

101.851-12 – including *Taq* polymerase
101.851-12u – without *Taq* polymerase

Visit <https://labproducts.caredx.com> for
“Instructions for Use” (IFU)

Lot No.: **4K5**

Lot-specific Information

Olerup SSP® HLA-B*51:11N

| | |
|----------------------------------|---|
| Product number: | 101.851-12 – including <i>Taq</i> polymerase 101.851-12u – without <i>Taq</i> polymerase |
| Lot number: | 4K5 |
| Expiry date: | 2023-10-01 |
| Number of tests: | 12 |
| Number of wells per test: | 2+1 |
| Storage - pre-aliquoted primers: | dark at -20°C |
| - PCR Master Mix: | -20°C |
| - Adhesive PCR seals | RT |
| - Product Insert | RT |

This Product Description is only valid for Lot No. 4K5.

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

The HLA-B*51:11N is unchanged compared to the previous *Olerup SSP®* HLA-B*51:11N Lot (4F3).

- The product documentation has been updated for new alleles of IMGT 3.37.0
- The kit resolution focuses on common and well documented (CWD) alleles¹.

¹As described in section Uniquely Identified Alleles.

The HLA-B*51:11N specificity and interpretation tables have been updated for the HLA-B alleles described since the previous *Olerup SSP®* HLA-B*51:11N lot (**Lot No. 4F3**).

The HLA-B*51:11N primer set is unchanged compared to the previous *Olerup SSP®* HLA-B*51:11N (**Lot No. 4F3**).

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Well **3** contains Negative Control primer pairs, that will amplify a majority of the Olerup SSP® 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 200 base pairs.

| Length of PCR product | 105 | 200 | 105 | 80 | 75 | 80 | 85 |
|------------------------------|----------------------|-------------------------|----------------------|----------------------|----------------------|----------------------|----------------------|
| 5'-primer¹ | 164 | 340 | 440 | 45 | 45 | 43 | 36 |
| | 5'-CAC ^{3'} | 5'-Agg ^{3'} | 5'-TTA ^{3'} | 5'-Tgg ^{3'} | 5'-Tgg ^{3'} | 5'-Tgg ^{3'} | 5'-TAC ^{3'} |
| | | | | | | | 36 |
| | | | | | | | 5'-TAT ^{3'} |
| 3'-primer² | 231 | 2nd I | 507 | 59 | 58 | 57 | 47 |
| | 5'-TgC ^{3'} | 5'-AAA ^{3'} | 5'-TTg ^{3'} | 5'-CTC ^{3'} | 5'-ggC ^{3'} | 5'-CTC ^{3'} | 5'-ACA ^{3'} |
| | | | | | | | 48 |
| | | | | | | | 5'-gCA ^{3'} |
| | | | | | | | 48 |
| | | | | | | | 5'-gCC ^{3'} |
| | | | | | | | 52 |
| | | | | | | | 5'-TgT ^{3'} |
| A* | + | + | + | | | | |
| B* | + | + | + | | | | |
| C* | + | + | + | | | | |
| DRB1 | | | | + | + | | |
| DRB3 | | | | + | + | | |
| DRB5 | | | | + | | | |
| DQB1 | | | | | + | | |
| DPB1 | | | | | | + | |
| DQA1 | | | | | | | + |

¹The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon, matching the specificity-determining 3'-end of the primer is given. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

²The nucleotide position for HLA class I genes and the codon for HLA class II genes, in the 2nd or 3rd exon or the 2nd intron, matching the specificity-determining 3'-end of the primer is given in the anti-sense direction. Nucleotide and codon numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

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Lot-specific Information

PRODUCT DESCRIPTION

HLA-B*51:11N SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the HLA-B*51:11N allele.

PLATE LAYOUT

Each test consists of 3 PCR reactions in an 8 well cut PCR plate. Wells 4 to 8 are empty.

| | | | | | | | |
|---|---|----|-------|-------|-------|-------|-------|
| 1 | 2 | NC | empty | empty | empty | empty | empty |
|---|---|----|-------|-------|-------|-------|-------|

The 8 well cut PCR plate is marked with '4K5' in silver/gray ink.

Well No. 1 is marked with the Lot No. '4K5'.

Wells 1 to 2 – HLA-B*51:11N high resolution primers.

Well 3 – 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 heat-sealed with a PCR-compatible foil.

Please note: When removing each 8 well PCR plate, make sure that the remaining plates stay sealed. Use a scalpel or a similar instrument to carefully cut the foil between the plates.

INTERPRETATION

Due to the sharing of sequence motifs between HLA-B alleles non-HLA-B*51:11N alleles will be amplified by primer mix 1.

For further details see Specificity Table.

UNIQUELY IDENTIFIED ALLELES

The HLA-B*51:11N allele will give rise to a unique amplification pattern by the primers in the HLA-B*51:11N kit^{1,2}.

¹HLA-B alleles listed on the IMGT/HLA web page 2019-July-10, release 3.37.0, www.ebi.ac.uk/imgt/hla.

²Alleles 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>.

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SPECIFICITY TABLE

HLA-B*51:11N SSP subtyping

Specificities and sizes of the PCR products of the 2+1 primer mixes used for HLA-B*51:11N SSP subtyping

| Primer Mix | Size of spec. PCR product ¹ | Size of control band ² | Amplified HLA-B alleles |
|----------------|--|-----------------------------------|---|
| 1 ³ | 95 bp | 800 bp | *07:65 ^w , 07:134 ^w , 08:32, 08:133, 08:180, 08:239, 15:308, 18:01:01:01-18:03:01, 18:04:01-18:11, 18:13-18:15, 18:17N-18:36, 18:38-18:47, 18:49-18:65, 18:67-18:106, 18:108-18:124, 18:126-18:177, 18:179-18:185, 35:01:01:01-35:01:55, 35:01:57-35:08:04, 35:08:06-35:09:03, 35:11:01-35:12:04, 35:14:01-35:15:02, 35:17:01-35:18, 35:20:01-35:24:02, 35:27, 35:29:01-35:43:01, 35:43:03-35:45, 35:48, 35:50-35:62, 35:64:01-35:68:02, 35:70-35:72, 35:74-35:75, 35:76 ^w , 35:77-35:79, 35:81-35:153, 35:155-35:185, 35:187-35:190, 35:192-35:197, 35:199-35:206, 35:208:01-35:209, 35:211-35:216N, 35:218-35:225, 35:227-35:253, 35:255-35:269, 35:272-35:273, 35:275-35:310, 35:312-35:316, 35:319-35:360, 35:362-35:449, 35:451-35:460, 37:08, 37:67, 38:06-38:07, 39:19:01-39:19:02, 44:06, 45:22, 51:01:01:01-51:24:05, 51:26-51:46, 51:48-51:103, 51:105-51:111, 51:113-51:117, 51:119-51:146, 51:148-51:230:01:02, 51:232-51:266, 51:268-51:283, 51:286-51:303, 53:01:01:01-53:16, 53:18-53:27, 53:29, 53:31-53:37, 53:40-53:56, 56:06 ^w , 56:45 ^w , 78:01:01:01-78:04, 78:07-78:10 |
| 2 | 495 bp | 1070 bp | *51:11N |
| 3 ⁴ | - | - | Negative Control |

¹Alleles are assigned by the presence of specific PCR product(s). However, the sizes of the specific PCR products may be helpful in the interpretation of HLA-B*51:11N SSP typings.

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

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

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

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherent feature of the primer pair(s) of a primer mix. More often it is due to other factors such as too low amount of DNA in the PCR reactions, taking too long time in setting up the PCR reactions, working at elevated room temperature or using thermal cyclers that are not pre-heated.

²The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the

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table. Well number 1 contains the shorter, 800 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.

³HLA-specific PCR products shorter than 125 base pairs have a lower intensity and are less sharp than longer PCR products.

⁴Primer mix 3 contains a negative control, which will amplify a majority 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 200 base pairs.

Abbreviations

‘w’, might be weakly amplified.

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PRIMER SPECIFICATION

| Well No. | 1 | 2 |
|---|-------------------|---------------------------------|
| Length of spec. PCR product | 95 | 495 |
| Length of int. pos. control ¹ | 800 | 1070 |
| 5'-primer(s) ² | 206 5' -gAC 3' | 3 rd I 5' -CTT 3' |
| 3'-primer(s) ³ | 259 5' -gTT 3' | 621 5' -ggg 3' |
| Well No. | 1 | 2 |

¹The internal positive control primer pairs amplify segments of the human growth hormone gene. The internal positive control bands are 1070 or 800 base pairs respectively, well distribution as outlined in the table. Well number 1 contains the shorter, 800 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.

²The nucleotide position matching the specificity-determining 3'-end of the primer is given. Nucleotide numbering as on the www.ebi.ac.uk/imgt/hla web site. The sequence of the 3 terminal nucleotides of the primer is given.

³The 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 web site. The sequence of the 3 terminal nucleotides of the primer is given.

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| CELL LINE VALIDATION SHEET | | | | | | |
|-----------------------------------|------|------------|--------|--------|-----------|-----------|
| HLA-B*51:11N SSP kit ² | | | | | | |
| | | | | | Well | |
| | | | | | 1 | 2 |
| | | | | | 201782101 | 201782102 |
| | | | | | Prod No.: | |
| IHWC cell line ¹ | | | HLA-B | | | |
| 1 | 9001 | SA | *07:02 | | - | - |
| 2 | 9280 | LK707 | *52:01 | *73:01 | - | - |
| 3 | 9011 | E4181324 | *52:01 | | - | - |
| 4 | 9275 | GU373 | *15:10 | *53:01 | + | - |
| 5 | 9009 | KAS011 | *37:01 | | - | - |
| 6 | 9353 | SM | *39:01 | *51:01 | + | - |
| 7 | 9020 | QBL | *18:01 | | + | - |
| 8 | 9025 | DEU | *35:01 | | + | - |
| 9 | 9026 | YAR | *38:01 | | - | - |
| 10 | 9107 | LKT3 | *54:01 | | - | - |
| 11 | 9051 | PITOUT | *44:03 | | - | - |
| 12 | 9052 | DBB | *57:01 | | - | - |
| 13 | 9004 | JESTHOM | *27:05 | | - | - |
| 14 | 9071 | OLGA | *15:01 | *15:20 | - | - |
| 15 | 9075 | DKB | *40:01 | | - | - |
| 16 | 9037 | SWEIG007 | *40:02 | | - | - |
| 17 | 9282 | CTM3953540 | *08:01 | *55:01 | - | - |
| 18 | 9257 | 32367 | *14:01 | *56:01 | - | - |
| 19 | 9038 | BM16 | *18:01 | | + | - |
| 20 | 9059 | SLE005 | *40:01 | | - | - |
| 21 | 9064 | AMALA | *15:01 | | - | - |
| 22 | 9056 | KOSE | *35:03 | | + | - |
| 23 | 9124 | IHL | *40:02 | *56:02 | - | - |
| 24 | 9035 | JBUSH | *38:01 | | - | - |
| 25 | 9049 | IBW9 | *14:02 | | - | - |
| 26 | 9285 | WT49 | *58:01 | | - | - |
| 27 | 9191 | CH1007 | *07:05 | *51:01 | + | - |
| 28 | 9320 | BEL5GB | *44:02 | *44:03 | - | - |
| 29 | 9050 | MOU | *44:03 | | - | - |
| 30 | 9021 | RSH | *42:01 | | - | - |
| 31 | 9019 | DUCAF | *18:01 | | + | - |
| 32 | 9297 | HAG | *41:02 | | - | - |
| 33 | 9098 | MT14B | *40:01 | | - | - |
| 34 | 9104 | DHIF | *38:01 | | - | - |
| 35 | 9302 | SSTO | *44:02 | | - | - |
| 36 | 9024 | KT17 | *15:01 | *35:01 | + | - |
| 37 | 9065 | HHKB | *07:02 | | - | - |
| 38 | 9099 | LZL | *15:01 | | - | - |
| 39 | 9315 | CML | *08:01 | *27:05 | - | - |
| 40 | 9134 | WHONP199 | *13:02 | *46:01 | - | - |
| 41 | 9055 | H0301 | *14:02 | | - | - |
| 42 | 9066 | TAB089 | *46:01 | | - | - |
| 43 | 9076 | T7526 | *46:01 | | - | - |
| 44 | 9057 | TEM | *38:01 | | - | - |
| 45 | 9239 | SHJO | *42:01 | *50:01 | - | - |
| 46 | 9013 | SCHU | *07:02 | | - | - |
| 47 | 9045 | TUBO | *51:01 | | + | - |
| 48 | 9303 | TER-ND | *35:01 | *44:03 | + | - |

¹The 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.

²The 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.

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Lot-specific Information

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