

101.212.24/04 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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 “Instructions for Use” (IFU)

Lot No.: **08N**

Lot-specific information  
**Olerup SSP<sup>®</sup> DQB1\*06**

**Product number:** 101.212-24/04 – including *Taq* pol.  
 101.212-24u/04u – without *Taq* pol.

**Lot number:** 08N

**Expiry date:** 2014-July-01

**Number of tests:** 24 test – Product No. 101.212-24/24u  
 4 tests – Product No. 101.212-04/04u

**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. 08N.**

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP<sup>®</sup> DQB1\*06 LOT**

The DQB1\*06 specificity and interpretation tables have been updated for the DQB1 alleles described since the previous *Olerup SSP<sup>®</sup> DQB1\*06* lot (Lot No. 40K).

Two wells have been added to the DQB1\*06 kit, wells **31 and 32**.

The Lot-specific information for DQB1\*06 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
24	-	Modified	Increased yield of HLA-specific PCR product.
26	Modified	-	Increased yield of HLA-specific PCR product.
30	Modified	Modified	Increased yield of HLA-specific PCR product.
31	New	New	New primer pairs for the DQB1*06:43 and DQB1*06:44 alleles.
32	New	New	New primer pair for the DQB1*06:41 allele.

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Change in revision R01 compared to R00:

1. A footnote (no. 3), concerning primers in incompletely sequenced regions, has been added to the specificity table.

Changes in revision R02 compared to R01:

1. Primer mix 15 may give rise to unspecific amplifications.
2. The DQB1\*06:20 allele is weakly amplified by primer mix 10. This has been changed in the specificity and interpretation tables.

Change in revision R03 compared to R02:

1. A typing error in the section “Uniquely Identified Alleles” and in the foot-notes to the Interpretation Table has been corrected: The nucleotide sequence of the DQB1\*06:45 and DQB1\*06:46 alleles are not yet retrievable.

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## PRODUCT DESCRIPTION

### DQB1\*06 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQB1\*06:01 to DQB1\*06:47 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 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 'DQB1\*06' in silver/gray ink.

Well No. 1 is marked with the Lot No. '08N'.

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

Only the DQB1\*06 alleles will be amplified by the DQB1\*06 subtyping kit, except that the DQB1\*03:23 allele will be amplified by primer mix 5, and DQB1\*03:30, 04:01:01-04:03:02 and 04:06-04:08 alleles will be amplified by primer mix 24. Thus, the interpretation of DQB1\*06 subtypings is only influenced by a few non-DQB1\*06 alleles and not by other groups of DQB1 alleles or the DQB2 and DQB3 genes.

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**UNIQUELY IDENTIFIED ALLELES**

All the DQB1\*06 alleles, i.e. **DQB1\*06:01 to DQB1\*06:47**, recognized by the HLA Nomenclature Committee in January 2012<sup>1</sup> will give rise to unique amplification patterns by the primers in the DQB1\*06 subtyping kit<sup>2</sup>.

The DQB1\*06 subtyping kit cannot distinguish the DQB1\*06:01:01-06:01:06 alleles, the DQB1\*06:02:01-06:02:02 alleles, the DQB1\*06:03:01-06:03:02 alleles or the DQB1\*06:04:01 and 06:04:03 alleles.

<sup>1</sup>HLA-B alleles listed on the IMGT/HLA web page 2012-January-12, release 3.7.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

<sup>2</sup>The nucleotide sequence of the DQB1\*06:45 and DQB1\*06:46 alleles are not yet retrievable.

**RESOLUTION IN HOMO- AND HETEROZYGOTES**

A total of 59 alleles generate 51 amplification patterns that can be combined in 1326 homozygous and heterozygous combinations. 152 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.

+++-----	-----	-----+--	-----++-	*06:01:01, *06:47 = *06:02:01, *06:43 = *06:43, *06:47
+++++---	-----	-----+--	-----++-	*06:01:01, *06:44 = *06:03:01, *06:43 = *06:43, *06:44
++-----	-----	-----+--	-----++-	*06:01:01, *06:43 = *06:43, *06:43
-+++++--	-+-----	-----+--	-----++-	*06:20, *06:40 = *06:31, *06:33
-+++++--	-+-----	-----+--	-----++-	*06:20, *06:44 = *06:31, *06:47
-+++++--	-+-----	-----+--	-----++-	*06:02:01, *06:31 = *06:03:01, *06:20
-+++++--	-+-----	-----+--	-----++-	*06:11:01, *06:14:01 = *06:11:02, *06:14:01 =
-+++++--	-+-----	-----+--	-----++-	*06:11:02, *06:14:02
-+++++--	-+-----	-----+--	-----++-	*06:11:02, *06:37 = *06:26N, *06:37
-+++++--	-+-----	-----+--	-----++-	*06:33, *06:44 = *06:40, *06:47
-+++++--	-+-----	-----+--	-----++-	*06:02:01, *06:40 = *06:03:01, *06:33
-+++++--	-+-----	-----+--	-----++-	*06:02:01, *06:44 = *06:03:01, *06:47 = *06:44, *06:47
-+++++--	-+-----	-----+--	-----++-	*06:02:01, *06:47 = *06:47, *06:47
-+++++--	-+-----	-----+--	-----++-	*06:04:01, *06:11:02 = *06:04:02, *06:11:02
-+++++--	-+-----	-----+--	-----++-	*06:08:01, *06:11:02 = *06:08:02, *06:11:02
-+++++--	-+-----	-----+--	-----++-	*06:11:01, *06:31 = *06:11:02, *06:31
-+++++--	-+-----	-----+--	-----++-	*06:11:01, *06:26N = *06:11:02, *06:26N
-+++++--	-+-----	-----+--	-----++-	*06:11:01, *06:28 = *06:11:02, *06:28
-+++++--	-+-----	-----+--	-----++-	*06:11:01, *06:40 = *06:11:02, *06:40
-+++++--	-+-----	-----+--	-----++-	*06:11:01, *06:44 = *06:11:02, *06:44
-+++++--	-+-----	-----+--	-----++-	*06:03:01, *06:11:01 = *06:03:01, *06:11:02
-+++++--	-+-----	-----+--	-----++-	*06:11:01, *06:41 = *06:11:02, *06:41
-+++++--	-+-----	-----+--	-----++-	*06:11:01, *06:11:02 = *06:11:02, *06:11:02
-+++++--	-+-----	-----+--	-----++-	*06:08:01, *06:11:01 = *06:08:02, *06:11:01
-+++++--	-+-----	-----+--	-----++-	*06:04:01, *06:11:01 = *06:04:02, *06:11:01 =
-+++++--	-+-----	-----+--	-----++-	*06:04:02, *06:18
-+++++--	-+-----	-----+--	-----++-	*06:14:01, *06:31 = *06:14:02, *06:31
-+++++--	-+-----	-----+--	-----++-	*06:14:01, *06:26N = *06:14:02, *06:26N
-+++++--	-+-----	-----+--	-----++-	*06:14:01, *06:28 = *06:14:02, *06:28
-+++++--	-+-----	-----+--	-----++-	*06:14:01, *06:40 = *06:14:02, *06:40
-+++++--	-+-----	-----+--	-----++-	*06:14:01, *06:44 = *06:14:02, *06:44
-+++++--	-+-----	-----+--	-----++-	*06:03:01, *06:14:01 = *06:03:01, *06:14:02
-+++++--	-+-----	-----+--	-----++-	*06:14:01, *06:41 = *06:14:02, *06:41
-+++++--	-+-----	-----+--	-----++-	*06:14:01, *06:14:01 = *06:14:01, *06:14:02
-+++++--	-+-----	-----+--	-----++-	*06:04:01, *06:31 = *06:04:02, *06:31
-+++++--	-+-----	-----+--	-----++-	*06:04:01, *06:26N = *06:04:02, *06:26N
-+++++--	-+-----	-----+--	-----++-	*06:07:02, *06:08:01 = *06:38, *06:41
-+++++--	-+-----	-----+--	-----++-	*06:07:01, *06:08:01 = *06:07:01, *06:08:02
-+++++--	-+-----	-----+--	-----++-	*06:04:01, *06:28 = *06:04:02, *06:28
-+++++--	-+-----	-----+--	-----++-	*06:04:01, *06:40 = *06:04:02, *06:40



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-----+	-----+	-----+	-----+	*06:04:01, *06:44 = *06:04:02, *06:44
-----+	-----+	-----+	-----+	*06:03:01, *06:04:01 = *06:03:01, *06:04:02 = *06:39, *06:41
-----+	-----+	-----+	-----+	*06:04:01, *06:41 = *06:04:02, *06:41
-----+	-----+	-----+	-----+	*06:07:01, *06:44 = *06:07:02, *06:44
-----+	-----+	-----+	-----+	*06:03:01, *06:07:01 = *06:03:01, *06:07:02
-----+	-----+	-----+	-----+	*06:08:01, *06:32 = *06:08:02, *06:32
-----+	-----+	-----+	-----+	*06:03:01, *06:05:02 = *06:03:01, *06:32
-----+	-----+	-----+	-----+	*06:08:01, *06:31 = *06:08:02, *06:31
-----+	-----+	-----+	-----+	*06:08:01, *06:30 = *06:08:02, *06:30
-----+	-----+	-----+	-----+	*06:08:01, *06:26N = *06:08:02, *06:26N
-----+	-----+	-----+	-----+	*06:08:01, *06:28 = *06:08:02, *06:28
-----+	-----+	-----+	-----+	*06:08:01, *06:40 = *06:08:02, *06:40
-----+	-----+	-----+	-----+	*06:08:01, *06:44 = *06:08:02, *06:44
-----+	-----+	-----+	-----+	*06:03:01, *06:08:01 = *06:03:01, *06:08:02
-----+	-----+	-----+	-----+	*06:08:01, *06:41 = *06:08:02, *06:41
-----+	-----+	-----+	-----+	*06:03:01, *06:44 = *06:44, *06:44
-----+	-----+	-----+	-----+	*06:04:01, *06:30 = *06:04:02, *06:30
-----+	-----+	-----+	-----+	*06:04:01, *06:07:01 = *06:04:02, *06:07:01 = *06:04:02, *06:07:02
-----+	-----+	-----+	-----+	*06:04:01, *06:32 = *06:04:02, *06:32
-----+	-----+	-----+	-----+	*06:07:01, *06:07:01 = *06:07:01, *06:07:02
-----+	-----+	-----+	-----+	*06:04:01, *06:07:02 = *06:07:02, *06:38
-----+	-----+	-----+	-----+	*06:04:01, *06:08:01 = *06:04:02, *06:08:01 = *06:04:02, *06:08:02
-----+	-----+	-----+	-----+	*06:08:01, *06:08:01 = *06:08:01, *06:08:02
-----+	-----+	-----+	-----+	*06:04:02, *06:25 = *06:04:02, *06:36
-----+	-----+	-----+	-----+	*06:04:01, *06:04:02 = *06:04:02, *06:04:02 = *06:04:02, *06:05:02
-----+	-----+	-----+	-----+	*06:12, *06:25 = *06:12, *06:36
-----+	-----+	-----+	-----+	*06:04:01, *06:42 = *06:09, *06:17
-----+	-----+	-----+	-----+	*06:09, *06:25 = *06:09, *06:36
-----+	-----+	-----+	-----+	*06:04:01, *06:25 = *06:04:01, *06:36 = *06:36, *06:36
-----+	-----+	-----+	-----+	*06:04:01, *06:34 = *06:34, *06:34
-----+	-----+	-----+	-----+	*06:04:01, *06:04:01 = *06:04:01, *06:05:02
-----+	-----+	-----+	-----+	*06:05:01, *06:05:01 = *06:05:01, *06:05:02
-----+	-----+	-----+	-----+	*06:05:02, *06:06 = *06:06, *06:06

\*06:01:01 = \*06:01:01-06:01:06  
\*06:02:01 = \*06:02:01-06:02:02  
\*06:03:01 = \*06:03:01-06:03:02  
\*06:04:01 = \*06:04:01 and 06:04:03



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Lot-specific information  
**SPECIFICITY TABLE**

**DQB1\*06 SSP subtyping**

Specificities and sizes of the PCR products of the 32 primer mixes used for DQB1\*06 SSP subtyping

Primer Mix	Size of spec. PCR product <sup>1</sup>	Size of control band <sup>2</sup>	Amplified DQB1*06 alleles <sup>3</sup>	Amplified non-DQB1*06 alleles <sup>4</sup>
<b>1</b>	220 bp	<b>515 bp</b>	*06:01:01-06:01:06, 06:35, 06:43	
<b>2</b>	210 bp	430 bp	*06:01:01-06:02:02, 06:05:02 <sup>?</sup> -06:06 <sup>?</sup> , 06:10-06:11:02, 06:13, 06:16, 06:18-06:20, 06:24, 06:29, 06:33, 06:35, 06:37, 06:43, 06:47	
<b>3</b>	185 bp	430 bp	*06:02:01-06:02:02, 06:14:01-06:16, 06:19-06:20, 06:23-06:24, 06:33, 06:37, 06:47	
<b>4</b>	130 bp	430 bp	*06:03:01-06:03:02, 06:07:01-06:07:02, 06:11:02, 06:14:01, 06:26N, 06:28, 06:30-06:32, 06:40-06:41, 06:44	
<b>5</b>	160 bp	430 bp	*06:03:01-06:03:02, 06:04:02, 06:07:01, 06:08:01, 06:11:01-06:11:02, 06:26N, 06:28, 06:30-06:32, 06:40-06:41, 06:44	*03:23
<b>6</b>	170 bp	<b>515 bp</b>	*06:03:01-06:03:02, 06:08:01-06:08:02, 06:11:02-06:12, 06:14:01, 06:21, 06:26N, 06:28, 06:31, 06:40-06:41, 06:44	
<b>7</b>	210 bp	<b>515 bp</b>	*06:04:01-06:04:03, 06:07:01-06:07:02, 06:17, 06:21, 06:25, 06:34, 06:36, 06:38-06:39	
<b>8<sup>6</sup></b>	175 bp	430 bp	*06:04:01-06:07:02, 06:09, 06:18, 06:25, 06:27, 06:32, 06:34, 06:36, 06:38-06:39	

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<b>9<sup>6</sup></b>	130 bp	430 bp	*06:04:01-06:05:01, 06:06, 06:08:01-06:09, 06:12, 06:17-06:18, 06:21, 06:27, 06:34, 06:36, 06:38-06:39, 06:42	
<b>10<sup>9</sup></b>	260 bp	<b>515 bp</b>	*06:05:01, 06:05:02 <sup>?</sup> -06:06 <sup>?</sup> , 06:20 <sup>w</sup> , 06:31	
<b>11</b>	210 bp	430 bp	*06:05:01, 06:05:02 <sup>?</sup> -06:06 <sup>?</sup> , 06:09, 06:12, 06:15, 06:22, 06:42	
<b>12</b>	180 bp	430 bp	*06:06	
<b>13</b>	185 bp	430 bp	*06:10	
<b>14</b>	130 bp	430 bp	*06:13, 06:22	
<b>15<sup>5,8,10</sup></b>	100 bp, 185 bp	430 bp	*06:14:01-06:14:02, 06:29	
<b>16</b>	195 bp	430 bp	*06:16	
<b>17<sup>5</sup></b>	110 bp	430 bp	*06:23	
<b>18<sup>7</sup></b>	175 bp	430 bp	*06:17, 06:24, 06:30, 06:42	
<b>19</b>	135 bp	430 bp	*06:10, 06:25, 06:36	
<b>20<sup>5,11</sup></b>	110 bp, 215 bp	<b>515 bp</b>	*06:26N, 06:37	
<b>21</b>	160 bp	430 bp	*06:02:01-06:02:02, 06:10, 06:13-06:16, 06:20, 06:23-06:24, 06:29, 06:33, 06:37, 06:47	
<b>22<sup>12</sup></b>	130 bp, 195 bp	<b>515 bp</b>	*06:07:01-06:07:02, 06:15, 06:38	
<b>23</b>	160 bp	<b>515 bp</b>	*06:03:01-06:03:02, 06:08:01-06:08:02, 06:14:01-06:14:02, 06:21, 06:28, 06:31, 06:40-06:41, 06:44	
<b>24</b>	155 bp	430 bp	*06:19	*03:30, 04:01:01- 04:03:02, 04:06- 04:08
<b>25</b>	210 bp	430 bp	*06:03:01-06:03:02, 06:08:01-06:08:02, 06:14:01-06:14:02, 06:27-06:28, 06:30-06:32, 06:40-06:41, 06:44	
<b>26<sup>13</sup></b>	165 bp, 190 bp	430 bp	*06:28, 06:35	

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<b>27<sup>14</sup></b>	205 bp, 265 bp	430 bp	*06:33, 06:40
<b>28</b>	300 bp	430 bp	*06:34
<b>29<sup>5</sup></b>	90 bp	430 bp	*06:04:01-06:05:01, 06:05:02 <sup>?</sup> -06:06 <sup>?</sup> , 06:07:01-06:07:02, 06:09, 06:15, 06:22, 06:25, 06:34, 06:36, 06:38-06:39
<b>30<sup>5,6</sup></b>	115 bp	430 bp	*06:02:01-06:03:02, 06:05:01 <sup>?</sup> -06:07:01 <sup>?</sup> , 06:08:01 <sup>?</sup> -06:08:02 <sup>?</sup> , 06:10 <sup>?</sup> -06:11:02 <sup>?</sup> , 06:13 <sup>?</sup> - 06:33 <sup>?</sup> , 06:35 <sup>?</sup> , 06:37 <sup>?</sup> , 06:39, 06:40 <sup>?</sup> , 06:44, 06:47
<b>31<sup>5,8,15</sup></b>	100 bp, 220 bp	430 bp	*06:43-06:44, 06:47
<b>32<sup>5,6</sup></b>	125 bp	430 bp	*06:04:01-06:04:03, 06:05:01 <sup>?</sup> -06:06 <sup>?</sup> , 06:07:01-06:07:02, 06:08:01 <sup>?</sup> -06:08:02 <sup>?</sup> , 06:09, 06:10 <sup>?</sup> -06:11:02 <sup>?</sup> , 06:12, 06:13 <sup>?</sup> -06:33 <sup>?</sup> , 06:34, 06:35 <sup>?</sup> , 06:36, 06:37 <sup>?</sup> , 06:40 <sup>?</sup> , 06:41- 06:42

<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\*06 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\*06 subtyping.

In addition, wells number 6, 7, 10, 20, 22 and 23 contain 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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101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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**Lot No.: 08N****Lot-specific information**

<sup>3</sup>For several DQB1 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 DQB1 alleles are conserved within allelic groups.

<sup>4</sup>Due to the sharing of sequence motif between DQB1 alleles, the DQB1\*03:23 alleles will be amplified by primer mix 5, and the DQB1\*03:30, 04:01:01-04:03:02 and 04:06-04:08 alleles will be amplified by primer mix 24.

<sup>5</sup>Specific PCR fragments shorter than 125 base pairs have a lower intensity than longer PCR bands.

<sup>6</sup>Primer mix 8, 9, 30 and 32 may yield less specific PCR product than the other DQB1\*06 primer mixes, most pronounced in primer mix 32.

<sup>7</sup>Primer mix 18 may give rise to primer oligomer formation.

<sup>8</sup>Primer mixes 15 and 31 may give rise to unspecific amplifications.

<sup>9</sup>The nucleotide sequence of codon 14 of the DQB1\*06:05:02 allele is not yet known. If codon 14 is CTg, then the DQB1\*06:05:02 allele will retain its name and will be amplified by the primer pair in well No. 10. If the sequence of codon 14 is ATg, then DQB1\*06:05:02 will be renamed to DQB1\*06:09:02 (Steven Marsh personal communication), and will not be amplified by the primer pair in well No. 10.

<sup>10</sup>Primer mix 15: Specific PCR fragment of 100 bp in the DQB1\*06:14:01 and \*06:14:02 alleles. Specific PCR fragment of 185 bp in the DQB1\*06:29 allele.

<sup>11</sup>Primer mix 20: Specific PCR fragment of 110 bp in the DQB1\*06:37 allele. Specific PCR fragment of 215 bp in the DQB1\*06:26N allele.

<sup>12</sup>Primer mix 22: Specific PCR fragment of 130 bp in the DQB1\*06:07:01-06:07:02 and 06:15 alleles. Specific PCR fragment of 195 bp in the DQB1\*06:38 allele.

<sup>13</sup>Primer mix 26: Specific PCR fragment of 165 bp in the DQB1\*06:35 allele. Specific PCR fragment of 190 bp in the DQB1\*06:28 allele.

<sup>14</sup>Primer mix 27: Specific PCR fragment of 205 bp in the DQB1\*06:40 allele. Specific PCR fragment of 265 bp in the DQB1\*06:33 allele.

<sup>15</sup>Primer mix 31: Specific PCR fragment of 100 bp in the DQB1\*06:44 and 06:47 alleles. Specific PCR fragment of 220 bp in the DQB1\*06:43 allele.

‘w’, might be weakly amplified.

“?”, nucleotide sequence information is not available for the primer matching sequence.

101.212.24/04 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot-specific information

INTERPRETATION TABLE																
DQB1*06 SSP subtyping																
Amplification patterns of the DQB1*06:01 to 06:47 alleles																
	Well <sup>5</sup>															
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
Length of spec.	220	210	185	130	160	170	210	175	130	260	210	180	185	130	100	195
PCR product(s)															185	
Length of int.	515	430	430	430	430	515	515	430	430	515	430	430	430	430	430	430
pos. control <sup>1</sup>																
5'-primer(s) <sup>2</sup>	26(173)	30(184)	9(122)	27(177)	9(122)	27(177)	30(184)	27(177)	27(177)	14(136)	30(184)	27(177)	9(122)	27(177)	9(122)	9(122)
	5'-TTA 3'	5'-gAT 3'	5'-gTT 3'	5'-gTA 3'	5'-gTA 3'	5'-gTA 3'	5'-gAC 3'	5'-gTA 3'	5'-gTA 3'	5'-gCC 3'	5'-gAT 3'	5'-gTA 3'	5'-gTT 3'	5'-gTg 3'	5'-gTT 3'	5'-gTT 3'
		30(184)														
		5'-gAT 3'														
3'-primer(s) <sup>3</sup>	86(353)	86(353)	57(266)	57(266)	48(240)	70(304)	86(353)	70(304)	57(266)	86(353)	86(353)	74(317)	57(265)	57(266)	27(177)	60(274)
	5'-ACg 3'	5'-ACg 3'	5'-CAT 3'	5'-CAT 3'	5'-gCg 3'	5'-CCC 3'	5'-ACC 3'	5'-CCT 3'	5'-CAA 3'	5'-ACC 3'	5'-ACC 3'	5'-CCg 3'	5'-gCT 3'	5'-CAA 3'	5'-gTT 3'	5'-gTT 3'
								74(317)		87(356)					30(184)	
								5'-CCg 3'		5'-ggA 3'					5'-gTg 3'	
															5'-Cgg 3'	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
DQB1 allele <sup>4</sup>																
*06:01:01-06:01:06	1	2														
*06:02:01-06:02:02		2	3													
*06:03:01-06:03:02				4	5	6										
*06:04:01, 06:04:03							7	8	9							
*06:04:02					5		7	8	9							
*06:05:01								8	9	10	11					
*06:05:02		?						8		?	?					
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16



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 101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: 08N

Lot-specific information

INTERPRETATION TABLE															
DQB1*06 SSP subtyping															
Amplification patterns of the DQB1*06:01 to 06:47 alleles															
Well <sup>5</sup>															
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
110	175	135	110	160	130	160	155	210	165	205	300	90	115	100	125
			215		195				190	265				220	
430	430	430	515	430	515	515	430	430	430	430	430	430	430	430	430
Length of spec. PCR product(s)															
Length of int. pos. control <sup>1</sup>															
5'-primer(s) <sup>2</sup>															
5'-ggg <sup>3'</sup>	5'-TCT <sup>3'</sup>	5'-TCT <sup>3'</sup>	5'-CCT <sup>3'</sup>	5'-gTT <sup>3'</sup>	5'-TgA <sup>3'</sup>	5'-gAC <sup>3'</sup>	5'-gTT <sup>3'</sup>	5'-gAC <sup>3'</sup>	5'-CgT <sup>3'</sup>	5'-TTA <sup>3'</sup>	5'-TCT <sup>3'</sup>	5'-AgA <sup>3'</sup>	5'-CCg <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-TCT <sup>3'</sup>
		5'-ACT <sup>3'</sup>	5'-AAg <sup>3'</sup>		5'-TCA <sup>3'</sup>				5'-ggA <sup>3'</sup>	5'-ACg <sup>3'</sup>				5'-ACT <sup>3'</sup>	
3'-primer(s) <sup>3</sup>															
5'-gCg <sup>3'</sup>	5'-ggC <sup>3'</sup>	5'-gCT <sup>3'</sup>	5'-ACg <sup>3'</sup>	5'-gCg <sup>3'</sup>	5'-ACC <sup>3'</sup>	5'-CCC <sup>3'</sup>	5'-CgA <sup>3'</sup>	5'-ACg <sup>3'</sup>	5'-ggA <sup>3'</sup>	5'-ACg <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-ACC <sup>3'</sup>	5'-AAA <sup>3'</sup>	5'-CCA <sup>3'</sup>	5'-ACT <sup>3'</sup>
		5'-CCg <sup>3'</sup>			5'-Cgg <sup>3'</sup>									5'-ACT <sup>3'</sup>	
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
Well No.															
DQB1 allele <sup>4</sup>															
				21									30		
						23		25					30		
												29			32
												29		32	
												29	?	?	
												?	?	?	
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32
Well No.															



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 101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot-specific information

Length of spec. PCR product(s)	220	210	185	130	160	170	210	175	130	260	210	180	185	130	100	195
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*06:06		?						8	9	?	?	12				
*06:07:01				4	5		7	8								
*06:07:02				4			7	8								
*06:08:01					5	6			9							
*06:08:02						6			9							
*06:09								8	9		11					
*06:10		2											13			
*06:11:01		2			5											
*06:11:02		2		4	5	6										
*06:12						6			9		11					
*06:13		2												14		
*06:14:01			3	4		6									15	
*06:14:02			3												15	
*06:15			3								11					
*06:16		2	3													16
*06:17							7		9							
*06:18		2						8	9							
*06:19		2	3													
*06:20		2	3							w						
*06:21						6	7		9							
*06:22											11			14		
*06:23			3													
*06:24		2	3													
*06:25							7	8								
*06:26N				4	5	6										
*06:27								8	9							
*06:28				4	5	6										
*06:29		2													15	
*06:30				4	5											
*06:31				4	5	6				10						
*06:32				4	5			8								
*06:33		2	3													
*06:34							7	8	9							
*06:35	1	2														
*06:36							7	8	9							
*06:37		2	3													
*06:38							7	8	9							
*06:39							7	8	9							
*06:40				4	5	6										
*06:41				4	5	6										
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

101.212.24/04 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **08N**

Lot-specific information

110	175	135	110	160	130	160	155	210	165	205	300	90	115	100	125	Length of spec. PCR product(s)
			215		195				190	265				220		
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
												?	?		?	*06:06
					22							29	?		32	*06:07:01
					22							29			32	*06:07:02
						23		25					?		?	*06:08:01
						23		25					?		?	*06:08:02
												29			32	*06:09
		19		21									?		?	*06:10
													?		?	*06:11:01
													?		?	*06:11:02
															32	*06:12
				21									?		?	*06:13
				21		23		25					?		?	*06:14:01
				21		23		25					?		?	*06:14:02
				21	22							29	?		?	*06:15
				21									?		?	*06:16
18													?		?	*06:17
													?		?	*06:18
							24						?		?	*06:19
				21									?		?	*06:20
						23							?		?	*06:21
												29	?		?	*06:22
17				21									?		?	*06:23
	18			21									?		?	*06:24
		19										29	?		?	*06:25
			20										?		?	*06:26N
								25					?		?	*06:27
						23		25	26				?		?	*06:28
				21									?		?	*06:29
18								25					?		?	*06:30
						23		25					?		?	*06:31
								25					?		?	*06:32
				21						27			?		?	*06:33
											28	29			32	*06:34
									26				?		?	*06:35
		19										29			32	*06:36
			20	21									?		?	*06:37
					22							29				*06:38
												29	30			*06:39
						23		25		27			?		?	*06:40
						23		25							32	*06:41
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.



101.212.24/04 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **08N**

Lot-specific information

Length of spec.	220	210	185	130	160	170	210	175	130	260	210	180	185	130	100	195
PCR product(s)															185	
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
*06:42									9		11					
*06:43	1	2														
*06:44				4	5	6										
*06:47		2	3													
*03:23					5											
*03:30, 04:01:01- 04:03:02, 04:06- 04:08																
DQB1 allele																
Well No.	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16

<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. 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\*06 subtyping.

In addition, wells number 6, 7, 10, 20, 22 and 23 contain 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> or 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. 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.

101.212.24/04 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **08N**

Lot-specific information

110	175	135	110	160	130	160	155	210	165	205	300	90	115	100	125	Length of spec. PCR product(s)
			215		195				190	265				220		
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.
	18														32	*06:42
														31		*06:43
						23		25					30	31		*06:44
				21									30	31		*06:47
																*03:23
							24									*03:30, 04:01:01- 04:03:02, 04:06- 04:08
																DQB1 allele
17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	Well No.

<sup>4</sup>The nucleotide sequence of the DQB1\*06:45 and DQB1\*06:46 alleles are not yet retrievable

<sup>5</sup>Primer mix 15: Specific PCR fragment of 100 bp in the DQB1\*06:14:01 and \*06:14:02 alleles.

Specific PCR fragment of 185 bp in the DQB1\*06:29 allele.

Primer mix 20: Specific PCR fragment of 110 bp in the DQB1\*06:37 allele. Specific PCR fragment of 215 bp in the DQB1\*06:26N allele.

Primer mix 22: Specific PCR fragment of 130 bp in the DQB1\*06:07:01-06:07:02 and 06:15 alleles. Specific PCR fragment of 195 bp in the DQB1\*06:38 allele.

Primer mix 26: Specific PCR fragment of 165 bp in the DQB1\*06:35 allele. Specific PCR fragment of 190 bp in the DQB1\*06:28 allele.

Primer mix 27: Specific PCR fragment of 205 bp in the DQB1\*06:40 allele. Specific PCR fragment of 265 bp in the DQB1\*06:33 allele.

Primer mix 31: Specific PCR fragment of 100 bp in the DQB1\*06:44 and 06:47 alleles. Specific PCR fragment of 220 bp in the DQB1\*06:43 allele.

'w', might be weakly amplified.

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

101.212.24/04 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **08N**

Lot-specific information

<b>CELL LINE VALIDATION SHEET</b>																			
<b>DQB1*06 SSP subtyping kit</b>																			
			Prod. No.	Well															
				1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
				201075701	201075702	201075703	201075704	201075705	201075706	201075707	201075708	201075709	201075710	201075711	201075712	201075713	201075714	201075715	201075716
	<b>IHWC cell line</b>	<b>DQB1</b>																	
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		-	-	-	-	-	-	-	-	-	-	-	-	-	-		





101.212.24/04 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **08N**

Lot-specific information

<b>CELL LINE VALIDATION SHEET</b>																				
<b>DQB1*06 SSP subtyping kit</b>																				
				Well																
				17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	
				Prod. No.	201075717	201075718	201075719	201075720	201075721	201075722	201075723	201294224	201075725	201294226	201075727	201075728	201075729	201294230	201294231	201294232
	IHC 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		-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-



101.212.24/04 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **08N**

Lot-specific information

## CERTIFICATE OF ANALYSIS

### OLERUP SSP® DQB1\*06 SSP

**Product number:** 101.212-24/04 – including *Taq* pol.  
 101.212-24u/04u – without *Taq* pol.

**Lot number:** 08N

**Expiry date:** 2014-July-01

**Number of tests:** 24 test – Product No. 101.212-24/24u  
 4 tests – Product No. 101.212-04/04u

**Number of wells per test:** 32

#### Well specifications:

Well No.	Production No.	Well No.	Production No.	Well No.	Production No.
1	2010-757-01	13	2010-757-13	25	2010-757-25
2	2010-757-02	14	2010-757-14	26	2012-942-26
3	2010-757-03	15	2010-757-15	27	2010-757-27
4	2010-757-04	16	2010-757-16	28	2010-757-28
5	2010-757-05	17	2010-757-17	29	2010-757-29
6	2010-757-06	18	2010-757-18	30	2012-942-30
7	2010-757-07	19	2010-757-19	31	2012-942-31
8	2010-757-08	20	2010-757-20	32	2012-942-32
9	2010-757-09	21	2010-757-21		
10	2010-757-10	22	2010-757-22		
11	2010-757-11	23	2010-757-23		
12	2010-757-12	24	2012-942-24		

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

No DNAs carrying the alleles to be amplified by primer solutions 10, 12 to 20, 22, 26 to 28 and 31 were available. The specificities of the primers in primer solutions 10, 12 to 15, 17, 19, 22 and 26 were tested by separately adding additional 5'-primers, respectively additional 3'-primers. In primer solutions 16, 18, 28 and 31 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 20 and 27 it was only possible to test the 3'-primer, the 5'-primer was not possible to test. In primer solution 19, one 3'-primer was not possible to test, and in primer solution 22 one 5'-primer was not possible to test.

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

**Date of approval:** 2012-January-26

**Approved by:**

#### Production Quality Control

101.212.24/04 – including *Taq* pol., IFU-01 Rev. No. 03  
101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **08N**

Lot-specific information

## Declaration of Conformity

**Product name:** *Olerup* SSP® DQB1\*06  
**Product number:** 101.212-24/24u, -04/04u  
**Lot number:** 08N

**Intended use:** DQB1\*06 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 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-January-26

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs

101.212.24/04 – including *Taq* pol., IFU-01 Rev. No. 03  
101.212.24u/04u – without *Taq* pol., IFU-02 Rev. No. 03

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Lot No.: **08N**

Lot-specific information

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