

101.903-24 – including *Taq* polymerase, IFU-01
 101.903-24u – without *Taq* polymerase, IFU-02

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

Lot No.: **3N9**

Lot-specific information

Olerup SSP[®] DQA1*02,05;DQB1*02,03:02

Product number: 101.903-24 – including *Taq* polymerase
 101.903-24u – without *Taq* polymerase
Lot number: 3N9
Expiry date: 2025-06-01
Number of tests: 24
Number of wells per test: 22 + 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. 3N9.

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

**CHANGES COMPARED TO THE PREVIOUS OLERUP SSP[®]
 DQA1*02,05;DQB1*02,03:02 LOT (0L9)**

The DQA1*02,05;DQB1*02,03:02 kit has been redesigned and improved with regards to allelic detection and discrimination and facilitated interpretation. The kit resolution focuses on common and well documented (CWD) alleles¹.

The kit contains 22 primer mixes for the DQA1 and DQB1 alleles and includes a negative control.

The DQA1*02,05;DQB1*02,03:02 specificity and interpretation tables have been updated for the DQA1 and DQB1 alleles described since the previous *Olerup SSP[®] DQA1*02,05;DQB1*02,03:02 lot (Lot No. 0L9)* was made. The kit design is based on IMGT/HLA database 3.44.0.

The primers of the wells detailed below have been exchanged, added or modified compared to the previous lot (**Lot No. 0L9**).

| Well | 5'-primer | 3'-primer | rationale |
|------|-----------|-----------|---|
| 8 | Modified | Modified | Primer pair was optimized for improving HLA-specific amplification. |

¹S. J. Mack, P. Cano, J. A. Hollenbach et al.
 Common and well-documented HLA alleles: 2012 update to the CWD catalogue. Tissue Antigens, 2013, 81, 194–203



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Well **23** contains Negative Control primer pairs, that will amplify the 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

DQA1*02,05;DQB1*02,03:02 SSP subtyping

CONTENT

The primer set contains 5'- and 3'-primers for identifying the following on CWD level:

DQA1*05:01 DQB1*02:01 (DQ2)
DQA1*05:05 DQB1*03:01 / DQA1*02:01 **DQB1*02:02** (DQ2)
DQA1*03:01 DQB1*03:02 (DQ8)
DQA1*05 DQB1*02 / DQA1*03:01 DQB1*03:02 (DQ2 + DQ8)
DQA1*05:01 X
DQA1*05:05 X
DQB1*02:01 X
DQB1*02:02 X
DQB1*03:02 X

α and β chains associated with the disease in bold^{1,2,3}.

X = other allele.

Please note that DQB1 amplifications usually are somewhat less pronounced than e.g. DRB and DQA1 amplifications even when using the same DNA preparation and exactly the same experimental procedures.

¹Catassi C, Kryszak D, Louis-Jacques O, et al.

Detection of Celiac disease in primary care: a multicenter case-finding study in North America.
 Am J Gastroenterol. 2007 Jul;102(7):1454-60. Epub 2007 Mar 13.

²Megiorni F, Mora B, Bonamico M, Barbato M, Nenna R, Maiella G, Lulli P, Mazzilli MC.

HLA-DQ and risk gradient for celiac disease.
 Hum Immunol. 2009 Jan;70(1):55-9

³Karell K, Louka AS, Moodie SJ, et al. HLA types in celiac disease patients not carrying the DQA1*05-DQB1*02 (DQ2)

heterodimer: results from the European Genetics Cluster on Celiac Disease.
 Hum Immunol. 2003 Apr;64(4):469-77

Positive and negative control DNAs are included in the kit:

DNA 1; positive control DNA (containing mixed DNA of the cell lines **IHW 9020, QBL** and **IHW 9024, KT17**). The positive control DNA will be positive for the alleles DQA1*05:01, DQA1*03:01, DQB1*02:01, DQB1*03:02.

DNA 2; negative control DNA, **IHW 9025, DEU**, DQA1*03, DQB1*03:01. The cell line is negative for DQA1*02, DQA1*05, DQB1*02 and DQB1*03:02.

The kit contains enough control DNAs to perform 1 test set up of positive and negative control. If more than 1 test set up per kit are run other positive and negative DNA samples can be used as controls (e.g. positive and negative samples from previous tests).

Legal notice: The DNA in this kit is included under licensing agreement between CareDx AB and Public Health England.



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Lot-specific information

PLATE LAYOUT

Each test consists of 23 PCR reactions in a 24 well PCR plate. Well 24 is empty.

| | | | | | | | |
|------|------|------|------|------|------|------|-------|
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
| DQA1 | DQA1 | DQA1 | DQA1 | DQA1 | DQA1 | DQA1 | DQA1 |
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| DQA1 | DQA1 | DQA1 | DQB1 | DQB1 | DQB1 | DQB1 | DQB1 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 | |
| DQB1 | DQB1 | DQB1 | DQB1 | DQB1 | DQB1 | NC | empty |

The 24 well cut PCR plate is marked with ‘3N9’ in silver/gray ink.

Well No. 1 is marked with the Lot No ‘3N9’.

Wells 1 to 11 – DQA1 high resolution primers.

Wells 12 to 22 – DQB1 resolution primers.

Well 23 – 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.

UNIQUELY IDENTIFIED ALLELES

DQA1 and DQB1 alleles recognized by the HLA Nomenclature Committee in April 2021^{1,2} have been considered in the specificity and interpretation tables of the DQA1*02,05;DQB1*02,03:02 kit.

For further details see Content section.

¹DQA1 and DQB1 alleles listed on the IMGT/HLA web page 2021-April-20, release 3.44.0, 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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Lot-specific information

EXPECTED RESULTS

Table 1 describes expected results for the (groups of) alleles that the kit is able to detect and separate.

Table 1: Expected results for targeted DQA1 and DQB1 alleles.

| DQA1 alleles | DQB1 alleles | Positive DQA1 wells | Positive DQB1 wells |
|--------------------------------|----------------------------|-------------------------|--|
| 05:01 | 02:01 (DQ2) | 3, 5, 11 | 12, 14, 16 |
| (02:01) 05:05 | 02:02 (DQ2) (03:01) | 1, 8 3, 5, 6, 10 | 12, 13, 16 14, 19, 21 |
| 03:01 03:02, 03:03 | 03:02 (DQ8) 03:02 (DQ8) | 2, 8 2 | 14, 16, 17, 19, 22 14, 16, 17, 19, 22 |
| 05:01 05:05 | | 3, 5, 11 3, 5, 6, 10 | |
| 02:01 03:01 03:02, 03:03 | | 1, 8 2, 8 2 | |
| | 02:01 | | 12, 14, 16 |
| | 02:02 | | 12, 13, 16 |
| | 03:01 | | 14, 19, 21 |
| | 03:02 | | 14, 16, 17, 19, 22 |

The negative control DNA must only give rise to the internal control bands of 430 or 515 base pairs respectively and no DQA1*02,05;DQB1*02,03:02 specific bands. Additional bands might indicate inappropriate test conditions or contamination.



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Lot-specific information
SPECIFICITY TABLE

DQA1*02,05;DQB1*02,03:02 SSP subtyping

Specificities and sizes of the PCR products of the 22+1 primer mixes used for DQA1*02,05;DQB1*02,03:02 SSP typing

| Primer Mix | Size of spec. PCR product ¹ | Size of control band ² | Amplified DQA1 alleles ³ | Amplified DQB1 alleles ³ |
|------------------|--|-----------------------------------|---|-------------------------------------|
| 1 | 175 bp | 430 bp | *02:01:01:01-02:05, 02:07-02:15, 02:17-02:18 | |
| 2 | 185 bp | 515 bp | *03:01:01:01, 03:01:03-03:20 | |
| 3 | 165 bp | 515 bp | *05:01:01:01-05:01:02, 05:01:04-05:09, 05:11-05:35, 05:37-05:38 | |
| 4 ⁴ | 90 bp, 200 bp | 515 bp | *05:02-05:03:02, 05:04 [?] , 05:06:01:01-05:07 | |
| 5 | 205 bp | 515 bp | *05:01:01:01-05:01:02, 05:01:04-05:03:02, 05:05:01:01-05:09, 05:11-05:38 | |
| 6 ⁴ | 100 bp | 515 bp | *05:02 [?] , 05:04 [?] , 05:05:01:01-05:05:06, 05:08-05:09, 05:10 [?] , 05:11, 05:12 [?] , 05:13-05:14, 05:15N [?] -05:17N [?] , 05:20, 05:21 [?] -05:22 [?] , 05:24, 05:25 [?] -05:28 [?] , 05:29Q, 05:30 [?] , 05:32 [?] -05:35 [?] , 05:37 [?] | |
| 7 ⁴ | 80 bp | 515 bp | *05:09 | |
| 8 ^{4,7} | 85 bp | 430 bp | *02:01:01:01-02:02N, 02:04-02:05, 02:07-02:16, 02:18, 03:01:01:01, 03:01:03-03:01:06, 03:05 [?] , 03:06, 03:10, 03:12, 03:15, 03:16 [?] , 03:18 | |
| 9 | 145 bp, 170 bp | 430 bp | *01:01:01:01-01:01:01:03, 01:01:01:05-01:65 | |
| 10 ⁴ | 80 bp | 515 bp | *05:02 [?] , 05:04 [?] , 05:05:01:01-05:05:06, 05:08, | |



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| | | | |
|-----------------|--------|--------|---|
| | | | 05:10 [?] , 05:11, 05:12 [?] , 05:13-05:14, 05:15N [?] -05:17N [?] , 05:20, 05:21 [?] - 05:22 [?] , 05:24, 05:25 [?] -05:28 [?] , 05:29Q, 05:30 [?] , 05:32 [?] -05:35 [?] , 05:37 [?] |
| 11 | 235 bp | 515 bp | *05:01:01:01- 05:01:02, 05:01:04- 05:01:06, 05:02 [?] , 05:03:01:01- 05:03:02, 05:04 [?] , 05:06:01:01-05:07, 05:15N, 05:16 [?] , 05:18-05:19, 05:22- 05:23, 05:27, 05:30 [?] , 05:31, 05:32 [?] - 05:34 [?] , 05:35- 05:36N, 05:37 [?] , 05:38 |
| 12 ⁶ | 210 bp | 515 bp | *02:01:01:01-02:39, 02:41-02:71, 02:73-02:182 |
| 13 ⁶ | 140 bp | 515 bp | *02:02:01:01-02:02:14, 02:05 [?] , 02:06, 02:10-02:12, 02:13 [?] , 02:15 [?] - 02:19 [?] , 02:20N, 02:21 [?] -02:25 [?] , 02:26, 02:28 [?] -02:47 [?] , 02:49 [?] , 02:50, 02:51 [?] - 02:52 [?] , 02:54 [?] -02:56 [?] , 02:58N [?] , 02:60 [?] -02:61 [?] , 02:62, 02:64-02:65, 02:66 [?] -02:70 [?] , 02:71, 02:73 [?] -02:78 [?] , 02:80, 02:84, 02:89:01-02:89:02, 02:95, 02:97, 02:110, 02:113, 02:116-02:117, 02:120-02:122, 02:124, 02:126-02:127, 02:131, 02:137-02:138, 02:141-02:147, 02:150, 02:153, 02:156, 02:161- 02:162N, 02:165, 02:167N, 02:169, 02:171Q-02:172, 02:175-02:176N, 02:179-02:180 |
| 14 | 145 bp | 515 bp | *02:01:01:01-02:01:35, 02:01:37- 02:01:39, 02:03:02-02:05, 02:07:01- 02:09, 02:13-02:25, 02:27-02:47, 02:49, 02:51-02:61, 02:63, 02:66- 02:79, 02:81-02:83, 02:85-02:88, 02:90-02:94, 02:96N, 02:98-02:109, 02:111-02:112, 02:114-02:115, 02:118-02:119, 02:123, 02:125, 02:128-02:130, 02:132N-02:136, 02:139-02:140, 02:148-02:149, 02:151-02:152, 02:154-02:155, 02:157-02:160, 02:163N-02:164, 02:166, 02:168, 02:170, 02:173- 02:174, 02:177N-02:178, 02:181- 02:182, 03:01:01:01-03:01:01:12, 03:01:01:14-03:23:03, |



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| | | | |
|----|--------|--------|---|
| | | | 03:25:01-03:78, 03:80-03:96, 03:98-03:163, 03:166-03:318, 03:320-03:324, 03:326-03:328, 03:330-03:346, 03:348, 03:350-03:380, 03:382-03:446, 03:448-03:457, 04:01:01:01-04:02:01:01, 04:02:01:04-04:43, 04:45-04:69, 04:72-04:80, 04:82-04:86, 05:01:01:01-05:02:10, 05:02:12-05:13, 05:15-05:83, 05:85-05:195, 05:197-05:210, 05:212-05:276, 06:01:01:01-06:02:46, 06:02:48-06:04:15, 06:04:17-06:37, 06:39-06:85, 06:87-06:101, 06:105-06:217, 06:219, 06:221-06:226, 06:228-06:283, 06:285-06:349, 06:351-06:362, 06:364-06:365, 06:367-06:386, 06:388-06:390 |
| 15 | 135 bp | 515 bp | *02:77, 02:180, 03:03:02:01-03:03:05, 03:03:07-03:03:25, 03:03:27, 03:12, 03:15, 03:20, 03:23:03, 03:26, 03:30-03:31, 03:33-03:34, 03:38:01-03:41, 03:43, 03:65, 03:74, 03:79, 03:86-03:91Q, 03:95N-03:99Q, 03:104-03:105, 03:111-03:113, 03:117, 03:123-03:124, 03:126, 03:136-03:137, 03:141, 03:145, 03:149, 03:155-03:156, 03:168, 03:176-03:177, 03:200, 03:209, 03:212, 03:222, 03:227, 03:230, 03:234, 03:238-03:239, 03:248-03:249, 03:258, 03:270, 03:280, 03:282N-03:283, 03:304, 03:313, 03:316, 03:319, 03:332, 03:336-03:337, 03:351, 03:356N-03:357N, 03:359, 03:363, 03:365, 03:374-03:375N, 03:382, 03:384, 03:393, 03:395, 03:397-03:398, 03:402, 03:405-03:406, 03:411N, 03:414, 03:445, 03:453, 06:02:43, 06:03:10, 06:03:33, 06:51:01, 06:66, 06:96:01, 06:168, 06:172, 06:322:01-06:322:02, 06:377 |
| 16 | 135 bp | 515 bp | *02:01:01:01-02:01:06, 02:01:08-02:01:20, 02:01:22-02:01:27, 02:01:29-02:01:33, 02:01:35-02:01:37, 02:01:39-02:02:10, 02:02:12-02:02:14, 02:04-02:16, 02:18N-02:36, 02:38-02:76, 02:78-02:94, 02:96N-02:115, 02:117-02:146, 02:148-02:171Q, 02:173-02:179, 02:182, 03:02:01:01-03:02:09, 03:02:11-03:02:13, 03:02:15-03:02:34, 03:07-03:08, 03:11, 03:18, 03:32, 03:37, 03:45:01-03:45:02, 03:62-03:64, |



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| 17 ⁴ | 110 bp | 430 bp | *03:02:01:01-03:02:10, 03:02:12- 03:03:04, 03:03:06-03:03:27, 03:06, 03:08, 03:11-03:12, 03:15, 03:18, 03:20, 03:23:02-03:23:03, 03:25:01- 03:26, 03:30-03:34, 03:37-03:41, 03:43, 03:45:01-03:45:02, 03:62- 03:63, 03:65-03:68, 03:70, 03:79, 03:81, 03:85-03:89, 03:91Q, 03:95N- 03:99Q, 03:104-03:107, 03:110, 03:112, 03:117, 03:123-03:126, 03:136-03:137, 03:145-03:146, 03:149, 03:153, 03:155-03:156, 03:161, 03:168, 03:174-03:179, 03:185, 03:189-03:190, 03:200, 03:203-03:204, 03:209-03:213N, 03:215, 03:217, 03:221-03:225, 03:227-03:230, 03:233-03:234, 03:237N-03:239, 03:245, 03:247- 03:249, 03:251, 03:258, 03:261, 03:263:01:01-03:263:01:02, 03:265, 03:269N-03:270, 03:273-03:274, 03:277-03:279, 03:282N-03:283, 03:287, 03:289, 03:295-03:296, 03:298, 03:300-03:301, 03:304, 03:308, 03:310N, 03:313, 03:315- 03:316, 03:319-03:324, 03:332- 03:334N, 03:336, 03:339N, 03:343- 03:345, 03:348-03:349, 03:351- 03:352, 03:356N-03:357N, 03:359, |



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| 18 | 135 bp, 170 bp | 515 bp | *03:04:01:01-03:04:04, 03:09, 03:11, 03:14:01-03:14:02, 03:80, 03:138, 03:318, 03:327, 03:443, 06:246 |
| 19⁵ | 145 bp, 185 bp | 515 bp | *03:01:01:01-03:01:01:12, 03:01:01:14-03:03:15, 03:03:17-03:103, 03:106-03:108, 03:110-03:153, 03:155-03:188, 03:190-03:257, 03:259-03:324, 03:326-03:334N, 03:336-03:442, 03:444-03:457, 04:01:03, 04:02:16, 04:03:03, 04:09, 04:63, 04:75 |
| 20 | 175 bp | 430 bp | *03:06 [?] -03:07 [?] , 03:14:01 [?] -03:15 [?] , 03:17:01 [?] -03:18 [?] , 03:19:01:01-03:19:05, 03:20 [?] , 03:23:01 [?] , 03:23:03 [?] , 03:25:02 [?] -03:26 [?] , 03:48 [?] , 03:52 [?] -03:54 [?] , 03:56 [?] -03:67 [?] , 03:69 [?] -03:70 [?] , 03:71, 03:74 [?] -03:78 [?] , 03:81 [?] -03:82 [?] , 03:101 [?] -03:104 [?] , 03:106 [?] -03:112 [?] , 03:118N [?] , 03:120 [?] -03:131 [?] , 03:133 [?] -03:135 [?] , 03:137 [?] , 03:140 [?] -03:149 [?] , 03:150, 03:151 [?] -03:163 [?] , 03:165 [?] -03:167 [?] , 03:170 [?] -03:171 [?] , 03:173 [?] -03:179 [?] , 03:183 [?] , 03:185 [?] , 03:187, 03:188 [?] -03:189 [?] , 03:192 [?] -03:194 [?] , 03:201 [?] -03:205 [?] , 03:207 [?] -03:210 [?] , 03:212 [?] -03:221 [?] , 03:223 [?] -03:228 [?] , 03:230 [?] , 03:232 [?] -03:238 [?] , 03:240 [?] , 03:244 [?] , 03:255 [?] -03:262 [?] , 03:267 [?] -03:270 [?] , 03:273 [?] -03:275 [?] , 03:278 [?] , 03:286, 03:335, 03:351 [?] -03:353 [?] , 03:356N [?] , 03:359 [?] , 03:376N, 03:381, 03:387 [?] , 03:394, 03:401, 03:425 [?] , 03:433 [?] , 03:437 [?] -03:438 [?] , 03:441 [?] , 03:449 [?] -03:450 [?] , 03:455 [?] -03:456 [?] |
| 21 | 220 bp | 515 bp | *03:01:01:01-03:01:01:12, 03:01:01:14-03:01:07, 03:01:09-03:01:49, 03:04:01:01-03:04:04, 03:09-03:10:03, 03:13-03:14:02, 03:16, 03:19:01:01-03:19:05, 03:21-03:22:02, 03:24, 03:27-03:29, |



101.903-24 – including *Taq* polymerase, IFU-01
 101.903-24u – without *Taq* polymerase, IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **3N9**

Lot-specific information

| | | | |
|----|--------|--------|--|
| | | | 03:35-03:36, 03:42, 03:44, 03:46-03:60, 03:69, 03:71, 03:73, 03:75-03:77, 03:80, 03:82-03:84N, 03:92-03:94, 03:101-03:103, 03:108, 03:114-03:116, 03:118N-03:122, 03:127-03:131, 03:133-03:135, 03:138-03:140, 03:142-03:144, 03:147-03:148, 03:150, 03:152, 03:157-03:160, 03:162-03:167, 03:169-03:173, 03:180, 03:182-03:183, 03:186-03:188, 03:191-03:198:02, 03:201-03:202, 03:206-03:208, 03:216, 03:218-03:219, 03:231-03:232, 03:235-03:236, 03:241-03:243, 03:246, 03:252-03:257, 03:260, 03:264, 03:266-03:268, 03:271, 03:275-03:276N, 03:281, 03:284-03:286, 03:288, 03:290-03:294, 03:297, 03:302-03:303N, 03:305-03:307, 03:309, 03:311-03:312, 03:317:01-03:318, 03:326-03:331, 03:338N, 03:340N-03:342, 03:347, 03:350, 03:353-03:355, 03:358N, 03:360-03:361, 03:366, 03:370, 03:372-03:373, 03:376N-03:378, 03:380-03:381, 03:385N, 03:387, 03:389-03:391, 03:394, 03:396, 03:399N-03:401, 03:404, 03:407N-03:408, 03:417-03:421, 03:423-03:428, 03:430-03:432, 03:434-03:436, 03:438-03:439, 03:448-03:449, 03:451, 03:454-03:455 |
| 22 | 130 bp | 515 bp | *03:02:01:01-03:02:34, 03:07-03:08, 03:11, 03:18, 03:32, 03:37, 03:45:01-03:45:02, 03:63-03:64, 03:66N-03:68, 03:70, 03:85, 03:106-03:107, 03:125, 03:146, 03:153, 03:161, 03:174-03:175, 03:178-03:179, 03:184-03:185, 03:189-03:190, 03:199, 03:203-03:205, 03:210-03:211, 03:213N-03:215, 03:220-03:221, 03:223-03:224, 03:228-03:229, 03:233, 03:237N, 03:240, 03:245, 03:247, 03:251, 03:261, 03:263:01:01-03:263:01:02, 03:265, 03:269N, 03:273-03:274, 03:277-03:279, 03:287, 03:289, 03:295-03:296, 03:298-03:301, 03:310N, 03:315, 03:320-03:324, 03:333-03:334N, 03:339N, 03:343-03:345, 03:348-03:349, 03:352, 03:362, 03:364, 03:367-03:369, 03:371, 03:379, 03:383, 03:386, 03:388, 03:392, 03:403N, 03:409-03:410, 03:412, 03:415-03:416, 03:422N, |



101.903-24 – including *Taq* polymerase, IFU-01
 101.903-24u – without *Taq* polymerase, IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **3N9**

Lot-specific information

| | | | |
|-----------------------|---|---|---|
| | | | 03:429, 03:433, 03:437, 03:440N- 03:442, 03:444, 03:446-03:447, 03:450, 03:452, 03:456-03:457, 06:29, 06:123, 06:139, 06:337 |
| 23⁸ | - | - | 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 DQA1 and DQB1 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.

²The 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 shorter, 430 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.

³For several DQA1 and DQB1 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 matched with the target sequences or not. Assumption is made that unknown sequences in these regions are conserved within allelic groups.

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

⁵The primer pair in well 19 will in some samples give rise to two HLA-specific PCR fragments and may give rise to a lower yield for the DQB1*03xx alleles.

⁶Primer mixes 12 and 13 may have tendencies of unspecific amplification, most pronounced in primer mix 12.

⁷Primer mix 8 may give rise to a lower yield of HLA-specific PCR product than the other DQA1*02,05;DQB1*02,03:02 primer mixes.

⁸Primer mix 23 contains a negative control, which will amplify the 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

?: nucleotide sequence information not available for the primer matching sequence.



101.903-24 – including *Taq* polymerase, IFU-01
 101.903-24u – without *Taq* polymerase, IFU-02

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Lot No.: **3N9**

Lot-specific information
DQA1 PRIMER SPECIFICATION

| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |
|--|----------------------|----------------------|----------------------|----------------------|----------------------|--------------------------------|----------------------|-----------------------|----------------------|----------------------|-----------------------|
| Length of spec. PCR product | 175 | 185 | 165 | 90 | 205 | 100 | 80 | 85 | 145 | 80 | 235 |
| Length of int. pos. control ¹ | 430 | 515 | 515 | 515 | 515 | 515 | 515 | 430 | 430 | 515 | 515 |
| 5'-primer(s) ² | 7(90) 5'-CAC 3' | 7(90) 5'-CAT 3' | 34(169) 5'-AgC 3' | 59(245) 5'-CCg 3' | 21(131) 5'-TCC 3' | -14(31) 5'-ggA 3' | -14(31) 5'-ggA 3' | 160(548) 5'-TgC 3' | 25(143) 5'-gTA 3' | -14(31) 5'-ggA 3' | 107(389) 5'-CAT 3' |
| 3'-primer(s) ³ | 52(224) 5'-TgT 3' | 55(232) 5'-TCT 3' | 75(293) 5'-gAC 3' | 75(293) 5'-gAC 3' | 75(293) 5'-gAC 3' | 1 st I 5'-TgC 3' | 1(70) 5'-TTT 3' | 174(591) 5'-TCA 3' | 69(274) 5'-TgC 3' | 1(70) 5'-TTC 3' | 172(585) 5'-Agg 3' |
| Well No. | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 |

DQB1 PRIMER SPECIFICATION

| Well No. | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |
|--|----------------------|-----------------------|-----------------------|----------------------|----------------------|----------------------|----------------------|----------------------|-----------------------|----------------------|----------------------|
| Length of spec. PCR product | 210 | 140 | 145 | 135 | 135 | 110 | 135 | 145 | 175 | 220 | 130 |
| Length of int. pos. control ¹ | 515 | 515 | 515 | 515 | 515 | 430 | 515 | 515 | 430 | 515 | 515 |
| 5'-primer(s) ² | 30(184) 5'-gAg 3' | 102(400) 5'-TCT 3' | 135(500) 5'-TgA 3' | 26(173) 5'-TCT 3' | 26(173) 5'-TCT 3' | 26(173) 5'-TCT 3' | 14(136) 5'-gCC 3' | 38(210) 5'-gCA 3' | 140(516) 5'-ACC 3' | 26(173) 5'-TTA 3' | 28(179) 5'-gAC 3' |
| 3'-primer(s) ³ | 86(353) 5'-gCT 3' | 135(500) 5'-ggC 3' | 170(604) 5'-gAC 3' | 57(266) 5'-CgT 3' | 57(266) 5'-Cgg 3' | 47(237) 5'-CgA 3' | 57(266) 5'-Cgg 3' | 86(353) 5'-gTT 3' | 185(650) 5'-CgA 3' | 86(353) 5'-gCT 3' | 57(266) 5'-Cgg 3' |
| Well No. | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 |

¹The 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 shorter, 430 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.



101.903-24 – including Taq polymerase, IFU-01
 101.903-24u – without Taq polymerase, IFU-02

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Lot No.: **3N9**

Lot-specific information

| CELL LINE VALIDATION SHEET | | | | | | | | | | | | | | | |
|--|------|------------|--------|------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|---|
| DQA1*02,05;DQB1*02,03:02 typing kit ² | | | | | | | | | | | | | | | |
| | | | | Well | | | | | | | | | | | |
| | | | | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | |
| | | | | 201784101 | 202018802 | 201784103 | 201784104 | 201784105 | 201784106 | 201784107 | 202133708 | 201784109 | 201784121 | 202133711 | |
| IHWC cell line ¹ | | DQA1* | | Prod. No.: | | | | | | | | | | | |
| 1 | 9001 | SA | *01:01 | - | - | - | - | - | - | - | - | - | + | - | - |
| 2 | 9280 | LK707 | *01:03 | *03:03 | - | + | - | - | - | - | - | - | + | - | - |
| 3 | 9011 | E4181324 | *01:03 | | - | - | - | - | - | - | - | - | + | - | - |
| 4 | 9275 | GU373 | *05:01 | | - | - | + | - | + | - | - | - | - | - | + |
| 5 | 9009 | KAS011 | *01:02 | | - | - | - | - | - | - | - | - | + | - | - |
| 6 | 9353 | SM | *01:03 | *03:01 | - | + | - | - | - | - | - | + | + | - | - |
| 7 | 9020 | QBL | *05:01 | | - | - | + | - | + | - | - | - | - | - | + |
| 8 | 9025 | DEU | *03 | | - | + | - | - | - | - | - | - | - | - | - |
| 9 | 9026 | YAR | *03:01 | | - | + | - | - | - | - | - | + | - | - | - |
| 10 | 9107 | LKT3 | *03:03 | | - | + | - | - | - | - | - | - | - | - | - |
| 11 | 9051 | PITOUT | *02:01 | | + | - | - | - | - | - | - | + | - | - | - |
| 12 | 9052 | DBB | *02:01 | | + | - | - | - | - | - | - | + | - | - | - |
| 13 | 9004 | JESTHOM | *01:01 | | - | - | - | - | - | - | - | - | + | - | - |
| 14 | 9071 | OLGA | *04:01 | | - | - | - | - | - | - | - | - | - | - | - |
| 15 | 9075 | DKB | *03:02 | | - | + | - | - | - | - | - | - | - | - | - |
| 16 | 9037 | SWEIG007 | *05:05 | | - | - | + | - | + | + | - | - | - | + | - |
| 17 | 9282 | CTM3953540 | *01:03 | *05:01 | - | - | + | - | + | - | - | - | + | - | + |
| 18 | 9257 | 32367 | *01:02 | *03:03 | - | + | - | - | - | - | - | - | + | - | - |
| 19 | 9038 | BM16 | *05:05 | | - | - | + | - | + | + | - | - | - | + | - |
| 20 | 9059 | SLE005 | *01:02 | | - | - | - | - | - | - | - | - | + | - | - |
| 21 | 9064 | AMALA | *05:03 | | - | - | + | + | + | - | - | - | - | - | + |
| 22 | 9056 | KOSE | *01:02 | *01:04 | - | - | - | - | - | - | - | - | + | - | - |
| 23 | 9124 | IHL | *01:03 | *01:04 | - | - | - | - | - | - | - | - | + | - | - |
| 24 | 9035 | JBUSH | *05:05 | | - | - | + | - | + | + | - | - | - | + | - |
| 25 | 9049 | IBW9 | *02:01 | | + | - | - | - | - | - | - | + | - | - | - |
| 26 | 9285 | WT49 | *05:01 | | - | - | + | - | + | - | - | - | - | - | + |
| 27 | 9191 | CH1007 | *03:03 | *01:05 | - | + | - | - | - | - | - | - | + | - | - |
| 28 | 9320 | BEL5GB | *02:01 | *03:03 | + | + | - | - | - | - | - | + | - | - | - |
| 29 | 9050 | MOU | *02:01 | | + | - | - | - | - | - | - | + | - | - | - |
| 30 | 9021 | RSH | *04:01 | | - | - | - | - | - | - | - | - | - | - | - |
| 31 | 9019 | DUCAF | *05:01 | | - | - | + | - | + | - | - | - | - | - | + |
| 32 | 9297 | HAG | *05:05 | | - | - | + | - | + | + | - | - | - | + | - |
| 33 | 9098 | MT14B | *03:01 | | - | + | - | - | - | - | - | + | - | - | - |
| 34 | 9104 | DHIF | *05:05 | | - | - | + | - | + | + | - | - | - | + | - |
| 35 | 9302 | SSTO | *03:01 | | - | + | - | - | - | - | - | + | - | - | - |
| 36 | 9024 | KT17 | *03:01 | | - | + | - | - | - | - | - | + | - | - | - |
| 37 | 9065 | HHKB | *01:03 | | - | - | - | - | - | - | - | - | + | - | - |
| 38 | 9099 | LZL | *05:03 | | - | - | + | + | + | - | - | - | - | - | + |
| 39 | 9315 | CML | *03:03 | *05:01 | - | + | + | - | + | - | - | - | - | - | + |
| 40 | 9134 | WHONP199 | *02:01 | *03:02 | + | + | - | - | - | - | - | + | - | - | - |
| 41 | 9055 | H0301 | *01:02 | | - | - | - | - | - | - | - | - | + | - | - |
| 42 | 9066 | TAB089 | *01:03 | | - | - | - | - | - | - | - | - | + | - | - |
| 43 | 9076 | T7526 | *03:02 | | - | + | - | - | - | - | - | - | - | - | - |
| 44 | 9057 | TEM | *01:04 | | - | - | - | - | - | - | - | - | + | - | - |
| 45 | 9239 | SHJO | *02:01 | *03:03 | + | + | - | - | - | - | - | + | - | - | - |
| 46 | 9013 | SCHU | *01:02 | | - | - | - | - | - | - | - | - | + | - | - |
| 47 | 9045 | TUBO | *05:05 | | - | - | + | - | + | + | - | - | - | + | - |
| 48 | 9303 | TER-ND | *01:01 | | - | - | - | - | - | - | - | - | + | - | - |



101.903-24 – including *Taq* polymerase, IFU-01
 101.903-24u – without *Taq* polymerase, IFU-02

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 “Instructions for Use” (IFU)

Lot No.: **3N9**

Lot-specific information

| CELL LINE VALIDATION SHEET | | | | | | | | | | | | | | | | |
|--|-----------------------------|--------|--------|----------------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|-----------|--|
| DQA1*02,05;DQB1*02,03:02 typing kit ² | | | | | | | | | | | | | | | | |
| | | | | Production No. | Well | | | | | | | | | | | |
| | | | | | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | |
| | | | | | 201784110 | 201784111 | 201784112 | 201784113 | 201784114 | 201784115 | 202133718 | 201891518 | 201784118 | 201891520 | 201784120 | |
| | IHWC cell line ¹ | DQB1 | | | | | | | | | | | | | | |
| 1 | 9001 SA | *05:01 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 2 | 9280 LK707 | *06:01 | *02:02 | | + | + | + | - | + | - | - | - | - | - | - | |
| 3 | 9011 E4181324 | *06:01 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 4 | 9275 GU373 | *02:01 | | | + | - | + | - | + | - | - | - | - | - | - | |
| 5 | 9009 KAS011 | *05:02 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 6 | 9353 SM | *03:02 | *06:01 | | - | - | + | - | + | + | - | + | - | - | + | |
| 7 | 9020 QBL | *02:01 | | | + | - | + | - | + | - | - | - | - | - | - | |
| 8 | 9025 DEU | *03:01 | | | - | - | + | - | - | - | - | + | - | + | - | |
| 9 | 9026 YAR | *03:02 | | | - | - | + | - | + | + | - | + | - | - | + | |
| 10 | 9107 LKT3 | *04:01 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 11 | 9051 PITOUT | *02:02 | | | + | + | - | - | + | - | - | - | - | - | - | |
| 12 | 9052 DBB | *03:03 | | | - | - | + | + | - | + | - | + | - | - | - | |
| 13 | 9004 JESTHOM | *05:01 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 14 | 9071 OLGA | *04:02 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 15 | 9075 DKB | *03:03 | | | - | - | + | + | - | + | - | + | - | - | - | |
| 16 | 9037 SWEIG007 | *03:01 | | | - | - | + | - | - | - | - | + | - | + | - | |
| 17 | 9282 CTM3953540 | *02:01 | *06:03 | | + | - | + | - | + | - | - | - | - | - | - | |
| 18 | 9257 32367 | *06:02 | *02:02 | | + | + | + | - | + | - | - | - | - | - | - | |
| 19 | 9038 BM16 | *03:01 | | | - | - | + | - | - | - | - | + | - | + | - | |
| 20 | 9059 SLE005 | *06:04 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 21 | 9064 AMALA | *03:01 | | | - | - | + | - | - | - | - | + | - | + | - | |
| 22 | 9056 KOSE | *05:03 | *06:04 | | - | - | + | - | - | - | - | - | - | - | - | |
| 23 | 9124 IHL | *05:03 | *06:01 | | - | - | + | - | - | - | - | - | - | - | - | |
| 24 | 9035 JBUSH | *03:01 | | | - | - | + | - | - | - | - | + | - | + | - | |
| 25 | 9049 IBW9 | *02:02 | | | + | + | - | - | + | - | - | - | - | - | - | |
| 26 | 9285 WT49 | *02:01 | | | + | - | + | - | + | - | - | - | - | - | - | |
| 27 | 9191 CH1007 | *04:01 | *05:01 | | - | - | + | - | - | - | - | - | - | - | - | |
| 28 | 9320 BEL5GB | *02:02 | *03:01 | | + | + | + | - | + | - | - | + | - | + | - | |
| 29 | 9050 MOU | *02:02 | | | + | + | - | - | + | - | - | - | - | - | - | |
| 30 | 9021 RSH | *04:02 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 31 | 9019 DUCAF | *02:01 | | | + | - | + | - | + | - | - | - | - | - | - | |
| 32 | 9297 HAG | *03:01 | | | - | - | + | - | - | - | - | + | - | + | - | |
| 33 | 9098 MT14B | *03:02 | | | - | - | + | - | + | + | - | + | - | - | + | |
| 34 | 9104 DHIF | *03:01 | | | - | - | + | - | - | - | - | + | - | + | - | |
| 35 | 9302 SSTO | *03:05 | | | - | - | + | - | - | - | - | + | - | - | - | |
| 36 | 9024 KT17 | *03:02 | | | - | - | + | - | + | + | - | + | - | - | + | |
| 37 | 9065 HHKB | *06:03 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 38 | 9099 LZL | *03:01 | | | - | - | + | - | - | - | - | + | - | + | - | |
| 39 | 9315 CML | *02:01 | *03:01 | | + | - | + | - | + | - | - | + | - | + | - | |
| 40 | 9134 WHONP199 | *02:02 | *03:03 | | + | + | + | + | + | + | - | + | - | - | - | |
| 41 | 9055 H0301 | *06:09 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 42 | 9066 TAB089 | *06:01 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 43 | 9076 T7526 | *03:03 | | | - | - | + | + | - | + | - | + | - | - | - | |
| 44 | 9057 TEM | *05:03 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 45 | 9239 SHJO | *02:02 | | | + | + | - | - | + | - | - | - | - | - | - | |
| 46 | 9013 SCHU | *06:02 | | | - | - | + | - | - | - | - | - | - | - | - | |
| 47 | 9045 TUBO | *03:01 | | | - | - | + | - | - | - | - | + | - | + | - | |
| 48 | 9303 TER-ND | *05:01 | | | - | - | + | - | - | - | - | - | - | - | - | |



101.903-24 – including *Taq* polymerase, IFU-01
101.903-24u – without *Taq* polymerase, IFU-02

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

Lot No.: **3N9**

Lot-specific information

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.

In primer solutions 4, 12 and 22 one 5'-primer were not possible to be tested, and in primer solutions 17 to 19, 21 and 22 one or two 3'-primers were not possible to be tested.

In addition, one or more primers in primer solutions 4 and 18 were tested by separately adding either one 5'-primer, or two 3'-primers accordingly.



101.903-24 – including *Taq* polymerase, IFU-01
101.903-24u – without *Taq* polymerase, IFU-02

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

Lot No.: **3N9**

Lot-specific information

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Fax: +46-8-717 88 18

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