

101.211.24 – including *Taq* pol., IFU-01
 101.211.24u – without *Taq* pol., IFU-02

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

Lot No.: **66R**

Lot-specific information
Olerup SSP[®] DQB1*05

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Product number: 101.211-24 – including *Taq* polymerase
 101.211-24u - without *Taq* polymerase
 Lot number: 66R
 Expiry date: 2015-June-01
 Number of tests: 24
 Number of wells per test: 15
 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. 66R

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®]
 DQB1*05 LOT (83N)**

The DQB1*05 specificity and interpretation tables have been updated for the HLA-DQB1 alleles described since the previous *Olerup SSP[®]* DQB1*05 lot was made (Lot No. 83N).

Three wells have been added to the DQB1*05 kit, wells **13 to 15**.

The Lot-specific information for DQB1*05 including and without *Taq* polymerase is described in one common Product Insert.

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

Well	5'-primer	3'-primer	rationale
13	New	New	New primer pair for the DQB1*05:15 allele.
14	New	New	New primer pair for the DQB1*05:16 allele.
15	New	New	New primer pair for the DQB1*05:17 allele.

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PRODUCT DESCRIPTION

DQB1*05 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQB1*05:01 to DQB1*05:18 alleles.

Please note that DQB1 amplifications usually are somewhat less pronounced than e.g. DRB and DQA1 amplifications even when using the same DNA preparation and exactly the same experimental procedures.

PLATE LAYOUT

Each test consists of 15 PCR reactions in a 16 well PCR plate. Well 16 is empty.

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

The 16 well cut PCR plate is marked with ‘DQ5’ in silver gray ink.

Well No. 1 is marked with the Lot No. ‘66R’.

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 16 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Only DQB1*05 alleles will be amplified by the DQB1*05 subtyping kit. Thus, the interpretation of DQB1*05 SSP subtypings is only influenced by this allele and not by other groups of DQB1 alleles or the DQB2 and DQB3 genes.

UNIQUELY IDENTIFIED ALLELES

All the DQB1*05 alleles, i.e. **DQB1*05:01 to DQB1*05:18**, recognized by the HLA Nomenclature Committee in October 2012¹ will give rise to unique amplification patterns by the primers in the DQB1*05 subtyping kit.

The DQB1*05 subtyping kit cannot distinguish the silent mutations in the DQB1*05:01:01:01-05:01:03, the DQB1*05:02:01 and 05:02:03 alleles or the DQB1*05:03:01:01-05:03:05 alleles.

¹DQB1 alleles listed on the IMGT/HLA web page 2012-October-17, release 3.10.0, www.ebi.ac.uk/imgt/hla.

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RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 28 alleles generate 19 amplification patterns that can be combined in 190 homozygous and heterozygous combinations. 78 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.

```

+----+----- -+-----+ *05:03:01:01, *05:16 = *05:16, *05:16
+----+----- -+-----+ *05:03:01:01, *05:15 = *05:15, *05:15
+----+----- -+-----+ *05:03:01:01, *05:13 = *05:13, *05:13
+----+----- +----- *05:03:01:01, *05:08 = *05:08, *05:08
+----+-----+ -+----- *05:03:01:01, *05:09 = *05:09, *05:09
+----+-----+ -+----- *05:03:01:01, *05:06 = *05:06, *05:06
+----+-----+ -+----- *05:03:01:01, *05:04 = *05:03:01:01, *05:10 = *05:04, *05:10 =
*05:10, *05:10
+--+----- -+-----+ *05:02:01, *05:17 = *05:17, *05:17
+--+----- -+-----+ *05:02:01, *05:14 = *05:14, *05:14
+--+-----+ -+----- *05:02:01, *05:05 = *05:05, *05:05
+--+-----+ -+----- *05:02:01, *05:02:02 = *05:02:01, *05:03:01:01 = *05:02:02,
*05:02:02 = *05:02:02, *05:03:01:01
++----- -+----- *05:01:01:01, *05:12 = *05:12, *05:12
++----- +----- *05:01:01:01, *05:18 = *05:18, *05:18
++-----+ -+----- *05:01:01:01, *05:07 = *05:07, *05:07
++-----+ -+----- *05:01:01:01, *05:11 = *05:11, *05:11
+----+----- -+-----+ *05:04, *05:16 = *05:10, *05:16
+----+----- -+-----+ *05:04, *05:15 = *05:10, *05:15
+----+----- -+-----+ *05:04, *05:13 = *05:10, *05:13
+----+----- +----- *05:04, *05:08 = *05:08, *05:10
+----+-----+ -+----- *05:04, *05:09 = *05:09, *05:10
+----+-----+ -+----- *05:04, *05:06 = *05:06, *05:10
+----+----- -+-----+ *05:02:02, *05:17 = *05:03:01:01, *05:17
+----+----- -+-----+ *05:02:01, *05:16 = *05:02:02, *05:16
+----+----- -+-----+ *05:02:01, *05:15 = *05:02:02, *05:15
+----+----- -+-----+ *05:02:02, *05:14 = *05:03:01:01, *05:14
+----+----- -+-----+ *05:02:01, *05:13 = *05:02:02, *05:13
+----+----- +----- *05:02:01, *05:08 = *05:02:02, *05:08
+----+-----+ -+----- *05:02:01, *05:09 = *05:02:02, *05:09
+----+-----+ -+----- *05:02:01, *05:06 = *05:02:02, *05:06
+----+-----+ -+----- *05:02:02, *05:05 = *05:03:01:01, *05:05
+----+----- -+-----+ *05:02:01, *05:10 = *05:02:02, *05:04 = *05:02:02, *05:10
++-----+ -+----- *05:01:01:01, *05:08 = *05:03:01:01, *05:18 = *05:08, *05:18
++-----+ -+----- *05:01:01:01, *05:06 = *05:03:01:01, *05:07 = *05:06, *05:07
++++-----+ -+----- *05:01:01:01, *05:05 = *05:02:01, *05:11 = *05:05, *05:11
++++-----+ +----- *05:06, *05:18 = *05:07, *05:08
    
```

*05:01:01:01 = *05:01:01:01-05:01:03
 *05:02:01 = *05:02:01 and 05:02:03
 *05:03:01:01 = *05:03:01:01-05:03:05



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Lot-specific information

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SPECIFICITY TABLE

DQB1*05 SSP subtyping

Specificities and sizes of the PCR products of the 15 primer mixes used for DQB1*05 SSP subtyping

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DQB1*05 alleles ³
1	225 bp	515 bp	*05:01:01:01-05:18
2	135 bp	430 bp	*05:01:01:01-05:01:03, 05:07, 05:11-05:12, 05:18
3 ^{4,5}	120 bp	430 bp	*05:02:01-05:02:03, 05:05, 05:14, 05:17
4 ^{4,5}	95 bp	515 bp	*05:02:02, 05:03:01:01-05:03:05, 05:06, 05:08-05:10, 05:13, 05:15-05:16
5 ^{4,6}	120 bp, 185 bp	430 bp	*05:04, 05:10
6	185 bp	430 bp	*05:05, 05:11
7	185 bp	430 bp	*05:06-05:07
8	190 bp	430 bp	*05:09
9	135 bp	430 bp	*05:08, 05:18
10	195 bp	430 bp	*05:12
11 ⁴	95 bp	430 bp	*05:13
12	150 bp	430 bp	*05:14
13	190 bp	430 bp	*05:15
14	200 bp	430 bp	*05:16
15 ^{4,5}	105 bp	430 bp	*05:17

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 DQB1*05 SSP typings.

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 respective lengths of the HLA-specific PCR product(s) are given for the alleles amplified by these primer mixes.

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.

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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 430 base pairs, for most wells, or a band of 515 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to help in the correct orientation of the DQB1*05 subtyping.

In addition, well number 4 contains the primer pair giving rise to the longer, 515 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 DQB1 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. We assume that unknown sequences in these regions are conserved within allelic groups.

⁴HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁵Primer mixes 3, 4 and 15 may have tendencies of unspecific amplifications.

⁶Primer mix 5: Specific PCR fragment of 120 bp in the DQB1*05:04 allele. Specific PCR fragment of 185 bp in the DQB1*05:10 allele.

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INTERPRETATION TABLE								
DQB1*05 SSP subtyping								
Amplification patterns of the DQB1*05:01 to DQB1*05:18 alleles								
	Well ⁴							
	1	2	3	4	5	6	7	8
Length of spec.	225	135	120	95	120	185	185	190
PCR product(s)					185			
Length of int.	515	430	430	515	430	430	430	430
pos. control ¹								
5'-primer ²	26(173) 5'-ggg 3'	26(173) 5'-ggg 3'	29(184) 5'-gAC 3'	29(184) 5'-gAC 3'	29(184) 5'-gAT 3'	38(210) 5'-gCg 3'	39(212) 5'-gCA 3'	36(205) 5'-Agg 3'
					135(500) 5'-TgA 3'	38(210) 5'-gCA 3'	40(216) 5'-TTg 3'	
3'-primer ³	87(356) 5'-ggT 3'	57(266) 5'-CAA 3'	56(265) 5'-gCT 3'	47(237) 5'-CgA 3'	56(265) 5'-gCT 3'	86(353) 5'-ACg 3'	87(356) 5'-ggT 3'	86(353) 5'-ACg 3'
					182(642) 5'-ggT 3'			
Well No.	1	2	3	4	5	6	7	8
DQB1 allele								
*05:01:01:01-05:01:03	1	2						
*05:02:01, 05:02:03	1		3					
*05:02:02	1		3	4			7	
*05:03:01:01-05:03:05	1			4				
*05:04	1				5			
*05:05	1		3			6		
*05:06	1			4			7	
*05:07	1	2					7	
*05:08	1			4				
*05:09	1			4				8
*05:10	1			4	5			
*05:11	1	2				6		
*05:12	1	2						
*05:13	1			4				
*05:14	1		3					
*05:15	1			4				
*05:16	1			4				
*05:17	1		3					
*05:18	1	2						
DQB1 allele								
Well No.	1	2	3	4	5	6	7	8

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INTERPRETATION TABLE							
DQB1*05 SSP subtyping							
Amplification patterns of the DQB1*05:01 to DQB1*05:18 alleles							
Well⁴							
9	10	11	12	13	14	15	
135	195	95	150	190	200	105	Length of spec. PCR product(s)
430	430	430	430	430	430	430	Length of int. pos. control ¹
135(501)	26(173)	13(136)	133(494)	29(184)	29(184)	135(501)	5'-primer ²
5' -gAT 3'	5' -ggg 3'	5' -gCC 3'	5' -TCA 3'	5' -gAC 3'	5' -gAC 3'	5' -gAT 3'	
167(596)	77(328)	32(191)	169(604)	80(335)	82(341)	157(566)	3'-primer ³
5' -CAT 3'	5' -CAA 3'	5' -TAC 3'	5' -gAC 3'	5' -gTT 3'	5' -AgC 3'	5' -ggg 3'	
9	10	11	12	13	14	15	Well No. DQB1 allele
							*05:01:01:01-05:01:03
							*05:02:01, 05:02:03
							*05:02:02
							*05:03:01:01-05:03:05
							*05:04
							*05:05
							*05:06
							*05:07
9							*05:08
							*05:09
							*05:10
							*05:11
	10						*05:12
		11					*05:13
			12				*05:14
				13			*05:15
					14		*05:16
						15	*05:17
9							*05:18
9	10	11	12	13	14	15	DQB1 allele Well No.



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In addition, well number 4 contains the primer pair giving rise to the longer, 515 bp, internal positive control band in order to allow kit identification.

²The codon, and in parenthesis the nucleotide, in the 2nd and 3rd exons, matching the specificity-determining 3'-end of the primer is given. Codon and 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 codon, and in parenthesis the nucleotide, in the 2nd or 3rd exons, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Codon and 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.

⁴Primer mix 5: Specific PCR fragment of 120 bp in the DQB1*05:04 allele. Specific PCR fragment of 185 bp in the DQB1*05:10 allele.

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CELL LINE VALIDATION SHEET																			
DQB1*05 SSP subtyping kit																			
				Production No.	Well														
					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
	IHWC cell line		DQB1		201211201	201211202	201211203	201211204	201211205	201211206	201211207	201211208	201211209	201211210	201211211	201211212	201211213	201211214	201211215
1	9001 SA		*05:01		+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280 LK707		*06:01	*02:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
3	9011 E4181324		*06:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
4	9275 GU373		*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009 KAS011		*05:02		+	-	+	-	-	-	-	-	-	-	-	-	-	-	-
6	9353 SM		*03:02	*06:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020 QBL		*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025 DEU		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026 YAR		*03:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107 LKT3		*04:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051 PITOUT		*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052 DBB		*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004 JESTHOM		*05:01		+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071 OLGA		*04:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075 DKB		*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037 SWEIG007		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282 CTM3953540		*02:01	*06:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257 32367		*06:02	*02:02	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038 BM16		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059 SLE005		*06:04		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064 AMALA		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056 KOSE		*05:03	*06:04	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-
23	9124 IHL		*05:03	*06:01	+	-	-	+	-	-	-	-	-	-	-	-	-	-	-
24	9035 JBUSH		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049 IBW9		*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285 WT49		*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191 CH1007		*04:01	*05:01	+	+	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320 BEL5GB		*02:02	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050 MOU		*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021 RSH		*04:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019 DUCAF		*02:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297 HAG		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098 MT14B		*03:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104 DHIF		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302 SSTO		*03:05		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024 KT17		*03:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065 HHKB		*06:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099 LZL		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315 CML		*02:01	*03:01	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134 WHONP199		*02:02	*03:03	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055 H0301		*06:09		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066 TAB089		*06:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076 T7526		*03:03		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057 TEM		*05:03		+	-	-	+	-	-	-	-	-	-	-	-	-	-	-
45	9239 SHJO		*02:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013 SCHU		*06:02		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
47	9045 TUBO		*03:01		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303 TER-ND		*05:01		+	+	-	-	-	-	-	-	-	-	-	-	-	-	-



101.211.24 – including *Taq* pol., IFU-01
 101.211.24u – without *Taq* pol., IFU-02

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

Lot No.: **66R**

Lot-specific information

www.olerup-ssp.com

CERTIFICATE OF ANALYSIS

Olerup SSP® DQB1*05 SSP

Product number: 101.211-24 – including *Taq* polymerase
 101.211-24u - without *Taq* polymerase
Lot number: 66R
Expiry date: 2015-June-01
Number of tests: 24
Number of wells per test: 15

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2012-112-01	9	2012-112-09
2	2012-112-02	10	2012-112-10
3	2012-112-03	11	2012-112-11
4	2012-112-04	12	2012-112-12
5	2012-112-05	13	2012-112-13
6	2012-112-06	14	2012-112-14
7	2012-112-07	14	2012-112-15
8	2012-112-08		

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 5 to 15 were available. The specificities of the primers in primer solutions 5, 6 and 8 were tested by separately adding one 5'-primer, respectively one 3'-primer. In primer solutions 7 and 12 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In primer solutions 9 to 11 and 13 to 15 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solution 5 one 3'-primer was not possible to test,

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

Date of approval: 2012-December-19

Approved by:

Production Quality Control

101.211.24 – including *Taq* pol., IFU-01
101.211.24u – without *Taq* pol., IFU-02

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Lot No.: **66R**

Lot-specific information

www.olerup-ssp.com

Declaration of Conformity

Product name: *Olerup* SSP® DQB1*05

Product number: 101.211-24/24u

Lot number: 66R

Intended use: DQB1*05 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 III, 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.

Stockholm, Sweden
2012-December-19

Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

101.211.24 – including *Taq* pol., IFU-01
101.211.24u – without *Taq* pol., IFU-02

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

Lot No.: **66R**

Lot-specific information

www.olerup-ssp.com

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