101.127-12/04 – including *Taq* polymerase, IFU-01
101.127-12u/04u – without *Taq* polymerase, IFU-02

Visit www.olerup.com for **"Instructions for Use" (IFU)**

Lot No.: 88Y

Lot-specific information

Olerup SSP® DRB1*08

Product number:	**101.127-12/04 – including *Taq* pol.** **101.127-12u/04u – without *Taq* pol.**
Lot number:	**88Y**
Expiry date:	**2018-March-01**
Number of tests:	**12 tests – Product No. 101.127-12/12u** **4 tests – Product No. 101.127-04/04u**
Number of wells per test:	**23+1**
Storage - pre-aliquoted primers:	**dark at -20ºC**
- PCR Master Mix:	**-20ºC**
- Adhesive PCR seals	**RT**
- Product Insert	**RT**

This Product Description is only valid for Lot No. 88Y.

Complete product documentation consists of generic Instructions for Use (IFU), lot specific Product Insert, Worksheet and Certificate.

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® DRB1*08 LOT (13X)

The DRB1*08 kit is updated to enable separation of:

- Confirmed DRB1*08 alleles as listed in the IMGT/HLA database[1]
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

A well containing Negative Control primer pairs has been added.

The format of the Product Insert and Worksheet have been changed.

[1]As described in section Uniquely Identified Alleles.

The DRB1*08 primer set, specificity and interpretation tables have been updated for the DRB1 alleles described since the previous *Olerup* SSP® DRB1*08 lot was made **(Lot No. 13X)**. The kit design is based on IMGT/HLA database 3.21.1.

As of lot series V, the Specificity Table is included in the lot-specific Product Insert, and the Interpretation Table is included in the Worksheet.

Lot No.: 88Y **Lot-specific information**

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

Well	5'-primer	3'-primer	rationale
1	Added	-	5'-primer added for improved HLA-specific amplification.
4	Added	-	5'-primer added for improved HLA-specific amplification.
7	Added	-	5'-primer added for improved HLA-specific amplification.
14	-	Added	3'-primer added for the DRB1*08:60N allele.
24	-	-	Updated negative control.

Change in revision R01 compared to R00:
1. Primer mix 10 does not amplify the DRB1*14:152N allele. This has been corrected in the Specificity and Interpretation Tables.

Lot No.: 88Y **Lot-specific information**

Well **24** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup* SSP® HLA Class I, DRB, DQB1, DPB1 and DQA1 amplicons as well as all the amplicons generated by the control primer pairs matching the human growth hormone gene.

HLA-specific PCR product sizes range from 75 to 200 base pairs.
The PCR product generated by the positive control primer pair is 430 base pairs.

Length of PCR product	**105**	**200**	**105**	**80**	**75**	**80**	**85**
5'-primer[1]	**164**	**340**	**440**	**45**	**45**	**43**	**36**
	5'-CAC3'	**5'-Agg3'**	**5'-TTA3'**	**5'-Tgg3'**	**5'-Tgg3'**	**5'-Tgg3'**	**5'-TAC3'**
							36
							5'-TAT3'
3'-primer[2]	**231**	**2nd I**	**507**	**59**	**58**	**57**	**47**
	5'-TgC3'	**5'-AAA3'**	**5'-TTg3'**	**5'-CTC3'**	**5'-ggC3'**	**5'-CTC3'**	**5'-ACA3'**
							48
							5'-gCA3'
							48
							5'-gCC3'
							52
							5'-TgT3'
A*	**+**	**+**	**+**				
B*	**+**	**+**	**+**				
C*	**+**	**+**	**+**				
DRB1				**+**	**+**		
DRB3				**+**	**+**		
DRB5				**+**			
DQB1					**+**		
DPB1						**+**	
DQA1							**+**

[1]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. Nucleotide and codonnumbering as on the www.ebi.ac.uk/imgt/hla web site. 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 or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

Lot No.: 88Y **Lot-specific information**

PRODUCT DESCRIPTION

DRB1*08 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1*08:01 to DRB1*08:76 alleles.

PLATE 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**	**NC**

The 24 well cut PCR plate is marked with 'DRB1*08' in silver/gray ink.
Well No. 1 is marked with the Lot No. '88Y'.
Wells 1 to 23 – DRB1*08 high resolution primers.
Well 24 – Negative Control (NC).
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 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

Due to the sharing of sequence motifs between DRB1 alleles, non-DRB1*08 alleles will be amplified by primer mixes 1 to 12, 14 to 18 and 20 to 23.
For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the phenotypically different DRB1*08 alleles, i.e. **DRB1*08:01 to DRB1*08:76**, recognized by the HLA Nomenclature Committee in August 2015[1,2] will be amplified by the primers in the DRB1*08 subtyping kit[3].

The DRB1*08 kit enables separation of the confirmed DRB1*08 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for DRB1*08 alleles is listed below.

The DRB1*08 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

The DRB1*08 subtyping kit cannot distinguish the following silent mutations: DRB1*08:01:01-08:01:06, the DRB1*08:02:01-08:02:04, DRB1*08:03:02-08:03:05, the DRB1*08:04:01 and 08:04:04-08:04:07 alleles, the DRB1*08:04:02-08:04:03 alleles, the DRB1*08:30:01-08:30:03 or the DRB1*08:36:01-08:36:02 alleles.

[1]DRB1 alleles listed on the IMGT/HLA web page 2015-August-11, release 3.21.1, www.ebi.ac.uk/imgt/hla.
[2]Alleles that have been deleted from or renamed in the official WHO HLA Nomenclature up to and including the last IMGT/HLA database release can be retrieved from web page http://hla.alleles.org/alleles/deleted.html.
[3]The DRB1*08:20 and the DRB1*14:12:01-14:12:02, 14:84 and 14:156 give rise to identical amplification patterns with the DRB1*08 subtyping kit. These alleles can be distinguished by e.g. the DR low resolution kit and/or the DRB1*14 subtyping kit.

ALLELE CONFIRMATION STATUS

Allele	Status[1]	Allele	Status[1]	Allele	Status[1]	Allele	Status[1]
DRB1*08:01:01	**Confirmed**	**DRB1*08:14**	**Confirmed**	DRB1*08:41	Unconfirmed	DRB1*08:71	Unconfirmed
DRB1*08:01:02	Unconfirmed	**DRB1*08:15**	**Confirmed**	DRB1*08:42	Unconfirmed	DRB1*08:72	Unconfirmed
DRB1*08:01:03	Unconfirmed	**DRB1*08:16**	**Confirmed**	**DRB1*08:43**	**Confirmed**	DRB1*08:73	Unconfirmed
DRB1*08:01:04	**Confirmed**	**DRB1*08:17**	**Confirmed**	**DRB1*08:44**	**Confirmed**	DRB1*08:74	Unconfirmed
DRB1*08:01:05	Unconfirmed	**DRB1*08:18**	**Confirmed**	**DRB1*08:45**	**Confirmed**	DRB1*08:75	Unconfirmed
DRB1*08:01:06	Unconfirmed	**DRB1*08:19**	**Confirmed**	DRB1*08:46	Unconfirmed	DRB1*08:76	Unconfirmed
DRB1*08:02:01	**Confirmed**	**DRB1*08:20**	**Confirmed**	DRB1*08:47	Unconfirmed		
DRB1*08:02:02	**Confirmed**	DRB1*08:21	Unconfirmed	DRB1*08:48	Unconfirmed		
DRB1*08:02:03	Unconfirmed	**DRB1*08:22**	**Confirmed**	**DRB1*08:49**	**Confirmed**		
DRB1*08:02:04	Unconfirmed	DRB1*08:23	Unconfirmed	DRB1*08:50	Unconfirmed		
DRB1*08:03:02	**Confirmed**	DRB1*08:24	Unconfirmed	DRB1*08:51	Unconfirmed		
DRB1*08:03:03	**Confirmed**	DRB1*08:25	Unconfirmed	**DRB1*08:52**	**Confirmed**		
DRB1*08:03:04	Unconfirmed	DRB1*08:26	Unconfirmed	DRB1*08:53	Unconfirmed		
DRB1*08:03:05	Unconfirmed	DRB1*08:27	Unconfirmed	DRB1*08:54	Unconfirmed		
DRB1*08:04:01	**Confirmed**	DRB1*08:28	Unconfirmed	DRB1*08:55	Unconfirmed		
DRB1*08:04:02	**Confirmed**	DRB1*08:29	Unconfirmed	DRB1*08:56	Unconfirmed		
DRB1*08:04:03	Unconfirmed	DRB1*08:30:01	Unconfirmed	DRB1*08:57	Unconfirmed		
DRB1*08:04:04	Unconfirmed	DRB1*08:30:02	Unconfirmed	DRB1*08:58	Unconfirmed		
DRB1*08:04:05	**Confirmed**	**DRB1*08:30:03**	**Confirmed**	DRB1*08:59	Unconfirmed		
DRB1*08:04:06	**Confirmed**	DRB1*08:31	Unconfirmed	DRB1*08:60N	Unconfirmed		
DRB1*08:04:07	Unconfirmed	**DRB1*08:32**	**Confirmed**	DRB1*08:61	Unconfirmed		
DRB1*08:05	**Confirmed**	DRB1*08:33	Unconfirmed	DRB1*08:62	Unconfirmed		
DRB1*08:06	**Confirmed**	DRB1*08:34	Unconfirmed	**DRB1*08:63**	**Confirmed**		
DRB1*08:07	**Confirmed**	**DRB1*08:35**	**Confirmed**	DRB1*08:64	Unconfirmed		
DRB1*08:08	**Confirmed**	DRB1*08:36:01	Unconfirmed	DRB1*08:65	Unconfirmed		
DRB1*08:09	**Confirmed**	DRB1*08:36:02	Unconfirmed	DRB1*08:66	Unconfirmed		
DRB1*08:10	**Confirmed**	DRB1*08:37	Unconfirmed	DRB1*08:67	Unconfirmed		
DRB1*08:11	**Confirmed**	DRB1*08:38	Unconfirmed	DRB1*08:68	Unconfirmed		
DRB1*08:12	**Confirmed**	DRB1*08:39	Unconfirmed	DRB1*08:69	Unconfirmed		
DRB1*08:13	**Confirmed**	DRB1*08:40	Unconfirmed	DRB1*08:70	Unconfirmed		

[1]Allele status "confirmed" or "unconfirmed" as listed on the IMGT/HLA web page 2015-August-11, release 3.21.1, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DRB1*08 homo- and heterozygotes is available upon request.

101.127-12/04 – including *Taq* polymerase, IFU-01
101.127-12u/04u – without *Taq* polymerase, IFU-02

Visit www.olerup.com for
"Instructions for Use" (IFU)

Lot No.: 88Y **Lot-specific information**

SPECIFICITY TABLE

DRB1*08 SSP subtyping

Specificities and sizes of the PCR products of the 23+1 primer mixes used for DRB1*08 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified DRB1*08 alleles[3]	Other amplified DRB1 alleles[4]
1	165 bp	**515 bp**	*08:01:01-08:01:06, 08:03:02-08:03:05, 08:05-08:06, 08:10, 08:12, 08:14, 08:16-08:18, 08:22-08:23, 08:26-08:27, 08:29, 08:32-08:33, 08:35-08:40, 08:43, 08:46-08:51, 08:53-08:56, 08:58, 08:60N-08:62, 08:64-08:66, 08:68-08:71, 08:74, 08:76	*12:46
2[6]	170 bp	430 bp	*08:02:01-08:02:04, 08:04:01-08:04:07, 08:09, 08:13, 08:21, 08:24, 08:28, 08:30:01-08:30:03, 08:42, 08:44-08:45, 08:59, 08:67, 08:72-08:73	*03:92, 12:09, 12:48[w], 13:17, 13:116, 13:175, 14:15, 14:52, 14:126:01-14:126:02
3[7]	195 bp	430 bp	*08:01:01-08:02:04, 08:04:01-08:09, 08:11, 08:16-08:17, 08:21-08:22, 08:24, 08:26, 08:28, 08:31, 08:39, 08:41-08:44, 08:50, 08:52, 08:54-08:55, 08:59, 08:64, 08:67, 08:70, 08:72-08:73, 08:75	*11:67, 12:02:01-12:02:06, 12:13, 12:15-12:16:03, 12:18-12:21, 12:23, 12:26-12:27, 12:31N-12:33, 12:37, 12:43-12:45, 12:49-12:52, 12:55-12:56, 14:15, 14:73
4	195 bp	430 bp	*08:03:02-08:03:05, 08:10, 08:12, 08:14-08:15, 08:18-08:19, 08:23, 08:25, 08:27, 08:29-08:30:03, 08:32-08:38, 08:40, 08:45-08:47, 08:49, 08:51, 08:53, 08:56, 08:58, 08:60N-08:63, 08:65-08:66, 08:68-08:69, 08:71, 08:74, 08:76	*12:01:01-12:01:09, 12:03:02-12:06, 12:08-12:11, 12:14, 12:17, 12:22, 12:24N-12:25, 12:28-12:30, 12:34-12:36, 12:38-12:41, 12:46-12:48, 12:53-12:54, 12:58, 13:17, 13:116, 13:175
5[6]	225 bp	**515 bp**	*08:01:01-08:04:07, 08:06-08:13, 08:15-08:17, 08:19-08:20, 08:22-08:23, 08:26-08:28, 08:30:01-08:30:03, 08:32-08:39, 08:42, 08:44-08:46, 08:48-08:55, 08:57-08:66, 08:68-08:76	*11:23:01-11:23:02, 11:25, 11:45, 11:55, 11:64, 11:67, 11:119, 13:13, 13:18, 13:47, 13:55, 13:119, 13:144, 13:146, 13:154, 13:156, 13:158, 13:164, 14:03:01-14:03:02, 14:12:01-14:12:02, 14:15, 14:27, 14:40, 14:55, 14:63, 14:67, 14:77-14:78, 14:84-14:85, 14:89, 14:102, 14:115-14:116, 14:135-14:136, 14:144, 14:156
6	215 bp	430 bp	*08:05, 08:18, 08:24-08:25, 08:31, 08:40-08:41, 08:47	*12:01:01-12:21, 12:23-12:41, 12:44-12:56, 12:58, 13:17, 13:116, 13:175, 14:31, 14:52
7	250 bp	430 bp	*08:01:01-08:03:05, 08:05, 08:07-08:09, 08:11, 08:13-08:19, 08:21, 08:23-08:27,	*12:16:01-12:16:03, 12:22, 12:39, 14:68:01-14:68:02, 14:93

Lot No.: 88Y **Lot-specific information**

			08:29-08:30:03, 08:32-08:53, 08:56, 08:58, 08:60N-08:63, 08:66, 08:68-08:69, 08:71-08:74, 08:76	
8[7]	250 bp	430 bp	*08:04:01-08:04:07, 08:06, 08:10, 08:12, 08:22, 08:28, 08:31, 08:54, 08:59, 08:67, 08:70, 08:75	*03:92, 11:67, 12:01:01-12:15, 12:17-12:21, 12:23-12:38, 12:40-12:41, 12:43-12:56, 12:58, 13:17, 13:116, 13:175, 14:04:01-14:04:02, 14:11, 14:15, 14:28, 14:31, 14:50, 14:52, 14:71, 14:73, 14:76, 14:79, 14:107, 14:120, 14:126:01-14:126:02, 14:138, 14:145, 14:148, 14:152N
9[5]	125 bp 175 bp	430 bp	*08:26, 08:35-08:36:02 *08:14	*03:12, 13:32, 13:65, 13:93, 13:120, 13:139, 14:13, 14:63, 14:65, 14:78, 14:85
10	205 bp 250 bp	**515 bp**	*08:40 *08:12, 08:22	*13:17, 13:116, 13:175 *12:01:01-12:02:06, 12:04-12:15, 12:17-12:18, 12:20-12:21, 12:23-12:38, 12:40-12:41, 12:43-12:56, 12:58, 14:28
11	170 bp	**515 bp**	*08:08, 08:15, 08:31, 08:41, 08:63, 08:75	*11:67, 12:04, 12:49, 14:04:01-14:04:02, 14:11, 14:28, 14:31, 14:50, 14:68:01-14:68:02, 14:71, 14:73, 14:76, 14:79, 14:93, 14:107, 14:120, 14:138, 14:145, 14:148, 14:152N
12[5]	95 bp 145 bp 195 bp 220 bp	430 bp	*08:27 *08:44 *08:13, 08:48 *08:43	 *12:12
13	135 bp 165 bp 260 bp	430 bp	*08:33 *08:11 *08:39	
14	135 bp 250 bp	430 bp	*08:17, 08:28, 08:37, 08:45, 08:63 *08:60N	*03:92, 11:67, 12:01:01-12:20, 12:22-12:37, 12:39-12:41, 12:43-12:52, 12:54-12:56, 12:58, 13:17, 13:175, 14:138
15	170 bp	430 bp	*08:19, 08:25, 08:34, 08:49, 08:52	*12:01:01-12:01:07, 12:01:09-12:02:05, 12:03:02-12:03:03, 12:05-12:08, 12:10-12:17, 12:19-12:32, 12:34-12:41, 12:43-12:45, 12:50-12:56, 12:58
16[5]	70 bp	430 bp	*08:03:02-08:03:05, 08:10, 08:12, 08:14, 08:18-08:19, 08:23, 08:27, 08:29, 08:32-08:33, 08:35-08:38, 08:40, 08:46-08:47, 08:49, 08:51, 08:53, 08:56, 08:58, 08:60N-08:62, 08:65-08:66, 08:68-08:69, 08:71, 08:74, 08:76	*04:12, 04:86, 04:106, 04:136, 07:12, 12:46, 13:03:01-13:04, 13:12:01-13:13, 13:30, 13:32-13:33:03, 13:38, 13:48, 13:58, 13:65-13:66:02, 13:81, 13:89, 13:93-13:95, 13:101, 13:115, 13:118, 13:120, 13:122, 13:139, 13:151-13:152, 13:154, 13:161, 13:167, 13:174, 13:188, 13:194,

				14:63, 14:78
17[5]	75 bp 175 bp	430 bp	*08:04:01, 08:04:04-08:04:07, 08:06, 08:10, 08:12, 08:20, 08:22, 08:28, 08:54, 08:59, 08:67, 08:70, 08:75 *08:04:02[w]-08:04:03[w], 08:14	*04:12, 04:18, 04:25, 04:58, 11:25, 11:67, 11:119, 13:18, 13:144, 13:156, 13:164, 14:12:01-14:12:02, 14:15, 14:78, 14:84, 14:156, 15:21
18	150 bp 225 bp	430 bp	*08:09, 08:21, 08:32, 08:35 *08:20	*14:15, 14:40, 14:55, 14:77, 14:84, 14:136 *11:23:01-11:23:02, 11:25, 11:45, 11:55, 11:64, 11:119, 13:13, 13:18, 13:47, 13:55, 13:119, 13:144, 13:146, 13:154, 13:156, 13:158, 13:164, 14:03:01-14:03:02, 14:12:01-14:12:02, 14:27, 14:40, 14:55, 14:63, 14:67, 14:77-14:78, 14:84-14:85, 14:89, 14:102, 14:115-14:116, 14:135-14:136, 14:144, 14:156
19[5]	100 bp 170 bp	**515 bp**	*08:16, 08:38 *08:07, 08:49	
20[5]	125 bp	**515 bp**	*08:06, 08:10, 08:12, 08:22, 08:54, 08:70	*03:12, 04:10:01-04:12, 04:67, 04:91, 04:126, 04:136, 04:147, 12:46, 13:04, 13:32, 13:48, 13:58, 13:75, 13:81, 13:89, 13:93-13:94:02, 13:108, 13:164, 13:169, 14:65, 14:78, 15:12
21[5]	120 bp	**515 bp**	*08:17, 08:28, 08:37, 08:45, 08:63	*11:23:01-11:23:02, 11:25, 11:45, 11:55, 11:64, 11:67, 11:119, 13:18, 13:119, 13:144, 13:146, 13:154, 13:156, 13:158, 15:21
22	130 bp 165 bp 215 bp	430 bp	*08:23 *08:19 *08:29	*14:04:01-14:04:02, 14:11, 14:28, 14:68:01-14:68:02, 14:71, 14:73, 14:93, 14:120, 14:126:01-14:126:02, 14:138, 14:145, 14:148, 14:152N
23	220 bp 250 bp	430 bp	*08:43 *08:04:01, 08:04:04-08:04:07, 08:06, 08:10, 08:28, 08:31, 08:54, 08:59, 08:67, 08:70, 08:75	*03:92, 11:67, 12:03:02-12:03:03, 12:19, 13:17, 13:116, 13:175, 14:04:01-14:04:02, 14:11, 14:15, 14:31, 14:50, 14:52, 14:73, 14:76, 14:79, 14:107, 14:120, 14:126:01-14:126:02, 14:138, 14:145, 14:148, 14:152N
24[8]			**Negative Control**	

[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 DRB1*08SSP subtypings.
When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits, the alleles listed are specified according to amplicon length.

101.127-12/04 – including *Taq* polymerase, IFU-01 Visit www.olerup.com for
101.127-12u/04u – without *Taq* polymerase, IFU-02 **"Instructions for Use" (IFU)**

Lot No.: 88Y **Lot-specific information**

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

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

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

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherit 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.

[2]The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 430 or 515 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the longer, 515 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

[3]For several DRB1 alleles 1st and/or 3rd exon(s) and beyond, as well as intron 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. Assumption is made that unknown sequences in these regions are conserved within allelic groups.

[4]Due to the sharing of sequence motifs between DRB1 alleles, non-DRB1*08 alleles will be amplified by primer mixes 1 to 12, 14 to 18 and 20 to 23.

[5]HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

[6]Primer mixes 2 and 5 may have tendencies of unspecific amplifications.

[7]Primer mixes 3 and 8 have a tendency to giving rise to primer oligomer formation.

[8]Primer mix 24 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 430 base pairs.

'w', may be weakly amplified.

101.127-12/04 – including *Taq* polymerase, IFU-01
101.127-12u/04u – without *Taq* polymerase, IFU-02

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"Instructions for Use" (IFU)

Lot No.: 88Y **Lot-specific information**

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	165	170	195	195	225	215	250	250	125	205	170	95
PCR product									175	250		145
												195
												220
Length of int.	515	430	430	430	515	430	430	430	430	515	515	430
pos. control[1]												
5'-primer(s)[2]	15(133)	15(133)	15(133)	15(133)	12(122)	15(133)	15(133)	15(133)	12(122)	15(133)	15(133)	15(133)
	5' -gTT 3'	5' -gTT 3'	5' -gTT 3'	5' -gTT 3'	5' -TAC 3'	5' -gTT 3'	5' -gTT 3'	5' -gTT 3'	5' -TAg 3'	5' -gTT 3'	5' -gTT 3'	5' -gTT 3'
	15(133)		15(133)				15(133)		25(161)			
	5' -gCT 3'		5' -gCT 3'				5' -gCT 3'		5' -gCT 3'			
									31(181)			
									5' -TCC 3'			
3'-primer(s)[3]	56(256)	57(257)	66(286)	66(286)	73(307)	73(307)	86(344)	86(344)	56(256)	71(299)	58(261)	34(188)
	5' -gCT 3'	5' -CAT 3'	5' -gAA 3'	5' -gAT 3'	5' -CAg 3'	5' -CgC 3'	5' -CAC 3'	5' -CCA 3'	5' -gCT 3'	5' -gCT 3'	5' -TCC 3'	5' -CTC 3'
		57(257)		66(286)				86(344)		85(341)	58(261)	51(239)
		5' -CAT 3'		5' -gAT 3'				5' -CAA 3'		5' -CAg 3'	5' -TCC 3'	5' -CCA 3'
		58(261)										66(286)
		5' -TCA 3'										5' -gAg 3'
												75(313)
												5' -gTA 3'
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18	19	20	21	22	23
Length of spec.	135	135	170	70	75	150	100	125	120	130	220
PCR product	165	250			175	225	170			165	250
	260									215	
Length of int.	430	430	430	430	430	430	515	515	515	430	430
pos. control[1]											
5'-primer(s)[2]	15(133)	15(133)	15(133)	57(258)	12(122)	13(125)	15(133)	57(258)	47(227)	15(133)	15(133)
	5' -gTT 3'	5' -gTT 3'	5' -gTT 3'	5' -AgC 3'	5' -TAg 3'	5' -gTC 3'	5' -gTT 3'	5' -AgC 3'	5' -gTT 3'	5' -gTT 3'	5' -gTT 3'
					74(308)	36(196)					
					5' -CCT 3'	5' -AgC 3'					
						37(197)					
						5' -gTT 3'					
3'-primer(s)[3]	47(229)	47(227)	57(257)	66(286)	56(256)	73(307)	32(184)	86(344)	73(307)	44(220)	75(313)
	5' -CCA 3'	5' -ggA 3'	5' -CgA 3'	5' -gAT 3'	5' -gCT 3'	5' -CAg 3'	5' -gTg 3'	5' -CCA 3'	5' -CAg 3'	5' -CCT 3'	5' -gTA 3'
	57(257)	84(340)	61(270)	66(286)	86(344)		36(196)			56(256)	85(341)
	5' -CAg 3'	5' -A.C 3'	5' -TTg 3'	5' -gAT 3'	5' -CCA 3'		5' -gTC 3'			5' -gAT 3'	5' -CAA 3'
	88(350)						57(257)			74(308)	
	5' -AgT 3'						5' -CAA 3'			5' -CCT 3'	
							61(270)				
							5' -TTg 3'				
Well No.	13	14	15	16	17	18	19	20	21	22	23

Lot No.: 88Y **Lot-specific information**

[1]The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 430 or 515 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the longer, 515 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

[2]The nucleotide position 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.

[3]The nucleotide position matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

101.127-12/04 – including *Taq* polymerase, IFU-01
101.127-12u/04u – without *Taq* polymerase, IFU-02

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Lot No.: 88Y **Lot-specific information**

CELL LINE VALIDATION SHEET

DRB1*08 SSP subtyping kit[2]

					Well													
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				Prod. No.:	201557101	201295602	201439003	201557104	201079105	201079106	201557107	201079108	201079124	201079110	201079111	201439012	201439013	201557114	201295615	201079116
	IHWC cell line[1]		DRB1																	
1	9001	SA	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*15:02	*04:05	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*15:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*16:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*04:07	*08:03	+	-	-	+	+	-	+	-	-	-	-	-	-	-	-	+
7	9020	QBL	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU	*04:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR	*04:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*04:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*08:02		-	+	+	-	+	-	+	-	-	-	-	-	-	-	-	-
15	9075	DKB	*09:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*03:01	*13:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*09:01	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16	*12:01		-	-	-	+	-	+	-	+	-	+	-	-	-	+	+	-
20	9059	SLE005	*13:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*13:02	*14:54	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*08:03	*14:14	+	-	-	+	+	-	+	-	-	-	-	-	-	-	-	+
24	9035	JBUSH	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*04:05	*10:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*04:16	*07:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*03:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*13:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	+
33	9098	MT14B	*04:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO	*04:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17	*04:03	*04:06	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*13:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*14:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*03:01	*04:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*07:01	*09:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*13:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*08:03		+	-	-	+	+	-	+	-	-	-	-	-	-	-	-	+
43	9076	T7526	*09:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*14:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*07:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*15:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*11:04	*12:01	-	-	-	+	-	+	-	+	-	+	-	-	-	+	+	-
48	9303	TER-ND	*01:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.127-12/04 – including *Taq* polymerase, IFU-01
101.127-12u/04u – without *Taq* polymerase, IFU-02

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Lot No.: 88Y **Lot-specific information**

CELL LINE VALIDATION SHEET

DRB1*08 SSP subtyping kit[2]

					Well						
					17	18	19	20	21	22	23
				Prod. No.:	201079117	201439018	201295619	201079120	201079121	201079122	201439023
	IHWC cell line[1]		DRB1								
1	9001	SA	*01:01		-	-	-	-	-	-	-
2	9280	LK707	*15:02	*04:05	-	-	-	-	-	-	-
3	9011	E4181324	*15:02		-	-	-	-	-	-	-
4	9275	GU373	*03:01		-	-	-	-	-	-	-
5	9009	KAS011	*16:01		-	-	-	-	-	-	-
6	9353	SM	*04:07	*08:03	-	-	-	-	-	-	-
7	9020	QBL	*03:01		-	-	-	-	-	-	-
8	9025	DEU	*04:01		-	-	-	-	-	-	-
9	9026	YAR	*04:02		-	-	-	-	-	-	-
10	9107	LKT3	*04:05		-	-	-	-	-	-	-
11	9051	PITOUT	*07:01		-	-	-	-	-	-	-
12	9052	DBB	*07:01		-	-	-	-	-	-	-
13	9004	JESTHOM	*01:01		-	-	-	-	-	-	-
14	9071	OLGA	*08:02		-	-	-	-	-	-	-
15	9075	DKB	*09:01		-	-	-	-	-	-	-
16	9037	SWEIG007	*11:01		-	-	-	-	-	-	-
17	9282	CTM3953540	*03:01	*13:01	-	-	-	-	-	-	-
18	9257	32367	*09:01	*11:01	-	-	-	-	-	-	-
19	9038	BM16	*12:01		-	-	-	-	-	-	-
20	9059	SLE005	*13:02		-	-	-	-	-	-	-
21	9064	AMALA	*14:02		-	-	-	-	-	-	-
22	9056	KOSE	*13:02	*14:54	-	-	-	-	-	-	-
23	9124	IHL	*08:03	*14:14	-	-	-	-	-	-	-
24	9035	JBUSH	*11:01		-	-	-	-	-	-	-
25	9049	IBW9	*07:01		-	-	-	-	-	-	-
26	9285	WT49	*03:01		-	-	-	-	-	-	-
27	9191	CH1007	*04:05	*10:01	-	-	-	-	-	-	-
28	9320	BEL5GB	*04:16	*07:01	-	-	-	-	-	-	-
29	9050	MOU	*07:01		-	-	-	-	-	-	-
30	9021	RSH	*03:02		-	-	-	-	-	-	-
31	9019	DUCAF	*03:01		-	-	-	-	-	-	-
32	9297	HAG	*13:03		-	-	-	-	-	-	-
33	9098	MT14B	*04:04		-	-	-	-	-	-	-
34	9104	DHIF	*11:01		-	-	-	-	-	-	-
35	9302	SSTO	*04:03		-	-	-	-	-	-	-
36	9024	KT17	*04:03	*04:06	-	-	-	-	-	-	-
37	9065	HHKB	*13:01		-	-	-	-	-	-	-
38	9099	LZL	*14:02		-	-	-	-	-	-	-
39	9315	CML	*03:01	*04:01	-	-	-	-	-	-	-
40	9134	WHONP199	*07:01	*09:01	-	-	-	-	-	-	-
41	9055	H0301	*13:02		-	-	-	-	-	-	-
42	9066	TAB089	*08:03		-	-	-	-	-	-	-
43	9076	T7526	*09:01		-	-	-	-	-	-	-
44	9057	TEM	*14:01		-	-	-	-	-	-	-
45	9239	SHJO	*07:01		-	-	-	-	-	-	-
46	9013	SCHU	*15:01		-	-	-	-	-	-	-
47	9045	TUBO	*11:04	*12:01	-	-	-	-	-	-	-
48	9303	TER-ND	*01:03		-	-	-	-	-	-	-

101.127-12/04 – including *Taq* polymerase, IFU-01
101.127-12u/04u – without *Taq* polymerase, IFU-02

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Lot No.: 88Y **Lot-specific information**

[1]The provided cell line HLA specificities are retrieved from the http://www.ihwg.org/hla web site. The specificity of an individual cell line may thus be subject to change.

[2]The specificity of each primer solution in the kit has been tested against 48 well characterized cell line DNAs and where applicable, additional cell line DNAs.
No DNAs carrying the alleles to be amplified by primer solutions 9, 12 and 21 were available.
The specificities of the primers in primer solutions 9 and 21 were tested by separately adding one additional 5'-primer, respectively, one additional 3'-primer. In primer solution 12 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solutions 2, 8, 13 to 15, 19, 22 and 23 one or two 3'-primers were not possible to test, and in primer solution 1, 3, 7, 9, and 17 one or two 5'-primers were not possible to test. Additional primers in primer solutions 2, 10, 11 and 17 to 19 were tested by separately adding one additional 5'-primer or 3'-primer.

101.127-12/04 – including *Taq* polymerase, IFU-01
101.127-12u/04u – without *Taq* polymerase, IFU-02

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Lot No.: 88Y **Lot-specific information**

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