

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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“Instructions for Use” (IFU)

Lot No.: **89N**

Lot-specific Information

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Olerup SSP[®] HLA-A*31

Product number:	101.430-12 – including <i>Taq</i> polymerase 101.430-12u – without <i>Taq</i> polymerase
Lot number:	89N
Expiry date:	2015-January-01
Number of tests:	12
Number of wells per test:	32
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. 89N.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] HLA-A*31 Lot (19M)

The HLA-A*31 specificity and interpretation tables have been updated for the HLA-A alleles described since the previous *Olerup SSP*[®] HLA-A*31 lot was made (Lot No. 19M).

The HLA-A*31 kit is updated for new alleles to enable separation of:

- Confirmed¹ alleles as listed in the IMGT/HLA database
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

The Lot-specific information for HLA-A*31 including and without *Taq* polymerase is now described in one common Product Insert.

¹As described in section Uniquely Identified Alleles.

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

Well	5'-primer	3'-primer	rationale
5	Added	.	Exchanged positive control primer pair, 5'-primer added for the A*31:38 allele.
6	-	Added	3'-primer added for the A*31:39 allele.
10	-	Added	3'-primer added for the A*31:41 allele.
11	Added	-	5'-primer added for the A*31:60N allele.
16	Added	Added	Primer pair added for the A*31:46 allele.
17	-	Added	3'-primer added for the A*31:40 allele.
20	Added	Added	Primer pair added for the A*31:56 allele.
22	Added	Added	Primer pair added for the A*31:55 allele.
23	Added	Modified, added	Primer pair added for the A*31:40 allele, modified 3'-primer.
24	Added	Added	Primer pair added for the A*31:55 allele.
25	Added	Added	Primer pair added for the A*31:59 allele.
26	-	Added	3'-primer added for the A*31:39 allele.
27	Added	-	Exchanged positive control primer pair, modified 3'-primer, 5'-primer added for the A*31:44 allele.
28	Added	-	5'-primers added for the A*31:38 and A*31:60N alleles.
29	Added	Added	Primer pair added for the A*31:48 allele.
32	-	Added	3'-primer added for the A*31:41 allele.

Change in revision R01 compared to R00:

1. Primer mix 14 does not amplify the A*31:14N allele. This has been corrected in the specificity and interpretation tables. Thus, this lot of the HLA-A*31 subtyping kit cannot distinguish the A*31:01:02-31:01:13, 31:42-31:43, 31:45, 31:47, 31:49-31:54, 31:57-31:58 and 31:61 alleles and the A*31:14N allele.

Change in revision R02 compared to R01:

1. Primer mixes 4 and 7 may weakly amplify the A*34:01 allele. This foot note has been reinserted in the specificity table.

Change in revision R03 compared to R02:

1. Primer mix 8 gives rise to a significantly lower yield of the A*31:09 specific PCR product than the other HLA-A*31 primer mixes. This has been changed in the foot notes to the Specificity Table.

Change in revision R04 compared to R03:

1. Primer mix 20 does not amplify the A*31:20 allele. This has been corrected in the Specificity and Interpretation Tables. Thus, this lot of the HLA-A*31 subtyping kit cannot distinguish the A*31:01:02-31:01:17 and the A*31:20 alleles.

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PRODUCT DESCRIPTION

HLA-A*31 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the A*31:01 to A*31:62 alleles.

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 'HLA-A*31' in silver/gray ink.

Well No. 1 is marked with the Lot Number '89N'.

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 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-A*31 SSP subtypings will be influenced by two A*01, several A*02, eight A*03, seven A*11, most A*23, seven A*24, two A*26, most A*29, four A*30, the A*32, the A*33, most A*34, the A*66:06, four A*68, the A*74 and the A*80 alleles when present on the other haplotype.

In addition, primer mix 1 will amplify the B*15:82 and B*40:186 alleles and primer mix 26 will amplify the C*02:02:15 allele.

UNIQUELY IDENTIFIED ALLELES

All the HLA-A*31 alleles, i.e. **A*31:01 to A*31:62 alleles**, recognized by the HLA Nomenclature Committee in April 2012¹ will be amplified by the primers in the HLA-A*31 subtyping kit².

The HLA-A*31 kit enables separation of the confirmed HLA- A*31alleles 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 HLA- A*31 alleles is listed below.

The HLA-A*31 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

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The HLA-A*31 subtyping kit cannot distinguish the silent mutations in the A*31:01:02-31:01:13 alleles.

The A*31:16 and A*31:46 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 16.

The A*31:20 and A*31:56 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

The A*31:29 and A*31:59 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 25

The A*31:36 and A*31:48 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 29.

¹HLA-A alleles listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

²Primer mix 14 does not amplify the A*31:14N allele. Thus, this lot of the HLA-A*31 subtyping kit cannot distinguish the A*31:01:02-31:01:13, 31:42-31:43, 31:45, 31:47, 31:49-31:54, 31:57-31:58 and 31:61 alleles and the A*31:14N allele.

Primer mix 20 does not amplify the A*31:20 allele. Thus, this lot of the HLA-A*31 subtyping kit cannot distinguish the A*31:01:02-31:01:17 and the A*31:20 alleles.

ALLELE CONFIRMATION STATUS

Allele	Status ¹	Allele	Status ¹	Allele	Status ¹	Allele	Status ¹
A*31:01:02	Confirmed	A*31:10	Unconfirmed	A*31:30	Unconfirmed	A*31:50	Unconfirmed
A*31:01:03	Unconfirmed	A*31:11	Confirmed	A*31:31	Confirmed	A*31:51	Unconfirmed
A*31:01:04	Confirmed	A*31:12	Confirmed	A*31:32	Unconfirmed	A*31:52	Unconfirmed
A*31:01:05	Unconfirmed	A*31:13	Unconfirmed	A*31:33	Unconfirmed	A*31:53	Unconfirmed
A*31:01:06	Unconfirmed	A*31:14N	Unconfirmed	A*31:34	Unconfirmed	A*31:54	Unconfirmed
A*31:01:07	Unconfirmed	A*31:15	Confirmed	A*31:35	Unconfirmed	A*31:55	Unconfirmed
A*31:01:08	Unconfirmed	A*31:16	Confirmed	A*31:36	Confirmed	A*31:56	Unconfirmed
A*31:01:09	Unconfirmed	A*31:17	Confirmed	A*31:37	Unconfirmed	A*31:57	Unconfirmed
A*31:01:10	Unconfirmed	A*31:18	Confirmed	A*31:38	Confirmed	A*31:58	Unconfirmed
A*31:01:11	Unconfirmed	A*31:19	Confirmed	A*31:39	Confirmed	A*31:59	Unconfirmed
A*31:01:12	Unconfirmed	A*31:20	Confirmed	A*31:40	Confirmed	A*31:60N	Unconfirmed
A*31:01:13	Unconfirmed	A*31:21	Unconfirmed	A*31:41	Confirmed	A*31:61	Unconfirmed
A*31:02	Confirmed	A*31:22	Unconfirmed	A*31:42	Unconfirmed	A*31:62	Unconfirmed
A*31:03	Unconfirmed	A*31:23	Unconfirmed	A*31:43	Unconfirmed		
A*31:04	Confirmed	A*31:24	Unconfirmed	A*31:44	Confirmed		
A*31:05	Confirmed	A*31:25	Unconfirmed	A*31:45	Unconfirmed		
A*31:06	Confirmed	A*31:26	Confirmed	A*31:46	Unconfirmed		
A*31:07	Unconfirmed	A*31:27	Confirmed	A*31:47	Unconfirmed		
A*31:08	Confirmed	A*31:28	Confirmed	A*31:48	Confirmed		
A*31:09	Confirmed	A*31:29	Unconfirmed	A*31:49	Unconfirmed		

¹Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

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RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 73 alleles generate 45 amplification patterns that can be combined in 1035 homozygous and heterozygous combinations. 405 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.

+-----	+-----	-----	-----	*31:01:02, *31:01:02 = *31:01:02, *31:62
+---+	-----	-----	-----	*31:06, *31:06 = *31:06, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:37 = *31:37, *31:37 = *31:37, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:35 = *31:35, *31:35 = *31:35, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:33 = *31:01:02, *31:34 = *31:33, *31:34 = *31:33, *31:62 = *31:34, *31:34 = *31:34, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:36 = *31:36, *31:36 = *31:36, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:32 = *31:32, *31:32 = *31:32, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:31 = *31:01:02, *31:44 = *31:31, *31:31 = *31:31, *31:44 = *31:31, *31:62 = *31:44, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:30 = *31:30, *31:30 = *31:30, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:29 = *31:29, *31:29 = *31:29, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:28 = *31:28, *31:28 = *31:28, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:23 = *31:23, *31:23 = *31:23, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:22 = *31:22, *31:22 = *31:22, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:21 = *31:21, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:20 = *31:20, *31:20 = *31:20, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:19 = *31:19, *31:19 = *31:19, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:18 = *31:18, *31:18 = *31:18, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:17 = *31:17, *31:17 = *31:17, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:16 = *31:16, *31:16 = *31:16, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:15 = *31:15, *31:15 = *31:15, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:14N = *31:14N, *31:14N = *31:14N, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:13 = *31:13, *31:13 = *31:13, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:12 = *31:12, *31:12 = *31:12, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:11 = *31:11, *31:11 = *31:11, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:09 = *31:09, *31:09 = *31:09, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:10 = *31:10, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:05 = *31:05, *31:05 = *31:05, *31:62
+-----	+-----	-----	-----+	*31:04, *31:04 = *31:04, *31:06 = *31:04, *31:62
+-----	+-----	-----	-----+	*31:01:02, *31:02 = *31:02, *31:02 = *31:02, *31:62
+-----	+-----	-----	-----+	*31:07, *31:07 = *31:07, *31:08 = *31:07, *31:10 = *31:08, *31:10
+-----	+-----	-----	-----+	*31:33, *31:37 = *31:34, *31:37
+-----	+-----	-----	-----+	*31:33, *31:35 = *31:34, *31:35
+-----	+-----	-----	-----+	*31:33, *31:36 = *31:34, *31:36
+-----	+-----	-----	-----+	*31:32, *31:33 = *31:32, *31:34
+-----	+-----	-----	-----+	*31:31, *31:37 = *31:37, *31:44
+-----	+-----	-----	-----+	*31:31, *31:35 = *31:35, *31:44
+-----	+-----	-----	-----+	*31:31, *31:33 = *31:31, *31:34 = *31:33, *31:44 = *31:34, *31:44
+-----	+-----	-----	-----+	*31:31, *31:36 = *31:36, *31:44
+-----	+-----	-----	-----+	*31:31, *31:32 = *31:32, *31:44
+-----	+-----	-----	-----+	*31:30, *31:33 = *31:30, *31:34
+-----	+-----	-----	-----+	*31:30, *31:31 = *31:30, *31:44
+-----	+-----	-----	-----+	*31:29, *31:33 = *31:29, *31:34
+-----	+-----	-----	-----+	*31:29, *31:31 = *31:29, *31:44
+-----	+-----	-----	-----+	*31:28, *31:33 = *31:28, *31:34
+-----	+-----	-----	-----+	*31:28, *31:31 = *31:28, *31:44
+-----	+-----	-----	-----+	*31:23, *31:33 = *31:23, *31:34
+-----	+-----	-----	-----+	*31:23, *31:31 = *31:23, *31:44
+-----	+-----	-----	-----+	*31:22, *31:33 = *31:22, *31:34
+-----	+-----	-----	-----+	*31:22, *31:31 = *31:22, *31:44
+-----	+-----	-----	-----+	*31:01:02, *31:55 = *31:22, *31:28 = *31:22, *31:55 = *31:28, *31:55 = *31:55, *31:55 = *31:55, *31:62
+-----	+-----	-----	-----+	*31:21, *31:31 = *31:21, *31:44
+-----	+-----	-----	-----+	*31:20, *31:33 = *31:20, *31:34

101.430-12 – including *Taq* polymerase, IFU-01
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+-----+ +--+-----+ +-----+ +-----+	*31:20, *31:31 = *31:20, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:19, *31:33 = *31:19, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:19, *31:31 = *31:19, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:18, *31:33 = *31:18, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:18, *31:31 = *31:18, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:17, *31:33 = *31:17, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:17, *31:31 = *31:17, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:01:02, *31:40 = *31:17, *31:23 = *31:17, *31:40 = *31:23, *31:40 = *31:40, *31:40 = *31:40, *31:62	
+-----+ +--+-----+ +-----+ +-----+	*31:16, *31:33 = *31:16, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:16, *31:31 = *31:16, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:15, *31:33 = *31:15, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:15, *31:31 = *31:15, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:01:02, *31:25 = *31:15, *31:17 = *31:15, *31:25 = *31:17, *31:25 = *31:25, *31:25 = *31:25, *31:62	
+-----+ +--+-----+ +-----+ +-----+	*31:14N, *31:33 = *31:14N, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:14N, *31:31 = *31:14N, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:13, *31:33 = *31:13, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:13, *31:31 = *31:13, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:12, *31:33 = *31:12, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:01:02, *31:60N = *31:12, *31:32 = *31:12, *31:60N = *31:32, *31:60N = *31:60N, *31:60N = *31:60N, *31:62	
+-----+ +--+-----+ +-----+ +-----+	*31:12, *31:31 = *31:12, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:01:02, *31:41 = *31:11, *31:37 = *31:11, *31:41 = *31:37, *31:41 = *31:41, *31:41 = *31:41, *31:62	
+-----+ +--+-----+ +-----+ +-----+	*31:11, *31:33 = *31:11, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:11, *31:31 = *31:11, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:09, *31:33 = *31:09, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:09, *31:31 = *31:09, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:01:02, *31:27 = *31:09, *31:22 = *31:09, *31:27 = *31:22, *31:27 = *31:27, *31:27 = *31:27, *31:62	
+-----+ +--+-----+ +-----+ +-----+	*31:01:02, *31:24 = *31:09, *31:14N = *31:09, *31:24 = *31:14N, *31:24 = *31:24, *31:24 = *31:24, *31:62	
+-----+ +--+-----+ +-----+ +-----+	*31:10, *31:31 = *31:10, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:05, *31:33 = *31:05, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:05, *31:31 = *31:05, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:01:02, *31:39 = *31:05, *31:30 = *31:05, *31:39 = *31:30, *31:39 = *31:39, *31:39 = *31:39, *31:62	
+-----+ +--+-----+ +-----+ +-----+	*31:01:02, *31:38 = *31:32, *31:38 = *31:38, *31:38 = *31:38, *31:38 = *31:38, *31:62	
+-----+ +--+-----+ +-----+ +-----+	*31:01:02, *31:26 = *31:12, *31:26 = *31:26, *31:26 = *31:26, *31:26 = *31:26, *31:62	
+-----+ +--+-----+ +-----+ +-----+	*31:06, *31:33 = *31:06, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:06, *31:31 = *31:06, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:03, *31:03 = *31:03, *31:04 = *31:03, *31:06 = *31:03, *31:62	
+-----+ +--+-----+ +-----+ +-----+	*31:02, *31:33 = *31:02, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:02, *31:31 = *31:02, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:07, *31:33 = *31:08, *31:33	
+-----+ +--+-----+ +-----+ +-----+	*31:07, *31:21 = *31:08, *31:21	
+-----+ +--+-----+ +-----+ +-----+	*31:01:02, *31:07 = *31:01:02, *31:08 = *31:02, *31:07 = *31:02, *31:08 = *31:02, *31:10 = *31:07, *31:62 = *31:08, *31:62	
+-----+ +--+-----+ +-----+ +-----+	*31:33, *31:55 = *31:34, *31:55	
+-----+ +--+-----+ +-----+ +-----+	*31:31, *31:55 = *31:44, *31:55	
+-----+ +--+-----+ +-----+ +-----+	*31:33, *31:40 = *31:34, *31:40	
+-----+ +--+-----+ +-----+ +-----+	*31:31, *31:40 = *31:40, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:25, *31:33 = *31:25, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:25, *31:31 = *31:25, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:15, *31:40 = *31:23, *31:25 = *31:25, *31:40	
+-----+ +--+-----+ +-----+ +-----+	*31:33, *31:60N = *31:34, *31:60N	
+-----+ +--+-----+ +-----+ +-----+	*31:31, *31:60N = *31:44, *31:60N	
+-----+ +--+-----+ +-----+ +-----+	*31:33, *31:41 = *31:34, *31:41	
+-----+ +--+-----+ +-----+ +-----+	*31:31, *31:41 = *31:41, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:27, *31:33 = *31:27, *31:34	
+-----+ +--+-----+ +-----+ +-----+	*31:27, *31:31 = *31:27, *31:44	
+-----+ +--+-----+ +-----+ +-----+	*31:09, *31:55 = *31:27, *31:28 = *31:27, *31:55	

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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Lot No.: 89N	Lot-specific Information	www.olerup-ssp.com
+-----+ +---+---+-----+-----+-----	*31:24, *31:33 = *31:24, *31:34	
+-----+ +---+---+-----+-----+-----	*31:24, *31:31 = *31:24, *31:44	
+-----+ +---+---+-----+-----+-----	*31:14N, *31:27 = *31:22, *31:24 = *31:24, *31:27	
+-----+ +---+---+-----+-----+-----	*31:33, *31:39 = *31:34, *31:39	
+-----+ +---+---+-----+-----+-----	*31:31, *31:39 = *31:39, *31:44	
+-----+ +---+---+-----+-----+-----	*31:33, *31:38 = *31:34, *31:38	
+-----+ +---+---+-----+-----+-----	*31:31, *31:38 = *31:38, *31:44	
+-----+ +---+---+-----+-----+-----	*31:26, *31:33 = *31:26, *31:34	
+-----+ +---+---+-----+-----+-----	*31:12, *31:38 = *31:26, *31:32 = *31:26, *31:38 = *31:26, *31:60N =	
+-----+ +---+---+-----+-----+-----	*31:38, *31:60N	
+-----+ +---+---+-----+-----+-----	*31:26, *31:31 = *31:26, *31:44	
+-----+ +---+---+-----+-----+-----	*31:04, *31:33 = *31:04, *31:34	
+-----+ +---+---+-----+-----+-----	*31:04, *31:31 = *31:04, *31:44	
+-----+ +---+---+-----+-----+-----	*31:07, *31:37 = *31:08, *31:37	
+-----+ +---+---+-----+-----+-----	*31:07, *31:35 = *31:08, *31:35	
+-----+ +---+---+-----+-----+-----	*31:07, *31:34 = *31:08, *31:34	
+-----+ +---+---+-----+-----+-----	*31:07, *31:36 = *31:08, *31:36	
+-----+ +---+---+-----+-----+-----	*31:07, *31:32 = *31:08, *31:32	
+-----+ +---+---+-----+-----+-----	*31:07, *31:31 = *31:07, *31:44 = *31:08, *31:31	
+-----+ +---+---+-----+-----+-----	*31:07, *31:30 = *31:08, *31:30	
+-----+ +---+---+-----+-----+-----	*31:07, *31:29 = *31:08, *31:29	
+-----+ +---+---+-----+-----+-----	*31:07, *31:28 = *31:08, *31:28	
+-----+ +---+---+-----+-----+-----	*31:07, *31:23 = *31:08, *31:23	
+-----+ +---+---+-----+-----+-----	*31:07, *31:22 = *31:08, *31:22	
+-----+ +---+---+-----+-----+-----	*31:07, *31:20 = *31:08, *31:20	
+-----+ +---+---+-----+-----+-----	*31:07, *31:19 = *31:08, *31:19	
+-----+ +---+---+-----+-----+-----	*31:07, *31:18 = *31:08, *31:18	
+-----+ +---+---+-----+-----+-----	*31:07, *31:17 = *31:08, *31:17	
+-----+ +---+---+-----+-----+-----	*31:07, *31:16 = *31:08, *31:16	
+-----+ +---+---+-----+-----+-----	*31:07, *31:15 = *31:08, *31:15	
+-----+ +---+---+-----+-----+-----	*31:07, *31:14N = *31:08, *31:14N	
+-----+ +---+---+-----+-----+-----	*31:07, *31:13 = *31:08, *31:13	
+-----+ +---+---+-----+-----+-----	*31:07, *31:12 = *31:08, *31:12	
+-----+ +---+---+-----+-----+-----	*31:07, *31:11 = *31:08, *31:11	
+-----+ +---+---+-----+-----+-----	*31:07, *31:09 = *31:08, *31:09	
+-----+ +---+---+-----+-----+-----	*31:05, *31:07 = *31:05, *31:08	
+-----+ +---+---+-----+-----+-----	*31:06, *31:07 = *31:06, *31:08	
+-----+ +---+---+-----+-----+-----	*31:03, *31:33 = *31:03, *31:34	
+-----+ +---+---+-----+-----+-----	*31:03, *31:32 = *31:03, *31:38 = *31:04, *31:38	
+-----+ +---+---+-----+-----+-----	*31:03, *31:31 = *31:03, *31:44	
+-----+ +---+---+-----+-----+-----	*31:03, *31:12 = *31:03, *31:26 = *31:04, *31:26	
+-----+ +---+---+-----+-----+-----	*31:07, *31:55 = *31:08, *31:55	
+-----+ +---+---+-----+-----+-----	*31:07, *31:40 = *31:08, *31:40	
+-----+ +---+---+-----+-----+-----	*31:07, *31:25 = *31:08, *31:25	
+-----+ +---+---+-----+-----+-----	*31:07, *31:60N = *31:08, *31:60N	
+-----+ +---+---+-----+-----+-----	*31:07, *31:41 = *31:08, *31:41	
+-----+ +---+---+-----+-----+-----	*31:07, *31:27 = *31:08, *31:27	
+-----+ +---+---+-----+-----+-----	*31:07, *31:24 = *31:08, *31:24	
+-----+ +---+---+-----+-----+-----	*31:07, *31:39 = *31:08, *31:39	
+-----+ +---+---+-----+-----+-----	*31:07, *31:38 = *31:08, *31:38	
+-----+ +---+---+-----+-----+-----	*31:07, *31:26 = *31:08, *31:26	
+-----+ +---+---+-----+-----+-----	*31:04, *31:07 = *31:04, *31:08	
+-----+ +---+---+-----+-----+-----	*31:03, *31:07 = *31:03, *31:08	

*31:01:02 = *31:01:02-31:01:13 and 31:42-31:43, 31:45, 31:47, 31:49-31:54, 31:57-31:58 and 31:61
*31:16 = *31:16 and 31:46
*31:20 = *31:20 and 31:56
*31:29 = *31:29 and 31:59
*31:36 = *31:36 and 31:48

101.430-12 – including *Taq* polymerase, IFU-01
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Lot-specific Information

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SPECIFICITY TABLE

HLA-A*31 SSP subtyping

Specificities and sizes of the PCR products of the 32 primer mixes used for HLA-A*31 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified HLA-A*31 alleles ³	Other amplified HLA-A alleles ⁴
1	155 bp	800 bp	*31:01:02-31:07, 31:09-31:43, 31:45-31:62	*01:07, 02:185, 23:21, 24:124, 26:19, 29:14, 30:12, 30:18, 30:55, 34:04, B*15:82 , B*40:186
2	215 bp	800 bp	*31:02, 31:07-31:08	*02:243, 24:82, 33:08, 33:53
3	155 bp	800 bp	*31:03-31:04	*02:309, 03:01:19, 26:43:01, 34:02:01, 34:02:03-34:04, 34:06-34:09, 66:06
4⁹	165 bp	1070 bp	*31:03-31:04, 31:06	*01:06, 02:114, 02:246, 02:279, 03:01:30, 03:05, 03:42, 03:98, 03:105, 03:122, 11:24:01-11:25, 11:31, 11:35, 29:01:01:01-29:01:02, 29:02:01:01-29:04, 29:06-29:23, 29:25-29:27, 29:29-29:31, 29:34-29:35, 30:26, 32:30, 32:32, 33:18, 34:02:01-34:04, 34:07-34:09, 68:08:01-68:08:02, 68:63, 80:01-80:02
5^{5,10}	110 bp, 135 bp, 285 bp	800 bp	*31:03, 31:26, 31:38	*11:43, 32:36, 33:13
6^{5,11}	130 bp, 165 bp	800 bp	*31:05, 31:39	*23:03:01, 29:03, 29:33, 32:13, 33:10
7⁹	505 bp	1070 bp	*31:07-31:08, 31:10	*02:81, 02:87, 02:112, 02:124, 02:129, 23:01:01-23:01:09, 23:03:01-23:13, 23:15-23:26, 23:28-23:33, 23:35-23:37, 23:39-23:51, 24:13:01, 24:18, 24:24, 24:94,

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				24:188, 29:13, 32:01:01-32:01:05, 32:01:07-32:01:13, 32:03-32:09, 32:11Q-32:21, 32:23-32:41
8^{6,12}	155 bp, 220 bp	1070 bp	*31:09, 31:24, 31:27	*11:01:28
9^{5,6}	75 bp	1070 bp	*31:01:02-31:02, 31:05, 31:07- 31:61	*02:24:02, 02:65, 02:152, 23:03:01, 29:32, 32:01:01-32:01:06, 32:01:08-32:01:11, 32:01:13-32:03, 32:05- 32:27N, 32:29, 32:31, 32:33-32:41, 33:01:01- 33:01:04, 33:01:06, 33:03:01-33:17, 33:20- 33:31, 33:33-33:59, 74:01-74:15
10^{5,8,13}	115 bp, 160 bp	1070 bp	*31:11, 31:41	*02:24:02, 29:33, 32:02, 32:06
11¹⁴	135 bp, 210 bp	1070 bp	*31:12, 31:26, 31:60N	*32:36
12	245 bp	1070 bp	*31:01:02-31:06, 31:09, 31:11- 31:20, 31:22- 31:32, 31:34- 31:62	*02:243, 11:43, 29:19, 33:01:01-33:01:06, 33:03:01-33:12, 33:14- 33:16, 33:18-33:47, 33:49-33:50, 33:52- 33:59, 68:29
13⁵	85 bp	1070 bp	*31:13	*02:251
14	150 bp	800 bp	*31:24	*11:01:28
15¹⁵	150 bp, 225 bp	1070 bp	*31:15, 31:25	*32:26
16^{5,16}	80 bp, 165 bp	1070 bp	*31:16, 31:46	*29:12, 33:58
17¹⁷	155 bp, 235 bp	1070 bp	*31:17, 31:25, 31:40	*32:26
18	200 bp	1070 bp	*31:18	*23:43
19^{5,8}	110 bp	1070 bp	*31:19	*03:52
20	165 bp, 325 bp	1070 bp	*31:56	
21	180 bp	1070 bp	*31:21	*01:07, 02:185, 30:55
22¹⁹	150 bp, 190 bp	1070 bp	*31:22, 31:27, 31:55	

101.430-12 – including **Taq** polymerase, IFU-01
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23²⁰	165 bp, 200 bp	1070 bp	*31:23, 31:40	
24^{7,21}	150 bp, 220 bp	1070 bp	*31:28, 31:55	
25²²	135 bp, 245 bp	800 bp	*31:29, 31:59	*23:03:01, 29:07
26⁵	130 bp	1070 bp	*31:30, 31:39	*29:28, 32:10, C*02:02:15
27⁵	95 bp	800 bp	*31:31, 31:44	
28^{5,23}	110 bp, 175 bp, 205 bp	1070 bp	*31:32, 31:38, 31:60N	
29^{5,24}	115 bp, 275 bp	1070 bp	*31:36, 31:48	*02:140, 33:15
30^{7,25}	160 bp, 245 bp	800 bp	*31:33-31:34	
31⁵	75 bp	1070 bp	*31:35	*01:07
32^{5,26}	75 bp, 115 bp	1070 bp	*31:37, 31:41	*02:24:02, 29:33, 32:02, 32:06

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-A*31 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.

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-A*31 subtyping.

In addition, wells number 2, 3, 5, 6, 14, 25, 27 and 30 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.

³For several HLA-A*31 alleles 4th exon or 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. We assume that unknown sequences in these regions are conserved within allelic groups.

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⁴Due to the sharing of sequence motifs between HLA-A alleles non-HLA-A*31 alleles will be amplified by primer mixes 1 to 19, 21, 25, 26, 29, 31 and 32. In addition, primer mix 1 will amplify the B*15:82 and B*40:186 alleles and primer mix 26 will amplify the C*02:02:15 allele.

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

⁶Primer mixes 8 and 9 may give rise to a lower yield of HLA-specific PCR product than the other HLA-A*31 primer mixes, most pronounced for the A*31:09 allele in primer mix 8.

⁷Primer mix 24 and 30 may give rise to nonspecific amplifications.

⁸Primer mix 10 and 19 may give rise to primer oligomer formation.

⁹Primer mixes 4 and 7 may weakly amplify the A*34:01 allele.

¹⁰Primer mix 5: Specific PCR product of 110 bp in the A*31:38 allele. Specific PCR product of 135 bp in the A*31:26 and the A*32:36 allele. Specific PCR product of 285 bp in the A*31:03 and in the A*11:43 and A*33:13 alleles.

¹¹Primer mix 6: Specific PCR product of 130 bp in the A*31:39 allele. Specific PCR product of 165 bp in the A*31:05 and in the A*23:03:01, 29:03, 29:33, 32:13 and 33:10 alleles.

¹²Primer mix 8: Specific PCR product of 155 bp in the A*31:24 and 31:27 and the A*11:01:28 alleles. Specific PCR product of 220 bp in the A*31:09 allele.

¹³Primer mix 10: Specific PCR product of 115 bp in the A*31:41 and the A*02:24:02, 29:33, 32:02 and 32:06 alleles. Specific PCR product of 160 bp in the A*31:11 allele.

¹⁴Primer mix 11: Specific PCR product of 135 bp in the A*31:26 and the A*32:36 allele. Specific PCR product of 210 bp in the A*31:12 and 31:60N alleles.

¹⁵Primer mix 15: Specific PCR product of 150 bp in the A*31:25 and the A*32:26 alleles. Specific PCR product of 225 bp in the A*31:15 allele.

¹⁶Primer mix 16: Specific PCR product of 80 bp in the A*31:46 allele. Specific PCR product of 165 bp in the A*31:16 and the A*29:12 and 33:58 alleles.

¹⁷Primer mix 17: Specific PCR product of 155 bp in the A*31:25 and 31:40 and the A*32:26 allele. Specific PCR product of 235 bp in the A*31:17 allele.

¹⁹Primer mix 22: Specific PCR product of 150 bp in the A*31:27 and 31:55 alleles. Specific PCR product of 190 bp in the A*31:22 allele.

²⁰Primer mix 23: Specific PCR product of 165 bp in the A*31:40 allele. Specific PCR product of 200 bp in the A*31:23 allele.

²¹Primer mix 24: Specific PCR product of 150 bp in the A*31:55 allele. Specific PCR product of 220 bp in the A*31:28 allele.

²²Primer mix 25: Specific PCR product of 135 bp in the A*31:29 and the A*23:03:01 and 29:07 alleles. Specific PCR product of 245 bp in the A*31:59 allele.

²³Primer mix 28: Specific PCR product of 110 bp in the A*31:38 allele. Specific PCR product of 175 bp in the A*31:32 allele. Specific PCR product of 205 bp in the A*31:60N allele.

²⁴Primer mix 29: Specific PCR product of 115 bp in the A*31:48 and the A*02:140 and 33:15 alleles. Specific PCR product of 275 bp in the A*31:36 allele.

²⁵Primer mix 30: Specific PCR product of 160 bp in the A*31:34 allele. Specific PCR product of 245 bp in the A*31:33 allele.

²⁶Primer mix 32: Specific PCR product of 75 bp in the A*31:37 allele. Specific PCR product of 115 bp in the A*31:41 and the A*02:24:02, 29:33, 32:02 and 32:06 alleles.

101.430-12 – including *Taq* polymerase, IFU-01
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INTERPRETATION TABLE																
HLA-A*31 SSP subtyping																
Amplification patterns of the A*31:01 to A*31:62 alleles																
	Well¹⁰															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec. PCR product(s)	155	215	155	165	110	130	505	155	75	115	135	245	85	150	150	80
					135	165		220		160	210				225	165
					285											
Length of int. pos. control¹	800	800	800	1070	800	800	1070	1070	1070	1070	1070	1070	1070	800	1070	1070
5'-primer²	127	97	423	413	97	448	317	97	413	448	362	97	413	448	98	98
	5'-ggg 3'	5'-TCA 3'	5'-gCT 3'	5'-CCg 3'	5'-TCA 3'	5'-CCT 3'	5'-gCT 3'	5'-TCA 3'	5'-CCA 3'	5'-CCT 3'	5'-gAA 3'	5'-TCA 3'	5'-CCA 3'	5'-CCT 3'	5'-CAC 3'	5'-CAC 3'
					445			448			375			375	448	769
					5'-TCC 3'			5'-CCT 3'			5'-TgA 3'			5'-ATA 3'	5'-CCT 3'	5'-Agg 3'
					467						445					
					5'-CTA 3'						5'-TCC 3'					
3'-primer³	238	270	538	539	341	536	538	214	448	524	538	299	456	559	281	221
	5'-CCT 3'	5'-ACT 3'	5'-CAA 3'	5'-TCA 3'	5'-CgT 3'	5'-ACg 3'	5'-CAA 3'	5'-CCA 3'	5'-CAA 3'	5'-CAT 3'	5'-CAA 3'	5'-CCA 3'	5'-TCg 3'	5'-CCg 3'	5'-AgC 3'	5'-ACA 3'
	238				538	570		278		565				621	559	808
	5'-CCT 3'				5'-CAA 3'	5'-CCg 3'		5'-ggC 3'		5'-CAG 3'				5'-ggg 3'	5'-CCT 3'	5'-AgA 3'
	245							559								
	5'-ACg 3'							5'-CCg 3'								
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
HLA-A allele^{4,5}																
*31:01:02-31:01:13, 31:14N, 31:20, 31:42-31:43, 31:45, 31:47, 31:49-31:54, 31:57-31:58, 31:61 ¹¹	1								9			12				
*31:02	1	2							9			12				
*31:03	1		3	4	5							12				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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Length of spec. PCR product(s)	155	215	155	165	110	130	505	155	75	115	135	245	85	150	150	80
					135	165		220		160	210				225	165
					285											
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*31:04	1		3	4								12				
*31:05	1					6			9			12				
*31:06	1			4								12				
*31:07	1	2					7		9							
*31:08		2					7		9							
*31:09	1							8	9			12				
*31:10	1						7		9							
*31:11	1								9	10		12				
*31:12	1								9		11	12				
*31:13	1								9			12	13			
*31:15	1								9			12			15	
*31:16, 31:46 ⁶	1								9			12				16
*31:17	1								9			12				
*31:18	1								9			12				
*31:19	1								9			12				
*31:21	1								9							
*31:22	1								9			12				
*31:23	1								9			12				
*31:24	1							8	9			12		14		
*31:25	1								9			12			15	
*31:26	1				5				9		11	12				
*31:27	1							8	9			12				
*31:28	1								9			12				
*31:29, 31:59 ⁸	1								9			12				
*31:30	1								9			12				
*31:31	1								9			12				
*31:32	1								9			12				
*31:33	1								9							
*31:34	1								9			12				
*31:35	1								9			12				
*31:36, 31:48 ⁹	1								9			12				
*31:37	1								9			12				
*31:38	1				5				9			12				
*31:39	1					6			9			12				
*31:40	1								9			12				
*31:41	1								9	10		12				
*31:44									9			12				
*31:55	1								9			12				
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.430-12 – including *Taq* polymerase, IFU-01
 101.430-12u – without *Taq* polymerase, IFU-02

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155	200	110	165	180	150	165	150	135	130	95	110	115	160	75	75	Length of spec. PCR product(s)
235			325		190	200	220	245			175	275	245		115	
											205					
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																*31:04
																*31:05
																*31:06
																*31:07
																*31:08
																*31:09
																*31:10
																*31:11
																*31:12
																*31:13
																*31:15
																*31:16, 31:46 ⁶
17																*31:17
	18															*31:18
		19														*31:19
				21												*31:21
					22											*31:22
						23										*31:23
																*31:24
17																*31:25
					22											*31:26
																*31:27
							24									*31:28
								25								*31:29, 31:59 ⁸
									26							*31:30
										27						*31:31
											28					*31:32
													30			*31:33
													30			*31:34
														31		*31:35
													29			*31:36, 31:48 ⁹
															32	*31:37
											28					*31:38
										26						*31:39
17						23										*31:40
															32	*31:41
										27						*31:44
					22		24									*31:55
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

101.430-12 – including *Taq* polymerase, IFU-01
 101.430-12u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **89N**

Lot-specific Information

www.olerup-ssp.com

Length of spec.	155	215	155	165	110	130	505	155	75	115	135	245	85	150	150	80
PCR product(s)					135	165		220		160	210				225	165
					285											
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*31:56	1								9			12				
*31:60N	1								9		11	12				
*31:62	1											12				
*01:06, 02:114, 02:246, 02:279, 03:01:30, 03:05, 03:42, 03:98, 03:105, 03:122, 11:24:01-11:25, 11:31, 11:35, 29:01:01:01- 29:01:02, 29:02:01:01- 29:02:11, 29:04, 29:06, 29:08N-29:11, 29:15- 29:18, 29:20-29:23, 29:25-29:27, 29:29- 29:31, 29:34-29:35, 30:26, 34:02:02, 68:08:01-68:08:02, 68:63, 80:01-80:02				4												
*01:07	1															
*02:24:02, 32:02									9	10						
*02:65, 02:152, 29:32, 32:01:06, 32:22, 33:17, 33:48, 33:51, 74:01- 74:15									9							
*02:81, 02:87, 02:112, 02:124, 02:129, 23:01:01-23:01:09, 23:03:02-23:13, 23:15- 23:20, 23:22-23:26, 23:28-23:33, 23:35- 23:37, 23:39-23:42, 23:44-23:51, 24:13:01, 24:18, 24:24, 24:94, 24:188, 32:01:07, 32:01:12, 32:04, 32:28							7									
*02:140																
*02:185, 30:55	1															
*02:243		2										12				
*02:251													13			
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.430-12 – including *Taq* polymerase, IFU-01
 101.430-12u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **89N**

Lot-specific Information

www.olerup-ssp.com

155	200	110	165	180	150	165	150	135	130	95	110	115	160	75	75	Length of spec. PCR product(s)
235			325		190	200	220	245			175	275	245		115	
											205					
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
			20													*31:56
											28					*31:60N
																*31:62
																*01:06, 02:114, 02:246, 02:279, 03:01:30, 03:05, 03:42, 03:98, 03:105, 03:122, 11:24:01-11:25, 11:31, 11:35, 29:01:01:01- 29:01:02, 29:02:01:01- 29:02:11, 29:04, 29:06, 29:08N-29:11, 29:15- 29:18, 29:20-29:23, 29:25-29:27, 29:29- 29:31, 29:34-29:35, 30:26, 34:02:02, 68:08:01-68:08:02, 68:63, 80:01-80:02
				21										31		*01:07
															32	*02:24:02, 32:02
																*02:65, 02:152, 29:32, 32:01:06, 32:22, 33:17, 33:48, 33:51, 74:01- 74:15
																*02:81, 02:87, 02:112, 02:124, 02:129, 23:01:01-23:01:09, 23:03:02-23:13, 23:15- 23:20, 23:22-23:26, 23:28-23:33, 23:35- 23:37, 23:39-23:42, 23:44-23:51, 24:13:01, 24:18, 24:24, 24:94, 24:188, 32:01:07, 32:01:12, 32:04, 32:28
												29				*02:140
				21												*02:185, 30:55
																*02:243
																*02:251
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

101.430-12 – including *Taq* polymerase, IFU-01
 101.430-12u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **89N**

Lot-specific Information

www.olerup-ssp.com

Length of spec.	155	215	155	165	110	130	505	155	75	115	135	245	85	150	150	80
PCR product(s)					135	165		220		160	210				225	165
					285											
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*02:309, 03:01:19, 26:43:01, 34:06, 66:06			3													
*03:52																
*11:01:28								8						14		
*11:43					5							12				
*23:03:01						6	7		9							
*23:21	1						7									
*23:43							7									
*24:82		2														
*24:124, 26:19, 30:12, 30:18, B*15:82, B*40:186	1															
*29:03				4		6										
*29:07				4												
*29:12				4												16
*29:13, 32:30, 32:32				4			7									
*29:14	1			4												
*29:19, 33:18				4								12				
*29:28, C*02:02:15																
*29:33						6				10						
*32:01:01-32:01:05, 32:01:08-32:01:11, 32:01:13, 32:03, 32:05, 32:07-32:09, 32:11Q- 32:12, 32:14-32:21, 32:23-32:25, 32:27N, 32:29, 32:31, 32:33- 32:35, 32:37-32:41							7		9							
*32:06							7		9	10						
*32:10									9							
*32:13						6	7		9							
*32:26							7		9						15	
*32:36					5		7		9		11					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.430-12 – including *Taq* polymerase, IFU-01
 101.430-12u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **89N**

Lot-specific Information

www.olerup-ssp.com

155	200	110	165	180	150	165	150	135	130	95	110	115	160	75	75	Length of spec. PCR product(s)
235			325		190	200	220	245			175	275	245		115	
											205					
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																*02:309, 03:01:19, 26:43:01, 34:06, 66:06
		19														*03:52
																*11:01:28
																*11:43
								25								*23:03:01
																*23:21
	18															*23:43
																*24:82
																*24:124, 26:19, 30:12, 30:18, B*15:82, B*40:186
																*29:03
								25								*29:07
																*29:12
																*29:13, 32:30, 32:32
																*29:14
																*29:19, 33:18
								26								*29:28, C*02:02:15
														32		*29:33
																*32:01:01-32:01:05, 32:01:08-32:01:11, 32:01:13, 32:03, 32:05, 32:07-32:09, 32:11Q- 32:12, 32:14-32:21, 32:23-32:25, 32:27N, 32:29, 32:31, 32:33- 32:35, 32:37-32:41
														32		*32:06
								26								*32:10
																*32:13
17																*32:26
																*32:36
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

101.430-12 – including *Taq* polymerase, IFU-01
 101.430-12u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
 “Instructions for Use” (IFU)

Lot No.: **89N**

Lot-specific Information

www.olerup-ssp.com

Length of spec.	155	215	155	165	110	130	505	155	75	115	135	245	85	150	150	80
PCR product(s)					135	165		220		160	210				225	165
					285											
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*33:01:01-33:01:04, 33:01:06, 33:03:01- 33:07, 33:09, 33:11- 33:12, 33:14, 33:16, 33:20-33:31, 33:33- 33:47, 33:49-33:50, 33:52, 33:54-33:57, 33:59									9			12				
*33:01:05, 33:19, 33:32:01-33:32:02, 68:29												12				
*33:08, 33:53		2							9			12				
*33:10						6			9			12				
*33:13					5				9							
*33:15									9			12				
*33:58									9			12				16
*34:02:01, 34:02:03- 34:03, 34:07-34:09			3	4												
*34:04	1		3	4												
HLA-A allele ^{4,5}																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

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-A*31 subtyping.

In addition, wells number 2, 3, 5, 6, 14, 25, 27 and 30 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.

²The nucleotide position, in the 2nd, 3rd or 4th exons or the 3rd intron, matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The nucleotide position, in the 2nd, 3rd or 4th exons, 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.

⁴The sequence of the A*31011 allele has been shown to be identical to A*31:01:02.

⁵HLA-A*31 alleles in bold lettering are listed as confirmed alleles on the on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.8.0, April 2012.

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: **89N**

Lot-specific Information

www.olerup-ssp.com

155	200	110	165	180	150	165	150	135	130	95	110	115	160	75	75	Length of spec.
235			325		190	200	220	245			175	275	245		115	PCR product(s)
											205					
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
																*33:01:01-33:01:04, 33:01:06, 33:03:01- 33:07, 33:09, 33:11- 33:12, 33:14, 33:16, 33:20-33:31, 33:33- 33:47, 33:49-33:50, 33:52, 33:54-33:57, 33:59
																*33:01:05, 33:19, 33:32:01-33:32:02, 68:29
																*33:08, 33:53
																*33:10
																*33:13
												29				*33:15
																*33:58
																*34:02:01, 34:02:03- 34:03, 34:07-34:09
																*34:04
																HLA-A allele ^{4,5}
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

⁶The A*31:16 and A*31:46 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 16.

⁸The A*31:29 and A*31:59 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 25

⁹The A*31:36 and A*31:48 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 29.

¹⁰Primer mix 5: Specific PCR product of 110 bp in the A*31:38 allele. Specific PCR product of 135 bp in the A*31:26 and the A*32:36 allele. Specific PCR product of 285 bp in the A*31:03 and in the A*11:43 and A*33:13 alleles.

Primer mix 6: Specific PCR product of 130 bp in the A*31:39 allele. Specific PCR product of 165 bp in the A*31:05 and in the A*23:03:01, 29:03, 29:33, 32:13 and 33:10 alleles.

Primer mix 8: Specific PCR product of 155 bp in the A*31:24 and 31:27 and the A*11:01:28 alleles. Specific PCR product of 220 bp in the A*31:09 allele.

Primer mix 10: Specific PCR product of 115 bp in the A*31:41 and the A*02:24:02, 29:33, 32:02 and 32:06 alleles. Specific PCR product of 160 bp in the A*31:11 allele.

¹¹Primer mix 11: Specific PCR product of 135 bp in the A*31:26 and the A*32:36 allele. Specific PCR product of 210 bp in the A*31:12 and 31:60N alleles.

Primer mix 15: Specific PCR product of 150 bp in the A*31:25 and the A*32:26 alleles. Specific PCR product of 225 bp in the A*31:15 allele.

Primer mix 16: Specific PCR product of 80 bp in the A*31:46 allele. Specific PCR product of 165 bp in the A*31:16 and the A*29:12 and 33:58 alleles.

Primer mix 17: Specific PCR product of 155 bp in the A*31:25 and 31:40 and the A*32:26 allele. Specific PCR product of 235 bp in the A*31:17 allele.

101.430-12 – including **Taq** polymerase, IFU-01
101.430-12u – without **Taq** polymerase, IFU-02

Visit www.olerup-ssp.com for
“Instructions for Use” (IFU)

Lot No.: 89N**Lot-specific Information****www.olerup-ssp.com**

Primer mix 22: Specific PCR product of 150 bp in the A*31:27 and 31:55 alleles. Specific PCR product of 190 bp in the A*31:22 allele.

Primer mix 23: Specific PCR product of 165 bp in the A*31:40 allele. Specific PCR product of 200 bp in the A*31:23 allele.

Primer mix 24: Specific PCR product of 150 bp in the A*31:55 allele. Specific PCR product of 220 bp in the A*31:28 allele.

Primer mix 25: Specific PCR product of 135 bp in the A*31:29 and the A*23:03:01 and 29:07 alleles. Specific PCR product of 245 bp in the A*31:59 allele.

Primer mix 28: Specific PCR product of 110 bp in the A*31:38 allele. Specific PCR product of 175 bp in the A*31:32 allele. Specific PCR product of 205 bp in the A*31:60N allele.

Primer mix 29: Specific PCR product of 115 bp in the A*31:48 and the A*02:140 and 33:15 alleles. Specific PCR product of 275 bp in the A*31:36 allele.

Primer mix 30: Specific PCR product of 160 bp in the A*31:34 allele. Specific PCR product of 245 bp in the A*31:33 allele.

Primer mix 32: Specific PCR product of 75 bp in the A*31:37 allele. Specific PCR product of 115 bp in the A*31:41 and the A*02:24:02, 29:33, 32:02 and 32:06 alleles.

¹¹Primer mix 14 does not amplify the A*31:14N allele. Thus, this lot of the HLA-A*31 subtyping kit cannot distinguish the A*31:01:02-31:01:13, 31:42-31:43, 31:45, 31:47, 31:49-31:54, 31:57-31:58 and 31:61 alleles and the A*31:14N allele.

Primer mix 20 does not amplify the A*31:20 allele. Thus, this lot of the HLA-A*31 subtyping kit cannot distinguish the A*31:01:02-31:01:17 and the A*31:20 alleles.

101.430-12 – including *Taq* polymerase, IFU-01101.430-12u – without *Taq* polymerase, IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **89N**

Lot-specific Information

www.olerup-ssp.com

CELL LINE VALIDATION SHEET																				
HLA-A*31 SSP subtyping kit																				
					Well															
				Lot No.:	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					201186101	201186102	200969703	201186104	201202905	201202906	200969707	200969708	200969709	201202910	201202911	200969712	200969713	200969714	200969715	201202916
	IHCW cell line		A*	A*																
1	9001	SA	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275	GU373	*30:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*01:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
6	9353	SM	*02:01	*26:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU	*31:01		+	-	-	-	-	-	-	-	+	-	-	+	-	-	-	-
9	9026	YAR	*26:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT	*29:02		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA	*31:01		+	-	-	-	-	-	-	-	+	-	-	+	-	-	-	-
15	9075	DKB	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007	*29:02		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540	*03:01	*80:01	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367	*33:03	*74:01	-	-	-	-	-	-	-	-	+	-	-	+	-	-	-	-
19	9038	BM16	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL	*02:01	*34:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH	*32:01		-	-	-	-	-	-	+	-	+	-	-	-	-	-	-	-
25	9049	IBW9	*33:01		-	-	-	-	-	-	-	-	+	-	-	+	-	-	-	-
26	9285	WT49	*02:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007	*24:10	*29:01	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB	*02:01	*29:02	-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU	*29:02		-	-	-	+	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH	*30:01	*68:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF	*30:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG	*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B	*31:01		+	-	-	-	-	-	-	-	+	-	-	+	-	-	-	-
34	9104	DHIF	*31:01		+	-	-	-	-	-	-	-	+	-	-	+	-	-	-	-
35	9302	SSTO	*32:01		-	-	-	-	-	-	+	-	+	-	-	-	-	-	-	-
36	9024	KT17	*02:06	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL	*02:17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML	*01:01	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199	*02:07	*30:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089	*02:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526	*02:06	*02:07	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM	*66:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO	*23:01	*24:02	-	-	-	-	-	-	+	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO	*02:16	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND	*02:01	*11:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.430-12 – including *Taq* polymerase, IFU-01101.430-12u – without *Taq* polymerase, IFU-02Visit www.olerup-ssp.com for

“Instructions for Use” (IFU)

Lot No.: **89N**

Lot-specific Information

www.olerup-ssp.com

CELL LINE VALIDATION SHEET																																
HLA-A*31 SSP subtyping kit																																
					Prod. No.:	Well																										
						17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32											
						201202917	200969718	200969719	201202920	200969721	201202922	201202923	201202924	201202925	201202926	201202927	201202928	201202929	201186130	201186131	201202932											
	IHCW cell line		A*																													
1	9001	SA	*24:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
2	9280	LK707	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
3	9011	E4181324	*01:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
4	9275	GU373	*30:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
5	9009	KAS011	*01:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
6	9353	SM	*02:01	*26:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
7	9020	QBL	*26:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
8	9025	DEU	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
9	9026	YAR	*26:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
10	9107	LKT3	*24:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
11	9051	PITOUT	*29:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
12	9052	DBB	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
13	9004	JESTHOM	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
14	9071	OLGA	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
15	9075	DKB	*24:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
16	9037	SWEIG007	*29:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
17	9282	CTM3953540	*03:01	*80:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
18	9257	32367	*33:03	*74:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
19	9038	BM16	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
20	9059	SLE005	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
21	9064	AMALA	*02:17			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
22	9056	KOSE	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
23	9124	IHL	*02:01	*34:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
24	9035	JBUSH	*32:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
25	9049	IBW9	*33:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
26	9285	WT49	*02:05			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
27	9191	CH1007	*24:10	*29:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
28	9320	BEL5GB	*02:01	*29:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
29	9050	MOU	*29:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
30	9021	RSH	*30:01	*68:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
31	9019	DUCAF	*30:02			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
32	9297	HAG	*02:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
33	9098	MT14B	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
34	9104	DHIF	*31:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
35	9302	SSTO	*32:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
36	9024	KT17	*02:06	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
37	9065	HHKB	*03:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
38	9099	LZL	*02:17			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
39	9315	CML	*01:01	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
40	9134	WHONP199	*02:07	*30:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
41	9055	H0301	*03:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
42	9066	TAB089	*02:07			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
43	9076	T7526	*02:06	*02:07		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
44	9057	TEM	*66:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
45	9239	SHJO	*23:01	*24:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
46	9013	SCHU	*03:01			-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
47	9045	TUBO	*02:16	*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										
48	9303	TER-ND	*02:01	*11:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-										

101.430-12 – including *Taq* polymerase, IFU-01
 101.430-12u – without *Taq* polymerase, IFU-02

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Lot No.: **89N**

Lot-specific Information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® HLA-A*31 SSP

Product number: 101.430-12 – including *Taq* polymerase
 101.430-12u – without *Taq* polymerase
 Lot number: 89N
 Expiry date: 2015-January-01
 Number of tests: 12
 Number of wells per test: 32

Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2011-861-01	13	2009-697-13	25	2012-029-25
2	2011-861-02	14	2009-697-14	26	2012-029-26
3	2009-697-03	15	2009-697-15	27	2012-029-27
4	2011-861-04	16	2012-029-16	28	2012-029-28
5	2012-029-05	17	2012-029-17	29	2012-029-29
6	2012-029-06	18	2009-697-18	30	2011-861-30
7	2009-697-07	19	2009-697-19	31	2011-861-31
8	2009-697-08	20	2012-029-20	32	2012-029-32
9	2009-697-09	21	2009-697-21		
10	2012-029-10	22	2012-029-22		
11	2012-029-11	23	2012-029-23		
12	2009-697-12	24	2012-029-24		

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

No DNAs carrying the alleles to be amplified by primer solutions 2, 5, 6, 8, 10, 11 and 13 to 32 were available.

The specificities of the primers in primer solutions 2, 5, 6, 8, 10, 14, 16, 20, 21, 25, 26, 31 and 32 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 13, 15, 17, 18, 22 to 24, 29 and 30 it was only possible to test the 5'-primer, the 3'-primer was not possible to test. In primer solutions 11, 19, 27 and 28 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 5, 16, 20 and 25 one or two 5'-primers were not possible to test, and in primer solutions 1, 6, 8, 10, 14, 16, 20, 26 and 32 one or two 3'-primers were not possible to test.

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

2013-January-10

Approved by:

Production Quality Control

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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Lot No.: **89N**

Lot-specific Information

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Declaration of Conformity

Product name: *Olerup* SSP® HLA-A*31
Product number: 101.430-12/12u
Lot number: 89N

Intended use: HLA-A*31 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
2013-January-10

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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101.430-12 – including *Taq* polymerase, IFU-01
101.430-12u – without *Taq* polymerase, IFU-02

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Lot No.: **89N**

Lot-specific Information

www.olerup-ssp.com

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For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.