101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 5F2 **Lot-specific information**

Olerup SSP® DRB5

Product number:	**101.123-24/06 – including *Taq* pol.** **101.123-24u/06u – without *Taq* pol.**
Lot number:	**5F2**
Expiry date:	**2021-10-01**
Number of tests:	**24 tests – Product No. 101.123-24/24u** **6 tests – Product No. 101.123-06/06u**
Number of wells per test:	**18+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. 5F2.

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

CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® DRB5 LOT (1E2)

The DRB5 kit is updated to enable separation of:

- Confirmed DRB5 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

Three wells have been added to DRB5, wells **17 to 19**.

The format of the Worksheet has been changed.

The DRB5 primer set, specificity and interpretation tables have been updated for the HLA-DRB alleles described since the previous *Olerup* SSP® DRB5 lot was made **(Lot No. 1E2)**. The kit design is based on IMGT/HLA database 3.28.0.

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 5F2 **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
16	Added	Added	Negative control moved to well 19, primer pairs added for the DRB5*01:20, DRB5*01:21 and DRB5*02:10 alleles.
17	New	New	New primer pairs added for the DRB5*01:27N and DRB5*02:12 alleles.
18	New	New	New primer pair added for the DRB5*02:13 allele.
19	-	-	Negative control added from well 16.

Changes in revision R01 compared to R00:

1. The expiry date has been altered due to extension of shelf-life.

Lot No.: 5F2 **Lot-specific information**

Well **19** 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.

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 5F2 **Lot-specific information**

PRODUCT DESCRIPTION

DRB5 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB5*01:01:01 to DRB5*01:31 and the DRB5*02:02 to DRB5*02:16 alleles.

PLATE LAYOUT

Each test consists of 19 PCR reactions in a 24 well cut PCR plate. Wells 20 to 24 are empty.

1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
9	**10**	**11**	**12**	**13**	**14**	**15**	**16**
17	**18**	**NC**	**empty**	**empty**	**empty**	**empty**	**empty**

The 24 well cut PCR plate is marked with 'DRB5' in silver/gray ink.
Well No. 1 is marked with the Lot No. '5F2'.
Wells 1 to 18 – DRB5 primers.
Well 19 – 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 DRB5 alleles, non-DRB5 alleles will be amplified by some primer mixes. For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

All the DRB5 alleles, i.e. **DRB5*01:01:01 to DRB5*01:31 and DRB5*02:02 to DRB5*02:16**, recognized by the HLA Nomenclature Committee in April 2016[1,2] will be amplified by the primers in the DRB5 subtyping kit.

The DRB5 kit enables separation of the confirmed DRB5 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 DRB5 alleles is listed below.

The DRB5 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 5F2 **Lot-specific information**

[1]DRB5 alleles listed on the IMGT/HLA web page 2017-April-13, release 3.28.0, 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.

ALLELE CONFIRMATION STATUS

Allele	Status[1]	Allele	Status[1]	Allele	Status[1]
DRB5*01:01:01	**Confirmed**	DRB5*01:19	Unconfirmed	DRB5*02:09	Unconfirmed
DRB5*01:01:02	Unconfirmed	**DRB5*01:20**	**Confirmed**	**DRB5*02:10**	**Confirmed**
DRB5*01:01:03	Unconfirmed	**DRB5*01:21**	**Confirmed**	DRB5*02:11	Unconfirmed
DRB5*01:02	**Confirmed**	DRB5*01:22	Unconfirmed	**DRB5*02:12**	**Confirmed**
DRB5*01:03	**Confirmed**	DRB5*01:23	Unconfirmed	**DRB5*02:13**	**Confirmed**
DRB5*01:04	Unconfirmed	DRB5*01:24	Unconfirmed	DRB5*02:14	Unconfirmed
DRB5*01:05	Unconfirmed	DRB5*01:25	Unconfirmed	DRB5*02:15	Unconfirmed
DRB5*01:06	Unconfirmed	DRB5*01:26	Unconfirmed	DRB5*02:16	Unconfirmed
DRB5*01:07	Unconfirmed	DRB5*01:27N	Unconfirmed		
DRB5*01:08N	**Confirmed**	DRB5*01:28	Unconfirmed		
DRB5*01:09	Unconfirmed	DRB5*01:29	Unconfirmed		
DRB5*01:10N	**Confirmed**	DRB5*01:30	Unconfirmed		
DRB5*01:11	Unconfirmed	DRB5*01:31	Unconfirmed		
DRB5*01:12	Unconfirmed	**DRB5*02:02**	**Confirmed**		
DRB5*01:13	**Confirmed**	**DRB5*02:03**	**Confirmed**		
DRB5*01:14	Unconfirmed	DRB5*02:04	Unconfirmed		
DRB5*01:15	Unconfirmed	DRB5*02:05	Unconfirmed		
DRB5*01:16	Unconfirmed	DRB5*02:06	Unconfirmed		
DRB5*01:17	**Confirmed**	**DRB5*02:07**	**Confirmed**		
DRB5*01:18	**Confirmed**	DRB5*02:08	Unconfirmed		

[1]Allele status "confirmed" or "unconfirmed" as listed on the IMGT/HLA web page 2017-April-13, release 3.28.0, www.ebi.ac.uk/imgt/hla.

RESOLUTION IN HOMO- AND HETEROZYGOTES

Results file with resolution in DRB5 homo- and heterozygotes is available upon request.

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 5F2

Lot-specific information

SPECIFICITY TABLE

DRB5 SSP subtyping

Specificities and sizes of the PCR products of the 18+1 primer mixes used for DRB5 SSP subtyping

Primer Mix	Size of spec. PCR product[1]	Size of control band[2]	Amplified DRB5 alleles[3]	Other amplified DRB alleles
1	255 bp	**515 bp**	*01:01:01-01:05, 01:07-01:20, 01:22-01:30, 02:03	**DRB1*09:07**
2	210 bp	**515 bp**	*01:01:01-01:05, 01:07-01:10N, 01:12-01:20, 01:22-01:31, 02:04, 02:08, 02:12	**DRB1*09:07**
3	225 bp	430 bp	*01:01:01-01:02, 01:04-01:05, 01:07-01:10N, 01:12-01:20, 01:22-01:31, 02:05, 02:08, 02:12	**DRB1*09:07**
4[4]	100 bp 150 bp	**515 bp**	*01:01:01-01:01:03, 01:04, 01:06-01:07, 01:09, 01:11, 01:15-01:19, 01:21-01:24, 01:26, 01:29-01:31 *02:06	
5	150 bp	**515 bp**	*01:01:01, 01:05, 01:07, 01:09, 01:13, 01:16-01:19, 01:22-01:24, 01:26, 01:29-01:31	
6	145 bp	430 bp	*01:02-01:03, 01:05, 01:08N, 01:10N, 01:20, 01:25, 01:27N-01:28, 02:08, 02:12	
7	145 bp	430 bp	*01:02-01:03, 01:08N, 01:10N, 01:17, 01:20, 01:25, 01:27N-01:28, 02:05, 02:08, 02:12	
8	215 bp	430 bp	*01:03, 01:06, 01:09, 01:11, 01:21, 02:02-02:04, 02:06-02:07, 02:09-02:11, 02:13-02:16	
9[4]	85 bp 175 bp 225 bp	430 bp	*01:16 *01:13 *01:04	
10	130 bp 160 bp	430 bp	*01:07 *01:12, 01:15	
11[4]	110 bp 200 bp	430 bp	*01:14 *01:06, 01:11, 01:21, 02:02-02:03, 02:06-02:07, 02:09-02:11, 02:13-02:16	
12	185 bp	**515 bp**	*02:02, 02:04-02:12, 02:14-02:16	
13	150 bp	430 bp	*01:01:02?, 01:03?, 01:07?, 01:09?, 01:18, 02:04?	**DRB1*15:02:03?, DRB1*15:86, DRB1*16:01:02?, DRB1*16:02:02?,**

CE 0088

For *In Vitro* Diagnostic Use.

101.123-24/06 – including *Taq* polymerase, IFU-01 Visit https://labproducts.caredx.com for
101.123-24u/06u – without *Taq* polymerase, IFU-02 **"Instructions for Use" (IFU)**

Lot No.: 5F2 **Lot-specific information**

				DRB1*16:05:01[?], DRB4*01:05[?], DRB1*01:07:01[?]
	195 bp		*01:08N	
14	145 bp	430 bp	*02:07	
15	235 bp	430 bp	*01:10N, 01:12, 01:15	**DRB1*09:07**
16[4]	125 bp 225 bp	430 bp	*01:21, 02:10 *01:20, 02:08	 **DRB1*08:59, DRB1*11:210**
17	130 bp	430 bp	*02:12	
	180 bp		*01:27N	
18	185 bp	430 bp	*02:13	**DRB1*03:112, DRB1*09:06**
19[5]	-	-	**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 DRB5 SSP 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.
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. In the presence of a specific amplification the intensity of the control band often decreases.

[3]For several DRB alleles 1st and/or 3rd exon(s) and above, 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 and that unknown sequences of codons 87 to 92 are identical with the DRB1*01:01 consensus sequence.

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

[5]Primer mix 19 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.
'?', nucleotide sequence information not available for the primer matching sequence.

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 5F2 **Lot-specific information**

PRIMER SPECIFICATION

Well No.	1	2	3	4	5	6	7	8	9	10	11	12
Length of spec.	255	210	225	100	150	145	145	215	85	130	110	185
PCR product(s)				150					175	160	200	
									225			
Length of int.	515	515	430	515	515	430	430	430	430	430	430	515
pos. control[1]												
5'-primer(s)[2]	13(125)	13(125)	13(125)	38(199)	37(196)	38(199)	37(196)	13(125)	13(125)	38(199)	13(125)	37(196)
	5' -gTA 3'	5' -gTA 3'	5' -gTA 3'	5' -ACT 3'	5' -Agg 3'	5' -ACg 3'	5' -AgA 3'	5' -gTA 3'	5' -gTA 3'	5' -ACT 3'	5' -gTA 3'	5' -AgA 3'
				98(379)		38(199)	41(209)		120(446)			
				5' -CTg 3'		5' -ACg 3'	5' -Cgg 3'		5' -gAC 3'			
3'-primer(s)[3]	85(341)	67(286)	71(299)	57(258)	72(303)	72(303)	70(295)	70(295)	58(260)	67(286)	37(196)	85(341)
	5' -CAA 3'	5' -gAA 3'	5' -gCC 3'	5' -gCg 3'	5' -gCg 3'	5' -gCg 3'	5' -CTg 3'	5' -gTT 3'	5' -CCT 3'	5' -gAT 3'	5' -gTA 3'	5' -CAg 3'
		67(286)	74(307)	135(490)			72(303)	71(299)	74(307)	78(319)	67(286)	
		5' -gAA 3'	5' -CAg 3'	5' -gCC 3'			5' -gCg 3'	5' -gCg 3'	5' -CAg 3'	5' -CAC 3'	5' -gAT 3'	
		70(296)	78(319)					71(299)	135(490)			
		5' -TCC 3'	5' -CAC 3'					5' -gCg 3'	5' -gCT 3'			
		72(303)										
		5' -gCg 3'										
Well No.	1	2	3	4	5	6	7	8	9	10	11	12

Well No.	13	14	15	16	17	18
Length of spec.	150	145	235	125	130	185
PCR product(s)	195			225	180	
Length of int.	430	430	430	430	430	430
pos. control[1]						
5'-primer(s)[2]	57(258)	24(157)	13(125)	6(103)	37(196)	37(196)
	5' -gAC 3'	5' -ggT 3'	5' -gTA 3'	5' -CAT 3'	5' -AgA 3'	5' -AgA 3'
	108(409)					
3'-primer(s)[3]	5' -AgA 3'					
	93(365)	58(261)	78(319)	30(176)	67(286)	85(341)
	5' -gCg 3'	5' -TCA 3'	5' -CAC 3'	5' -TgT 3'	5' -gAT 3'	5' -CAA 3'
	160(565)		79(323)	38(199)	83(336)	
	5' -CAT 3'		5' -TgC 3'	5' -CAA 3'	5' -CCC 3'	
				67(286)		
				5' -gAA 3'		
Well No.	13	14	15	16	17	18

[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 or the 3 terminal nucleotides of the primer is given.

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 5F2 **Lot-specific information**

CELL LINE VALIDATION SHEET

DRB5 SSP subtyping kit

				Well[2]															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
			Prod. No.:	201556401	201556402	201669803	201556404	201556405	201556406	201669807	201669808	201783309	201556410	201669811	201556412	201669813	201669814	201556415	201783316
	IHWC cell line[1]		DRB5																
1	9001	SA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
2	9280	LK707	*01:02	+	+	+	-	-	+	+	-	-	-	-	-	-	-	-	-
3	9011	E4181324	*01:02	+	+	+	-	-	+	+	-	-	-	-	-	-	-	-	-
4	9275	GU373		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
5	9009	KAS011	*02:02	-	-	-	-	-	-	-	+	-	-	+	+	-	-	-	-
6	9353	SM		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
7	9020	QBL		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
8	9025	DEU		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
9	9026	YAR		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
10	9107	LKT3		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
11	9051	PITOUT		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
12	9052	DBB		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
13	9004	JESTHOM		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
14	9071	OLGA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
15	9075	DKB		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
16	9037	SWEIG007		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
17	9282	CTM3953540		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
18	9257	32367		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
19	9038	BM16		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
20	9059	SLE005		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
21	9064	AMALA		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
22	9056	KOSE		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
23	9124	IHL		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
24	9035	JBUSH		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
25	9049	IBW9		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
26	9285	WT49		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
27	9191	CH1007		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
28	9320	BEL5GB		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
29	9050	MOU		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
30	9021	RSH		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
31	9019	DUCAF		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
32	9297	HAG		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
33	9098	MT14B		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
34	9104	DHIF		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
35	9302	SSTO		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
36	9024	KT17		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
37	9065	HHKB		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
38	9099	LZL		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
39	9315	CML		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
40	9134	WHONP199		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
41	9055	H0301		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
42	9066	TAB089		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
43	9076	T7526		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
44	9057	TEM		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
45	9239	SHJO		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
46	9013	SCHU	*01:01	+	+	+	+	+	-	-	-	-	-	-	-	-	-	-	-
47	9045	TUBO		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
48	9303	TER-ND		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-

101.123-24/06 – including *Taq* polymerase, IFU-01 Visit https://labproducts.caredx.com for
101.123-24u/06u – without *Taq* polymerase, IFU-02 **"Instructions for Use" (IFU)**

Lot No.: 5F2 **Lot-specific information**

CELL LINE VALIDATION SHEET

DRB5 SSP subtyping kit

				Well[2]	
				17	18
			Prod. No.:	201783317	201783318
	IHWC cell line[1]		DRB5		
1	9001	SA		-	-
2	9280	LK707	*01:02	-	-
3	9011	E4181324	*01:02	-	-
4	9275	GU373		-	-
5	9009	KAS011	*02:02	-	-
6	9353	SM		-	-
7	9020	QBL		-	-
8	9025	DEU		-	-
9	9026	YAR		-	-
10	9107	LKT3		-	-
11	9051	PITOUT		-	-
12	9052	DBB		-	-
13	9004	JESTHOM		-	-
14	9071	OLGA		-	-
15	9075	DKB		-	-
16	9037	SWEIG007		-	-
17	9282	CTM3953540		-	-
18	9257	32367		-	-
19	9038	BM16		-	-
20	9059	SLE005		-	-
21	9064	AMALA		-	-
22	9056	KOSE		-	-
23	9124	IHL		-	-
24	9035	JBUSH		-	-
25	9049	IBW9		-	-
26	9285	WT49		-	-
27	9191	CH1007		-	-
28	9320	BEL5GB		-	-
29	9050	MOU		-	-
30	9021	RSH		-	-
31	9019	DUCAF		-	-
32	9297	HAG		-	-
33	9098	MT14B		-	-
34	9104	DHIF		-	-
35	9302	SSTO		-	-
36	9024	KT17		-	-
37	9065	HHKB		-	-
38	9099	LZL		-	-
39	9315	CML		-	-
40	9134	WHONP199		-	-
41	9055	H0301		-	-
42	9066	TAB089		-	-
43	9076	T7526		-	-
44	9057	TEM		-	-
45	9239	SHJO		-	-
46	9013	SCHU	*01:01	-	-
47	9045	TUBO		-	-
48	9303	TER-ND		-	-

101.123-24/06 – including *Taq* polymerase, IFU-01
101.123-24u/06u – without *Taq* polymerase, IFU-02

Visit https://labproducts.caredx.com for **"Instructions for Use" (IFU)**

Lot No.: 5F2 **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, 10 and 14 to 18 were available. The specificities of the primers in primer solutions 9, 10, 15, 17 and 18 were tested by separately adding one, two or three additional 5'-primers, respectively one or two additional 3'-primers. In primer solutions 14 and 16 it was only possible to test the 3'-primers, the 5'-primer was not possible to test. In primer solutions 4, 7 and 9 one 5'-primer was not possible to test, and in primer solutions 2, 8, 13 and 15 to 17 one 3'-primer was not possible to test. Additional primers in primer solutions 1 to 4, 7, 8, 11 and 13 were tested by separately adding additional 5'-primers and/or 3'-primers.

ADDRESSES:

Manufacturer:
***Olerup* SSP AB**, Franzengatan 5, SE-112 51 Stockholm, Sweden.
Tel: +46-8-508 939 00
Fax: +46-8-717 88 18
E-mail: olerup-se@caredx.com
Web page: https://labproducts.caredx.com/

Distributed by:
Olerup GmbH, Löwengasse 47 / 6, AT-1030 Vienna, Austria.
Tel: +43-1-710 15 00
Fax: +43-1-710 15 00 10
E-mail: olerup-at@caredx.com
Web page: https://labproducts.caredx.com/

Olerup Inc., 901 S. Bolmar St., Suite R, West Chester, PA 19382
Tel: 1-877-OLERUP1
Fax: 610-344-7989
E-mail: olerup-us@caredx.com
Web page: https://labproducts.caredx.com/

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