

Olerup SSP[®] HLA-B*41

Product number:	101.542-06u – without <i>Taq</i> polymerase
Lot number:	43M
Expiry date:	2014-January-01
Number of tests:	6
Number of wells per test:	16
Storage - pre-aliquoted primers:	dark at -20°C
- PCR Master Mix:	-20°C
- Adhesive PCR seals	RT
- Product Insert	RT

This Product Description is only valid for Lot No. 43M.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-B*41 LOT.

The HLA-B*41 specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP*[®] HLA-B*41 lot was made (**Lot No. 68K**).

The amplification patterns for some rare HLA-B*41 alleles only differ by the length of the specific PCR products.

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

Well	5'-primer	3'-primer	rationale
14	Modified	-	Improved specificity of primer pair.

Change in revision R01 compared to R00:

1. The following alleles are amplified by primer mix 14: HLA-B*08:09, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20 and 56:13. This has been corrected in the Specificity and Interpretation Tables.

HLA-B*41
101.542-06u – without *Taq* polymerase

Product Insert

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General “Instructions for Use”
IFU-02 can be downloaded from

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Lot-specific information

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PRODUCT DESCRIPTION

HLA-B*41 SSP typing

CONTENT

The primer set contains 5'- and 3'-primers for identifying the B*41:01 to B*41:16 alleles.

PLATE LAYOUT

Each HLA-B*41 test consists of 16 PCR reactions in a 16 well cut PCR plate.

1	2	3	4	5	6	7	8
9	10	11	12	13	14	15	16

The 16 well PCR plate is marked with 'HLA-B*41' in silver/gray ink.

Well No. 1 with the Lot No. '43M'.

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded.

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

Please note: When removing each 16 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

The interpretation of HLA-B*41 SSP subtypings will be influenced by seven B*07, most B*08, most B*13, two B*14, several B*15, most B*18, ten B*27, several B*35, the B*37, the B*38:19, twelve B*39, most B*40, the B*42, ten B*44, the B*45, three B*46, four B*48, the B*49, the B*50, most B*51, the B*52, two B*53, the B*54, most B*55, most B*56, three B*58, the B*59, the B*73 and the B*78 alleles when present on the other haplotype. In addition, the C*07:04:03 allele will be amplified by primer mix 12 and the C*03:05, C*03:25, C*03:27 and C*08:08 alleles will be amplified by primer mix 16.

UNIQUELY IDENTIFIED ALLELES

All the HLA-B*41¹, i.e. **B*41:01 to B*41:16** recognized by the HLA Nomenclature Committee in October 2010² will be amplified by the primers in the HLA-B*41 SSP kit.

The HLA-B*41 subtyping kit cannot distinguish the B*41:02:01-41:02:03 alleles.

The B*41:07 and 41:12 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 4.

¹The 41:08 and 40:136 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*40 kits.

The B*41:09 and 45:08 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*45 kits.

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The 41:15 and 37:09 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*37 kits.

²HLA-B alleles listed on the IMGT/HLA web page 2010-October-15, release 3.2.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 21 alleles generate 16 amplification patterns that can be combined in 136 homozygous and heterozygous combinations. 53 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products were not considered in these calculations.

++-+-++	-++-+-	*41:04, *41:16 = *41:07, *41:13
++-+-++	-++-+-	*41:04, *41:14 = *41:07, *41:11
++-+-++	-++-+-	*41:01, *41:04 = *41:02:01, *41:07 = *41:04, *41:07
++-+-++	-++-+-	*41:11, *41:16 = *41:13, *41:14
++-+-++	-++-+-	*41:01, *41:13 = *41:02:01, *41:16 = *41:13, *41:16
++-+-++	-++-+-	*41:01, *41:11 = *41:02:01, *41:14 = *41:11, *41:14
++-+-++	-++-+-	*41:01, *41:07 = *41:07, *41:07
++-+-++	-++-+-	*41:01, *41:05 = *41:05, *41:05
++-+-++	-++-+-	*41:01, *41:16 = *41:16, *41:16
++-+-++	-++-+-	*41:01, *41:14 = *41:14, *41:14
-++-+-	-++-+-	*41:03:01, *41:04 = *41:04, *41:10
-++-+-	-++-+-	*41:03:01, *41:13 = *41:10, *41:13
-++-+-	-++-+-	*41:03:01, *41:11 = *41:10, *41:11
-++-+-	-++-+-	*41:03:01, *41:15 = *41:10, *41:15
-++-+-	-++-+-	*41:02:01, *41:03:01 = *41:02:01, *41:10 = *41:03:01, *41:10 =
-++-+-	-++-+-	*41:03:02, *41:10 = *41:10, *41:10
-++-+-	-++-+-	*41:02:01, *41:04 = *41:03:02, *41:04 = *41:04, *41:04
-++-+-	-++-+-	*41:02:01, *41:13 = *41:03:02, *41:13 = *41:13, *41:13
-++-+-	-++-+-	*41:02:01, *41:11 = *41:03:02, *41:11 = *41:11, *41:11
-++-+-	-++-+-	*41:02:01, *41:15 = *41:03:02, *41:15
-++-+-	-++-+-	*41:02:01, *41:02:01 = *41:02:01, *41:03:02
-++-+-	-++-+-	*41:03:01, *41:03:01 = *41:03:01, *41:03:02
-++-+-	-++-+-	*41:06, *41:09 = *41:09, *41:09

*41:02:01 = *41:02:01-41:02:03

*41:07 = *41:07 and 41:12

SPECIFICITY TABLE

HLA-B*41 SSP subtyping

Specificities and sizes of the PCR products of the 16 primer mixes used for HLA-B*41 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-B*41 alleles ³	Other amplified HLA Class I alleles ⁴
1	285 bp	800 bp	*41:01, 41:05, 41:07, 41:12, 41:14, 41:16	*08:09, 42:04, 55:20
2	215 bp	1070 bp	*41:02:01-41:02:03, 41:04, 41:10-41:11, 41:13, 41:15	*07:04, 07:19, 07:25, 08:01:01-08:05, 08:07-08:08N, 08:10-08:11, 08:14-08:15, 08:17-08:19N, 08:21-08:24, 08:26-08:39, 08:41-08:48, 08:50-08:54, 08:56-08:59, 08:61-08:66, 35:87, 37:09, 42:01:01-42:02, 42:05:01-42:12, 42:14, 44:106
3^{5,6}	80 bp	1070 bp	*41:03:01, 41:10	
4^{5,8}	90 bp, 265 bp	800 bp	*41:04, 41:07, 41:12	*15:46, 15:106, 35:47, 40:10:01-40:10:02, 53:15, 55:20
5	255 bp	1070 bp	*41:05	
6	220 bp	1070 bp	*41:01, 41:05-41:07, 41:09, 41:12, 41:14, 41:16	*08:09, 15:83, 42:04, 44:15, 44:18, 44:20, 44:100, 45:01-45:13, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 56:13
7⁷	295 bp	800 bp	*41:06, 41:09	*13:02:01-13:04, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:30-13:35, 13:37-13:38, 13:40, 15:04, 15:16:01, 15:42, 15:67, 15:83, 15:95, 15:137, 15:155, 27:14, 35:37, 35:60, 39:06:01-39:06:02, 39:33-39:34, 39:50, 39:57, 39:62, 40:06:01:01-40:06:03, 40:44, 40:53, 40:70, 40:75, 40:83, 40:86, 40:93, 40:95-40:96, 40:103, 40:109-40:110, 40:127, 40:131, 40:148, 44:15, 44:18, 44:20, 44:47, 44:100, 45:01-45:13,

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				46:11, 46:18, 49:01:01-49:15, 50:01:01-50:02, 50:04-50:11, 51:01:01-51:03, 51:05, 51:07:01-51:24:04, 51:26- 51:41N, 51:43-51:44N, 51:48- 51:55, 51:57-51:58, 51:60- 51:61, 51:63, 51:65-51:80, 51:82-51:95, 51:97-51:106, 52:01:01:01-52:22, 54:01:01- 54:05N, 54:07-54:08N, 54:10- 54:23, 55:01:01-55:03, 55:05, 55:07, 55:09-55:13, 55:15- 55:19, 55:21-55:48, 56:01:01- 56:01:04, 56:05:01-56:08, 56:13-56:17, 56:19N-56:30, 58:08, 59:01:01:01-59:05, 73:01-73:02, 78:01-78:07
8^{6,7}	215 bp	1070 bp	*41:01-41:16	*13:23, 15:71, 15:175, 15:204, 18:01:01-18:03, 18:05-18:06, 18:08-18:15, 18:17N-18:24, 18:26-18:28, 18:30-18:32, 18:34-18:42, 18:44-18:52, 27:18, 27:29, 35:63, 37:01:01- 37:20, 37:22-37:25, 40:01:01- 40:02:02, 40:02:04-40:06:03, 40:09, 40:11:01-40:11:02, 40:14:01-40:16, 40:18-40:20, 40:22N-40:39, 40:42-40:48, 40:50-40:57, 40:59-40:60, 40:62-40:67, 40:69-40:74, 40:76-40:102, 40:104-40:105, 40:107-40:109, 40:111-40:128, 40:130-40:136, 40:138-40:158, 44:15, 44:18, 44:55, 44:103, 45:01-45:05, 45:07-45:13, 48:22, 49:01:01-49:09, 49:11- 49:15, 50:01:01-50:02, 50:04- 50:12
9^{5,6}	105 bp	1070 bp	*41:08	*07:04, 07:25, 40:136, 42:05:01-42:05:02
10⁵	105 bp	800 bp	*41:01-41:05, 41:07, 41:10- 41:14, 41:16	*08:01:01-08:05, 08:07- 08:12:03, 08:14-08:19N, 08:21-08:24, 08:26-08:30N, 08:32-08:39, 08:41-08:42, 08:44-08:54, 08:56-08:66, 35:87, 42:01:01-42:02, 42:04,

				42:06-42:07, 42:09-42:13, 55:20
11	245 bp	800 bp	*41:01, 41:05- 41:07, 41:09, 41:12, 41:14, 41:16	*08:09, 15:42, 15:83, 35:60, 39:06:01-39:06:02, 39:34, 39:57, 39:62, 42:04, 45:08, 46:18, 51:21, 51:36, 51:101, 54:01:01-54:02, 54:04-54:05N, 54:07-54:08N, 54:10-54:23, 55:01:01-55:03, 55:05, 55:07, 55:10-55:13, 55:15-55:21, 55:23, 55:25-55:48, 56:23, 59:01:01:01-59:03, 59:05, 78:07
12	210 bp	1070 bp	*41:02:01- 41:04, 41:08, 41:10-41:11, 41:13, 41:15	*07:04, 07:19, 07:25, 08:01:01- 08:05, 08:07-08:08N, 08:10- 08:12:02, 08:14-08:19N, 08:21-08:24, 08:26, 08:28- 08:32, 08:34-08:39, 08:41- 08:48, 08:50-08:54, 08:56- 08:59, 08:61-08:66, 15:51, 15:179, 15:199, 35:87, 37:09, 37:12, 40:136, 42:01:01-42:02, 42:05:01-42:12, 42:14, 44:41:01, 44:106, C*07:04:03
13	285 bp	1070 bp	*41:09	*13:02:01-13:04, 13:08Q- 13:09, 13:14-13:16, 13:18- 13:19, 13:27, 13:30-13:35, 13:37-13:38, 13:40, 15:04, 15:16:01, 15:42, 15:67, 15:83, 15:95, 15:137, 15:155, 27:14, 35:37, 35:60, 39:06:01- 39:06:02, 39:33-39:34, 39:50, 39:57, 39:62, 40:06:01:01- 40:06:03, 40:44, 40:53, 40:70, 40:75, 40:83, 40:86, 40:93, 40:95-40:96, 40:103, 40:109- 40:110, 40:127, 40:131, 40:148, 44:15, 44:18, 44:20, 44:47, 44:100, 45:01-45:13, 46:11, 46:18, 49:01:01-49:13, 49:15, 50:01:01-50:02, 50:04- 50:11, 51:01:01-51:03, 51:05, 51:07:01-51:24:04, 51:26- 51:41N, 51:43-51:44N, 51:48- 51:55, 51:57-51:58, 51:60- 51:61, 51:63, 51:65-51:80, 51:82-51:95, 51:97-51:106, 52:01:01:01-52:22, 54:01:01-

				54:05N, 54:07-54:08N, 54:10-54:23, 55:01:01-55:03, 55:05, 55:07, 55:09-55:13, 55:15-55:19, 55:21-55:48, 56:01:01-56:01:04, 56:05:01-56:08, 56:13-56:17, 56:19N-56:30, 58:08, 59:01:01:01-59:05, 73:01-73:02, 78:01-78:07
14^{5,9}	115 bp, 215 bp	1070 bp	*41:13, 41:16	*08:09, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20, 56:13
15¹⁰	155 bp, 375 bp	800 bp	*41:11, 41:14	*13:30, 40:79
16	290 bp	1070 bp	*41:15	*07:33, 07:53, 07:60, 07:100, 14:05, 14:13, 15:07:01-15:07:02, 15:45, 15:55, 15:68, 15:126, 15:207, 18:14, 27:07, 27:11, 27:24, 27:32-27:34, 27:43, 35:05:01-35:05:02, 35:22, 35:31, 35:51, 35:58, 35:72, 35:89, 35:97, 35:114, 37:09, 38:19, 39:03, 39:14, 39:24:01, 39:29, 39:37, 40:02:01-40:03, 40:05, 40:08-40:09, 40:13, 40:18-40:19, 40:24, 40:27:01, 40:29, 40:35, 40:37, 40:39-40:40, 40:50, 40:56-40:58, 40:71, 40:78, 40:82, 40:85, 40:89-40:91, 40:94, 40:97, 40:104-40:105, 40:107, 40:111, 40:115, 40:119, 40:122, 40:133Q, 40:142N-40:145, 40:157, 42:08, 42:14, 44:54, 44:106, 46:12, 48:04, 48:13, 48:24, 51:64, 51:81, 53:14, 55:04, 58:18, 58:27, C*03:05, C*03:25, C*03:27, C*08:08

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-B*41 SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

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PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*41 subtyping.

In addition, wells number 4, 7, 10, 11 and 15 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

In the presence of a specific amplification the intensity of the control band often decreases.

³The B*41:07 and 41:12 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 4.

⁴Due to the sharing of sequence motifs between HLA-B alleles some non-HLA-B*41 alleles will be amplified by primer mixes 1, 2, 4, 6 to 13, 15 and 16. In addition, the C*07:04:03 allele will be amplified by primer mix 12 and the C*03:05, C*03:25, C*03:27 and C*08:08 alleles will be amplified by primer mix 16.

The 41:08 and 40:136 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*40 kits.

The B*41:09 and 45:08 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*45 kits.

The 41:15 and 37:09 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*37 kits.

⁵Short specific PCR fragments are less intense and not as sharp as longer specific bands.

⁶Primer mixes 3, 8 and 9 may give rise to nonspecific amplifications.

⁷Primer mixes 7 and 8 have tendencies of giving rise to primer oligomer artefacts.

⁸Primer mix 4: Specific PCR fragment of 90 bp in the B*41:12 and the B*15:46, 15:106, 35:47 and 40:10:01-40:10:02 alleles. Specific PCR fragment of 265 bp in the B*41:04 and 41:07 and in the B*53:15 and 55:20 alleles.

⁹Primer mix 14: Specific PCR fragment of 115 bp in the B*41:13 allele. Specific PCR fragment of 215 bp in the B*41:16 and the B*08:09, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20 and 56:13 alleles.

¹⁰Primer mix 15: Specific PCR fragment of 155 bp in the B*41:11 and the B*13:30 alleles. Specific PCR fragment of 375 bp in the B*41:14 and the B*40:79 alleles.

INTERPRETATION TABLE								
HLA-B*41 SSP subtyping								
Amplification patterns of the HLA-B*41:01 to B*41:16 alleles								
	Well⁸							
	1	2	3	4	5	6	7	8
Length of spec.	285	215	80	90	255	220	295	215
PCR product(s)				265				
Length of int.	800	1070	1070	800	1070	1070	800	1070
pos. control ¹								
5'-primer ²	357	363	97	144	97	357	357	97
	5'-Tgg ^{3'}	5'-AgC ^{3'}	5'-TCC ^{3'}	5'-gCA ^{3'}	5'-TCC ^{3'}	5'-Tgg ^{3'}	5'-Tgg ^{3'}	5'-TCC ^{3'}
			363	379				
			5'-AgC ^{3'}	5'-ACC ^{3'}				
3'-primer ³	603	538	126	193	312	538	610	272
	5'-gTg ^{3'}	5'-gTC ^{3'}	5'-TCT ^{3'}	5'-CgT ^{3'}	5'-AgC ^{3'}	5'-gTC ^{3'}	5'-CTg ^{3'}	5'-Tgg ^{3'}
			407	603				
			5'-gCT ^{3'}	5'-gTg ^{3'}				
Well No.	1	2	3	4	5	6	7	8
HLA-B allele								
*41:01	1					6		8
*41:02:01-41:02:03		2						8
*41:03:01			3					8
*41:03:02								8
*41:04		2		4				8
*41:05	1				5	6		8
*41:06						6	7	8
*41:07, 41:12 ⁴	1			4		6		8
*41:08, 40:136 ⁵								8
*41:09, 45:08 ⁶						6	7	8
*41:10		2	3					8
*41:11		2						8
*41:13		2						8
*41:14	1					6		8
*41:15, 37:09 ⁷		2						8
*41:16	1					6		8
Well No.	1	2	3	4	5	6	7	8

INTERPRETATION TABLE							
HLA-B*41 subtyping							
Amplification patterns of the HLA-B*41:01 to B*41:16 alleles							
Well ⁸							
9	10	11	12	13	14	15	16
105	105	245	210	285	115	155	290
					215	375	
1070	800	800	1070	1070	1070	800	1070
540	540	357	369	357	366	160	363
5'-gAC 3'	5'-gAC 3'	5'-Tgg 3'	5'-TAC 3'	5'-Tgg 3'	5'-ATT 3'	5'-ACT 3'	5'-AgC 3'
					463	322	
					5'-TgT 3'	5'-gCC 3'	
605	603	559	538	603	538	272	610
5'-gCT 3'	5'-gTg 3'	5'-CgT 3'	5'-gTC 3'	5'-gTC 3'	5'-gTC 3'	5'-Tgg 3'	5'-CTg 3'
						412	
						5'-gTT 3'	
9	10	11	12	13	14	15	16
Well No.							
HLA-B allele							
	10	11					
	10		12				
	10		12				
	10		12				
	10		12				
	10	11					
		11					
	10	11					
9			12				
		11		13			
	10		12				
	10		12			15	
	10		12		14		
	10	11				15	
			12				16
	10	11			14		
9	10	11	12	13	14	15	16
Well No.							

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Length of spec.	285	215	80	90	255	220	295	215
PCR product(s)				265				
Well No.	1	2	3	4	5	6	7	8
*07:04, 07:25, 42:05:01-42:05:02		2						
*07:19, 08:31, 08:43		2						
*07:33, 07:53, 07:60, 07:100, 14:05, 14:13, 15:07:01-15:07:02, 15:45, 15:55, 15:68, 15:126, 15:207, 27:07, 27:11, 27:24, 27:32-27:34, 27:43, 35:05:01-35:05:02, 35:22, 35:31, 35:51, 35:58, 35:72, 35:89, 35:97, 35:114, 38:19, 39:03, 39:14, 39:24:01, 39:29, 39:37, 40:02:03, 40:08, 40:13, 40:40, 40:58, 44:54, 46:12, 48:04, 48:13, 48:24, 51:64, 51:81, 53:14, 55:04, 58:18, 58:27, C*03:05, C*03:25, C*03:27, C*08:08								
*08:01:01-08:05, 08:07-08:08N, 08:10-08:11, 08:14-08:15, 08:17-08:19N, 08:21-08:24, 08:26, 08:28-08:30N, 08:32, 08:34-08:39, 08:41-08:42, 08:44-08:48, 08:50-08:54, 08:56-08:59, 08:61-08:66, 35:87, 42:01:01-42:02, 42:06-42:07, 42:09-42:12		2						
*08:09, 42:04	1					6		
*08:12:01-08:12:02, 08:16								
*08:12:03, 08:49, 08:60, 42:13								
*08:27, 08:33		2						
*13:02:01-13:04, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:31-13:35, 13:37-13:38, 13:40, 15:04, 15:16:01, 15:67, 15:95, 15:137, 15:155, 27:14, 35:37, 39:33, 39:50, 40:75, 40:103, 40:110, 44:47, 46:11, 49:10, 51:01:01-51:03, 51:05, 51:07:01-51:07:02, 51:09:01-51:19, 51:22-51:24:04, 51:26-51:35, 51:37-51:41N, 51:43, 51:48-51:55, 51:57-51:58, 51:60-51:61, 51:63, 51:65-51:80, 51:82-51:95, 51:98N-51:100, 51:102-51:106, 52:01:01-52:18, 52:20-52:22, 54:03, 55:09, 55:22, 55:24, 56:01:01-56:01:04, 56:05:01-56:08, 56:14-56:17, 56:19N-56:22, 56:24-56:30, 58:08, 59:04, 73:01-73:02, 78:01-78:06							7	
Well No.	1	2	3	4	5	6	7	8

Lot No.: **43M**

Lot-specific information

www.olerup-ssp.com

105	105	245	210	285	115	155	290	Length of spec. PCR product(s)
					215	375		
9	10	11	12	13	14	15	16	Well No.
9			12					*07:04, 07:25, 42:05:01-42:05:02
			12					*07:19, 08:31, 08:43
							16	*07:33, 07:53, 07:60, 07:100, 14:05, 14:13, 15:07:01-15:07:02, 15:45, 15:55, 15:68, 15:126, 15:207, 27:07, 27:11, 27:24, 27:32-27:34, 27:43, 35:05:01-35:05:02, 35:22, 35:31, 35:51, 35:58, 35:72, 35:89, 35:97, 35:114, 38:19, 39:03, 39:14, 39:24:01, 39:29, 39:37, 40:02:03, 40:08, 40:13, 40:40, 40:58, 44:54, 46:12, 48:04, 48:13, 48:24, 51:64, 51:81, 53:14, 55:04, 58:18, 58:27, C*03:05, C*03:25, C*03:27, C*08:08
	10		12					*08:01:01-08:05, 08:07-08:08N, 08:10-08:11, 08:14-08:15, 08:17-08:19N, 08:21-08:24, 08:26, 08:28-08:30N, 08:32, 08:34-08:39, 08:41-08:42, 08:44-08:48, 08:50-08:54, 08:56-08:59, 08:61-08:66, 35:87, 42:01:01-42:02, 42:06-42:07, 42:09-42:12
	10	11			14			*08:09, 42:04
	10		12					*08:12:01-08:12:02, 08:16
	10							*08:12:03, 08:49, 08:60, 42:13
	10							*08:27, 08:33
				13				*13:02:01-13:04, 13:08Q-13:09, 13:14-13:16, 13:18-13:19, 13:27, 13:31-13:35, 13:37-13:38, 13:40, 15:04, 15:16:01, 15:67, 15:95, 15:137, 15:155, 27:14, 35:37, 39:33, 39:50, 40:75, 40:103, 40:110, 44:47, 46:11, 49:10, 51:01:01-51:03, 51:05, 51:07:01-51:07:02, 51:09:01-51:19, 51:22-51:24:04, 51:26-51:35, 51:37-51:41N, 51:43, 51:48-51:55, 51:57-51:58, 51:60-51:61, 51:63, 51:65-51:80, 51:82-51:95, 51:98N-51:100, 51:102-51:106, 52:01:01-52:18, 52:20-52:22, 54:03, 55:09, 55:22, 55:24, 56:01:01-56:01:04, 56:05:01-56:08, 56:14-56:17, 56:19N-56:22, 56:24-56:30, 58:08, 59:04, 73:01-73:02, 78:01-78:06
9	10	11	12	13	14	15	16	Well No.

Lot No.: **43M**

Lot-specific information

www.olerup-ssp.com

Length of spec.	285	215	80	90	255	220	295	215
PCR product(s)				265				
Well No.	1	2	3	4	5	6	7	8
*13:23, 15:71, 15:175, 15:204, 18:01:01-18:03, 18:05-18:06, 18:08-18:13, 18:15, 18:17N-18:24, 18:26-18:28, 18:30-18:32, 18:34-18:42, 18:44-18:52, 27:18, 27:29, 35:63, 37:01:01-37:08, 37:10-37:11, 37:13-37:20, 37:22-37:25, 40:01:01-40:01:17, 40:04, 40:11:01-40:11:02, 40:14:01-40:16, 40:20, 40:22N-40:23, 40:25-40:26, 40:28, 40:30-40:34, 40:36, 40:38, 40:42-40:43, 40:45-40:48, 40:51-40:52, 40:54-40:55, 40:59-40:60, 40:62-40:67, 40:69, 40:72:01-40:74, 40:76-40:77, 40:80-40:81, 40:84, 40:87:01-40:88, 40:92, 40:98-40:102, 40:108, 40:112-40:114, 40:116-40:118N, 40:120-40:121, 40:123-40:126, 40:128, 40:130, 40:132, 40:134-40:135, 40:138-40:141, 40:146-40:147, 40:149-40:156, 40:158, 44:55, 44:103, 48:22, 50:12								8
*13:30							7	
*15:42, 35:60, 39:06:01-39:06:02, 39:34, 39:57, 39:62, 46:18, 51:21, 51:101, 54:01:01-54:02, 54:04-54:05N, 54:07-54:08N, 54:10-54:23, 55:01:01-55:03, 55:05, 55:07, 55:10-55:13, 55:15-55:19, 55:21, 55:23, 55:25-55:48, 56:23, 59:01:01-59:03, 59:05, 78:07							7	
*15:46, 15:106, 35:47, 40:10:01-40:10:02, 53:15				4				
*15:51, 15:179, 15:199, 44:41:01, C*07:04:03								
*15:83, 51:36						6	7	
*18:14, 40:02:01-40:02:02, 40:02:04-40:03, 40:05, 40:09, 40:18-40:19, 40:24, 40:27:01, 40:29, 40:35, 40:37, 40:39, 40:50, 40:56-40:57, 40:71, 40:78, 40:82, 40:85, 40:89-40:91, 40:94, 40:97, 40:104-40:105, 40:107, 40:111, 40:115, 40:119, 40:122, 40:133Q, 40:142N-40:145, 40:157								8
*37:12								8
*40:06:01:01-40:06:03, 40:44, 40:53, 40:70, 40:83, 40:86, 40:93, 40:95-40:96, 40:109, 40:127, 40:131, 40:148, 49:01:01-49:09, 49:11-49:13, 49:15, 50:01:01-50:02, 50:04-50:11							7	8
*40:79								8
*42:08, 42:14, 44:106		2						
*44:15, 44:18, 45:01-45:05, 45:07, 45:09-45:13						6	7	8
*44:20, 51:08, 51:20, 51:44N, 51:97, 52:19, 56:13						6	7	
*44:100, 45:06						6	7	
*49:14							7	8
*55:20	1			4		6		
Well No.	1	2	3	4	5	6	7	8

Lot No.: **43M**

Lot-specific information

www.olerup-ssp.com

105	105	245	210	285	115	155	290	Length of spec. PCR product(s)
9	10	11	12	13	14	15	16	Well No.
								*13:23, 15:71, 15:175, 15:204, 18:01:01-18:03, 18:05-18:06, 18:08-18:13, 18:15, 18:17N-18:24, 18:26-18:28, 18:30-18:32, 18:34-18:42, 18:44-18:52, 27:18, 27:29, 35:63, 37:01:01-37:08, 37:10-37:11, 37:13-37:20, 37:22-37:25, 40:01:01-40:01:17, 40:04, 40:11:01-40:11:02, 40:14:01-40:16, 40:20, 40:22N-40:23, 40:25-40:26, 40:28, 40:30-40:34, 40:36, 40:38, 40:42-40:43, 40:45-40:48, 40:51-40:52, 40:54-40:55, 40:59-40:60, 40:62-40:67, 40:69, 40:72:01-40:74, 40:76-40:77, 40:80-40:81, 40:84, 40:87:01-40:88, 40:92, 40:98-40:102, 40:108, 40:112-40:114, 40:116-40:118N, 40:120-40:121, 40:123-40:126, 40:128, 40:130, 40:132, 40:134-40:135, 40:138-40:141, 40:146-40:147, 40:149-40:156, 40:158, 44:55, 44:103, 48:22, 50:12
				13		15		*13:30
		11		13				*15:42, 35:60, 39:06:01-39:06:02, 39:34, 39:57, 39:62, 46:18, 51:21, 51:101, 54:01:01-54:02, 54:04-54:05N, 54:07-54:08N, 54:10-54:23, 55:01:01-55:03, 55:05, 55:07, 55:10-55:13, 55:15-55:19, 55:21, 55:23, 55:25-55:48, 56:23, 59:01:01:01-59:03, 59:05, 78:07
								*15:46, 15:106, 35:47, 40:10:01-40:10:02, 53:15
			12					*15:51, 15:179, 15:199, 44:41:01, C*07:04:03
		11		13	14			*15:83, 51:36
							16	*18:14, 40:02:01-40:02:02, 40:02:04-40:03, 40:05, 40:09, 40:18-40:19, 40:24, 40:27:01, 40:29, 40:35, 40:37, 40:39, 40:50, 40:56-40:57, 40:71, 40:78, 40:82, 40:85, 40:89-40:91, 40:94, 40:97, 40:104-40:105, 40:107, 40:111, 40:115, 40:119, 40:122, 40:133Q, 40:142N-40:145, 40:157
			12					*37:12
				13				*40:06:01:01-40:06:03, 40:44, 40:53, 40:70, 40:83, 40:86, 40:93, 40:95-40:96, 40:109, 40:127, 40:131, 40:148, 49:01:01-49:09, 49:11-49:13, 49:15, 50:01:01-50:02, 50:04-50:11
						15		*40:79
			12				16	*42:08, 42:14, 44:106
				13				*44:15, 44:18, 45:01-45:05, 45:07, 45:09-45:13
				13	14			*44:20, 51:08, 51:20, 51:44N, 51:97, 52:19, 56:13
				13				*44:100, 45:06
								*49:14
	10	11			14			*55:20
9	10	11	12	13	14	15	16	Well No.

Lot No.: 43M

Lot-specific information

www.olerup-ssp.com

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-B*41 SSP subtyping.

In addition, wells number 4, 7, 10, 11 and 15 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

²The nucleotide position, in the 2nd or 3rd exons, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in the 2nd or 3rd exons, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

⁴The B*41:07 and 41:12 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 4.

⁵The 41:08 and 40:136 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*40 kits.

⁶The B*41:09 and 45:08 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*45 kits.

⁷The 41:15 and 37:09 alleles give rise to identical amplification patterns with the HLA-B*41 high resolution kit. These two alleles can be distinguished by the HLA-B low resolution and/or HLA-B*37 kits.

⁸Primer mix 4: Specific PCR fragment of 90 bp in the B*41:12 and the B*15:46, 15:106, 35:47 and 40:10:01-40:10:02 alleles. Specific PCR fragment of 265 bp in the B*41:04 and 41:07 and in the B* 53:15 and 55:20 alleles.

Primer mix 14: Specific PCR fragment of 115 bp in the B*41:13 allele. Specific PCR fragment of 215 bp in the B*41:16 and the B*08:09, 15:83, 42:04, 44:20, 51:08, 51:20, 51:36, 51:44N, 51:97, 52:19, 55:20 and 56:13 alleles.

Primer mix 15: Specific PCR fragment of 155 bp in the B*41:11 and the B*13:30 alleles. Specific PCR fragment of 375 bp in the B*41:14 and the B*40:79 alleles.

[illegible]

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-B*41 SSP

Product number: 101.542-06u – without *Taq* polymerase
Lot number: 43M
Expiry date: 2014-January-01
Number of tests: 6
Number of wells per test: 16

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-620-01	9	2009-620-09
2	2008-454-02	10	2009-620-10
3	2010-793-03	11	2008-454-11
4	2010-793-04	12	2008-454-12
5	2008-454-05	13	2010-793-13
6	2008-454-06	14	2011-884-14
7	2008-454-07	15	2010-793-15
8	2008-454-08	16	2010-793-16

The specificity of each primer solution of the HLA-B*41 primer set has been tested against 48 well characterized IHWC cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 3, 5, 9, 14 and 15 were available. The specificities of the primers in primer solution 9 were tested by separately adding one additional 3'-primer, respectively one additional 5'-primer. In primer solution 3 and 5 it was only possible to test the 5'-primers, the 3'-primers were not possible to test, and in primer solutions 14 and 15 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. Additional 5' and 3'-primers in primer solution 4 were tested by separately adding two additional 3'-primers, respectively one additional 5'-primer.

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

Date of approval: 2011-July-15

Approved by:

Quality Control, Supervisor

Lot No.: **43M**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup SSP*® HLA-B*41
Product number: 101.542-06u
Lot number: 43M

Intended use: HLA-B*41 high resolution histocompatibility testing

Manufacturer: *Olerup SSP AB*
Franzengatan 5
SE-112 51 Stockholm, Sweden
Phone: +46-8-717 88 27
Fax: +46-8-717 88 18

We, *Olerup SSP AB*, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex II List B, conformity assessed using Annex IV, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup SSP AB*, Franzengatan 5, SE-112 51 Stockholm, 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.)

Stockholm, Sweden
2011-July-15

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

Lot No.: **43M**

Lot-specific information

www.olerup-ssp.com

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

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