

101.211.24 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.211.24u – without *Taq* pol., IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **83N**

Lot-specific information  
**Olerup SSP<sup>®</sup> DQB1\*05**

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**Product number:** 101.211-24 – including *Taq* polymerase  
 101.211-24u - without *Taq* polymerase  
**Lot number:** 83N  
**Expiry date:** 2014-December-01  
**Number of tests:** 24  
**Number of wells per test:** 12  
**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. 83N**

### CHANGES COMPARED TO THE PREVIOUS OLERUP SSP<sup>®</sup> DQB1\*05 LOT

The DQB1\*05 specificity and interpretation tables have been updated for the HLA-DQB1 alleles described since the previous *Olerup SSP<sup>®</sup> DQB1\*05* lot was made (Lot No. 04M).

Four wells have been added to the DQB1\*05 kit, wells **9 to 12**.

The Lot-specific information for DQB1\*05 including and without *Taq* polymerase is now 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
6	Modified, moved	Moved	Primer pair moved to well 9, modified 5'-primers for improved specificity and yield of HLA-specific PCR product.
9	New	New	Primer pair from well 6.
10	New	New	New primer pair for the DQB1*05:12 allele.
11	New	New	New primer pair for the DQB1*05:13 allele.
12	New	New	New primer pair for the DQB1*05:14 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\*05:14 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 12 PCR reactions in a 16 well PCR plate. Wells 13 to 16 are empty.

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>	<b>6</b>	<b>7</b>	<b>8</b>
<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	empty	empty	empty	empty

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

Well No. 1 is marked with the Lot No. ‘83N’.

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\*05:14**, recognized by the HLA Nomenclature Committee in April 2012<sup>1</sup> 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.

<sup>1</sup>DQB1 alleles listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

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### RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 24 alleles generate 15 amplification patterns that can be combined in 120 homozygous and heterozygous combinations. 55 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, *05:13 = *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, *05:14 = *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, *05:07 = *05:07, *05:07
++-----+ ---+ *05:01:01:01, *05:11 = *05:11, *05:11
++++-----+ ---+ *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, *05:14 = *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, *05:06 = *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
  
```

\*05:01:01:01 = \*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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## SPECIFICITY TABLE

### DQB1\*05 SSP subtyping

Specificities and sizes of the PCR products of the 12 primer mixes used for DQB1\*05 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified DQB1*05 alleles <sup>3</sup>
1	225 bp	<b>515 bp</b>	*05:01:01:01-05:14
2	135 bp	430 bp	*05:01:01:01-05:01:03, 05:07, 05:11-05:12
3 <sup>4</sup>	120 bp	430 bp	*05:02:01-05:02:03, 05:05, 05:14
4 <sup>4</sup>	95 bp	<b>515 bp</b>	*05:02:02, 05:03:01:01-05:03:05, 05:06, 05:08-05:10, 05:13
5 <sup>4,6</sup>	120 bp, 185 bp	430 bp	*05:04, 05:10
6 <sup>5</sup>	185 bp	430 bp	*05:05, 05:11
7 <sup>5</sup>	180 bp	430 bp	*05:06-05:07
8	190 bp	430 bp	*05:09
9	135 bp	430 bp	*05:08
10	195 bp	430 bp	*05:12
11 <sup>4</sup>	95 bp	430 bp	*05:13
12	150 bp	430 bp	*05:14

<sup>1</sup>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 DQB1\*05 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.

<sup>2</sup>The 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.

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**Lot No.: 83N****Lot-specific information****www.olerup-ssp.com**

<sup>3</sup>For several DQB alleles only second exon nucleotide sequences are 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 of codons 87 to 92 are conserved within allelic groups.

<sup>4</sup>Specific PCR fragments shorter than 125 base pairs have a lower intensity than longer PCR bands.

<sup>5</sup>Primer mixes 6 and 7 may give rise to nonspecific amplifications.

<sup>6</sup>Primer 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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Lot No.: **83N**

Lot-specific information

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<b>INTERPRETATION TABLE</b>								
<b>DQB1*05 SSP subtyping</b>								
Amplification patterns of the DQB1*05:01 to DQB1*05:14 alleles								
	Well <sup>4</sup>							
	1	2	3	4	5	6	7	8
Length of spec. PCR product(s)	225	135	120	95	120	185	180	190
Length of int. pos. control <sup>1</sup>	515	430	430	515	430	430	430	430
5'-primer <sup>2</sup>	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 <sup>3</sup>	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. DQB1 allele	1	2	3	4	5	6	7	8
*05:01:01:01-05:01:03	1	2						
*05:02:01, 05:02:03	1		3					
*05:02:02	1		3	4				
*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					
DQB1 allele								
Well No.	1	2	3	4	5	6	7	8

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<b>INTERPRETATION TABLE</b>				
<b>DQB1*05 SSP subtyping</b>				
<b>Amplification patterns of the DQB1*05 alleles</b>				
<b>Well<sup>4</sup></b>				
<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	
<b>135</b>	<b>195</b>	<b>95</b>	<b>150</b>	<b>Length of spec. PCR product(s)</b>
<b>430</b>	<b>430</b>	<b>430</b>	<b>430</b>	<b>Length of int. pos. control<sup>1</sup></b>
<b>135(501)</b>	<b>26(173)</b>	<b>13(136)</b>	<b>133(494)</b>	<b>5'-primer<sup>2</sup></b>
5' -gAT 3'	5' -ggg 3'	5' -gCC 3'	5' -TCA 3'	
<b>167(596)</b>	<b>77(328)</b>	<b>32(191)</b>	<b>169(604)</b>	<b>3'-primer<sup>3</sup></b>
5' -CAT 3'	5' -CAA 3'	5' -TAC 3'	5' -gAC 3'	
<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>Well No.</b>
				<b>DQB1 allele</b>
				<b>*05:01:01:01-05:01:03</b>
				<b>*05:02:01, 05:02:03</b>
				<b>*05:02:02</b>
				<b>*05:03:01:01-05:03:05</b>
				<b>*05:04</b>
				<b>*05:05</b>
				<b>*05:06</b>
				<b>*05:07</b>
<b>9</b>				<b>*05:08</b>
				<b>*05:09</b>
				<b>*05:10</b>
				<b>*05:11</b>
	<b>10</b>			<b>*05:12</b>
		<b>11</b>		<b>*05:13</b>
			<b>12</b>	<b>*05:14</b>
<b>9</b>	<b>10</b>	<b>11</b>	<b>12</b>	<b>DQB1 allele</b>
				<b>Well No.</b>

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<sup>1</sup>The 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.

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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.

<sup>2</sup>The codon, and in parenthesis the nucleotide, in the 2<sup>nd</sup> and 3<sup>rd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>3</sup>The codon, and in parenthesis the nucleotide, in the 2<sup>nd</sup> or 3<sup>rd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>4</sup>Primer 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
					200969601	201184602	200969603	200969604	201184605	201202406	201184607	201184608	201202409	201202410	201202411	201202412
	IHWC cell line		DQB1													
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 Rev. No. 03  
 101.211.24u – without *Taq* pol., IFU-02 Rev. No. 03

Visit [www.olerup-ssp.com](http://www.olerup-ssp.com) for  
 “Instructions for Use” (IFU)

Lot No.: **83N**

Lot-specific information

[www.olerup-ssp.com](http://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:** 83N  
**Expiry date:** 2014-December-01  
**Number of tests:** 24  
**Number of wells per test:** 12

#### Well specifications:

Well No.	Production No.	Well No.	Production No.
1	2009-696-01	9	2012-024-09
2	2011-846-02	10	2012-024-10
3	2009-696-03	11	2012-024-11
4	2009-696-04	12	2012-024-12
5	2011-846-05		
6	2012-024-06		
7	2011-846-07		
8	2011-846-08		

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 12 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 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-June-29

**Approved by:**

#### Production Quality Control

101.211.24 – including *Taq* pol., IFU-01 Rev. No. 03  
101.211.24u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot-specific information

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## Declaration of Conformity

**Product name:** *Olerup* SSP® DQB1\*05

**Product number:** 101.211-24/24u

**Lot number:** 83N

**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-June-29

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs

101.211.24 – including *Taq* pol., IFU-01 Rev. No. 03  
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Lot No.: **83N**

Lot-specific information

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