062-4066, 4069, 4070, 4072-4078
														+		*440301-440303, 4407, 4413, 4426, 4430-4432, 4436-4440, 4443, 4445-4447, 4450, 4454, 4457, 4606, 47010101-4705, 510901-5110, 5131, 5140, 5142, 5203, 5210, 530101-530104, 5303, 5305, 5307, 5309, 5310, 5312, 5313, 570101-570103, 570301-570302, 5706-5708, 5710, 5711, 5801, 5802, 5804, 5807, 5810N, 5811, 5813-5815, 7804
											+			+		*1303, 3503, 3506, 3513, 3536, 3555, 3556, 3559, 3570, 3574, 3575, 4071, 4410, 4611, 5115, 5304, 5607, 5608, 5614
										+				+		*1315
																*1318
		+				+	+		+							*1401, 1407N
		+				+			+							*140201-1404
		+				+										*1405-140602
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.

Length of spec.	230	170	200	145	105	170	165	180	230	105	160	175	80	80	190	165
PCR product							220			165			215			225
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*1503, 1547, 1554, 1562, 1568, 9527, 9531, 9532			+			+										
*1509, 1510, 1518, 1523, 1537, 1551, 1572, 1580, 1590, 1593, 1599, 9508, 9515, 9519, 9534		+	+													
*1529, 1538, 3521, 5137, 5145, 5306			+													
*1542, 1583, 4101, 4105-4107, 5121, 5136																
*1549, 1574			+													
*1552, 9514, 9524		+	+													
*1558, 1573											+					
*1564, 1813, 1815, 1819, 1821, 3708			+			+										
*1569	+		+			+				+		+				
*1591, 9523, 1812, 3702, 4012, 480101-4804, 4807, 4809-4814, 4817, 4818			+			+										
*1598, 9503, 370101-370104, 3703N-3707, 3709-3713, 4805, 4808, 4815, 4819			+			+										
*9533		+	+													
*9537, 3538																
*180101-1803, 1805, 1806, 1808-1811, 1814, 1817N, 1818, 1820, 1822-1827, 4816			+			+										
*1804, 1807, 3524, 3525, 5302, 5714, 5809, 5812			+													
*3526					+			+								
*3535										+		+				
*3560, 5412, 5518, 5901, 5902																
*3576, 4061, 5409, 5504, 5508, 5522, 5609, 5610, 5612, 5615, 5618, 8101, 8103															+	
*3582										+						
*380101-380202, 3809, 3811, 3812, 3815, 3817	+	+	+													
*3803	+					+										
*3804	+	+	+													
*3805	+	+	+													
*3806	+		+													
*3807	+		+													
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

180	160	385	100	220	225	85	185	230	265	80	180	245	60	150	230	Length of spec.
										185						PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.
	+															*1503, 1547, 1554, 1562, 1568, 9527, 9531, 9532
																*1509, 1510, 1518, 1523, 1537, 1551, 1572, 1580, 1590, 1593, 1599, 9508, 9515, 9519, 9534
																*1529, 1538, 3521, 5137, 5145, 5306
												+				*1542, 1583, 4101, 4105-4107, 5121, 5136
	+															*1549, 1574
														+		*1552, 9514, 9524
											+					*1558, 1573
																*1564, 1813, 1815, 1819, 1821, 3708
	+		+	+									+			*1569
	+													+		*1591, 9523, 1812, 3702, 4012, 480101-4804, 4807, 4809-4814, 4817, 4818
	+															*1598, 9503, 370101-370104, 3703N-3707, 3709-3713, 4805, 4808, 4815, 4819
											+					*9533
											+					*9537, 3538
														+		*180101-1803, 1805, 1806, 1808-1811, 1814, 1817N, 1818, 1820, 1822-1827, 4816
														+		*1804, 1807, 3524, 3525, 5302, 5714, 5809, 5812
														+		*3526
															+	*3535
												+		+		*3560, 5412, 5518, 5901, 5902
														+		*3576, 4061, 5409, 5504, 5508, 5522, 5609, 5610, 5612, 5615, 5618, 8101, 8103
														+		*3582
		+		+			+									*380101-380202, 3809, 3811, 3812, 3815, 3817
	+			+			+									*3803
	+			+												*3804
		+		+												*3805
		+		+												*3806
		+		+			+									*3807
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.

Length of spec.	230	170	200	145	105	170	165	180	230	105	160	175	80	80	190	165
PCR product							220			165			215			225
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*3808	W	+	+													
*3810		+	+													
*3813, 3814	+	+														
*3816	+															
*4025, 4068																
*4204														+		
*4506, 5514, 5524, 560501-5606, 8301														+		
*4806			+													
*511301-511302																
*5119																
*5122, 7803										+						
*5401, 5402, 5404, 5405N, 5407, 5408N, 5411, 5413, 550201-550202, 5507, 5510, 5512, 5513, 5516, 5519, 5523, 5526, 5527														+		
*5403, 5601, 5602, 5604, 5611, 5616, 5617, 5619N, 5620														+		
*5410, 5521											+			+		
*550101-550104, 5503, 5505, 5511, 5515, 5517, 5520, 5525, 5528														+		
*5509											+			+		
*5613, 8201, 8202														+		
*670101	+				+									+		
*6702	+													+		
*8102														+		
HLA-B allele ⁴																
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Cw*1515																
Tube No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

HLA-B*39
 101.566-12/04 – licensed for PCR
 101.566-12u/04u – not licensed for PCR
 Lot No.: **Y49**

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180	160	385	100	220	225	85	185	230	265	80	180	245	60	150	230	Length of spec.
										185						PCR product
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.
		+		W			+									*3808
		+					+									*3810
		+		+			+									*3813, 3814
		+		+			+									*3816
		?												+		*4025, 4068
		+										+				*4204
																*4506, 5514, 5524, 560501-5606, 8301
		+												+		*4806
										+	+					*511301-511302
										+						*5119
																*5122, 7803
												+		+		*5401, 5402, 5404, 5405N, 5407, 5408N, 5411, 5413, 550201-550202, 5507, 5510, 5512, 5513, 5516, 5519, 5523, 5526, 5527
											+			+		*5403, 5601, 5602, 5604, 5611, 5616, 5617, 5619N, 5620
												+				*5410, 5521
												+				*550101-550104, 5503, 5505, 5511, 5515, 5517, 5520, 5525, 5528
																*5509
											+					*5613, 8201, 8202
		+		+		+	+									*670101
				+												*6702
		+												+		*8102
																HLA-B allele ⁴
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.
											+					Cw*1515
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Tube No.

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 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-B*39 subtyping. .

In addition, tubes number 5, 6, 9, 10, 15 to 18, 20 to 23, 26, 27, 29 to 32 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.

²The nucleotide position, in the 1st, 2nd or 3rd exon or 5' untranslated region 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.

³The nucleotide position, in the 1st, 2nd or 3rd exon or 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.

⁴The nucleotide sequence of the B*390102 allele has been shown to be identical B*390101.

The nucleotide sequence of the B*3921 allele has been shown to be identical B*3924.

⁵Primer solution 7: Specific PCR fragment of 165 bp in the B*3917 allele. Specific PCR fragment of 220 bp in the B*3903, B*3914, B*3924, B*3929 and B*3937 alleles.

Primer solution 10: Specific PCR fragment of 105 bp in the B*3919, B*5122 and B*7803 alleles.

Specific PCR fragment of 165 bp in the B*3907, B*1569, B*3535 and B*3582 alleles.

Primer solution 13: Specific PCR fragment of 80 bp in the B*3923 allele. Specific PCR fragment of 215 bp in the B*3909 allele.

Primer solution 16: Specific PCR fragment of 165 bp in the B*3914 and B*3929 alleles. Specific PCR fragment of 225 bp in the B*3916 allele.

Primer mix 27: Specific PCR fragment of 80 bp in the B*3932 and B*5119 alleles. Specific PCR fragment of 185 bp in the B*3938Q and B*1315 and B*511301-511302 alleles.

⁶The B*3910 and B*670102 alleles will give rise to identical amplification patterns with the HLA-B*39 subtyping kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*67 kits.

'w', might be weakly amplified.

'?', nucleotide sequence information not available for the primer matching sequence.

CELL LINE VALIDATION SHEET																					
HLA-B*39 SSP subtyping kit																					
				Prod. No.:	Tube																
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	
					200511201	200511202	200740103	200511204	200740105	200625106	200511207	200511208	200511209	200625110	200740111	200740112	200511213	200511214	200511215	200740116	
	cell line		B*																		
1	9001 SA		*0702		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707		*5201	*7301	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324		*52011		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373		*1510	*5301	-	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011		*3701		-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM		*3901	*5101	+	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL		*1801		-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-
8	9007 DEM		*5701		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR		*3801		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3		*5401		-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
11	9051 PITOUT		*440301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB		*5701		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9067 BTB		*270502		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA		*1501	*1520	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB		*4001		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007		*4002		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9008 WILJON		*1801		-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367		*1401	*5601	-	+	-	-	+	-	-	-	-	-	-	-	-	+	-	-	-
19	9038 BM16		*1801		-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005		*4001		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA		*1501		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE		*3503		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL		*4002	*5602	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
24	9035 JBUSH		*3801		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9		*1402		-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49		*5801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007		*0705	*5101	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
28	9320 BEL5GB		*4402	*4403	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU		*440301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH		*4201		-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-	-
31	9019 DUCAF		*1801		-	-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG		*4102		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B		*4001		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF		*3801		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO		*4402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17		*1501	*3501	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
37	9065 HHKB		*0702		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
38	9099 LZL		*1501		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
39	9315 CML		*0801	*2705	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199		*1302	*4601	-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
41	9055 H0301		*1402		-	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089		*4601		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
43	9076 T7526		*4601		-	-	-	-	-	-	-	-	-	-	+	-	-	-	-	-	-
44	9057 TEM		*3801		+	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO		*4201	*5001	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
46	9013 SCHU		*0702		-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-	-
47	9045 TUBO		*5101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND		*3501	*4403	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

CELL LINE VALIDATION SHEET																					
HLA-B*39 SSP subtyping kit																					
				Prod. No.:	Tube																
					17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
					200740117	200511218	200625119	200511220	200740121	200511222	200511223	200511224	200511225	200511226	200625127	200625128	200511229	200511230	200511231	200740132	
	cell line		B*																		
1	9001 SA		*0702		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707		*5201	*7301	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324		*52011		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373		*1510	*5301	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
5	9009 KAS011		*3701		-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM		*3901	*5101	-	-	+	-	+	-	+	+	-	-	-	-	-	-	-	-	-
7	9020 QBL		*1801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
8	9007 DEM		*5701		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
9	9026 YAR		*3801		-	-	+	-	+	-	-	+	-	-	-	-	-	-	-	-	-
10	9107 LKT3		*5401		-	-	-	-	-	-	-	-	-	-	-	-	+	-	+	-	-
11	9051 PITOUT		*440301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
12	9052 DBB		*5701		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
13	9067 BTB		*270502		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
14	9071 OLGA		*1501	*1520	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
15	9075 DKB		*4001		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
16	9037 SWEIG007		*4002		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
17	9008 WILJON		*1801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
18	9257 32367		*1401	*5601	-	-	+	-	-	-	+	+	-	+	-	+	-	-	+	-	-
19	9038 BM16		*1801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
20	9059 SLE005		*4001		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
21	9064 AMALA		*1501		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE		*3503		-	-	-	-	-	-	-	-	-	-	-	+	-	-	+	-	-
23	9124 IHL		*4002	*5602	-	-	-	-	-	-	-	-	-	-	-	+	-	-	+	-	-
24	9035 JBUSH		*3801		-	-	+	-	+	-	-	+	-	-	-	-	-	-	-	-	-
25	9049 IBW9		*1402		-	-	+	-	-	-	+	-	-	+	-	-	-	-	-	-	-
26	9285 WT49		*5801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
27	9191 CH1007		*0705	*5101	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB		*4402	*4403	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
29	9050 MOU		*440301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
30	9021 RSH		*4201		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF		*1801		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
32	9297 HAG		*4102		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B		*4001		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
34	9104 DHIF		*3801		-	-	+	-	+	-	-	+	-	-	-	-	-	-	-	-	-
35	9302 SSTO		*4402		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17		*1501	*3501	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
37	9065 HHKB		*0702		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL		*1501		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML		*0801	*2705	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	+	-
40	9134 WHONP199		*1302	*4601	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-
41	9055 H0301		*1402		-	-	+	-	-	-	+	-	-	+	-	-	-	-	-	-	-
42	9066 TAB089		*4601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526		*4601		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM		*3801		-	-	+	-	+	-	-	+	-	-	-	-	-	-	-	-	-
45	9239 SHJO		*4201	*5001	-	-	+	-	-	-	-	-	-	-	-	+	-	-	-	-	-
46	9013 SCHU		*0702		-	-	+	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO		*5101		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND		*3501	*4403	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+	-

CERTIFICATE OF ANALYSIS

Olerup SSP™ HLA-B*39 SSP

Product number: 101.566-12/04 – licensed for PCR
101.566-12u/04u – not licensed for PCR
Lot number: Y49
Expiry date: 2009-October-01
Number of tests: 12 tests – Product No. 101.566-12
4 tests – Product No. 101.566-04
Number of tubes per test: 32

Tube specifications:

Tube No.	Production No.	Tube No.	Production No.	Tube No.	Production No.
1	2005-112-01	13	2005-112-13	25	2005-112-25
2	2005-112-02	14	2005-112-14	26	2005-112-26
3	2007-401-03	15	2005-112-15	27	2006-251-27
4	2005-112-04	16	2007-401-16	28	2006-251-28
5	2007-401-05	17	2005-112-17	29	2005-112-29
6	2006-251-06	18	2005-112-18	30	2005-112-30
7	2005-112-07	19	2006-251-19	31	2005-112-31
8	2005-112-08	20	2005-112-20	32	2007-401-32
9	2005-112-09	21	2007-401-21		
10	2006-251-10	22	2005-112-21		
11	2007-401-11	23	2005-112-23		
12	2007-401-12	24	2005-112-24		

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

No DNAs carrying the alleles to be amplified by primer solutions 4, 7, 8, 10, 13, 15, 16, 17, 20, 22, 25, 27, 30 and 32 were available. The specificities of the primers in primer solutions 7, 8, 10, 15, 20, 27 and 30 were tested by separately adding one or two additional 5'-primer(s), respectively one or two additional 3'-primer(s). In primer solution 4 it was only possible to the 5'-primer, the 3'-primer was not possible to test. In primer solutions 17, 22, 25 and 32 it was only possible to the 3'-primers, the 5'-primers were not possible to test. In primer solutions 13 and 16 one of the 5'-primers was not possible to test. Additional 3'-primer in primer solutions 11 was not possible to test.

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

Date of approval: 2007-December-21

Approved by:

Quality Control, Supervisor

Declaration of Conformity

Product name: Olerup SSP™ HLA-B*39
Product number: 101.566-12/04, 101.566-12u/04u
Lot number: Y49

Intended use: HLA-B*39 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 II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at Olerup SSP AB, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

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

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

Saltsjöbaden, Sweden
2007-December-21

Olle Olerup
Managing Director

HLA-B*39
101.566-12/04 – licensed for PCR
101.566-12u/04u – not licensed for PCR
Lot No.: **Y49**

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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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PCRTM is a trademark of F. Hoffmann-La Roche Ltd.
ARMSTM is a trademark of Zeneca Ltd.

HLA-B*39
101.566-12/04 – licensed for PCR
101.566-12u/04u – not licensed for PCR
Lot No.: **Y49**

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