

Lot No.: **07F**

Lot-specific information

Olerup SSP[®] DQA1*02,05;DQB1*02,0302

Product number: 101.903-24u – without *Taq* polymerase
Lot number: 07F
Expiry date: 2010-October-01
Number of tests: 24
Number of wells per test: 15 + 1
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. 07F.

CHANGES COMPARED TO THE PREVIOUS *OLERUP SSP*[®] DQA1*02,05;DQB1*02,0302 LOT

The DQA1 and DQB1 specificity and interpretation tables have been updated for the DQB1 alleles described since the previous *Olerup SSP*[®] DQA1*02,05;DQB1*02,0302 lot (**Lot No. 05E**) was made

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

Well	5'-primer	3'-primer	rationale
12	Moved	Moved	Primer pair from well 13.
13	Moved	Moved	Primer pair from well 14.
14	Moved	Moved	Primer pair from well 15.
15	Moved	Moved	Primer pair from well 16.
16	Moved	Moved	Negative control moved from well 12.

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Well **16** contains Negative Control primer pairs, that will amplify more than 95% of the *Olerup* SSP[®] HLA Class I, DRB, DQB1 and DPB1 amplicons as well as the amplicons generated by control primer pairs.

PCR product sizes range from 75 to 430 base pairs.
The PCR product generated by the control primer pair is 430 base pairs.

Length of PCR product	105	200	105	80	75	80
5'-primer¹	164	340	440	45	45	43
	5'-CAC ^{3'}	5'-Agg ^{3'}	5'-TTA ^{3'}	5'-Tg g ^{3'}	5'-Tg g ^{3'}	5'-Tg g ^{3'}
3'-primer²	231	2nd I	507	59	58	57
	5'-TgC ^{3'}	5'-AAA ^{3'}	5'-TTg ^{3'}	5'-CTC ^{3'}	5'-ggC ^{3'}	5'-CTC ^{3'}
A*	+	+	+			
B*	+	+	+			
Cw*	+	+	+			
DRB1				+	+	
DRB3				+	+	
DRB5				+		
DQB1					+	
DPB1						+

¹The 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 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.

²The 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.

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PRODUCT DESCRIPTION

DQA1*02,05;DQB1*02,0302 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQA1*02, DQA1*05, DQB1*02 and DQB1*0302 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 16 PCR reactions in a 16 well PCR plate.

1 DQA1	2 DQA1	3 DQB1	4 DQB1	5 DQB1	6 DQB1	7 DQB1	8 DQB1
9 DQB1	10 DQB1	11 DQB1	12 DQA1	13 DQA1	14 DQA1	15 DQA1	16 Neg ctr

The 16 well cut PCR plate is marked with '07F' in silver/gray ink.

Well No. 1 is marked with the Lot No '07F'.

Wells 1, 2, 12 to 15: DQA1 primers.

Wells 3 to 11: DQB1 primers.

Well 16: Negative control primers.

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.

UNIQUELY IDENTIFIED ALLELES

All the DQA1*02 and DQA1*05 alleles as well as all the DQB1*02 and DQB1*03 alleles, i.e. **DQA1*0201, DQA1*0501 to 0509, DQB1*0201 to 0205 and DQB1*0301 to 0322**, recognized by the HLA Nomenclature Committee in July 2008¹ have been considered in the specificity and interpretation tables of the DQA1*02,05;DQB1*02,0302 kit.

¹HLA-Cw alleles listed on the IMGT/HLA web page 2008-July-11, release 2.22.0, www.ebi.ac.uk/imgt/hla.

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SPECIFICITY TABLE

DQA1*02,05;DQB1*02,0302 SSP subtyping

Specificities and sizes of the PCR products of the 15 primer mixes used for DQA1*02,05;DQB1*02,0302 SSP typing

Primer Mix	Size of spec. PCR product ¹	Size of control band ²	Amplified DQA1 alleles ³	Amplified DQB1 alleles ³
1	175 bp	430 bp	0201	
2	165 bp	515 bp	050101-0509	
3⁶	205 bp	515 bp		020101-0205
4^{4,5}	80 bp	515 bp		030101-030104, 030302-030303, 0309, 0310, 0312, 0313, 0315, 0317, 0319-0322, 060101- 060103 ^{weakly} , 0607 ^{weakly} , 0615 ^{weakly}
5^{5,6}	135 bp	430 bp		020101-0202, 0204, 0205, 030201-030204, 0307, 0308, 0311, 0318, 0629
6⁵	130 bp	515 bp		030201-030204, 030302-030303, 0306-0308, 0311, 0312, 0315, 0318, 0320, 0629
7^{4,6}	115 bp	515 bp		0306
8⁷	150, 220 bp	515 bp		0307, 0318
9	135 bp	515 bp		0308, 060202, 060302
10⁸	135, 260 bp	515 bp		0309, 0311
11⁶	135 bp	515 bp		030101-030204, 030302-0322
12⁴	90 bp	515 bp	0502	
13	200 bp	430 bp	050101-050102, 0502 [?] , 0504 [?] , 0505, 0508, 0509	

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14	200 bp	515 bp	0502 [?] , 0503, 0504 [?] , 0506, 0507
15	205 bp	515 bp	050101-0503, 0505- 0509

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 DQA1 and DQB1 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 length 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 515 base pairs, for most wells, or a band of 430 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 430 bp, internal positive control band in order to help in the correct orientation of the DQA1*02,05;DQB1*02,0302 typing.

In addition, wells number 5 and 13 contain the primer pair giving rise to the shorter, 430 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 DQA1 and DQB1 alleles only partial second exon nucleotide sequences are available or nucleotide sequence information is not available for the 1st and 3rd exons. 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 of DQA1 and DQB1 alleles are conserved within allelic groups.

⁴Specific PCR fragments shorter than 125 base pairs are less intense and not as sharp as longer specific bands.

⁵Primer mixes 4, 5 and 6 may yield less specific PCR products than the other DQB1 primer mixes.

⁶Primer mixes 3, 5, 7 and 11 have a tendency of primer oligomer formation

⁷Primer mix 8: Specific PCR fragment of 150 bp in the DQB1*0307 allele. Specific PCR fragment of 220 bp in the DQB1*0318 allele.

⁸Primer mix 10: Specific PCR fragment of 135 bp in the DQB1*0309 allele. Specific PCR fragment of 260 bp in the DQB1*0311 allele.

'?', nucleotide sequence information not available for the primer matching sequence.

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INTERPRETATION TABLE								
DQA1*02,05;DQB1*02,0302 typing								
Amplification patterns of the DQA1*02 and 05 and DQB1*02 and 03 alleles								
	Well⁵							
	1	2	3	4	5	6	7	8
Length of spec.	175	165	205	80	135	130	115	150
PCR product								220
Length of int.	430	515	515	515	430	515	515	515
pos. control¹								
5'-primer(s)²	7	34	30	57	26	26	38	27
	5'-CAC ^{3'}	5'-Ag C ^{3'}	5'-A Ag ^{3'}	5'-T gA ^{3'}	5'-T CT ^{3'}	5'-T CT ^{3'}	5'-g CA ^{3'}	5'-TT C ^{3'}
								49
								5'-g gT ^{3'}
3'-primer(s)³	52	75	86	70	57	55	62	86
	5'-T gT ^{3'}	5'-g AC ^{3'}	5'-g CT ^{3'}	5'-CCT ^{3'}	5'-C gg ^{3'}	5'-g Cg ^{3'}	5'-CT A ^{3'}	5'-g CT ^{3'}
Well No.	1	2	3	4	5	6	7	8
DQA1 or DQB1 allele⁴								
DQA1*0201	1							
DQA1*050101-050102, 0505, 0508, 0509		2						
DQA1*0502		2						
DQA1*0503, 0506, 0507		2						
DQA1*0504		2						
DQB1*020101-0202, 0204, 0205			3		5			
DQB1*0203			3					
DQB1*030101-030104, 0310, 0313, 0317, 0319, 0321, 0322				4				
DQB1*030201-030204					5	6		
DQB1*030302-030303, 0312, 0315, 0320				4		6		
DQB1*0304, 030501-030504, 0314, 0316								
DQB1*0306						6	7	
DQB1*0307, 0318					5	6		8
DQB1*0308					5	6		
DQB1*0309				4				
DQB1*0311					5	6		
DQB1*060101-060103, 0607, 0615				w				
DQB1*060202, 060302								
DQB1*0629					5	6		
DQA1 or DQB1 allele⁴								
Well No.	1	2	3	4	5	6	7	8

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INTERPRETATION TABLE							
DQA1*02,05;DQB1*02,0302 typing							
Amplification patterns of the DQA1*02 and 05 and DQB1*02 and 03 alleles							
Well⁵							
9	10	11	12	13	14	15	
135	135	135	90	200	200	205	Length of spec. PCR product
	260						
515	515	515	515	430	515	515	Length of int. pos. control¹
38	14	55	59	107	107	21	5'-primer(s)²
⁵ -g CA ³	⁵ -g C C ³	⁵ -g CC ³	⁵ -C Cg ³	⁵ -C AT ³	⁵ -C AT ³	⁵ -T CC ³	
	135	55					
	⁵ -T gA ³	⁵ -g CA ³					
70	86	86	75	160	160	75	3'-primer(s)³
⁵ -CCC ³	⁵ -g CT ³	⁵ -g CT ³	⁵ -g AC ³	⁵ -AgC ³	⁵ -AgA ³	⁵ -g AC ³	
	167						
	⁵ -C AT ³						
9	10	11	12	13	14	15	Well No.
							DQA1 or DQB1 allele⁴
							DQA1*0201
				13		15	DQA1*050101-050102, 0505, 0508, 0509
			12	?	?	15	DQA1*0502
					14	15	DQA1*0503, 0506, 0507
				?	?		DQA1*0504
							DQB1*020101-0202, 0204, 0205
							DQB1*0203
		11					DQB1*030101-030104, 0310, 0313, 0317, 0319, 0321, 0322
		11					DQB1*030201-030204
		11					DQB1*030302-030303, 0312, 0315, 0320
		11					DQB1*0304, 030501-030504, 0314, 0316
		11					DQB1*0306
		11					DQB1*0307, 0318
9		11					DQB1*0308
	10	11					DQB1*0309
	10	11					DQB1*0311
							DQB1*060101-060103, 0607, 0615
9							DQB1*060202, 060302
							DQB1*0629
							DQA1 or DQB1 allele⁴
9	10	11	12	13	14	15	Well No.



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In addition, wells number 5 and 13 contain the primer pair giving rise to the shorter, 430 bp, internal positive control band in order to allow kit identification.

²The codon, in the 1st, 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Codon numbering as in www.ebi.ac.uk/imgt/hla. 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. Empty spaces indicate codon boundaries.

³The codon, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. 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. Empty spaces indicate codon boundaries.

⁴DQA1*050103 has been renamed to DQA1*0505.

The sequence of the DQB1*030301 allele has been shown to be identical to DQB1*030302.

⁵Primer mix 8: Specific PCR fragment of 150 bp in the DQB1*0307 allele. Specific PCR fragment of 220 bp in the DQB1*0318 allele.

Primer mix 10: Specific PCR fragment of 135 bp in the DQB1*0309 allele. Specific PCR fragment of 260 bp in the DQB1*0311 allele.

'w', might be weakly amplified.

'?', nucleotide sequence information not available for the primer matching sequence.

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CELL LINE VALIDATION SHEET															
DQA1*02,05;DQB1*02,0302 typing kit															
				Production No.	Well										
					3	4	5	6	7	8	9	10	11		
					200840803	200840804	200840805	200840806	200840807	200840808	200840809	200840810	200840811		
	IHWC cell line	DQB1													
1	9001 SA	*0501			-	-	-	-	-	-	-	-	-		
2	9280 LK707	*0601	*0202		+	W	+	-	-	-	-	-	-		
3	9011 E4181324	*0601			-	W	-	-	-	-	-	-	-		
4	9275 GU373	*0201			+	-	+	-	-	-	-	-	-		
5	9009 KAS011	*0502			-	-	-	-	-	-	-	-	-		
6	9353 SM	*0302	*0601		-	+	-	-	-	-	-	-	+		
7	9020 QBL	*0201			+	-	+	-	-	-	-	-	-		
8	9007 DEM	*0302	*0502		-	+	-	-	-	-	-	-	+		
9	9026 YAR	*0302			-	-	+	+	-	-	-	-	+		
10	9107 LKT3	*0401			-	-	-	-	-	-	-	-	-		
11	9051 PITOUT	*0202			+	-	+	-	-	-	-	-	-		
12	9052 DBB	*0303			-	+	-	+	-	-	-	-	+		
13	9067 BTB	*0402			-	-	-	-	-	-	-	-	-		
14	9071 OLGA	*0402			-	-	-	-	-	-	-	-	-		
15	9075 DKB	*0303			-	+	-	+	-	-	-	-	+		
16	9037 SWEIG007	*0301			-	+	-	-	-	-	-	-	+		
17	9008 WILJON	*0602	*0603		-	-	-	-	-	-	-	-	-		
18	9257 32367	*0602	*0202		+	-	+	-	-	-	-	-	-		
19	9038 BM16	*0301			-	+	-	-	-	-	-	-	+		
20	9059 SLE005	*0604			-	-	-	-	-	-	-	-	-		
21	9064 AMALA	*0301			-	+	-	-	-	-	-	-	+		
22	9056 KOSE	*0503	*0604		-	-	-	-	-	-	-	-	-		
23	9124 IHL	*0503	*0601		-	W	-	-	-	-	-	-	-		
24	9035 JBUSH	*0301			-	+	-	-	-	-	-	-	+		
25	9049 IBW9	*0202			+	-	+	-	-	-	-	-	-		
26	9285 WT49	*0201			+	-	+	-	-	-	-	-	-		
27	9191 CH1007	*0401	*0501		-	-	-	-	-	-	-	-	-		
28	9320 BEL5GB	*0202	*0301		+	+	+	-	-	-	-	-	+		
29	9050 MOU	*0202			+	-	+	-	-	-	-	-	-		
30	9021 RSH	*0402			-	-	-	-	-	-	-	-	-		
31	9019 DUCAF	*0201			+	-	+	-	-	-	-	-	-		
32	9297 HAG	*0301			-	+	-	-	-	-	-	-	+		
33	9098 MT14B	*0302			-	-	+	+	-	-	-	-	+		
34	9104 DHIF	*0301			-	+	-	-	-	-	-	-	+		
35	9302 SSTO	*0305			-	-	-	-	-	-	-	-	+		
36	9024 KT17	*0302			-	-	+	+	-	-	-	-	+		
37	9065 HHKB	*0603			-	-	-	-	-	-	-	-	-		
38	9099 LZL	*0301			-	+	-	-	-	-	-	-	+		
39	9315 CML	*0201	*0301		+	+	+	-	-	-	-	-	+		
40	9134 WHONP199	*0202	*0303		+	+	+	+	-	-	-	-	+		
41	9055 H0301	*0609			-	-	-	-	-	-	-	-	-		
42	9066 TAB089	*0601			-	W	-	-	-	-	-	-	-		
43	9076 T7526	*0303			-	+	-	+	-	-	-	-	+		
44	9057 TEM	*0503			-	-	-	-	-	-	-	-	-		
45	9239 SHJO	*0202			+	-	+	-	-	-	-	-	-		
46	9013 SCHU	*0602			-	-	-	-	-	-	-	-	-		
47	9045 TUBO	*0301			-	+	-	-	-	-	-	-	+		
48	9303 TER-ND	*0501			-	-	-	-	-	-	-	-	-		



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CELL LINE VALIDATION SHEET										
DQA1*02,05;DQB1*02,0302 typing kit										
				Well						
				1	2	12	13	14	15	
				Prod. No.:	200840801	200840802	200840813	200840814	200840815	200840816
	IHWC cell line		DQA1*							
1	9001	SA	*0101		-	-	-	-	-	-
2	9280	LK707	*0103	*0303	-	-	-	-	-	-
3	9011	E4181324	*0103		-	-	-	-	-	-
4	9275	GU373	*0501		-	+	-	+	-	+
5	9009	KAS011	*0102		-	-	-	-	-	-
6	9353	SM	*0103	*0301	-	-	-	-	-	-
7	9020	QBL	*0501		-	+	-	+	-	+
8	9007	DEM	*0303	*0102	-	-	-	-	-	-
9	9026	YAR	*0301		-	-	-	-	-	-
10	9107	LKT3	*0303		-	-	-	-	-	-
11	9051	PITOUT	*0201		+	-	-	-	-	-
12	9052	DBB	*0201		+	-	-	-	-	-
13	9067	BTB	*0401		-	-	-	-	-	-
14	9071	OLGA	*0401		-	-	-	-	-	-
15	9075	DKB	*0302		-	-	-	-	-	-
16	9037	SWEIG007	*0505		-	+	-	+	-	+
17	9008	WILJON	*0102		-	-	-	-	-	-
18	9257	32367	*0102	*0303	-	-	-	-	-	-
19	9038	BM16	*0505		-	+	-	+	-	+
20	9059	SLE005	*0102		-	-	-	-	-	-
21	9064	AMALA	*0503		-	+	-	-	+	+
22	9056	KOSE	*0102	*0104	-	-	-	-	-	-
23	9124	IHL	*0103	*0104	-	-	-	-	-	-
24	9035	JBUSH	*0505		-	+	-	+	-	+
25	9049	IBW9	*0201		+	-	-	-	-	-
26	9285	WT49	*0501		-	+	-	+	-	+
27	9191	CH1007	*0303	*0105	-	-	-	-	-	-
28	9320	BEL5GB	*0201	*0303	+	-	-	-	-	-
29	9050	MOU	*0201		+	-	-	-	-	-
30	9021	RSH	*0401		-	-	-	-	-	-
31	9019	DUCAF	*0501		-	+	-	+	-	+
32	9297	HAG	*0505		-	+	-	+	-	+
33	9098	MT14B	*0301		-	-	-	-	-	-
34	9104	DHIF	*0505		-	+	-	+	-	+
35	9302	SSTO	*0301		-	-	-	-	-	-
36	9024	KT17	*0301		-	-	-	-	-	-
37	9065	HHKB	*0103		-	-	-	-	-	-
38	9099	LZL	*0503		-	+	-	-	+	+
39	9315	CML	*0303	*0501	-	+	-	+	-	+
40	9134	WHONP199	*0201	*0302	+	-	-	-	-	-
41	9055	H0301	*0102		-	-	-	-	-	-
42	9066	TAB089	*0103		-	-	-	-	-	-
43	9076	T7526	*0302		-	-	-	-	-	-
44	9057	TEM	*0104		-	-	-	-	-	-
45	9239	SHJO	*0201	*0303	+	-	-	-	-	-
46	9013	SCHU	*0102		-	-	-	-	-	-
47	9045	TUBO	*0505		-	+	-	+	-	+
48	9303	TER-ND	*0101		-	-	-	-	-	-



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CERTIFICATE OF ANALYSIS

Olerup SSP[®] DQA1*02,05;DQB1*02,0302 SSP

Product number: 101.903-24u – without Taq polymerase
Lot number: 07F
Expiry date: 2010-October-01
Number of tests: 24
Number of wells per test: 15 + 1

Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2008-408-01	9	2008-408-09
2	2008-408-02	10	2008-408-10
3	2008-408-03	11	2008-408-11
4	2008-408-04	12	2008-408-13
5	2008-408-05	13	2008-408-14
6	2008-408-06	14	2008-408-15
7	2008-408-07	15	2008-408-16
8	2008-408-08		

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 7, 8, 9, 10 and 12 were available. The specificities of the primers in primer solutions 7 and 9 were tested by separately adding one additional 5'-primers, respectively one additional 3'-primers. In primer solution 10 one of the 3'-primers was not possible to test. In primer solutions 8 and 12 it was only possible to test the 3'-primers, the 5'-primers were not possible to test.

The negative control primer pairs, **Production No. 2008-417-01**, can detect contamination with PCR products diluted 10^{-7} .

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

Date of approval: 2009-May-25

Approved by:

Quality Control, Supervisor

Lot No.: **07F**

Lot-specific information

Declaration of Conformity

Product name: *Olerup* SSP® DQA1*02,05;DQB1*02,0302
Product number: 101.903-24u
Lot number: 07F

Intended use: DQA1*02, DQA1*05, DQB1*02 and DQB1*03 medium resolution histocompatibility testing

Manufacturer: *Olerup* SSP AB
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SE-133 33 Saltsjöbaden, Sweden
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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 9001:2000 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, Hasselstigen 1, SE-133 33 Saltsjöbaden, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Saltsjöbaden, Sweden
2009-May-25

Olle Olerup
Managing Director



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