

101.213.24 – including *Taq* pol., IFU-01 Rev. No. 03  
 101.213.24u – 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.: **63N**

Lot-specific information  
**Olerup SSP<sup>®</sup> DQB1\*02**

Product number: 101.213-24 – including *Taq* polymerase  
 101.213-24u – without *Taq* polymerase  
 Lot number: 63N  
 Expiry date: 2014-October-01  
 Number of tests: 24  
 Number of wells per test: 7  
 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. 63N.**

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP<sup>®</sup>  
 DQB1\*02 LOT**

The DQB1\*02 specificity and interpretation tables have been updated with the DQB1 alleles described since the previous *Olerup SSP<sup>®</sup> DQB1\*02* lot (Lot No. 77K) was made.

One well has been added to the DQB1\*02 kit, well **7**.

The Lot-specific information for DQB1\*02 including and without *Taq* polymerase is now described in one common Product Insert.

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

| Well | 5'-primer | 3'-primer | rationale                                  |
|------|-----------|-----------|--|
| 7    | New       | New       | New primer pair for the DQB1*02:06 allele. |

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## PRODUCT DESCRIPTION

### DQB1\*02 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the DQB1\*02:01 to DQB1\*02:06 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 7 PCR reactions in an 8 well PCR plate. Well 8 is empty.

|   |   |   |   |   |   |   |       |
|---|---|---|---|---|---|---|-------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | empty |
|---|---|---|---|---|---|---|-------|

The 8 well PCR plate is marked with 'DQ2' in silver/gray ink.

Well No. 1 is marked with the Lot No. '63N'.

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 heat-sealed with a PCR-compatible foil.

**Please note:** When removing each 8 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

The interpretation of DQB1\*02 SSP subtypings will be influenced by the DQB1\*03, the DQB1\*04, the DQB1\*05 and DQB1\*06 alleles, when present on the other haplotype. The interpretation of DQB1\*02 subtypings is not influenced by the DQB2 and DQB3 genes.

#### UNIQUELY IDENTIFIED ALLELES

All the DQB1\*02 alleles, i.e. **DQB1\*02:01 to DQB1\*02:06**, 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\*02 subtyping kit.

The DQB1\*02 kit cannot distinguish the silent mutation in the DQB1\*02:01:01-02:01:04 alleles.

<sup>1</sup>HLA-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 9 alleles generate 6 amplification patterns that can be combined in 21 homozygous and heterozygous combinations. 6 of these genotypes do not give rise to unique amplification patterns.

|                                |                                    |
|--------------------------------|------------------------------------|
| +++---+                        | *02:02, *02:06 = *02:06, *02:06    |
| +-+---+-                       | *02:01:01, *02:05 = *02:05, *02:05 |
| +--+---                        | *02:01:01, *02:04 = *02:04, *02:04 |
| *02:01:01 = *02:01:01-02:01:04 |                                    |

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## SPECIFICITY TABLE

### DQB1\*02 SSP subtyping

Specificities and sizes of the PCR products of the 7 primer mixes used for DQB1\*02 SSP subtyping

| Primer Mix     | Size of spec. PCR product <sup>1</sup> | Size of control band <sup>2</sup> | Amplified DQB1*02 alleles <sup>3</sup> | Other amplified DQB1 alleles <sup>4</sup>  |
|----------------|--|-----------------------------------|--|--|
| 1 <sup>5</sup> | 120 bp                                 | 515 bp                            | *02:01:01-02:02,<br>02:04-02:06        |  |
| 2 <sup>5</sup> | 85 bp                                  | 430 bp                            | *02:03                                 |  |
| 3 <sup>6</sup> | 145 bp                                 | 515 bp                            | *02:01:01-<br>02:01:04,<br>02:04-02:05 | *03:01:01:01-03:23,<br>03:25-03:40,<br>04:01:01-04:08,<br>05:01:01:01-05:13,<br>06:01:01-06:37,<br>06:39-06:49 |
| 4              | 140 bp                                 | 430 bp                            | *02:02-02:03,<br>02:06                 |  |
| 5              | 145 bp                                 | 430 bp                            | *02:04                                 |  |
| 6 <sup>7</sup> | 180 bp                                 | 430 bp                            | *02:05                                 |  |
| 7              | 245 bp                                 | 430 bp                            | *02:06                                 | *03:24   |

<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\*02 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\*02 subtyping.

In addition, well number 3 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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<sup>3</sup>For several DQB1 alleles only partial 3<sup>rd</sup> 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 the 3<sup>rd</sup> exon of DQB1 alleles are conserved within allelic groups.

<sup>4</sup>Due to the sharing of sequence motifs, non-DQB1\*02 alleles will be amplified by primer mixes 3 and 7.

<sup>5</sup>Short specific PCR fragments are less intense and not as sharp as longer specific bands.

<sup>6</sup>Primer mix 3 may have a tendency of giving rise to unspecific amplifications.

<sup>7</sup>Primer mix 6 may give rise to primer oligomer formation.

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| <b>INTERPRETATION TABLE</b>  |                |                |                 |                 |                 |                |                 |
|--|----------------|----------------|-----------------|-----------------|-----------------|----------------|-----------------|
| <b>DQB1*02 SSP subtyping</b>   |                |                |                 |                 |                 |                |                 |
| <b>Amplification patterns of the 02:01 to 02:06 alleles</b>  |                |                |                 |                 |                 |                |                 |
|  | <b>Well</b>    |                |                 |                 |                 |                |                 |
|  | <b>1</b>       | <b>2</b>       | <b>3</b>        | <b>4</b>        | <b>5</b>        | <b>6</b>       | <b>7</b>        |
| <b>Length of spec.</b>   | <b>120</b>     | <b>85</b>      | <b>145</b>      | <b>140</b>      | <b>145</b>      | <b>180</b>     | <b>245</b>      |
| <b>PCR product</b>   |                |                |                 |                 |                 |                |                 |
| <b>Length of int. pos. control<sup>1</sup></b>   | <b>515</b>     | <b>430</b>     | <b>515</b>      | <b>430</b>      | <b>430</b>      | <b>430</b>     | <b>430</b>      |
| <b>5'-primer<sup>2</sup></b>   | <b>30(185)</b> | <b>57(266)</b> | <b>135(500)</b> | <b>101(400)</b> | <b>135(502)</b> | <b>30(185)</b> | <b>101(400)</b> |
|  | 5' -AAg 3'     | 5' -TgA 3'     | 5' -TgA 3'      | 5' -TCT 3'      | 5' -ACg 3'      | 5' -AAg 3'     | 5' -TCT 3'      |
| <b>3'-primer<sup>3</sup></b>   | <b>57(266)</b> | <b>71(309)</b> | <b>169(604)</b> | <b>135(500)</b> | <b>169(604)</b> | <b>77(326)</b> | <b>169(604)</b> |
|  | 5' -Cgg 3'     | 5' -CgT 3'     | 5' -gAC 3'      | 5' -ggC 3'      | 5' -gAC 3'      | 5' -CCg 3'     | 5' -gAT 3'      |
| <b>Well No.</b>  | <b>1</b>       | <b>2</b>       | <b>3</b>        | <b>4</b>        | <b>5</b>        | <b>6</b>       | <b>7</b>        |
| <b>DQB1 allele</b>   |                |                |                 |                 |                 |                |                 |
| <b>*02:01:01-02:01:04</b>  | <b>1</b>       |                | <b>3</b>        |                 |                 |                |                 |
| <b>*02:02</b>  | <b>1</b>       |                |                 | <b>4</b>        |                 |                |                 |
| <b>*02:03</b>  |                | <b>2</b>       |                 | <b>4</b>        |                 |                |                 |
| <b>*02:04</b>  | <b>1</b>       |                | <b>3</b>        |                 | <b>5</b>        |                |                 |
| <b>*02:05</b>  | <b>1</b>       |                | <b>3</b>        |                 |                 | <b>6</b>       |                 |
| <b>*02:06</b>  | <b>1</b>       |                |                 | <b>4</b>        |                 |                | <b>7</b>        |
| <b>*03:01:01:01-03:23, 03:25-03:40, 04:01:01-04:08, 05:01:01:01-05:13, 06:01:01-06:37, 06:39-06:49</b> |                |                | <b>3</b>        |                 |                 |                |                 |
| <b>*03:24</b>  |                |                |                 |                 |                 |                | <b>7</b>        |
| <b>DQB1 allele</b>   |                |                |                 |                 |                 |                |                 |
| <b>Well No.</b>  | <b>1</b>       | <b>2</b>       | <b>3</b>        | <b>4</b>        | <b>5</b>        | <b>6</b>       | <b>7</b>        |

<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\*02 subtyping.

In addition, well number 3 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> or 3<sup>rd</sup> exon, 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> exon, 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.

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| <b>CELL LINE VALIDATION SHEET</b> |      |            |        |                |           |           |           |           |           |           |   |
|-----------------------------------|------|------------|--------|----------------|-----------|-----------|-----------|-----------|-----------|-----------|---|
| <b>DQB1*02 SSP subtyping kit</b>  |      |            |        |                |           |           |           |           |           |           |   |
|                                   |      |            |        | Well           |           |           |           |           |           |           |   |
|                                   |      |            |        | 1              | 2         | 3         | 4         | 5         | 6         | 7         |   |
|                                   |      |            |        | 200961701      | 200961702 | 200961703 | 200961704 | 200961705 | 200961706 | 201200107 |   |
|                                   |      |            |        | Production No. |           |           |           |           |           |           |   |
| 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 |                | -         | -         | +         | -         | -         | -         | - |



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## CERTIFICATE OF ANALYSIS

### Olerup SSP® DQB1\*02 SSP

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 101.213-24u – without *Taq* polymerase  
 Lot number: 63N  
 Expiry date: 2014-October-01  
 Number of tests: 24  
 Number of wells per test: 7

#### Well specifications:

| Well No. | Production No. |
|----------|----------------|
| 1        | 2009-617-01    |
| 2        | 2009-617-02    |
| 3        | 2009-617-03    |
| 4        | 2009-617-04    |
| 5        | 2009-617-05    |
| 6        | 2009-617-06    |
| 7        | 2012-001-07    |

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

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

**Date of approval:** 2012-May-28

**Approved by:**

#### Production Quality Control



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## Declaration of Conformity

**Product name:** *Olerup* SSP® DQB1\*02  
**Product number:** 101.213-24/24u  
**Lot number:** 63N

**Intended use:** DQB1\*02 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-May-28

Ann-Cathrin Jareman  
Head of QA and Regulatory Affairs

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Lot-specific information

101.213.24 – including *Taq* pol., IFU-01 Rev. No. 03  
101.213.24u – 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.: **63N**

Lot-specific information

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