

**101.128-12 – including *Taq* polymerase, IFU-01**

**101.128-12u – without *Taq* polymerase, IFU-02**

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“Instructions for Use” (IFU)

**Lot No.: 6F1**

**Lot-specific information**

## **Olerup SSP<sup>®</sup> DRB1\*12**

|                                         |                                                                                                           |
|-----------------------------------------|-----------------------------------------------------------------------------------------------------------|
| <b>Product number:</b>                  | <b>101.128-12 – including <i>Taq</i> polymerase</b><br><b>101.128-12u – without <i>Taq</i> polymerase</b> |
| <b>Lot number:</b>                      | <b>6F1</b>                                                                                                |
| <b>Expiry date:</b>                     | <b>2020-04-01</b>                                                                                         |
| <b>Number of tests:</b>                 | <b>12</b>                                                                                                 |
| <b>Number of wells per test:</b>        | <b>23+1</b>                                                                                               |
| <b>Storage - pre-aliquoted primers:</b> | <b>dark at -20°C</b>                                                                                      |
| - PCR Master Mix:                       | <b>-20°C</b>                                                                                              |
| - Adhesive PCR seals                    | <b>RT</b>                                                                                                 |
| - Product Insert                        | <b>RT</b>                                                                                                 |

**This Product Description is only valid for Lot No. 6F1.**

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

### **CHANGES COMPARED TO THE PREVIOUS OLERUP SSP<sup>®</sup> DRB1\*12 LOT (6D4)**

The DRB1\*12 kit is updated to enable separation of:

- Confirmed DRB1\*12 alleles as listed in the IMGT/HLA database<sup>1</sup>
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

The format of the Worksheet has been changed.

<sup>1</sup>As described in section Uniquely Identified Alleles.

The DRB1\*12 specificity and interpretation tables have been updated for the DRB1 alleles described since the previous Olerup SSP<sup>®</sup> DRB1\*12 lot was made (**Lot No. 6D4**). The kit design is based on IMGT/HLA database 3.29.0.

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

| <b>Well</b> | <b>5'-primer</b> | <b>3'-primer</b> | <b>rationale</b>                                              |
|-------------|------------------|------------------|---------------------------------------------------------------|
| 3           | -                | Added            | 3'-primer added for increased yield of the DRB1*12:48 allele. |
| 17          | Added            | -                | 5'-primer added for the DRB1*12:60N allele.                   |
| 23          | Added            | -                | 5'-primer added for the DRB1*12:60N allele.                   |

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Well **24** contains Negative Control primer pairs, that will amplify more than 95% of the Olerup SSP<sup>®</sup> HLA Class I, DRB, DQB1, DPB1 and DQA1 amplicons as well as all the amplicons generated by the control primer pairs matching the human growth hormone gene.

HLA-specific PCR product sizes range from 75 to 200 base pairs.

The PCR product generated by the positive control primer pair is 430 base pairs.

| Length of PCR product        | 105                  | 200                     | 105                  | 80                   | 75                   | 80                   | 85                   |
|------------------------------|----------------------|-------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| <b>5'-primer<sup>1</sup></b> | <b>164</b>           | <b>340</b>              | <b>440</b>           | <b>45</b>            | <b>45</b>            | <b>43</b>            | <b>36</b>            |
|                              | 5'-CAC <sup>3'</sup> | 5'-Agg <sup>3'</sup>    | 5'-TTA <sup>3'</sup> | 5'-Tgg <sup>3'</sup> | 5'-Tgg <sup>3'</sup> | 5'-Tgg <sup>3'</sup> | 5'-TAC <sup>3'</sup> |
|                              |                      |                         |                      |                      |                      |                      | <b>36</b>            |
|                              |                      |                         |                      |                      |                      |                      | 5'-TAT <sup>3'</sup> |
| <b>3'-primer<sup>2</sup></b> | <b>231</b>           | <b>2<sup>nd</sup> I</b> | <b>507</b>           | <b>59</b>            | <b>58</b>            | <b>57</b>            | <b>47</b>            |
|                              | 5'-TgC <sup>3'</sup> | 5'-AAA <sup>3'</sup>    | 5'-TTg <sup>3'</sup> | 5'-CTC <sup>3'</sup> | 5'-ggC <sup>3'</sup> | 5'-CTC <sup>3'</sup> | 5'-ACA <sup>3'</sup> |
|                              |                      |                         |                      |                      |                      |                      | <b>48</b>            |
|                              |                      |                         |                      |                      |                      |                      | 5'-gCA <sup>3'</sup> |
|                              |                      |                         |                      |                      |                      |                      | <b>48</b>            |
|                              |                      |                         |                      |                      |                      |                      | 5'-gCC <sup>3'</sup> |
|                              |                      |                         |                      |                      |                      |                      | <b>52</b>            |
|                              |                      |                         |                      |                      |                      |                      | 5'-TgT <sup>3'</sup> |
| <b>A*</b>                    | +                    | +                       | +                    |                      |                      |                      |                      |
| <b>B*</b>                    | +                    | +                       | +                    |                      |                      |                      |                      |
| <b>C*</b>                    | +                    | +                       | +                    |                      |                      |                      |                      |
| <b>DRB1</b>                  |                      |                         |                      | +                    | +                    |                      |                      |
| <b>DRB3</b>                  |                      |                         |                      | +                    | +                    |                      |                      |
| <b>DRB5</b>                  |                      |                         |                      | +                    |                      |                      |                      |
| <b>DQB1</b>                  |                      |                         |                      |                      | +                    |                      |                      |
| <b>DPB1</b>                  |                      |                         |                      |                      |                      | +                    |                      |
| <b>DQA1</b>                  |                      |                         |                      |                      |                      |                      | +                    |

<sup>1</sup>The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2<sup>nd</sup> or 3<sup>rd</sup> 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](http://www.ebi.ac.uk/imgt/hla) web site. The sequence of the 3 terminal nucleotides of the primer is given.

<sup>2</sup>The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2<sup>nd</sup> or 3<sup>rd</sup> exon or the 2<sup>nd</sup> 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](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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## PRODUCT DESCRIPTION

### DRB1\*12 SSP subtyping

#### CONTENT

The primer set contains 5'- and 3'-primers for identifying the DRB1\*12:01 to DRB1\*12:67 alleles.

#### PLATE LAYOUT

Each test consists of 24 PCR reactions in a 24 well cut PCR plate.

|           |           |           |           |           |           |           |           |
|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| <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> | <b>13</b> | <b>14</b> | <b>15</b> | <b>16</b> |
| <b>17</b> | <b>18</b> | <b>19</b> | <b>20</b> | <b>21</b> | <b>22</b> | <b>23</b> | <b>NC</b> |

The 24 well cut PCR plate is marked with 'DRB1\*12' in silver/gray ink.

Well No. 1 is marked with the Lot No. '6F1'.

Wells 1 to 23 – DRB1\*12 high resolution primers.

Well 24 – Negative Control (NC).

A faint row of numbers is seen between wells 1 and 2 or wells 7 and 8 of the PCR trays. These stem from the manufacture of the trays, and should be disregarded. The PCR plates are covered with a PCR-compatible foil.

**Please note:** When removing each 24 well PCR plate, make sure that the remaining plates stay covered. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

#### INTERPRETATION

Due to the sharing of sequence motifs between DRB1 alleles, non-DRB1\*12 alleles will be amplified by some primer mixes. For further details see Specificity Table.

#### UNIQUELY IDENTIFIED ALLELES

All the phenotypically different DRB1\*12 alleles, i.e. **DRB1\*12:01 to DRB1\*12:67**, recognized by the HLA Nomenclature Committee in August 2017<sup>1,2</sup> will be amplified by the primers in the DRB1\*12 subtyping kit.

The DRB1\*12 kit enables separation of the confirmed DRB1\*12 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for DRB1\*12 alleles is listed below.

The DRB1\*12 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

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<sup>1</sup>DRB1 alleles listed on the IMGT/HLA web page 2017-August-10, release 3.29.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

<sup>2</sup>Alleles that have been deleted from or renamed in the official WHO HLA Nomenclature up to and including the last IMGT/HLA database release can be retrieved from web page <http://hla.alleles.org/alleles/deleted.html>.

## ALLELE CONFIRMATION STATUS

| Allele                  | Status <sup>1</sup> | Allele             | Status <sup>1</sup> | Allele            | Status <sup>1</sup> | Allele     | Status <sup>1</sup> |
|-------------------------|---------------------|--------------------|---------------------|-------------------|---------------------|------------|---------------------|
| DRB1*12:01:01:01        | Confirmed           | DRB1*12:09         | Unconfirmed         | DRB1*12:37        | Unconfirmed         | DRB1*12:67 | Unconfirmed         |
| DRB1*12:01:01:02        | Unconfirmed         | DRB1*12:10         | Unconfirmed         | DRB1*12:38        | Unconfirmed         |            |                     |
| DRB1*12:01:01:03        | Unconfirmed         | <b>DRB1*12:11</b>  | <b>Confirmed</b>    | DRB1*12:39        | Unconfirmed         |            |                     |
| DRB1*12:01:01:04        | Unconfirmed         | DRB1*12:12         | Unconfirmed         | DRB1*12:40        | Unconfirmed         |            |                     |
| DRB1*12:01:01:05        | Unconfirmed         | DRB1*12:13         | Unconfirmed         | DRB1*12:41        | Unconfirmed         |            |                     |
| DRB1*12:01:02           | Unconfirmed         | DRB1*12:14         | Unconfirmed         | DRB1*12:42        | Unconfirmed         |            |                     |
| DRB1*12:01:03           | Unconfirmed         | DRB1*12:15         | Unconfirmed         | DRB1*12:43        | Unconfirmed         |            |                     |
| <b>DRB1*12:01:04</b>    | <b>Confirmed</b>    | DRB1*12:16:01      | Unconfirmed         | DRB1*12:44        | Unconfirmed         |            |                     |
| DRB1*12:01:05           | Unconfirmed         | DRB1*12:16:02      | Unconfirmed         | <b>DRB1*12:45</b> | <b>Confirmed</b>    |            |                     |
| DRB1*12:01:06           | Unconfirmed         | DRB1*12:16:03      | Unconfirmed         | DRB1*12:46        | Unconfirmed         |            |                     |
| DRB1*12:01:07           | Unconfirmed         | DRB1*12:17         | Unconfirmed         | DRB1*12:47        | Unconfirmed         |            |                     |
| DRB1*12:01:08           | Unconfirmed         | DRB1*12:18         | Unconfirmed         | <b>DRB1*12:48</b> | <b>Confirmed</b>    |            |                     |
| DRB1*12:01:09           | Unconfirmed         | DRB1*12:19         | Unconfirmed         | DRB1*12:49        | Unconfirmed         |            |                     |
| <b>DRB1*12:02:01:01</b> | <b>Confirmed</b>    | <b>DRB1*12:20</b>  | <b>Confirmed</b>    | DRB1*12:50        | Unconfirmed         |            |                     |
| DRB1*12:02:01:02        | Unconfirmed         | DRB1*12:21         | Unconfirmed         | DRB1*12:51        | Unconfirmed         |            |                     |
| DRB1*12:02:01:03        | Unconfirmed         | DRB1*12:22         | Unconfirmed         | DRB1*12:52        | Unconfirmed         |            |                     |
| DRB1*12:02:01:04        | Unconfirmed         | DRB1*12:23         | Unconfirmed         | DRB1*12:53        | Unconfirmed         |            |                     |
| <b>DRB1*12:02:02</b>    | <b>Confirmed</b>    | <b>DRB1*12:24N</b> | <b>Confirmed</b>    | DRB1*12:54        | Unconfirmed         |            |                     |
| DRB1*12:02:03           | Unconfirmed         | DRB1*12:25         | Unconfirmed         | DRB1*12:55        | Unconfirmed         |            |                     |
| DRB1*12:02:04           | Unconfirmed         | DRB1*12:26         | Unconfirmed         | DRB1*12:56        | Unconfirmed         |            |                     |
| DRB1*12:02:05           | Unconfirmed         | <b>DRB1*12:27</b>  | <b>Confirmed</b>    | DRB1*12:57        | Unconfirmed         |            |                     |
| DRB1*12:02:06           | Unconfirmed         | DRB1*12:28         | Unconfirmed         | DRB1*12:58        | Unconfirmed         |            |                     |
| DRB1*12:02:07           | Unconfirmed         | DRB1*12:29         | Unconfirmed         | DRB1*12:59        | Unconfirmed         |            |                     |
| <b>DRB1*12:03:02</b>    | <b>Confirmed</b>    | DRB1*12:30         | Unconfirmed         | DRB1*12:60N       | Unconfirmed         |            |                     |
| DRB1*12:03:03           | Unconfirmed         | DRB1*12:31N        | Unconfirmed         | DRB1*12:61        | Unconfirmed         |            |                     |
| <b>DRB1*12:04</b>       | <b>Confirmed</b>    | DRB1*12:32         | Unconfirmed         | DRB1*12:62        | Unconfirmed         |            |                     |
| DRB1*12:05              | Unconfirmed         | DRB1*12:33         | Unconfirmed         | DRB1*12:63        | Unconfirmed         |            |                     |
| DRB1*12:06              | Unconfirmed         | DRB1*12:34         | Unconfirmed         | DRB1*12:64        | Unconfirmed         |            |                     |
| DRB1*12:07              | Unconfirmed         | DRB1*12:35         | Unconfirmed         | DRB1*12:65        | Unconfirmed         |            |                     |
| <b>DRB1*12:08</b>       | <b>Confirmed</b>    | DRB1*12:36         | Unconfirmed         | DRB1*12:66        | Unconfirmed         |            |                     |

<sup>1</sup>Allele status “confirmed” or “unconfirmed” as listed on the IMGT/HLA web page 2017-August-10, release 3.29.0, [www.ebi.ac.uk/imgt/hla](http://www.ebi.ac.uk/imgt/hla).

## RESOLUTION IN HOMO- AND HETEROZYGOES

Results file with resolution in DRB1\*12 homo- and heterozygotes is available upon request.

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## **SPECIFICITY TABLE**

### **DRB1\*12 SSP subtyping**

**Specificities and sizes of the PCR products of the 23+1 primer mixes used for DRB1\*12 SSP subtyping**

| <b>Primer Mix</b>    | <b>Size of spec. PCR product<sup>1</sup></b> | <b>Size of control band<sup>2</sup></b> | <b>Amplified DRB1*12 alleles<sup>3</sup></b>                                                                                                                                                      | <b>Other amplified DRB1 alleles</b>                                                                                                                                                                                                                         |
|----------------------|----------------------------------------------|-----------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>1</b>             | 135 bp                                       | <b>515 bp</b>                           | *12:01:01:01-12:20, 12:22-12:37, 12:39-12:41, 12:43-12:52, 12:54-12:56, 12:58-12:67                                                                                                               | *03:92, 08:17, 08:28, 08:37, 08:45:01-08:45:02, 08:63, 11:67, 11:193:01-11:193:02, 11:209, 13:17, 13:175, 13:214, 14:138, 14:175                                                                                                                            |
| <b>2</b>             | 215 bp                                       | 430 bp                                  | *12:01:01:01-12:21, 12:23-12:41, 12:44-12:56, 12:58-12:65, 12:67                                                                                                                                  | *08:05, 08:18, 08:24:01-08:25, 08:31, 08:40-08:41, 08:47, 11:193:01-11:193:02, 11:209, 13:17, 13:116, 13:175, 13:214, 14:31, 14:52                                                                                                                          |
| <b>3</b>             | 165 bp                                       | 430 bp                                  | *12:09, 12:48, 12:62                                                                                                                                                                              | *03:92, 08:02:01:01-08:02:04, 08:04:01-08:04:05, 08:04:07, 08:09, 08:13, 08:21, 08:24:01-08:24:02, 08:28, 08:30:01, 08:30:03, 08:42, 08:44-08:45:02, 08:59, 08:67, 08:72-08:73, 08:81-08:82, 13:17, 13:116, 13:175, 13:214, 14:15, 14:52, 14:126:01, 14:175 |
| <b>4<sup>4</sup></b> | 105 bp                                       | 430 bp                                  | *12:01:01:01-12:04, 12:06-12:13, 12:16:01-12:37, 12:39-12:41, 12:43-12:55, 12:59-12:67                                                                                                            | *08:32, 08:53                                                                                                                                                                                                                                               |
| <b>5</b>             | 170 bp                                       | <b>515 bp</b>                           | *12:01:01:01-12:03:03, 12:05-12:08, 12:10-12:17, 12:19-12:32, 12:34-12:41, 12:43-12:45, 12:50-12:56, 12:58-12:61, 12:63-12:67                                                                     | *08:19, 08:25, 08:34, 08:52                                                                                                                                                                                                                                 |
| <b>6</b>             | 250 bp                                       | 430 bp                                  | *12:01:01:01-12:02:07, 12:04-12:15, 12:17-12:18, 12:20-12:21, 12:23-12:38, 12:40-12:41, 12:43-12:56, 12:58-12:67                                                                                  | *08:12, 08:22, 14:28                                                                                                                                                                                                                                        |
| <b>7</b>             | 225 bp                                       | 430 bp                                  | *12:01:01:01-12:02:07, 12:04-12:07, 12:09-12:12, 12:13 <sup>w</sup> , 12:14-12:15, 12:17-12:18, 12:20-12:21, 12:24N-12:26, 12:28-12:36, 12:38, 12:40-12:56, 12:58-12:59, 12:61-12:63, 12:66-12:67 |                                                                                                                                                                                                                                                             |
| <b>8</b>             | 195 bp                                       | 430 bp                                  | *12:01:01:01-12:01:09, 12:03:02-12:06, 12:08-12:11, 12:14, 12:17, 12:22,                                                                                                                          | *08:03:02:01-08:03:06, 08:10, 08:12, 08:15, 08:18-08:19, 08:23, 08:25, 08:27, 08:29-08:30:03,                                                                                                                                                               |

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|                       |                            |               |                                                                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|-----------------------|----------------------------|---------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|                       |                            |               | 12:24N-12:25, 12:28-12:30,<br>12:34-12:36, 12:38-12:41,<br>12:46-12:48, 12:53-12:54,<br>12:58-12:59, 12:63                                                                                                          | 08:32-08:38, 08:40, 08:45:01-<br>08:47, 08:49, 08:51, 08:53, 08:56,<br>08:58, 08:60N-08:63, 08:65-<br>08:66, 08:68-08:69, 08:71, 08:74,<br>08:76                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>9</b>              | 165 bp                     | 430 bp        | *12:01:01:01-12:01:01:05,<br>12:01:04-12:02:01:04,<br>12:02:03-12:02:07, 12:03:03-<br>12:04, 12:06-12:13,<br>12:16:02, 12:17-12:21,<br>12:23-12:37, 12:39-12:42,<br>12:44-12:54, 12:59-12:61,<br>12:63-12:65, 12:67 |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>10</b>             | 195 bp                     | 430 bp        | *12:02:01:01-12:02:07,<br>12:13, 12:15-12:16:03,<br>12:18-12:21, 12:23, 12:26-<br>12:27, 12:31N-12:33, 12:37,<br>12:43-12:45, 12:49-12:52,<br>12:55-12:56, 12:60N-12:61,<br>12:64-12:65, 12:67                      | *08:01:01-08:01:02, 08:01:04-<br>08:01:05, 08:02:01:01-08:02:04,<br>08:04:01-08:09, 08:11, 08:16-<br>08:17, 08:21-08:22, 08:24:01-<br>08:24:02, 08:26, 08:28, 08:31,<br>08:39, 08:41-08:44, 08:50, 08:52,<br>08:54-08:55, 08:59, 08:64, 08:67,<br>08:70, 08:72-08:73, 08:75, 08:77-<br>08:79, 08:82, 11:67, 11:193:01-<br>11:193:02, 11:209, 14:15, 14:73                                                                                                                                                                                                                                                                                                                                                                                                                                                                      |
| <b>11</b>             | 250 bp                     | 430 bp        | *12:03:02-12:03:03, 12:19                                                                                                                                                                                           | *03:92, 08:04:01, 08:04:02 <sup>w</sup> -<br>08:04:03 <sup>w</sup> , 08:04:04-08:04:07,<br>08:06, 08:10, 08:28, 08:31, 08:54,<br>08:59, 08:67, 08:70, 08:75, 11:67,<br>11:209, 13:17, 13:116, 13:175,<br>13:214, 14:04:01-14:04:03, 14:11,<br>14:15, 14:31, 14:50, 14:52, 14:73,<br>14:76, 14:79, 14:107, 14:120,<br>14:126:01-14:126:02, 14:138,<br>14:145, 14:148, 14:152N, 14:175,<br>14:180                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>12<sup>5</sup></b> | 170 bp                     | 430 bp        | *12:04, 12:49                                                                                                                                                                                                       | *08:31, 08:41, 08:63, 08:75,<br>11:67, 11:193:01-11:193:02,<br>11:209, 14:11, 14:148                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| <b>13<sup>4</sup></b> | 115 bp<br>185 bp<br>255 bp | <b>515 bp</b> | *12:24N<br>*12:05, 12:14-12:15, 12:56<br>*12:20                                                                                                                                                                     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| <b>14</b>             | 135 bp                     | <b>515 bp</b> | *12:06                                                                                                                                                                                                              | *03:124 <sup>w</sup> , 15:01:01:01 <sup>w</sup> -<br>15:01:01:04 <sup>w</sup> , 15:01:01:05,<br>15:01:02 <sup>w</sup> -15:01:16 <sup>w</sup> , 15:01:18 <sup>w</sup> -<br>15:01:31 <sup>w</sup> , 15:01:32-15:01:33,<br>15:02:01:01 <sup>w</sup> -15:02:01:02 <sup>w</sup> ,<br>15:02:01:03, 15:02:02 <sup>w</sup> -15:15:02 <sup>w</sup> ,<br>15:15:03, 15:16 <sup>w</sup> -15:104:01 <sup>w</sup> ,<br>15:104:02, 15:105 <sup>w</sup> -15:139 <sup>w</sup> ,<br>15:140-15:147, 16:01:01 <sup>w</sup> -<br>16:01:11 <sup>w</sup> , 16:01:12-16:01:14,<br>16:02:01:01 <sup>w</sup> -16:02:06 <sup>w</sup> , 16:02:07,<br>16:03 <sup>w</sup> -16:04:01 <sup>w</sup> , 16:04:02,<br>16:05:01 <sup>w</sup> -16:05:02 <sup>w</sup> , 16:07 <sup>w</sup> -<br>16:44 <sup>w</sup> , 16:45-16:47,<br><b>DRB4*01:01:02<sup>?</sup></b> |

101.128-12 – including *Taq* polymerase, IFU-01

101.128-12u – without *Taq* polymerase, IFU-02

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Lot No.: **6F1**

Lot-specific information

|                         |                           |               |                                                                                                                                                                        |                                                                                                                                                                              |
|-------------------------|---------------------------|---------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>15</b>               | 170 bp<br>200 bp          | <b>515 bp</b> | *12:18, 12:47<br>*12:07                                                                                                                                                |                                                                                                                                                                              |
| <b>16<sup>4,6</sup></b> | 80 bp                     | 430 bp        | *12:08, 12:23, 12:27                                                                                                                                                   | *08:53, 11:76, 11:114, 11:183,<br>11:196, 13:34, 13:64, 13:136,<br>13:174, 13:204, 13:221, 14:41,<br>14:77, 14:110, 15:102,<br><b>DRB3*01:36, DRB3*02:37,<br/>DRB3*03:12</b> |
|                         | 115 bp                    |               | *12:31N                                                                                                                                                                |                                                                                                                                                                              |
| <b>17<sup>4,6</sup></b> | 80 bp<br>110 bp<br>225 bp | 430 bp        | *12:10<br>*12:25, 12:48<br>*12:60N                                                                                                                                     | *01:26, 13:163<br><b>DRB5*02:07</b>                                                                                                                                          |
| <b>18<sup>4</sup></b>   | 90 bp<br>135 bp           | <b>515 bp</b> | *12:26<br>*12:11                                                                                                                                                       |                                                                                                                                                                              |
| <b>19<sup>4</sup></b>   | 115 bp<br>195 bp          | 430 bp        | *12:45<br>*12:12, 12:62                                                                                                                                                | *08:13, 08:48                                                                                                                                                                |
| <b>20</b>               | 220 bp<br>265 bp          | 430 bp        | *12:13, 12:23<br>*12:57                                                                                                                                                |                                                                                                                                                                              |
| <b>21<sup>4</sup></b>   | 110 bp                    | 430 bp        | *12:01:01:01-12:02:06,<br>12:03:02-12:13, 12:15-12:28,<br>12:30-12:35, 12:37, 12:39-<br>12:41, 12:43-12:44, 12:46-<br>12:50, 12:53-12:55, 12:59-<br>12:62, 12:64-12:67 | *08:32, 08:53                                                                                                                                                                |
| <b>22<sup>4</sup></b>   | 105 bp<br>220 bp          | 430 bp        | *12:21, 12:38, 12:53<br>*12:16:01-12:16:03, 12:22,<br>12:39                                                                                                            | *08:32<br>*08:32, 13:145                                                                                                                                                     |
| <b>23<sup>4</sup></b>   | 120 bp<br>225 bp          | 430 bp        | *12:17, 12:25<br>*12:60N                                                                                                                                               | *01:01:01-01:83<br><b>DRB5*02:07</b>                                                                                                                                         |
| <b>24<sup>7</sup></b>   | -                         | -             | <b>Negative Control</b>                                                                                                                                                |                                                                                                                                                                              |

<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 DRB1\*12 SSP typings.

When the primers in a primer mix can give rise to HLA-specific PCR products of more than one length this is indicated if the size difference is more than 20 base pairs. Size differences of 20 base pairs or less are not given. For high resolution SSP kits, the alleles listed are specified according to amplicon length.

Nonspecific amplifications, i.e. a ladder or a smear of bands, may sometimes be seen. GC-rich primers have a higher tendency of giving rise to nonspecific amplifications than other primers.

PCR fragments longer than the control bands may sometimes be observed. Such bands should be disregarded and do not influence the interpretation of the SSP typings.

PCR fragments migrating faster than the control bands, but slower than a 400 bp fragment may be seen in some gel read-outs. Such bands can be disregarded and do not influence the interpretation of the SSP typings.

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an 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 internal positive control bands are 430 or 515 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the longer, 515 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

<sup>3</sup>For several DRB1 alleles 1st and/or 3rd exon(s) and beyond, as well as intron nucleotide sequences, are not available. In these instances it is not known whether some of the primers of the SSP sets are completely

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**101.128-12u – without *Taq* polymerase, IFU-02**

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**Lot-specific information**

matched with the target sequences or not. Assumption is made that unknown sequences in these regions are conserved within allelic groups.

<sup>4</sup>HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

<sup>5</sup>Primer mixes 12 has a tendency to giving rise to primer oligomer formation.

<sup>6</sup>Primer mixes 16 and 17 may have tendencies of unspecific amplifications.

<sup>7</sup>Primer mix 24 contains a negative control, which will amplify more than 95% of HLA amplicons as well as the amplicons generated by the control primer pairs matching the human growth hormone gene. HLA-specific PCR product sizes range from 75 to 200 base pairs and the PCR product generated by the HGH positive control primer pair is 430 base pairs.

‘w’, may be weakly amplified.

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

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Lot-specific information

## PRIMER SPECIFICATION

| Well No.                                 | 1                    | 2                    | 3                    | 4                    | 5                    | 6                    | 7                    | 8                    | 9                    | 10                   | 11                   | 12                   |
|------------------------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| Length of spec. PCR product              | 135                  | 215                  | 165                  | 105                  | 170                  | 250                  | 225                  | 195                  | 165                  | 195                  | 250                  | 170                  |
| Length of int. pos. control <sup>1</sup> | 515                  | 430                  | 430                  | 430                  | 515                  | 430                  | 430                  | 430                  | 430                  | 430                  | 430                  | 430                  |
| 5'-primer(s) <sup>2</sup>                | 16(133)<br>5'-gTT 3' | 16(133)<br>5'-gTT 3' | 16(133)<br>5'-gTT 3' | 16(133)<br>5'-gTT 3' | 16(133)<br>5'-gTT 3' | 16(133)<br>5'-gTT 3' | 23(154)<br>5'-AgA 3' | 16(133)<br>5'-gTT 3' | 37(196)<br>5'-AgC 3' | 16(133)<br>5'-gTT 3' | 16(133)<br>5'-gTT 3' | 16(133)<br>5'-gTT 3' |
|                                          |                      |                      |                      |                      |                      |                      | 25(162)<br>5'-CgA 3' |                      |                      |                      |                      |                      |
|                                          |                      |                      |                      |                      |                      |                      | 26(165)<br>5'-TTA 3' |                      |                      |                      |                      |                      |
| 3'-primer(s) <sup>3</sup>                | 47(227)<br>5'-ggA 3' | 74(307)<br>5'-CgC 3' | 57(257)<br>5'-CAT 3' | 37(196)<br>5'-gAg 3' | 57(257)<br>5'-CgA 3' | 85(341)<br>5'-CAG 3' | 85(341)<br>5'-CAG 3' | 67(286)<br>5'-gAT 3' | 78(321)<br>5'-CAA 3' | 67(286)<br>5'-gAA 3' | 85(341)<br>5'-CAA 3' | 58(260)<br>5'-CCT 3' |
|                                          |                      |                      | 57(257)<br>5'-CAT 3' |                      | 57(257)<br>5'-CgA 3' |                      |                      |                      |                      |                      |                      |                      |
|                                          |                      |                      |                      |                      | 58(261)<br>5'-TCC 3' |                      |                      |                      |                      |                      |                      |                      |
| Well No.                                 | 1                    | 2                    | 3                    | 4                    | 5                    | 6                    | 7                    | 8                    | 9                    | 10                   | 11                   | 12                   |

| Well No.                                 | 13                   | 14                    | 15                   | 16                   | 17                   | 18                   | 19                   | 20                   | 21                   | 22                   | 23                    |
|------------------------------------------|----------------------|-----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|-----------------------|
| Length of spec. PCR product              | 115                  | 135                   | 170                  | 80                   | 80                   | 90                   | 115                  | 220                  | 110                  | 105                  | 120                   |
|                                          | 185                  |                       | 200                  | 115                  | 110                  | 135                  | 195                  | 265                  |                      | 220                  | 225                   |
|                                          | 255                  |                       |                      |                      | 225                  |                      |                      |                      |                      |                      |                       |
| Length of int. pos. control <sup>1</sup> | 515                  | 515                   | 515                  | 430                  | 430                  | 515                  | 430                  | 430                  | 430                  | 430                  | 430                   |
| 5'-primer(s) <sup>2</sup>                | 13(125)<br>5'-gTg 3' | 149(534)<br>5'-CAG 3' | 16(133)<br>5'-gTT 3' | 14(127)<br>5'-gTT 3' | -17(40)<br>5'-CAA 3' | 16(133)<br>5'-gTT 3' | 16(133)<br>5'-gTT 3' | 11(119)<br>5'-gCT 3' | 16(133)<br>5'-gTT 3' | 26(165)<br>5'-TTA 3' | 24(158)<br>5'-g.T 3'  |
|                                          | 37(197)<br>5'-gTT 3' |                       |                      | 25(160)<br>5'-TgT 3' | 24(158)<br>5'-g.T 3' |                      |                      | 25(160)<br>5'-TgT 3' |                      |                      | 65(280)<br>5'-AgC 3'  |
|                                          | 61(269)<br>5'-CTA 3' |                       |                      | 26(165)<br>5'-TTC 3' | 60(266)<br>5'-gTC 3' |                      |                      | 25(161)<br>5'-gCT 3' |                      |                      | 152(543)<br>5'-gAT 3' |
|                                          |                      |                       |                      | 65(280)<br>5'-AgC 3' |                      |                      |                      |                      |                      |                      |                       |
| 3'-primer(s) <sup>3</sup>                | 85(341)<br>5'-CAG 3' | 181(630)<br>5'-CTT 3' | 59(262)<br>5'-CTg 3' | 38(199)<br>5'-CAG 3' | -4(79)<br>5'-AgC 3'  | 32(182)<br>5'-TAC 3' | 40(205)<br>5'-gAC 3' | 85(341)<br>5'-CAG 3' | 38(199)<br>5'-CAG 3' | 47(227)<br>5'-ggT 3' | 85(341)<br>5'-CAG 3'  |
|                                          |                      |                       | 69(293)<br>5'-CTC 3' |                      | 85(341)<br>5'-CAG 3' | 47(226)<br>5'-gAg 3' | 67(286)<br>5'-gAg 3' |                      | 42(213)<br>5'-TCA 3' | 86(344)<br>5'-CAC 3' | 179(624)<br>5'-ACA 3' |
| Well No.                                 | 13                   | 14                    | 15                   | 16                   | 17                   | 18                   | 19                   | 20                   | 21                   | 22                   | 23                    |

<sup>1</sup>The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 430 or 515 base pairs respectively, well distribution as outlined in the table. Wellnumber 1 contains the longer, 515 bp, internal positive control band. The well distribution of the internal controls can help in orientation of the kit on gel photo, as well as allow for kit identification. In the presence of a specific amplification the intensity of the control band often decreases.

<sup>2</sup>The nucleotide position matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the [www.ebi.ac.uk/imgt/hla](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 nucleotide position matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide numbering as on the [www.ebi.ac.uk/imgt/hla](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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| CELL LINE VALIDATION SHEET             |                             |            |        |            |           |           |           |           |           |           |           |           |           |           |           |           |           |           |           |           |
|----------------------------------------|-----------------------------|------------|--------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|
| DRB1*12 SSP subtyping kit <sup>2</sup> |                             |            |        |            |           |           |           |           |           |           |           |           |           |           |           |           |           |           |           |           |
|                                        |                             |            |        |            | Well      |           |           |           |           |           |           |           |           |           |           |           |           |           |           |           |
|                                        |                             |            |        |            | 1         | 2         | 3         | 4         | 5         | 6         | 7         | 8         | 9         | 10        | 11        | 12        | 13        | 14        | 15        | 16        |
|                                        |                             |            |        | Prod. No.: | 201203901 | 201203902 | 201784103 | 201203904 | 201442505 | 201203906 | 201664907 | 201203908 | 201203909 | 201203910 | 201203911 | 201203912 | 201203913 | 201203914 | 201442515 | 201203916 |
|                                        | IHCW cell line <sup>1</sup> |            | DRB1   |            |           |           |           |           |           |           |           |           |           |           |           |           |           |           |           |           |
| 1                                      | 9001                        | SA         | *01:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 2                                      | 9280                        | LK707      | *15:02 | *04:05     | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | +         | -         | -         |
| 3                                      | 9011                        | E4181324   | *15:02 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | +         | -         | -         |
| 4                                      | 9275                        | GU373      | *03:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 5                                      | 9009                        | KAS011     | *16:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | W         | -         | -         |
| 6                                      | 9353                        | SM         | *04:07 | *08:03     | -         | -         | -         | -         | -         | -         | -         | +         | -         | -         | -         | -         | -         | -         | -         | -         |
| 7                                      | 9020                        | QBL        | *03:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 8                                      | 9025                        | DEU        | *04:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 9                                      | 9026                        | YAR        | *04:02 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 10                                     | 9107                        | LKT3       | *04:05 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 11                                     | 9051                        | PITOUT     | *07:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 12                                     | 9052                        | DBB        | *07:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 13                                     | 9004                        | JESTHOM    | *01:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 14                                     | 9071                        | OLGA       | *08:02 |            | -         | -         | +         | -         | -         | -         | -         | -         | -         | +         | -         | -         | -         | -         | -         | -         |
| 15                                     | 9075                        | DKB        | *09:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 16                                     | 9037                        | SWEIG007   | *11:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 17                                     | 9282                        | CTM3953540 | *03:01 | *13:01     | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 18                                     | 9257                        | 32367      | *09:01 | *11:01     | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 19                                     | 9038                        | BM16       | *12:01 |            | +         | +         | -         | +         | +         | +         | +         | +         | +         | -         | -         | -         | -         | -         | -         | -         |
| 20                                     | 9059                        | SLE005     | *13:02 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 21                                     | 9064                        | AMALA      | *14:02 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 22                                     | 9056                        | KOSE       | *13:02 | *14:54     | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 23                                     | 9124                        | IHL        | *08:03 | *14:14     | -         | -         | -         | -         | -         | -         | -         | +         | -         | -         | -         | -         | -         | -         | -         | -         |
| 24                                     | 9035                        | JBUSH      | *11:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 25                                     | 9049                        | IBW9       | *07:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 26                                     | 9285                        | WT49       | *03:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 27                                     | 9191                        | CH1007     | *04:05 | *10:01     | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 28                                     | 9320                        | BEL5GB     | *04:16 | *07:01     | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 29                                     | 9050                        | MOU        | *07:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 30                                     | 9021                        | RSH        | *03:02 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 31                                     | 9019                        | DUCAF      | *03:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 32                                     | 9297                        | HAG        | *13:03 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 33                                     | 9098                        | MT14B      | *04:04 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 34                                     | 9104                        | DHIF       | *11:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 35                                     | 9302                        | SSTO       | *04:03 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 36                                     | 9024                        | KT17       | *04:03 | *04:06     | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 37                                     | 9065                        | HHKB       | *13:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 38                                     | 9099                        | LZL        | *14:02 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 39                                     | 9315                        | CML        | *03:01 | *04:01     | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 40                                     | 9134                        | WHONP199   | *07:01 | *09:01     | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 41                                     | 9055                        | H0301      | *13:02 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 42                                     | 9066                        | TAB089     | *08:03 |            | -         | -         | -         | -         | -         | -         | -         | +         | -         | -         | -         | -         | -         | -         | -         | -         |
| 43                                     | 9076                        | T7526      | *09:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 44                                     | 9057                        | TEM        | *14:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 45                                     | 9239                        | SHJO       | *07:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |
| 46                                     | 9013                        | SCHU       | *15:01 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | +         | -         | -         |
| 47                                     | 9045                        | TUBO       | *11:04 | *12:01     | +         | +         | -         | +         | +         | +         | +         | +         | +         | -         | -         | -         | -         | -         | -         | -         |
| 48                                     | 9303                        | TER-ND     | *01:03 |            | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         | -         |

**101.128-12 – including *Taq* polymerase, IFU-01**

**101.128-12u – without *Taq* polymerase, IFU-02**

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“Instructions for Use” (IFU)

**Lot No.: 6F1**

**Lot-specific information**

| CELL LINE VALIDATION SHEET             |                             |            |        |            |           |           |           |           |           |           |           |   |
|----------------------------------------|-----------------------------|------------|--------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|---|
| DRB1*12 SSP subtyping kit <sup>2</sup> |                             |            |        |            |           |           |           |           |           |           |           |   |
|                                        |                             |            |        |            | Well      |           |           |           |           |           |           |   |
|                                        |                             |            |        |            | 17        | 18        | 19        | 20        | 21        | 22        | 23        |   |
|                                        |                             |            |        | Prod. No.: | 201784117 | 201203918 | 201664919 | 201664920 | 201203921 | 201664922 | 201784123 |   |
|                                        | IHWC cell line <sup>1</sup> |            | DRB1   |            |           |           |           |           |           |           |           |   |
| 1                                      | 9001                        | SA         | *01:01 |            | -         | -         | -         | -         | -         | -         | -         | + |
| 2                                      | 9280                        | LK707      | *15:02 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 3                                      | 9011                        | E4181324   | *15:02 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 4                                      | 9275                        | GU373      | *03:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 5                                      | 9009                        | KAS011     | *16:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 6                                      | 9353                        | SM         | *04:07 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 7                                      | 9020                        | QBL        | *03:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 8                                      | 9025                        | DEU        | *04:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 9                                      | 9026                        | YAR        | *04:02 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 10                                     | 9107                        | LKT3       | *04:05 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 11                                     | 9051                        | PITOUT     | *07:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 12                                     | 9052                        | DBB        | *07:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 13                                     | 9004                        | JESTHOM    | *01:01 |            | -         | -         | -         | -         | -         | -         | -         | + |
| 14                                     | 9071                        | OLGA       | *08:02 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 15                                     | 9075                        | DKB        | *09:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 16                                     | 9037                        | SWEIG007   | *11:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 17                                     | 9282                        | CTM3953540 | *03:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 18                                     | 9257                        | 32367      | *09:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 19                                     | 9038                        | BM16       | *12:01 |            | -         | -         | -         | -         | +         | -         | -         | - |
| 20                                     | 9059                        | SLE005     | *13:02 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 21                                     | 9064                        | AMALA      | *14:02 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 22                                     | 9056                        | KOSE       | *13:02 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 23                                     | 9124                        | IHL        | *08:03 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 24                                     | 9035                        | JBUSH      | *11:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 25                                     | 9049                        | IBW9       | *07:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 26                                     | 9285                        | WT49       | *03:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 27                                     | 9191                        | CH1007     | *04:05 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 28                                     | 9320                        | BEL5GB     | *04:16 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 29                                     | 9050                        | MOU        | *07:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 30                                     | 9021                        | RSH        | *03:02 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 31                                     | 9019                        | DUCAF      | *03:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 32                                     | 9297                        | HAG        | *13:03 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 33                                     | 9098                        | MT14B      | *04:04 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 34                                     | 9104                        | DHIF       | *11:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 35                                     | 9302                        | SSTO       | *04:03 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 36                                     | 9024                        | KT17       | *04:03 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 37                                     | 9065                        | HHKB       | *13:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 38                                     | 9099                        | LZL        | *14:02 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 39                                     | 9315                        | CML        | *03:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 40                                     | 9134                        | WHONP199   | *07:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 41                                     | 9055                        | H0301      | *13:02 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 42                                     | 9066                        | TAB089     | *08:03 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 43                                     | 9076                        | T7526      | *09:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 44                                     | 9057                        | TEM        | *14:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 45                                     | 9239                        | SHJO       | *07:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 46                                     | 9013                        | SCHU       | *15:01 |            | -         | -         | -         | -         | -         | -         | -         | - |
| 47                                     | 9045                        | TUBO       | *11:04 |            | -         | -         | -         | -         | +         | -         | -         | - |
| 48                                     | 9303                        | TER-ND     | *01:03 |            | -         | -         | -         | -         | -         | -         | -         | + |

**101.128-12 – including *Taq* polymerase, IFU-01**

**101.128-12u – without *Taq* polymerase, IFU-02**

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**Lot No.: 6F1**

**Lot-specific information**

<sup>1</sup>The provided cell line HLA specificities are retrieved from the <http://www.ihwg.org/hla> web site. The specificity of an individual cell line may thus be subject to change.

<sup>2</sup>The specificity of each primer solution in the kit has been tested against 48 well characterized cell line DNAs and where applicable, additional cell line DNAs.

No DNAs carrying the alleles to be amplified by primer solutions 13, 15, 16, 18 to 20 and 22 were available. The specificities of the primers in primer solutions 16, 19, 20 and 22 were tested by separately adding one or two additional 5'-primers, respectively one or two additional 3'-primers. In primer solutions 15 and 18 it was only possible to test the 5'-primer, the 3'-primers were not possible to test. In primer solution 13 it was only possible to test the 3'-primer, the 5'-primers were not possible to test. In primer solutions 7, 16, 17, 20 and 23 one, two or three 5'-primers were not possible to test. In primer solutions 5, 19 and 21 one 3'-primer was not possible to test. One additional 3'-primer in primer solutions 5, 17 and 23 was tested by separately adding one additional 5'-primer.

101.128-12 – including *Taq* polymerase, IFU-01

101.128-12u – without *Taq* polymerase, IFU-02

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**101.128-12 – including *Taq* polymerase, IFU-01****101.128-12u – without *Taq* polymerase, IFU-02**Visit [www.olerup.com](http://www.olerup.com) for  
“Instructions for Use” (IFU)**Lot No.: 6F1****Lot-specific information****ADDRESSES:****Manufacturer:****Olerup SSP AB**, Franzengatan 5, SE-112 51 Stockholm, Sweden.**Tel:** +46-8-717 88 27**Fax:** +46-8-717 88 18**E-mail:** [olerup-se@caredx.com](mailto:olerup-se@caredx.com)**Web page:** <http://www.olerup.com>**Distributed by:****Olerup GmbH**, Löwengasse 47 / 6, AT-1030 Vienna, Austria.**Tel:** +43-1-710 15 00**Fax:** +43-1-710 15 00 10**E-mail:** [olerup-at@caredx.com](mailto:olerup-at@caredx.com)**Web page:** <http://www.olerup.com>**Olerup Inc.**, 901 S. Bolmar St., Suite R, West Chester, PA 19382**Tel:** 1-877-OLERUP1**Fax:** 610-344-7989**E-mail:** [olerup-us@caredx.com](mailto:olerup-us@caredx.com)**Web page:** <http://www.olerup.com>For information on *Olerup* distributors worldwide, contact **Olerup GmbH**.