**101.612-12 – including *Taq* pol.**                    Visit www.olerup-ssp.com for
**101.612-12u– without *Taq* pol.**                    **"Instructions for Use" (IFU)**

**Lot No.: 79N**                    Lot-specific information
## *Olerup* SSP® HLA-C*04

| | |
|---|---|
| **Product number:** | **101.612-12 – including *Taq* polymerase** |
| | **101.612-12u – without *Taq* polymerase** |
| **Lot number:** | **79N** |
| **Expiry date:** | **2015-January-01** |
| **Number of tests:** | **12** |
| **Number of wells per test:** | **47** |
| **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. 79N.

### CHANGES COMPARED TO THE PREVIOUS *OLERUP* SSP® HLA-C*04 LOT (12M)

The HLA-C*04 specificity and interpretation tables have been updated for the HLA-C alleles described since the previous *Olerup* SSP® HLA-C*04 lot was made **(Lot No. 12M)**.

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The HLA-C*04 kit is updated for new alleles to enable separation of:

- Confirmed[1] alleles as listed in the IMGT/HLA database
- Polymorphisms in exons outside of the region encoding the peptide binding domain
- Null and Alternatively expressed alleles

The Lot-specific information for HLA-C*04 including and without *Taq* polymerase is now described in one common Product Insert.

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[1]As described in section Uniquely Identified Alleles.

CE

October 2013                    For In Vitro Diagnostic Use
Rev. No.: 01

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

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**"Instructions for Use" (IFU)**

**Lot No.: 79N**        **Lot-specific information**

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

| Well | 5'-primer | 3'-primer | rationale |
|------|-----------|-----------|-----------|
| 10 | - | Added | Improved yield of HLA-specific PCR product. |
| 18 | - | Added | 3'-primer added for the C*04:94:01-04:94:02 alleles. |
| 25 | - | Added | 3'-primer added for the C*04:94:01-04:94:02 alleles. |
| 31 | Added | Added | Primer pair added for the C*04:95N allele. |
| 34 | - | Added | 3'-primer added for the C*04:96 allele. |
| 39 | Added | Added | Primer pair added for the C*04:95N allele. |
| 41 | Added | Added | Primer pair added for the C*04:105N allele. |
| 43 | - | Modified, added | Improved specificity of primer pair, 3'-primer added for the C*04:88N allele. |
| 45 | Added | - | 5'-primer added for the C*04:103 allele. |
| 46 | Added | Added | Primer pair added for the C*04:93N allele. |
| 47 | Exchanged | Exchanged, added | Exchanged primer pair for improved specificity, 3'-primer added for the C*04:106 allele. |

Change in revision R01 compared to R00:
1.  Primer mix 1 may amplify the C*04:110 allele. This has been corrected in the Specificity and Interpretation Tables.

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For In Vitro Diagnostic Use

**101.612-12 – including *Taq* pol.**                    Visit www.olerup-ssp.com for
**101.612-12u– without *Taq* pol.**                    **"Instructions for Use" (IFU)**

**Lot No.: 79N**                    **Lot-specific information**

October 2013                    $C \epsilon$                    For In Vitro Diagnostic Use
Rev. No.: 01

**101.612-12 – including *Taq* pol.**                    Visit www.olerup-ssp.com for
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**Lot No.: 79N**                    **Lot-specific information**
# PRODUCT DESCRIPTION

## HLA-C*04 SSP subtyping

### CONTENT
The primer set contains 5'- and 3'-primers for identifying the HLA-C*04:01 to HLA-C*04:112 alleles.

### PLATE LAYOUT
Each test consists of 47 PCR reactions in a 48 well PCR plate. Well 48 is empty.

| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 |
|---|---|---|---|---|---|---|---|
| 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
| 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 |
| 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 |
| 41 | 42 | 43 | 44 | 45 | 46 | 47 | empty |

The 48 well cut PCR plate is marked with 'HLA-C*04' in silver/gray ink.
Well No. 1 is marked with the Lot No. '79N'.
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 48 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
The interpretation of HLA-C*04 SSP subtypings will be influenced by other HLA-C alleles, as primer mixes 1, 2, 4, 5, 7, 8, 10 to 12, 14 to 20, 24, 25, 30, 33, 34, 39, 41, 42 and 47 amplify non-HLA-C*04 alleles. In addition, the A*24:96 and A*24:146 alleles will be amplified by primer mix 15, the A*33:52 allele will be amplified by primer mix 20, the B*07:90 allele will be amplified by primer mix 30, the B*15:27:01-15:27:03 and 15:109 alleles will be amplified by primer mixes 18 and 25, the B*15:78:03 allele will be amplified by primer mix 16,  the B*40:100 allele will be amplified by primer mixes 32 and 33 and the B*58:02 allele will be amplified by primer mixes 5 and 8.

### UNIQUELY IDENTIFIED ALLELES
All the HLA-C*04 alleles, i.e. **C*04:01 to C*04:112**, recognized by the HLA Nomenclature Committee in April 2012[1] will be amplified by the primers in the HLA-C*04 kit[2].

The HLA-C*04 kit enables separation of the confirmed HLA-C*04 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if

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it has been sequenced by more than a single laboratory or from multiple sources. Current allele confirmation status for HLA-C*04 alleles is listed below.

The HLA-C*04 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

In this lot of the HLA-C*04 subtyping kit, primer mix 42 does not amplify the C*04:82 allele. Thus, this lot of the HLA-C*04 subtyping kit cannot distinguish the C* 04:01:01:01-04:01:09, 04:01:11-04:01:22, 04:01:24-04:01:27 and 04:01:29-04:01:37 alleles and the C*04:82 allele.

The HLA-C*04 primer set cannot distinguish the following silent mutations: the C∗04:01:01:01-04:01:09, 04:01:11-04:01:22, 04:01:24-04:01:27 and 04:01:29-04:01:37 alleles, the C*04:01:10 and 04:01:23 alleles, the C*04:04:01-04:04:02 alleles, the C*04:15:01 and 04:15:03 alleles and the C*04:94:01-04:94:02 alleles.

The C*04:15:02, C*04:44 and C*04:47alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.
The C*04:23, C*04:38 and C*04:39 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 21.
The C*04:25, C*04:40 and C*04:41 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 23.
The C*04:46 and C*04:50 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 27.
The C*04:48 and C*04:75 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 28.
The C*04:54 and C*04:105N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 41.
The C*04:56 and C*04:64 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 40.
The C*04:59Q and C*04:78 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 32.
The C*04:61 and C*04:96 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 34.
The C*04:62 and C*04:76 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 35.
The C*04:65 and C*04:72 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 33.
The C*04:67 and C*04:93N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 46.
The C*04:81 and C*04:88N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 43.
The C*04:84 and C*04:106 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 47.

[1]HLA-C alleles listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.
[2]The HLA-C*04 primer set cannot separate the C*04:03 and 02:49 alleles or the C*04:107 and the C*02:12 and 02:55 alleles. These alleles can be distinguished by the HLA-C low resolution kit and/or the HLA-C*02 high resolution kit.

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Lot No.: **79N**           Lot-specific information
## ALLELE CONFIRMATION STATUS

| Allele | Status[1] | Allele | Status[1] | Allele | Status[1] | Allele | Status[1] |
|---|---|---|---|---|---|---|---|
| **C*04:01:01:01** | **Confirmed** | **C*04:03** | **Confirmed** | C*04:42 | Unconfirmed | C*04:82 | Unconfirmed |
| C*04:01:01:02 | Unconfirmed | **C*04:04:01** | **Confirmed** | C*04:43 | **Confirmed** | **C*04:83** | **Confirmed** |
| C*04:01:01:03 | Unconfirmed | C*04:04:02 | Unconfirmed | C*04:44 | Unconfirmed | C*04:84 | Unconfirmed |
| C*04:01:01:04 | Unconfirmed | C*04:05 | Unconfirmed | **C*04:45** | **Confirmed** | C*04:85 | Unconfirmed |
| C*04:01:02 | Unconfirmed | **C*04:06** | **Confirmed** | C*04:46 | Unconfirmed | C*04:86 | Unconfirmed |
| C*04:01:03 | Unconfirmed | **C*04:07** | **Confirmed** | **C*04:47** | **Confirmed** | C*04:87 | Unconfirmed |
| **C*04:01:04** | **Confirmed** | **C*04:08** | **Confirmed** | **C*04:48** | **Confirmed** | C*04:88N | Unconfirmed |
| C*04:01:05 | Unconfirmed | **C*04:09N** | **Confirmed** | C*04:49 | Unconfirmed | C*04:89 | Unconfirmed |
| C*04:01:06 | Unconfirmed | **C*04:10** | **Confirmed** | C*04:50 | Unconfirmed | C*04:90 | Unconfirmed |
| C*04:01:07 | Unconfirmed | C*04:11 | Unconfirmed | C*04:51 | Unconfirmed | C*04:91 | Unconfirmed |
| **C*04:01:08** | **Confirmed** | C*04:12 | Unconfirmed | **C*04:52** | **Confirmed** | C*04:92 | Unconfirmed |
| **C*04:01:09** | **Confirmed** | **C*04:13** | **Confirmed** | C*04:53 | Unconfirmed | C*04:93N | Unconfirmed |
| **C*04:01:10** | **Confirmed** | **C*04:14** | **Confirmed** | **C*04:54** | **Confirmed** | **C*04:94:01** | **Confirmed** |
| **C*04:01:11** | **Confirmed** | C*04:15:01 | Unconfirmed | C*04:55 | Unconfirmed | C*04:94:02 | Unconfirmed |
| **C*04:01:12** | **Confirmed** | **C*04:15:02** | **Confirmed** | **C*04:56** | **Confirmed** | C*04:95N | Unconfirmed |
| **C*04:01:13** | **Confirmed** | C*04:15:03 | Unconfirmed | C*04:57 | Unconfirmed | **C*04:96** | **Confirmed** |
| **C*04:01:14** | **Confirmed** | **C*04:16** | **Confirmed** | **C*04:58** | **Confirmed** | C*04:97 | Unconfirmed |
| **C*04:01:15** | **Confirmed** | C*04:17 | Unconfirmed | **C*04:59Q** | **Confirmed** | C*04:98 | Unconfirmed |
| **C*04:01:16** | **Confirmed** | C*04:18 | Unconfirmed | C*04:60 | Unconfirmed | C*04:99 | Unconfirmed |
| C*04:01:17 | Unconfirmed | C*04:19 | Unconfirmed | **C*04:61** | **Confirmed** | C*04:100 | Unconfirmed |
| C*04:01:18 | Unconfirmed | C*04:20 | Unconfirmed | **C*04:62** | **Confirmed** | C*04:101 | Unconfirmed |
| C*04:01:19 | Unconfirmed | C*04:23 | Unconfirmed | **C*04:63** | **Confirmed** | C*04:102 | Unconfirmed |
| C*04:01:20 | Unconfirmed | C*04:24 | Unconfirmed | C*04:64 | Unconfirmed | **C*04:103** | **Confirmed** |
| **C*04:01:21** | **Confirmed** | C*04:25 | Unconfirmed | **C*04:65** | **Confirmed** | C*04:104 | Unconfirmed |
| C*04:01:22 | Unconfirmed | **C*04:26** | **Confirmed** | C*04:66 | Unconfirmed | C*04:105N | Unconfirmed |
| C*04:01:23 | Unconfirmed | **C*04:27** | **Confirmed** | C*04:67 | Unconfirmed | C*04:106 | Unconfirmed |
| C*04:01:24 | Unconfirmed | C*04:28 | Unconfirmed | **C*04:68** | **Confirmed** | C*04:107 | Unconfirmed |
| C*04:01:25 | Unconfirmed | **C*04:29** | **Confirmed** | **C*04:69** | **Confirmed** | C*04:108 | Unconfirmed |
| C*04:01:26 | Unconfirmed | C*04:30 | Unconfirmed | C*04:70 | Unconfirmed | C*04:109 | Unconfirmed |
| C*04:01:27 | Unconfirmed | C*04:31 | Unconfirmed | C*04:71 | Unconfirmed | C*04:110 | Unconfirmed |
| **C*04:01:28** | **Confirmed** | **C*04:32** | **Confirmed** | C*04:72 | Unconfirmed | C*04:111 | Unconfirmed |
| C*04:01:29 | Unconfirmed | **C*04:33** | **Confirmed** | C*04:73 | Unconfirmed | C*04:112 | Unconfirmed |
| **C*04:01:30** | **Confirmed** | C*04:34 | Unconfirmed | **C*04:74** | **Confirmed** | | |
| C*04:01:31 | Unconfirmed | C*04:35 | Unconfirmed | C*04:75 | Unconfirmed | | |
| C*04:01:32 | Unconfirmed | **C*04:36** | **Confirmed** | C*04:76 | Unconfirmed | | |
| **C*04:01:33** | **Confirmed** | **C*04:37** | **Confirmed** | **C*04:77** | **Confirmed** | | |
| C*04:01:34 | Unconfirmed | **C*04:38** | **Confirmed** | C*04:78 | Unconfirmed | | |
| C*04:01:35 | Unconfirmed | **C*04:39** | **Confirmed** | C*04:79 | Unconfirmed | | |
| C*04:01:36 | Unconfirmed | **C*04:40** | **Confirmed** | C*04:80 | Unconfirmed | | |
| C*04:01:37 | Unconfirmed | C*04:41 | Unconfirmed | **C*04:81** | **Confirmed** | | |

[1]Allele status "confirmed" or "unconfirmed" as listed on the IMGT/HLA web page 2012-April-12, release 3.8.0, www.ebi.ac.uk/imgt/hla.

**Lot No.: 79N**　　　　　**Lot-specific information**

## RESOLUTION IN HOMO- AND HETEROZYGOTES

A total of 152 alleles generate 76 amplification patterns that can be combined in 2926 homozygous and heterozygous combinations. 1672 of these genotypes do not give rise to unique amplification patterns. The different lengths of the specific PCR products were not considered in these calculations.

```
+--+---- --+----- -------- -------- -------- -------   *04:03, *04:03 = *04:03, *04:107
-++----- --+---+- -------- -------- -------- -------   *04:14, *04:14 = *04:14, *04:111
-++-+--- --+----- -------- -------- -------- -------   *04:04:01, *04:04:01 = *04:04:01, *04:111
+------- --+--+-- -------- -------- -------- ----+--   *04:16, *04:16 = *04:16, *04:103
+--+---- --+----- -------- -------- -------- ----+--   *04:03, *04:103 = *04:103, *04:107
+--+---- --+----- -------+ -------- -------- -------   *04:03, *04:42 = *04:42, *04:107
+--+---- --+----- +------- -------- -------- -------   *04:03, *04:80 = *04:80, *04:80 = *04:80, *04:107
+--++--- --+----- -------- -------- -------- -------   *04:03, *04:06 = *04:06, *04:107
+-+----- --+----- -------- -------- ------+- -------   *04:01:28, *04:71 = *04:71, *04:71
+-+----- -++----- -------- -------- -------- -------   *04:01:28, *04:10 = *04:10, *04:10
+-++---- --+----- -------- -------- -------- -------   *04:01:28, *04:03 = *04:01:28, *04:107
++----+- --+----- -------- -------- -------- -------   *04:07, *04:07 = *04:07, *04:27 = *04:07, *04:87 = *04:27, *04:87
++-+---- --+----- -------- -------- -------- -------   *04:03, *04:87 = *04:87, *04:107
+++----- ----+--- -------- -------- -------- -------   *04:01:10, *04:52 = *04:52, *04:52
+++----- ---+---- -------- -------- -------- -------   *04:01:10, *04:33 = *04:33, *04:33
+++----- --+----- -------- -------- -------- -------   *04:01:01:01, *04:01:01:01 = *04:01:01:01, *04:01:10 = *04:01:01:01,
                                                        *04:01:28 = *04:01:01:01, *04:87 = *04:01:01:01, *04:111 =
                                                        *04:01:10, *04:01:28 = *04:01:10, *04:87 = *04:01:10, *04:111 =
                                                        *04:01:28, *04:87 = *04:01:28, *04:111 = *04:87, *04:111
-++----- --+---+- -------- -------- -+------ -------   *04:14, *04:68 = *04:68, *04:68 = *04:68, *04:111
-++-+--+ --+----- -------- -------- -------- -------   *04:04:01, *04:34 = *04:34, *04:34 = *04:34, *04:111
-+++--- --+----- -------- -------- -------- -------    *04:04:01, *04:06 = *04:06, *04:111
+--+---- --+--+-- -------- -------- -------- ----+--   *04:03, *04:16 = *04:16, *04:107
+-+----- --+-++-- -------- -------- -------- -------   *04:11, *04:55 = *04:55, *04:55
+-+----- -+++---- -------- -------- -------- -------   *04:01:28, *04:11 = *04:01:28, *04:36 = *04:10, *04:11 = *04:10,
                                                        *04:36 = *04:11, *04:36 = *04:36, *04:36
+-++---- --+----- -------- -------- ------+- -------   *04:03, *04:71 = *04:71, *04:107
+-+----- -++----- -------- -------- -------- -------   *04:03, *04:10 = *04:10, *04:107
++----+- --+----- -------- -------- -------- ----+--   *04:07, *04:103 = *04:27, *04:103
++----+- --+----- -------+ -------- -------- -------   *04:07, *04:42 = *04:27, *04:42
++-+--+- --+----- -------- -------- -------- -------   *04:03, *04:07 = *04:03, *04:27 = *04:07, *04:107
+++----- --+----- -------- -------- -------- ------+   *04:01:01:01, *04:84 = *04:01:10, *04:84 = *04:01:28, *04:84 =
                                                        *04:84, *04:84 = *04:84, *04:87 = *04:84, *04:111
+++----- --+----- -------- -------- -------- -----+-   *04:01:01:01, *04:67 = *04:01:10, *04:67 = *04:01:28, *04:67 =
                                                        *04:67, *04:67 = *04:67, *04:87 = *04:67, *04:111
+++----- --+----- -------- -------- -------- ----+--   *04:01:01:01, *04:66 = *04:01:01:01, *04:103 = *04:01:10, *04:66 =
                                                        *04:01:10, *04:103 = *04:01:28, *04:66 = *04:66, *04:66 = *04:66,
                                                        *04:87 = *04:66, *04:103 = *04:66, *04:111 = *04:103, *04:111
+++----- --+----- -------- -------- -------- ---+--    *04:01:01:01, *04:60 = *04:01:10, *04:60 = *04:01:28, *04:60 =
                                                        *04:60, *04:60 = *04:60, *04:87 = *04:60, *04:111
+++----- --+----- -------- -------- -------- --+----   *04:01:01:01, *04:81 = *04:01:10, *04:81 = *04:01:28, *04:81 =
                                                        *04:81, *04:81 = *04:81, *04:87 = *04:81, *04:111
+++----- --+----- -------- -------- -------- -+-----   *04:01:01:01, *04:69 = *04:01:10, *04:69 = *04:01:28, *04:69 =
                                                        *04:69, *04:69 = *04:69, *04:87 = *04:69, *04:111
+++----- --+----- -------- -------- -------- +------   *04:01:01:01, *04:54 = *04:01:10, *04:54 = *04:01:28, *04:54 =
                                                        *04:54, *04:54 = *04:54, *04:87 = *04:54, *04:111
+++----- --+----- -------- -------- -------+ -------   *04:01:01:01, *04:56 = *04:01:10, *04:56 = *04:01:28, *04:56 =
                                                        *04:56, *04:56 = *04:56, *04:87 = *04:56, *04:111
+++----- --+----- -------- -------- ------+- -------   *04:01:01:01, *04:71 = *04:01:01:01, *04:79 = *04:01:10, *04:71 =
                                                        *04:01:10, *04:79 = *04:01:28, *04:79 = *04:71, *04:79 = *04:71,
                                                        *04:87 = *04:71, *04:111 = *04:79, *04:79 = *04:79, *04:87 = *04:79,
                                                        *04:111
+++----- --+----- -------- -------- -----+-- -------   *04:01:01:01, *04:83 = *04:01:10, *04:83 = *04:01:28, *04:83 =
                                                        *04:83, *04:83 = *04:83, *04:87 = *04:83, *04:111
+++----- --+----- -------- -------- ----+--- -------   *04:01:01:01, *04:73 = *04:01:10, *04:73 = *04:01:28, *04:73 =
                                                        *04:73, *04:73 = *04:73, *04:87 = *04:73, *04:111
+++----- --+----- -------- -------- ---+---- -------   *04:01:01:01, *04:57 = *04:01:10, *04:57 = *04:01:28, *04:57 =
                                                        *04:57, *04:57 = *04:57, *04:87 = *04:57, *04:111
+++----- --+----- -------- -------- --+----- -------   *04:01:01:01, *04:62 = *04:01:10, *04:62 = *04:01:28, *04:62 =
                                                        *04:62, *04:62 = *04:62, *04:87 = *04:62, *04:111
+++----- --+----- -------- -------- -+------ -------   *04:01:01:01, *04:61 = *04:01:10, *04:61 = *04:01:28, *04:61 =
                                                        *04:61, *04:61 = *04:61, *04:87 = *04:61, *04:111
```

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

**Lot No.: 79N**                    **Lot-specific information**

| | |
|---|---|
| +++----- --+----- -------- ------- +------- ------- | \*04:01:01:01, \*04:65 = \*04:01:10, \*04:65 = \*04:01:28, \*04:65 = \*04:65, \*04:65 = \*04:65, \*04:87 = \*04:65, \*04:111 |
| +++----- --+----- -------- -------+ -------- ------- | \*04:01:01:01, \*04:59Q = \*04:01:10, \*04:59Q = \*04:01:28, \*04:59Q = \*04:59Q, \*04:59Q = \*04:59Q, \*04:87 = \*04:59Q, \*04:111 |
| +++----- --+----- -------- ------+- -------- ------- | \*04:01:01:01, \*04:51 = \*04:01:10, \*04:51 = \*04:01:28, \*04:51 = \*04:51, \*04:51 = \*04:51, \*04:87 = \*04:51, \*04:111 |
| +++----- --+----- -------- -----+-- -------- ------- | \*04:01:01:01, \*04:53 = \*04:01:10, \*04:53 = \*04:01:28, \*04:53 = \*04:53, \*04:53 = \*04:53, \*04:87 = \*04:53, \*04:111 |
| +++----- --+----- -------- ----+--- -------- ------- | \*04:01:01:01, \*04:49 = \*04:01:10, \*04:49 = \*04:01:28, \*04:49 = \*04:49, \*04:49 = \*04:49, \*04:87 = \*04:49, \*04:111 |
| +++----- --+----- -------- ---+---- -------- ------- | \*04:01:01:01, \*04:48 = \*04:01:10, \*04:48 = \*04:01:28, \*04:48 = \*04:48, \*04:48 = \*04:48, \*04:87 = \*04:48, \*04:111 |
| +++----- --+----- -------- --+----- -------- ------- | \*04:01:01:01, \*04:46 = \*04:01:10, \*04:46 = \*04:01:28, \*04:46 = \*04:46, \*04:46 = \*04:46, \*04:87 = \*04:46, \*04:111 |
| +++----- --+----- -------- -+------ -------- ------- | \*04:01:01:01, \*04:45 = \*04:01:10, \*04:45 = \*04:01:28, \*04:45 = \*04:45, \*04:45 = \*04:45, \*04:87 = \*04:45, \*04:111 |
| +++----- --+----- -------- +------- -------- ------- | \*04:01:01:01, \*04:43 = \*04:01:10, \*04:43 = \*04:01:28, \*04:43 = \*04:43, \*04:43 = \*04:43, \*04:87 = \*04:43, \*04:111 |
| +++----- --+----- -------+ -------- -------- ------- | \*04:01:01:01, \*04:26 = \*04:01:01:01, \*04:42 = \*04:01:10, \*04:26 = \*04:01:10, \*04:42 = \*04:01:28, \*04:26 = \*04:26, \*04:26 = \*04:26, \*04:42 = \*04:26, \*04:87 = \*04:26, \*04:111 = \*04:42, \*04:111 |
| +++----- --+----- ------+- -------- -------- ------- | \*04:01:01:01, \*04:25 = \*04:01:10, \*04:25 = \*04:01:28, \*04:25 = \*04:25, \*04:25 = \*04:25, \*04:87 = \*04:25, \*04:111 |
| +++----- --+----- -----+-- -------- -------- ------- | \*04:01:01:01, \*04:24 = \*04:01:10, \*04:24 = \*04:01:28, \*04:24 = \*04:24, \*04:24 = \*04:24, \*04:87 = \*04:24, \*04:111 |
| +++----- --+----- ----+--- -------- -------- ------- | \*04:01:01:01, \*04:23 = \*04:01:10, \*04:23 = \*04:01:28, \*04:23 = \*04:23, \*04:23 = \*04:23, \*04:87 = \*04:23, \*04:111 |
| +++----- --+----- ---+---- -------- -------- ------- | \*04:01:01:01, \*04:15:02 = \*04:01:10, \*04:15:02 = \*04:01:28, \*04:15:02 = \*04:15:02, \*04:15:02 = \*04:15:02, \*04:87 = \*04:15:02, \*04:111 |
| +++----- --+----- --+----- -------- -------- ------- | \*04:01:01:01, \*04:20 = \*04:01:10, \*04:20 = \*04:01:28, \*04:20 = \*04:20, \*04:20 = \*04:20, \*04:87 = \*04:20, \*04:111 |
| +++----- --+----- -+------ -------- -------- ------- | \*04:01:01:01, \*04:19/04:70 = \*04:01:10, \*04:19/04:70 = \*04:01:28, \*04:19/04:70 = \*04:19/04:70, \*04:19/04:70 = \*04:19/04:70, \*04:87 = \*04:19/04:70, \*04:111 |
| +++----- --+----+ -------- -------- -------- ------- | \*04:01:01:01, \*04:15:01 = \*04:01:10, \*04:15:01 = \*04:01:28, \*04:15:01 = \*04:15:01, \*04:15:01 = \*04:15:01, \*04:87 = \*04:15:01, \*04:111 |
| +++----- --+---+- -------- -------- -------- ------- | \*04:01:01:01, \*04:14 = \*04:01:01:01, \*04:28 = \*04:01:10, \*04:14 = \*04:01:10, \*04:28 = \*04:01:28, \*04:14 = \*04:01:28, \*04:28 = \*04:14, \*04:28 = \*04:14, \*04:87 = \*04:28, \*04:28 = \*04:28, \*04:87 = \*04:28, \*04:111 |
| +++----- --+--+-- -------- -------- -------- ------- | \*04:01:01:01, \*04:18 = \*04:01:10, \*04:18 = \*04:01:28, \*04:18 = \*04:18, \*04:18 = \*04:18, \*04:87 = \*04:18, \*04:111 |
| +++----- --+-+--- -------- -------- -------- ------- | \*04:01:01:01, \*04:12 = \*04:01:01:01, \*04:52 = \*04:01:10, \*04:12 = \*04:01:28, \*04:12 = \*04:01:28, \*04:52 = \*04:12, \*04:12 = \*04:12, \*04:52 = \*04:12, \*04:87 = \*04:12, \*04:111 = \*04:52, \*04:87 = \*04:52, \*04:111 |
| +++----- --++---- -------- -------- -------- ------- | \*04:01:01:01, \*04:29 = \*04:01:01:01, \*04:33 = \*04:01:10, \*04:29 = \*04:01:28, \*04:29 = \*04:01:28, \*04:33 = \*04:29, \*04:29 = \*04:29, \*04:33 = \*04:29, \*04:87 = \*04:29, \*04:111 = \*04:33, \*04:87 = \*04:33, \*04:111 |
| +++----- -+-+---- -------- -------- -------- ------- | \*04:01:10, \*04:11 = \*04:11, \*04:33 |
| +++----- --++---- -------- -------- -------- ------- | \*04:01:01:01, \*04:10 = \*04:01:01:01, \*04:31 = \*04:01:10, \*04:10 = \*04:01:10, \*04:31 = \*04:01:28, \*04:31 = \*04:10, \*04:31 = \*04:10, \*04:87 = \*04:10, \*04:111 = \*04:31, \*04:31 = \*04:31, \*04:87 = \*04:31, \*04:111 |
| +++----- +-+----- -------- -------- -------- ------- | \*04:01:01:01, \*04:09N = \*04:01:10, \*04:09N = \*04:01:28, \*04:09N = \*04:09N, \*04:09N = \*04:09N, \*04:87 = \*04:09N, \*04:111 |
| +++----+ --+----- -------- -------- -------- ------- | \*04:01:01:01, \*04:08 = \*04:01:10, \*04:08 = \*04:01:28, \*04:08 = \*04:08, \*04:08 = \*04:08, \*04:87 = \*04:08, \*04:111 |
| +++---+- --+----- -------- -------- -------- ------- | \*04:01:01:01, \*04:07 = \*04:01:01:01, \*04:27 = \*04:01:01:01, \*04:32 = \*04:01:10, \*04:07 = \*04:01:10, \*04:32 = \*04:01:28, \*04:07 = \*04:01:28, \*04:27 = \*04:01:28, \*04:32 = \*04:07, \*04:32 = \*04:07, \*04:111 = \*04:27, \*04:32 = \*04:27, \*04:111 = \*04:32, \*04:32 = \*04:32, \*04:87 = \*04:32, \*04:111 |
| +++--+-- --+----- -------- -------- -------- ------- | \*04:01:01:01, \*04:05 = \*04:01:10, \*04:05 = \*04:01:28, \*04:05 = \*04:05, \*04:05 = \*04:05, \*04:87 = \*04:05, \*04:111 |
| +++-+--- --+----- -------- -------- -------- ------- | \*04:01:01:01, \*04:04:01 = \*04:01:10, \*04:04:01 = \*04:01:28, \*04:04:01 = \*04:04:01, \*04:87 |
| +++++--- --+----- -------- -------- -------- ------- | \*04:01:01:01, \*04:03 = \*04:01:01:01, \*04:107 = \*04:01:10, \*04:03 = |

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**Lot No.: 79N**                    **Lot-specific information**

```
                                                        *04:03, *04:111 = *04:107, *04:111
-++-+--- --+--+-- ------- ------- -+------ -------       *04:04:01, *04:13 = *04:13, *04:13 = *04:13, *04:111
+-+----- -+++---- ------- ------- -------- ----+--       *04:11, *04:103 = *04:36, *04:103
+-+----- -+++---- -------- -------- ------+- -------      *04:11, *04:71 = *04:36, *04:71
+-+----- -+++---- ------+ -------- -------- -------      *04:11, *04:42 = *04:36, *04:42
+-+----- -++++--- ------- -------- -------- -------      *04:01:28, *04:55 = *04:10, *04:55 = *04:36, *04:55
+-++---- -+++---- ------- -------- -------- -------      *04:03, *04:11 = *04:03, *04:36 = *04:36, *04:107
++----+- --+--+-- ------- -------- -------- ----+--      *04:07, *04:16 = *04:16, *04:27
++-+--+- --+--+-- +------ -------- -------- -------      *04:07, *04:80 = *04:27, *04:80
++-++-+- --+----- ------- -------- -------- -------      *04:06, *04:07 = *04:06, *04:27
+++-+--- --+----- ------- -------- -------- ----+-+      *04:66, *04:84 = *04:84, *04:103
+++----- --+----- ------- -------- -------- ----++-      *04:66, *04:67 = *04:67, *04:103
+++----- --+----- ------- -------- -------- ---++--      *04:60, *04:66 = *04:60, *04:103
+++----- --+----- ------- -------- -------- --+-+--      *04:66, *04:81 = *04:81, *04:103
+++----- --+----- ------- -------- -------- -+-+--      *04:66, *04:69 = *04:69, *04:103
+++----- --+----- ------- -------- -------- +---+--      *04:54, *04:66 = *04:54, *04:103
+++----- --+----- ------- -------- -------+ ---+--       *04:56, *04:66 = *04:56, *04:103
+++----- --+----- ------- -------- ------+- ------+      *04:71, *04:84 = *04:79, *04:84
+++----- --+----- ------- -------- ------+- -----+-      *04:67, *04:71 = *04:67, *04:79
+++----- --+----- ------- -------- ------+- ----+--      *04:66, *04:71 = *04:66, *04:79 = *04:79, *04:103
+++----- --+----- ------- -------- ------+- ---+---      *04:60, *04:71 = *04:60, *04:79
+++----- --+----- ------- -------- ------+- --+----      *04:71, *04:81 = *04:79, *04:81
+++----- --+----- ------- -------- ------+- -+-----      *04:69, *04:71 = *04:69, *04:79
+++----- --+----- ------- -------- ------+- +------      *04:54, *04:71 = *04:54, *04:79
+++----- --+----- ------- -------- -------++ -------      *04:56, *04:71 = *04:56, *04:79
+++----- --+----- ------- -------- ------+-- ----+--     *04:66, *04:83 = *04:83, *04:103
+++----- --+----- ------- -------- -----++- -------      *04:71, *04:83 = *04:79, *04:83
+++----- --+----- ------- -------- ----+--- ----+--     *04:66, *04:73 = *04:73, *04:103
+++----- --+----- ------- -------- ----+-+- -------      *04:71, *04:73 = *04:73, *04:79
+++----- --+----- ------- -------- --+++-- -------      *04:01:01:01, *04:74 = *04:01:10, *04:74 = *04:01:28, *04:74 =
                                                        *04:73, *04:74 = *04:73, *04:83 = *04:74, *04:74 = *04:74, *04:83 =
                                                        *04:74, *04:87 = *04:74, *04:111
+++----- --+----- ------- -------- ---+---- ----+--     *04:57, *04:66 = *04:57, *04:103
+++----- --+----- ------- -------- ---+--+- -------      *04:57, *04:71 = *04:57, *04:79
+++----- --+----- ------- -------- ---++--- -------      *04:01:01:01, *04:63 = *04:01:10, *04:63 = *04:01:28, *04:63 =
                                                        *04:57, *04:63 = *04:57, *04:73 = *04:63, *04:63 = *04:63, *04:73 =
                                                        *04:63, *04:87 = *04:63, *04:111
+++----- --+----- ------- -------- --+----- ----+--     *04:62, *04:66 = *04:62, *04:103
+++----- --+----- ------- -------- --+---+- -------      *04:62, *04:71 = *04:62, *04:79
+++----- --+----- ------- -------- -+------ ----+--     *04:61, *04:66 = *04:61, *04:103
+++----- --+----- ------- -------- -+----+- -------      *04:61, *04:71 = *04:61, *04:79
+++----- --+----- ------- -------- +------- ----+--     *04:65, *04:66 = *04:65, *04:103
+++----- --+----- ------- -------- +-----+- -------      *04:65, *04:71 = *04:65, *04:79
+++----- --+----- ------- -------+ -------- ----+--     *04:59Q, *04:66 = *04:59Q, *04:103
+++----- --+----- ------- -------+ ------+- -------      *04:59Q, *04:71 = *04:59Q, *04:79
+++----- --+----- ------- -----+-- -------- ----+--     *04:51, *04:66 = *04:51, *04:103
+++----- --+----- ------- -----+-- -------+- -------     *04:01:01:01, *04:95N = *04:01:10, *04:95N = *04:01:28, *04:95N =
                                                        *04:51, *04:71 = *04:51, *04:79 = *04:51, *04:95N = *04:71, *04:95N
                                                        = *04:79, *04:95N = *04:87, *04:95N = *04:95N, *04:95N = *04:95N,
                                                        *04:111
+++----- --+----- ------- -----+-- -------- ----+--     *04:53, *04:66 = *04:53, *04:103
+++----- --+----- ------- -----+-- ------+- -------      *04:53, *04:71 = *04:53, *04:79
+++----- --+----- ------- ----+--- -------- ----+--     *04:49, *04:66 = *04:49, *04:103
+++----- --+----- ------- ----+--- ------+- -------      *04:49, *04:71 = *04:49, *04:79
+++----- --+----- ------- ---+---- -------- ----+--     *04:48, *04:66 = *04:48, *04:103
+++----- --+----- ------- ---+---- ------+- -------      *04:48, *04:71 = *04:48, *04:79
+++----- --+----- ------- --+----- -------- ----+--     *04:46, *04:66 = *04:46, *04:103
+++----- --+----- ------- --+----- ------+- -------      *04:46, *04:71 = *04:46, *04:79
+++----- --+----- ------- -+------ -------- ----+--     *04:45, *04:66 = *04:45, *04:103
+++----- --+----- ------- -+------ ------+- -------      *04:45, *04:71 = *04:45, *04:79
+++----- --+----- ------- +------- -------- ----+--     *04:43, *04:66 = *04:43, *04:103
+++----- --+----- ------- +------- ------+- -------      *04:43, *04:71 = *04:43, *04:79
+++----- --+----- ------+ -------- -------- ------+     *04:26, *04:84 = *04:42, *04:84
+++----- --+----- ------+ -------- -------- -----++     *04:26, *04:67 = *04:42, *04:67
+++----- --+----- ------+ -------- -------- ----+--     *04:26, *04:66 = *04:26, *04:103 = *04:42, *04:66
+++----- --+----- ------+ -------- -------- ---+---     *04:26, *04:60 = *04:42, *04:60
+++----- --+----- ------+ -------- -------- --+----     *04:26, *04:81 = *04:42, *04:81
+++----- --+----- ------+ -------- -------- -+-----     *04:26, *04:69 = *04:42, *04:69
+++----- --+----- ------+ -------- -------- +------     *04:26, *04:54 = *04:42, *04:54
+++----- --+----- ------+ -------- -------+ -------     *04:26, *04:56 = *04:42, *04:56
+++----- --+----- ------+ -------- ------+- -------     *04:26, *04:71 = *04:26, *04:79 = *04:42, *04:79
```

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Rev. No.: 01

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For In Vitro Diagnostic Use

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

**Lot No.: 79N**                      **Lot-specific information**

```
+++----- --+----- ------+ -------- -----+-- -------  *04:26, *04:83 = *04:42, *04:83
+++----- --+----- ------+ -------- ----+--- -------  *04:26, *04:73 = *04:42, *04:73
+++----- --+----- ------+ -------- ---+---- -------  *04:26, *04:57 = *04:42, *04:57
+++----- --+----- ------+ -------- --+----- -------  *04:26, *04:62 = *04:42, *04:62
+++----- --+----- ------+ -------- -+----- -------   *04:26, *04:61 = *04:42, *04:61
+++----- --+----- ------+ -------- +------- -------  *04:26, *04:65 = *04:42, *04:65
+++----- --+----- ------+ -------+ -------- -------  *04:26, *04:59Q = *04:42, *04:59Q
+++----- --+----- ------+ -----+-- -------- -------  *04:26, *04:51 = *04:42, *04:51
+++----- --+----- ------+ -----+-- -------- -------  *04:26, *04:53 = *04:42, *04:53
+++----- --+----- ------+ ----+--- -------- -------  *04:26, *04:49 = *04:42, *04:49
+++----- --+----- ------+ ---+---- -------- -------  *04:26, *04:48 = *04:42, *04:48
+++----- --+----- ------+ --+----- -------- -------  *04:26, *04:46 = *04:42, *04:46
+++----- --+----- ------+ -+------ -------- -------  *04:26, *04:45 = *04:42, *04:45
+++----- --+----- ------+ +------- -------- -------  *04:26, *04:43 = *04:42, *04:43
+++----- --+----- ------+- -------- -------- ----+--  *04:25, *04:66 = *04:25, *04:103
+++----- --+----- ------+- -------- ------+- -------  *04:25, *04:71 = *04:25, *04:79
+++----- --+----- ------++ -------- -------- -------  *04:25, *04:26 = *04:25, *04:42
+++----- --+----- -----+-- -------- -------- ----+--  *04:24, *04:66 = *04:24, *04:103
+++----- --+----- -----+-- -------- ------+- -------  *04:24, *04:71 = *04:24, *04:79
+++----- --+----- -----+-+ -------- -------- -------  *04:24, *04:26 = *04:24, *04:42
+++----- --+----- ----+--- -------- -------- ----+--  *04:23, *04:66 = *04:23, *04:103
+++----- --+----- ----+--- -------- ------+- -------  *04:23, *04:71 = *04:23, *04:79
+++----- --+----- ----+--+ -------- -------- -------  *04:23, *04:26 = *04:23, *04:42
+++----- --+----- ---+---- -------- -------- ----+--  *04:15:02, *04:66 = *04:15:02, *04:103
+++----- --+----- ---+---- -------- ------+- -------  *04:15:02, *04:71 = *04:15:02, *04:79
+++----- --+----- ---+---+ -------- -------- -------  *04:15:02, *04:26 = *04:15:02, *04:42
+++----- --+----- --+----- -------- -------- ----+--  *04:20, *04:66 = *04:20, *04:103
+++----- --+----- --+----- -------- ------+- -------  *04:20, *04:71 = *04:20, *04:79
+++----- --+----- --+----+ -------- -------- -------  *04:20, *04:26 = *04:20, *04:42
+++----- --+----- -+------ -------- -------- ----+--  *04:19/04:70, *04:66 = *04:19/04:70, *04:103
+++----- --+----- -+------ -------- ------+- -------  *04:19/04:70, *04:71 = *04:19/04:70, *04:79
+++----- --+----- -+------ +------- -------- -------  *04:01:01:01, *04:94:01 = *04:01:10, *04:94:01 = *04:01:28,
```
*04:94:01 = *04:19/04:70, *04:43 = *04:19/04:70, *04:94:01 = *04:43,
*04:94:01 = *04:87, *04:94:01 = *04:94:01, *04:94:01 = *04:94:01,
*04:111
```
+++----- --+----- -+------+ -------- -------- -------  *04:19/04:70, *04:26 = *04:19/04:70, *04:42
+++----- --+----- +--+---- -------- -------- -------  *04:01:01:01, *04:17 = *04:01:10, *04:17 = *04:01:28, *04:17 =
```
*04:15:02, *04:17 = *04:17, *04:17 = *04:17, *04:87 = *04:17, *04:111
```
+++----- --+----+ -------- -------- -------- ----+--  *04:15:01, *04:66 = *04:15:01, *04:103
+++----- --+----+ -------- -------- ------+- -------  *04:15:01, *04:71 = *04:15:01, *04:79
+++----- --+----+ -------+ -------- -------- -------  *04:15:01, *04:26 = *04:15:01, *04:42
+++----- --+----+ --+----- -------- -------- -------  *04:01:01:01, *04:37 = *04:01:10, *04:37 = *04:01:28, *04:37 =
```
*04:15:01, *04:20 = *04:15:01, *04:37 = *04:20, *04:37 = *04:37,
*04:37 = *04:37, *04:87 = *04:37, *04:111
```
+++----- --+--+- -------- -------- -------- ------+  *04:14, *04:84 = *04:28, *04:84
+++----- --+--+- -------- -------- -------- -----+-  *04:14, *04:67 = *04:28, *04:67
+++----- --+--+- -------- -------- -------- ----+--  *04:14, *04:66 = *04:14, *04:103 = *04:28, *04:66 = *04:28, *04:103
+++----- --+--+- -------- -------- -------- ---+---  *04:14, *04:60 = *04:28, *04:60
+++----- --+--+- -------- -------- -------- --+----  *04:14, *04:81 = *04:28, *04:81
+++----- --+--+- -------- -------- -------- -+-----  *04:14, *04:69 = *04:28, *04:69
+++----- --+--+- -------- -------- -------- +------  *04:14, *04:54 = *04:28, *04:54
+++----- --+--+- -------- -------- -------+ -------  *04:14, *04:56 = *04:28, *04:56
+++----- --+--+- -------- -------- ------+- -------  *04:14, *04:71 = *04:14, *04:79 = *04:28, *04:71 = *04:28, *04:79
+++----- --+--+- -------- -------- -----+-- -------  *04:14, *04:83 = *04:28, *04:83
+++----- --+--+- -------- -------- ----+--- -------  *04:14, *04:73 = *04:28, *04:73
+++----- --+--+- -------- -------- ---+---- -------  *04:14, *04:57 = *04:28, *04:57
+++----- --+--+- -------- -------- --+----- -------  *04:14, *04:62 = *04:28, *04:62
+++----- --+--+- -------- -------- -+------ -------  *04:01:01:01, *04:68 = *04:01:10, *04:68 = *04:01:28, *04:68 =
```
*04:14, *04:61 = *04:28, *04:61 = *04:28, *04:68 = *04:61, *04:68 =
*04:68, *04:87
```
+++----- --+--+- -------- -------- +------- -------  *04:14, *04:65 = *04:28, *04:65
+++----- --+--+- -------- -------+ -------- -------  *04:14, *04:59Q = *04:28, *04:59Q
+++----- --+--+- -------- ------+- -------- -------  *04:14, *04:51 = *04:28, *04:51
+++----- --+--+- -------- ----+--- -------- -------  *04:14, *04:53 = *04:28, *04:53
+++----- --+--+- -------- ----+--- -------- -------  *04:14, *04:49 = *04:28, *04:49
+++----- --+--+- -------- ---+---- -------- -------  *04:14, *04:48 = *04:28, *04:48
+++----- --+--+- -------- --+----- -------- -------  *04:14, *04:46 = *04:28, *04:46
+++----- --+--+- -------- -+------ -------- -------  *04:14, *04:45 = *04:28, *04:45
+++----- --+--+- -------- +------- -------- -------  *04:14, *04:43 = *04:28, *04:43
+++----- --+--+- ------+ -------- -------- -------  *04:14, *04:26 = *04:14, *04:42 = *04:26, *04:28 = *04:28, *04:42
+++----- --+--+- ------+- -------- -------- -------  *04:14, *04:25 = *04:25, *04:28
```

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## Lot No.: 79N        Lot-specific information

```
+++----- --+---+- -----+-- ------- ------- ------   *04:14, *04:24 = *04:24, *04:28
+++----- --+---+- ----+--- ------- ------- ------   *04:14, *04:23 = *04:23, *04:28
+++----- --+---+- ---+---- ------- ------- ------   *04:14, *04:15:02 = *04:15:02, *04:28
+++----- --+---+- --+----- ------- ------- ------   *04:14, *04:20 = *04:20, *04:28
+++----- --+---+- -+------ ------- ------- ------   *04:14, *04:19/04:70 = *04:19/04:70, *04:28
+++----- --+---++ ------- ------- ------- ------    *04:14, *04:15:01 = *04:15:01, *04:28
+++----- --+--+-- ------- ------- ------- ----+--   *04:01:01:01, *04:16 = *04:01:10, *04:16 = *04:16, *04:18 = *04:16,
                                                    *04:66 = *04:16, *04:111 = *04:18, *04:66 = *04:18, *04:103
+++----- --+--+-- ------- ------- ------+- ------   *04:18, *04:71 = *04:18, *04:79
+++----- --+--+-- ------+ ------- ------- ------    *04:18, *04:26 = *04:18, *04:42
+++----- --+--++- ------- ------- ------- ------    *04:14, *04:18 = *04:18, *04:28
+++----- --+-+--- ------- ------- ------- ------+   *04:12, *04:84 = *04:52, *04:84
+++----- --+-+--- ------- ------- ------- -----+-   *04:12, *04:67 = *04:52, *04:67
+++----- --+-+--- ------- ------- ------- ----+--   *04:12, *04:66 = *04:12, *04:103 = *04:52, *04:66 = *04:52, *04:103
+++----- --+-+--- ------- ------- ------- ---+---   *04:12, *04:60 = *04:52, *04:60
+++----- --+-+--- ------- ------- ------- --+----   *04:12, *04:81 = *04:52, *04:81
+++----- --+-+--- ------- ------- ------- -+-----   *04:12, *04:69 = *04:52, *04:69
+++----- --+-+--- ------- ------- ------- +------   *04:12, *04:54 = *04:52, *04:54
+++----- --+-+--- ------- ------- ------+ ------    *04:12, *04:56 = *04:52, *04:56
+++----- --+-+--- ------- ------- ------+- ------   *04:12, *04:71 = *04:12, *04:79 = *04:52, *04:71 = *04:52, *04:79
+++----- --+-+--- ------- ------- -----+-- ------   *04:12, *04:83 = *04:52, *04:83
+++----- --+-+--- ------- ------- ----+--- ------   *04:12, *04:73 = *04:52, *04:73
+++----- --+-+--- ------- ------- ---+---- ------   *04:12, *04:57 = *04:52, *04:57
+++----- --+-+--- ------- ------- --+----- ------   *04:12, *04:62 = *04:52, *04:62
+++----- --+-+--- ------- ------- -+------ ------   *04:12, *04:61 = *04:52, *04:61
+++----- --+-+--- ------- ------- +------- ------   *04:12, *04:65 = *04:52, *04:65
+++----- --+-+--- ------- ------+ ------- ------    *04:12, *04:59Q = *04:52, *04:59Q
+++----- --+-+--- ------- ------+- ------- ------   *04:12, *04:51 = *04:51, *04:52
+++----- --+-+--- ------- -----+-- ------- ------   *04:12, *04:53 = *04:52, *04:53
+++----- --+-+--- ------- ----+--- ------- ------   *04:12, *04:49 = *04:49, *04:52
+++----- --+-+--- ------- ---+---- ------- ------   *04:12, *04:48 = *04:48, *04:52
+++----- --+-+--- ------- --+----- ------- ------   *04:12, *04:46 = *04:46, *04:52
+++----- --+-+--- ------- -+------ ------- ------   *04:12, *04:45 = *04:45, *04:52
+++----- --+-+--- ------- +------- ------- ------   *04:12, *04:43 = *04:43, *04:52
+++----- --+-+--- ------+ ------- ------- ------    *04:12, *04:26 = *04:12, *04:42 = *04:26, *04:52 = *04:42, *04:52
+++----- --+-+--- ------+- ------- ------- ------   *04:12, *04:25 = *04:25, *04:52
+++----- --+-+--- -----+-- ------- ------- ------   *04:12, *04:24 = *04:24, *04:52
+++----- --+-+--- ----+--- ------- ------- ------   *04:12, *04:23 = *04:23, *04:52
+++----- --+-+--- ---+---- ------- ------- ------   *04:12, *04:15:02 = *04:15:02, *04:52
+++----- --+-+--- --+----- ------- ------- ------   *04:12, *04:20 = *04:20, *04:52
+++----- --+-+--- -+------ ------- ------- ------   *04:12, *04:19/04:70 = *04:19/04:70, *04:52
+++----- --+-+--+ ------- ------- ------- ------    *04:12, *04:15:01 = *04:15:01, *04:52
+++----- --+-+-+- ------- ------- ------- ------    *04:12, *04:14 = *04:12, *04:28 = *04:14, *04:52 = *04:28, *04:52
+++----- --+-++-- ------- ------- ------- ------    *04:12, *04:18 = *04:18, *04:52
+++----- --++---- ------- ------- ------- ------+   *04:29, *04:84 = *04:33, *04:84
+++----- --++---- ------- ------- ------- -----+-   *04:29, *04:67 = *04:33, *04:67
+++----- --++---- ------- ------- ------- ----+--   *04:29, *04:66 = *04:29, *04:103 = *04:33, *04:66 = *04:33, *04:103
+++----- --++---- ------- ------- ------- ---+---   *04:29, *04:60 = *04:33, *04:60
+++----- --++---- ------- ------- ------- --+----   *04:29, *04:81 = *04:33, *04:81
+++----- --++---- ------- ------- ------- -+-----   *04:29, *04:69 = *04:33, *04:69
+++----- --++---- ------- ------- ------- +------   *04:29, *04:54 = *04:33, *04:54
+++----- --++---- ------- ------- ------+ ------    *04:29, *04:56 = *04:33, *04:56
+++----- --++---- ------- ------- ------+- ------   *04:29, *04:71 = *04:29, *04:79 = *04:33, *04:71 = *04:33, *04:79
+++----- --++---- ------- ------- -----+-- ------   *04:29, *04:83 = *04:33, *04:83
+++----- --++---- ------- ------- ----+--- ------   *04:29, *04:73 = *04:33, *04:73
+++----- --++---- ------- ------- ---+---- ------   *04:29, *04:57 = *04:33, *04:57
+++----- --++---- ------- ------- --+----- ------   *04:29, *04:62 = *04:33, *04:62
+++----- --++---- ------- ------- -+------ ------   *04:29, *04:61 = *04:33, *04:61
+++----- --++---- ------- ------- +------- ------   *04:29, *04:65 = *04:33, *04:65
+++----- --++---- ------- ------+ ------- ------    *04:29, *04:59Q = *04:33, *04:59Q
+++----- --++---- ------- ------+- ------- ------   *04:29, *04:51 = *04:33, *04:51
+++----- --++---- ------- -----+-- ------- ------   *04:29, *04:53 = *04:33, *04:53
+++----- --++---- ------- ----+--- ------- ------   *04:29, *04:49 = *04:33, *04:49
+++----- --++---- ------- ---+---- ------- ------   *04:29, *04:48 = *04:33, *04:48
+++----- --++---- ------- --+----- ------- ------   *04:29, *04:46 = *04:33, *04:46
+++----- --++---- ------- -+------ ------- ------   *04:29, *04:45 = *04:33, *04:45
+++----- --++---- ------- +------- ------- ------   *04:29, *04:43 = *04:33, *04:43
+++----- --++---- ------+ ------- ------- ------    *04:26, *04:29 = *04:26, *04:33 = *04:29, *04:42 = *04:33, *04:42
+++----- --++---- ------+- ------- ------- ------   *04:25, *04:29 = *04:25, *04:33
+++----- --++---- -----+-- ------- ------- ------   *04:24, *04:29 = *04:24, *04:33
+++----- --++---- ----+--- ------- ------- ------   *04:23, *04:29 = *04:23, *04:33
```

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CE

For In Vitro Diagnostic Use

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

Visit www.olerup-ssp.com for
**"Instructions for Use" (IFU)**

**Lot No.: 79N**                    **Lot-specific information**

```
+++----- --++---- ---+---- ------- ------- ------   *04:15:02, *04:29 = *04:15:02, *04:33
+++----- --++---- --+----- ------- ------- ------   *04:20, *04:29 = *04:20, *04:33
+++----- --++---- -+------ ------- ------- ------   *04:19/04:70, *04:29 = *04:19/04:70, *04:33
+++----- --++---+ ------- ------- ------- ------   *04:15:01, *04:29 = *04:15:01, *04:33
+++----- --++--+- ------- ------- ------- ------   *04:14, *04:29 = *04:14, *04:33 = *04:28, *04:29 = *04:28, *04:33
+++----- --++-+-- ------- ------- ------- ------   *04:18, *04:29 = *04:18, *04:33
+++----- --+++--- ------- ------- ------- ------   *04:12, *04:29 = *04:12, *04:33 = *04:29, *04:52
+++----- --+-++-- ------- ------- ------- ------   *04:01:10, *04:55 = *04:11, *04:52 = *04:33, *04:55 = *04:52, *04:55
+++----- --++---- ------- ------- ------- -----+   *04:10, *04:84 = *04:31, *04:84
+++----- --++---- ------- ------- ------- -----+-   *04:10, *04:67 = *04:31, *04:67
+++----- --++---- ------- ------- ------- ----+--   *04:10, *04:66 = *04:31, *04:66 = *04:31, *04:103
+++----- --++---- ------- ------- ------- ---+---   *04:10, *04:60 = *04:31, *04:60
+++----- --++---- ------- ------- ------- --+----   *04:10, *04:81 = *04:31, *04:81
+++----- --++---- ------- ------- ------- -+-----   *04:10, *04:69 = *04:31, *04:69
+++----- --++---- ------- ------- ------- +------   *04:10, *04:54 = *04:31, *04:54
+++----- --++---- ------- ------- ------+ ------   *04:10, *04:56 = *04:31, *04:56
+++----- --++---- ------- ------- ------+- ------   *04:10, *04:79 = *04:31, *04:71 = *04:31, *04:79
+++----- --++---- ------- ------- -----+-- ------   *04:10, *04:83 = *04:31, *04:83
+++----- --++---- ------- ------- ----+--- ------   *04:10, *04:73 = *04:31, *04:73
+++----- --++---- ------- ------- ---+---- ------   *04:10, *04:57 = *04:31, *04:57
+++----- --++---- ------- ------- --+----- ------   *04:10, *04:62 = *04:31, *04:62
+++----- --++---- ------- ------- -+------ ------   *04:10, *04:61 = *04:31, *04:61
+++----- --++---- ------- ------- +------- ------   *04:10, *04:65 = *04:31, *04:65
+++----- --++---- ------- ------+ ------- ------   *04:10, *04:59Q = *04:31, *04:59Q
+++----- --++---- ------- ------+- ------- ------   *04:10, *04:51 = *04:31, *04:51
+++----- --++---- ------- -----+-- ------- ------   *04:10, *04:53 = *04:31, *04:53
+++----- --++---- ------- ----+--- ------- ------   *04:10, *04:49 = *04:31, *04:49
+++----- --++---- ------- ---+---- ------- ------   *04:10, *04:48 = *04:31, *04:48
+++----- --++---- ------- --+----- ------- ------   *04:10, *04:46 = *04:31, *04:46
+++----- --++---- ------- -+------ ------- ------   *04:10, *04:45 = *04:31, *04:45
+++----- --++---- ------- +------- ------- ------   *04:10, *04:43 = *04:31, *04:43
+++----- --++---- ------+ ------- ------- ------   *04:10, *04:26 = *04:26, *04:31 = *04:31, *04:42
+++----- --++---- ------+- ------- ------- ------   *04:10, *04:25 = *04:25, *04:31
+++----- --++---- -----+-- ------- ------- ------   *04:10, *04:24 = *04:24, *04:31
+++----- --++---- ----+--- ------- ------- ------   *04:10, *04:23 = *04:23, *04:31
+++----- --++---- ---+---- ------- ------- ------   *04:10, *04:15:02 = *04:15:02, *04:31
+++----- --++---- --+----- ------- ------- ------   *04:10, *04:20 = *04:20, *04:31
+++----- --++---- -+------ ------- ------- ------   *04:10, *04:19/04:70 = *04:19/04:70, *04:31
+++----- --++---+ ------- ------- ------- ------   *04:10, *04:15:01 = *04:15:01, *04:31
+++----- --++--+- ------- ------- ------- ------   *04:10, *04:14 = *04:10, *04:28 = *04:14, *04:31 = *04:28, *04:31
+++----- --++-+-- ------- ------- ------- ------   *04:10, *04:18 = *04:18, *04:31
+++----- --++-+-- ------- ------- ------- ------   *04:10, *04:12 = *04:10, *04:52 = *04:12, *04:31 = *04:31, *04:52
+++----- -+++---- ------- ------- ------- ------   *04:01:01:01, *04:11 = *04:01:01:01, *04:36 = *04:01:10, *04:36 =
                                                    *04:10, *04:29 = *04:10, *04:33 = *04:11, *04:29 = *04:11, *04:31 =
                                                    *04:11, *04:87 = *04:11, *04:111 = *04:29, *04:31 = *04:29, *04:36 =
                                                    *04:31, *04:33 = *04:31, *04:36 = *04:33, *04:36 = *04:36, *04:87 =
                                                    *04:36, *04:111
+++----- +-+----- ------- ------- ------- ----+--   *04:09N, *04:66 = *04:09N, *04:103
+++----- +-+----- ------- ------- ------+- ------   *04:09N, *04:71 = *04:09N, *04:79
+++----- +-+----- ------+ ------- ------- ------   *04:01:01:01, *04:30 = *04:01:10, *04:30 = *04:01:28, *04:30 =
                                                    *04:09N, *04:26 = *04:09N, *04:30 = *04:09N, *04:42 = *04:26,
                                                    *04:30 = *04:30, *04:30 = *04:30, *04:42 = *04:30, *04:87 = *04:30,
                                                    *04:111
+++----- +-+----- --+----- ------- ------- ------   *04:01:01:01, *04:35 = *04:01:10, *04:35 = *04:01:28, *04:35 =
                                                    *04:09N, *04:20 = *04:09N, *04:35 = *04:20, *04:35 = *04:35, *04:35
                                                    = *04:35, *04:87 = *04:35, *04:111
+++----- +-+--+- ------- ------- ------- ------   *04:09N, *04:14 = *04:09N, *04:28
+++----- +-+-+-- ------- ------- ------- ------   *04:09N, *04:12 = *04:09N, *04:52
+++----- +-++---- ------- ------- ------- ------   *04:09N, *04:29 = *04:09N, *04:33
+++----- +++----- ------- ------- ------- ------   *04:09N, *04:10 = *04:09N, *04:31
+++----+ --+----- ------- ------- ------- ----+--   *04:08, *04:66 = *04:08, *04:103
+++----+ --+----- ------- ------- ------+- ------   *04:08, *04:71 = *04:08, *04:79
+++----+ --+----- ------+ ------- ------- ------   *04:08, *04:26 = *04:08, *04:42
+++----+ --+--+- ------- ------- ------- ------   *04:08, *04:14 = *04:08, *04:28
+++----+ --+-+-- ------- ------- ------- ------   *04:08, *04:12 = *04:08, *04:52
+++----+ --++---- ------- ------- ------- ------   *04:08, *04:29 = *04:08, *04:33
+++----+ -++----- ------- ------- ------- ------   *04:08, *04:10 = *04:08, *04:31
+++---+- --+----- ------- ------- ------- -----+   *04:07, *04:84 = *04:27, *04:84 = *04:32, *04:84
+++---+- --+----- ------- ------- ------- -----+-   *04:07, *04:67 = *04:27, *04:67 = *04:32, *04:67
+++---+- --+----- ------- ------- ------- ----+--   *04:07, *04:66 = *04:27, *04:66 = *04:32, *04:66 = *04:32, *04:103
+++---+- --+----- ------- ------- ------- ---+---   *04:07, *04:60 = *04:27, *04:60 = *04:32, *04:60
```

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For In Vitro Diagnostic Use

**101.612-12 – including *Taq* pol.**                     Visit www.olerup-ssp.com for
**101.612-12u– without *Taq* pol.**                     **"Instructions for Use" (IFU)**

Lot No.: **79N**                     Lot-specific information

| | |
|---|---|
| +++---+- --+----- ------- ------- ------- --+---- | *04:07, *04:81 = *04:27, *04:81 = *04:32, *04:81 |
| +++---+- --+----- ------- ------- ------- -+----- | *04:07, *04:69 = *04:27, *04:69 = *04:32, *04:69 |
| +++---+- --+----- ------- ------- ------- +------ | *04:07, *04:54 = *04:27, *04:54 = *04:32, *04:54 |
| +++---+- --+----- ------- ------- -------+ ------- | *04:07, *04:56 = *04:27, *04:56 = *04:32, *04:56 |
| +++---+- --+----- ------- ------- ------+- ------- | *04:07, *04:71 = *04:07, *04:79 = *04:27, *04:71 = *04:27, *04:79 = *04:32, *04:71 = *04:32, *04:79 |
| +++---+- --+----- ------- ------- -----+-- ------- | *04:07, *04:83 = *04:27, *04:83 = *04:32, *04:83 |
| +++---+- --+----- ------- ------- ----+--- ------- | *04:07, *04:73 = *04:27, *04:73 = *04:32, *04:73 |
| +++---+- --+----- ------- ------- ---+---- ------- | *04:07, *04:57 = *04:27, *04:57 = *04:32, *04:57 |
| +++---+- --+----- ------- ------- --+----- ------- | *04:07, *04:62 = *04:27, *04:62 = *04:32, *04:62 |
| +++---+- --+----- ------- ------- -+------ ------- | *04:07, *04:61 = *04:27, *04:61 = *04:32, *04:61 |
| +++---+- --+----- ------- ------- +------- ------- | *04:07, *04:65 = *04:27, *04:65 = *04:32, *04:65 |
| +++---+- --+----- ------- -------+ -------- ------- | *04:01:01:01, *04:77 = *04:01:10, *04:77 = *04:01:28, *04:77 = *04:07, *04:59Q = *04:07, *04:77 = *04:27, *04:59Q = *04:27, *04:77 = *04:32, *04:59Q = *04:32, *04:77 = *04:59Q, *04:77 = *04:77, *04:77 = *04:77, *04:87 = *04:77, *04:111 |
| +++---+- --+----- ------- ------+- -------- ------- | *04:07, *04:51 = *04:27, *04:51 = *04:32, *04:51 |
| +++---+- --+----- ------- -----+-- -------- ------- | *04:07, *04:53 = *04:27, *04:53 = *04:32, *04:53 |
| +++---+- --+----- ------- ----+--- -------- ------- | *04:07, *04:49 = *04:27, *04:49 = *04:32, *04:49 |
| +++---+- --+----- ------- ---+---- -------- ------- | *04:07, *04:48 = *04:27, *04:48 = *04:32, *04:48 |
| +++---+- --+----- ------- --+----- -------- ------- | *04:07, *04:46 = *04:27, *04:46 = *04:32, *04:46 |
| +++---+- --+----- ------- -+------ -------- ------- | *04:07, *04:45 = *04:27, *04:45 = *04:32, *04:45 |
| +++---+- --+----- ------- +------- -------- ------- | *04:07, *04:43 = *04:27, *04:43 = *04:32, *04:43 |
| +++---+- --+----- ------+ -------- -------- ------- | *04:07, *04:26 = *04:26, *04:27 = *04:26, *04:32 = *04:32, *04:42 |
| +++---+- --+----- -----+- -------- -------- ------- | *04:07, *04:25 = *04:25, *04:27 = *04:25, *04:32 |
| +++---+- --+----- ----+-- -------- -------- ------- | *04:07, *04:24 = *04:24, *04:27 = *04:24, *04:32 |
| +++---+- --+----- ---+--- -------- -------- ------- | *04:07, *04:23 = *04:23, *04:27 = *04:23, *04:32 |
| +++---+- --+----- --+---- -------- -------- ------- | *04:07, *04:15:02 = *04:15:02, *04:27 = *04:15:02, *04:32 |
| +++---+- --+----- -+----- -------- -------- ------- | *04:07, *04:20 = *04:20, *04:27 = *04:20, *04:32 |
| +++---+- --+----- +------ -------- -------- ------- | *04:07, *04:19/04:70 = *04:19/04:70, *04:27 = *04:19/04:70, *04:32 |
| +++---+- --+----+ -------- -------- -------- ------- | *04:07, *04:15:01 = *04:15:01, *04:27 = *04:15:01, *04:32 |
| +++---+- --+---+- -------- -------- -------- ------- | *04:07, *04:14 = *04:07, *04:28 = *04:14, *04:27 = *04:14, *04:32 = *04:27, *04:28 = *04:28, *04:32 |
| +++---+- --+--+-- -------- -------- -------- ------- | *04:07, *04:18 = *04:18, *04:27 = *04:18, *04:32 |
| +++---+- --+-+--- -------- -------- -------- ------- | *04:07, *04:12 = *04:07, *04:52 = *04:12, *04:27 = *04:12, *04:32 = *04:32, *04:52 |
| +++---+- --++---- -------- -------- -------- ------- | *04:07, *04:29 = *04:07, *04:33 = *04:27, *04:29 = *04:29, *04:32 = *04:32, *04:33 |
| +++---+- -+++---- -------- -------- -------- ------- | *04:07, *04:10 = *04:07, *04:31 = *04:10, *04:27 = *04:10, *04:32 = *04:27, *04:31 = *04:31, *04:32 |
| +++---+- +-+----- -------- -------- -------- ------- | *04:07, *04:09N = *04:09N, *04:27 = *04:09N, *04:32 |
| +++---++ --+----- -------- -------- -------- ------- | *04:07, *04:08 = *04:08, *04:27 = *04:08, *04:32 |
| +++--+-- --+----- -------- -------- -------- ----+-- | *04:05, *04:66 = *04:05, *04:103 |
| +++--+-- --+----- -------- -------- ------+- ------- | *04:05, *04:71 = *04:05, *04:79 |
| +++--+-- --+----- -------+ -------- -------- ------- | *04:05, *04:26 = *04:05, *04:42 |
| +++--+-- --+---+- -------- -------- -------- ------- | *04:05, *04:14 = *04:05, *04:28 |
| +++--+-- --+-+--- -------- -------- -------- ------- | *04:05, *04:12 = *04:05, *04:52 |
| +++--+-- --++---- -------- -------- -------- ------- | *04:05, *04:29 = *04:05, *04:33 |
| +++--+-- -+++---- -------- -------- -------- ------- | *04:05, *04:10 = *04:05, *04:31 |
| +++--+++ --+----- -------- -------- -------- ------- | *04:05, *04:07 = *04:05, *04:27 = *04:05, *04:32 |
| +++-+--- --+----- -------- -------- -------- ----+-- | *04:04:01, *04:66 = *04:04:01, *04:103 |
| +++-+--- --+----- -------- -------- ------+- ------- | *04:04:01, *04:71 = *04:04:01, *04:79 |
| +++-+--- --+----- -------+ -------- -------- ------- | *04:04:01, *04:26 = *04:04:01, *04:42 |
| +++-+--- --+-+--- -------- -------- -------- ------- | *04:04:01, *04:12 = *04:04:01, *04:52 |
| +++-+--- --++---- -------- -------- -------- ------- | *04:04:01, *04:29 = *04:04:01, *04:33 |
| +++-+--- -+++---- -------- -------- -------- ------- | *04:04:01, *04:10 = *04:04:01, *04:31 |
| +++-+--+ --+----- -------- -------- -------- ------- | *04:01:01:01, *04:34 = *04:01:10, *04:34 = *04:01:28, *04:34 = *04:04:01, *04:08 = *04:08, *04:34 = *04:34, *04:87 |
| +++-+-+- --+----- -------- -------- -------- ------- | *04:04:01, *04:07 = *04:04:01, *04:27 = *04:04:01, *04:32 |
| ++++---- --+----- -------- -------- -------- ------+ | *04:03, *04:84 = *04:84, *04:107 |
| ++++---- --+----- -------- -------- -------- -----+- | *04:03, *04:67 = *04:67, *04:107 |
| ++++---- --+----- -------- -------- -------- ----+-- | *04:03, *04:66 = *04:66, *04:107 |
| ++++---- --+----- -------- -------- -------- ---+--- | *04:03, *04:60 = *04:60, *04:107 |
| ++++---- --+----- -------- -------- -------- --+---- | *04:03, *04:81 = *04:81, *04:107 |
| ++++---- --+----- -------- -------- -------- -+----- | *04:03, *04:69 = *04:69, *04:107 |
| ++++---- --+----- -------- -------- -------- +------ | *04:03, *04:54 = *04:54, *04:107 |
| ++++---- --+----- -------- -------- -------+ ------- | *04:03, *04:56 = *04:56, *04:107 |
| ++++---- --+----- -------- -------- ------+- ------- | *04:03, *04:79 = *04:79, *04:107 |
| ++++---- --+----- -------- -------- -----+-- ------- | *04:03, *04:83 = *04:83, *04:107 |
| ++++---- --+----- -------- -------- ----+--- ------- | *04:03, *04:73 = *04:73, *04:107 |
| ++++---- --+----- -------- -------- ---+---- ------- | *04:03, *04:57 = *04:57, *04:107 |

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October 2013                     For In Vitro Diagnostic Use
Rev. No.: 01

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

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**"Instructions for Use" (IFU)**

Lot No.: **79N**                    Lot-specific information

```
++++---- --+----- ------- ------- --+----- -------   *04:03, *04:62 = *04:62, *04:107
++++---- --+----- ------- ------- -+----- -------    *04:03, *04:61 = *04:61, *04:107
++++---- --+----- ------- ------- +------- -------    *04:03, *04:65 = *04:65, *04:107
++++---- --+----- ------- ------+ ------- -------     *04:03, *04:59Q = *04:59Q, *04:107
++++---- --+----- ------- -----+- ------- -------     *04:03, *04:51 = *04:51, *04:107
++++---- --+----- ------- -----+-- ------- -------    *04:03, *04:53 = *04:53, *04:107
++++---- --+----- ------- ----+--- ------- -------    *04:03, *04:49 = *04:49, *04:107
++++---- --+----- ------- ---+---- ------- -------    *04:03, *04:48 = *04:48, *04:107
++++---- --+----- ------- --+----- ------- -------    *04:03, *04:46 = *04:46, *04:107
++++---- --+----- ------- -+------ ------- -------    *04:03, *04:45 = *04:45, *04:107
++++---- --+----- ------- +------- ------- -------    *04:03, *04:43 = *04:43, *04:107
++++---- --+----- ------+ ------- ------- -------     *04:03, *04:26 = *04:26, *04:107
++++---- --+----- -----+- ------- ------- -------     *04:03, *04:25 = *04:25, *04:107
++++---- --+----- ----+-- ------- ------- -------     *04:03, *04:24 = *04:24, *04:107
++++---- --+----- ---+--- ------- ------- -------     *04:03, *04:23 = *04:23, *04:107
++++---- --+----- ---+---- ------- ------- -------    *04:03, *04:15:02 = *04:15:02, *04:107
++++---- --+----- --+----- ------- ------- -------    *04:03, *04:20 = *04:20, *04:107
++++---- --+----- -+------ ------- ------- -------    *04:03, *04:19/04:70 = *04:19/04:70, *04:107
++++---- --+----- +------- ------- ------- -------    *04:01:01:01, *04:80 = *04:01:10, *04:80 = *04:80, *04:111
++++---- --+----+ ------- ------- ------- -------     *04:03, *04:15:01 = *04:15:01, *04:107
++++---- --+---+- ------- ------- ------- -------     *04:03, *04:14 = *04:03, *04:28 = *04:14, *04:107 = *04:28, *04:107
++++---- --+--+-- ------- ------- ------- -------     *04:03, *04:18 = *04:18, *04:107
++++---- --+-+--- ------- ------- ------- -------     *04:03, *04:12 = *04:03, *04:52 = *04:12, *04:107
++++---- --++---- ------- ------- ------- -------     *04:03, *04:29 = *04:03, *04:33 = *04:29, *04:107
++++---- -++----- ------- ------- ------- -------     *04:03, *04:31 = *04:31, *04:107
++++---- +-+----- ------- ------- ------- -------     *04:03, *04:09N = *04:09N, *04:107
++++---+ --+----- ------- ------- ------- -------     *04:03, *04:08 = *04:08, *04:107
+++++--+- --+----- ------- ------- ------- -------    *04:03, *04:32 = *04:32, *04:107
+++++-+-- --+----- ------- ------- ------- -------    *04:03, *04:05 = *04:05, *04:107
+++++--- --+----- ------- ------- ------- -------     *04:01:01:01, *04:06 = *04:01:10, *04:06 = *04:03, *04:04:01 =
                                                        *04:04:01, *04:107
-++-+--- --+--+-- ------- ------- ++----- -------     *04:04:01, *04:58 = *04:13, *04:58 = *04:58, *04:58 = *04:58, *04:111
-++-+--- --+--++- ------- ------- -+----- -------     *04:13, *04:14 = *04:13, *04:68
+-+----- -+++-+-- ------- ------- ------- ----+--     *04:11, *04:16 = *04:16, *04:36
+-++---- -+++---- +------ ------- ------- -------     *04:11, *04:80 = *04:36, *04:80
+-+++--- -+++---- ------- ------- ------- -------     *04:06, *04:11 = *04:06, *04:36
+++----- --+----- ------- ------- ----++-- ----+--   *04:66, *04:74 = *04:74, *04:103
+++----- --+----- ------- ------- ----+++- -------    *04:71, *04:74 = *04:74, *04:79
+++----- --+----- ------- ------- ---++--- ----+--   *04:63, *04:66 = *04:63, *04:103
+++----- --+----- ------- ------- ---++-+- -------    *04:63, *04:71 = *04:63, *04:79
+++----- --+----- ------- ------- ---+++-- -------    *04:57, *04:74 = *04:63, *04:74 = *04:63, *04:83
+++----- --+----- ------- ------+ ------+- ----+--   *04:66, *04:95N = *04:95N, *04:103
+++----- --+----- ------+ ------- ----++-- -------    *04:26, *04:74 = *04:42, *04:74
+++----- --+----- ------+ ------- ---++--- -------    *04:26, *04:63 = *04:42, *04:63
+++----- --+----- ------+ ------+- ------+- -------   *04:26, *04:95N = *04:42, *04:95N
+++----- --+----- -+------ +------ ------- ----+--    *04:66, *04:94:01 = *04:94:01, *04:103
+++----- --+----- -+------ +------ ------+- -------   *04:71, *04:94:01 = *04:79, *04:94:01
+++----- --+----- -+------ +------ ------- -------    *04:26, *04:94:01 = *04:42, *04:94:01
+++----- --+----- +--+---- ------- ------- ----+--    *04:17, *04:66 = *04:17, *04:103
+++----- --+----- +--+---- ------- ------+- -------   *04:17, *04:71 = *04:17, *04:79
+++----- --+----- +--+---+ ------- ------- -------    *04:17, *04:26 = *04:17, *04:42
+++----- --+----+ --+----- ------- ------- ----+--    *04:37, *04:66 = *04:37, *04:103
+++----- --+----+ --+----- ------+- -------           *04:37, *04:71 = *04:37, *04:79
+++----- --+----+ --+----+ ------- ------- -------    *04:26, *04:37 = *04:37, *04:42
+++----- --+---+- ------- ------- ----++-- -------    *04:14, *04:74 = *04:28, *04:74
+++----- --+---+- ------- ------- ---++--- -------    *04:14, *04:63 = *04:28, *04:63
+++----- --+---+- ------- ------- -+----+- ----+--   *04:66, *04:68 = *04:68, *04:103
+++----- --+---+- ------- ------- -+----+- -------    *04:68, *04:71 = *04:68, *04:79
+++----- --+---+- ------- ------+ ------+- -------    *04:14, *04:95N = *04:28, *04:95N
+++----- --+---+- -------+ ------- -+----+- -------   *04:26, *04:68 = *04:42, *04:68
+++----- --+---+- -+------ +------ ------- -------    *04:14, *04:94:01 = *04:28, *04:94:01
+++----- --+---+- +--+---- ------- ------- -------    *04:14, *04:17 = *04:17, *04:28
+++----- --+---++ --+----- ------- ------- -------    *04:14, *04:37 = *04:28, *04:37
+++----- --+--++- ------- ------- ------- ----+--    *04:14, *04:16 = *04:16, *04:28
+++----- --+-+--- ------- ------- ----++-- -------    *04:12, *04:74 = *04:52, *04:74
+++----- --+-+--- ------- ------- ---++--- -------    *04:12, *04:63 = *04:52, *04:63
+++----- --+-+--- ------- ------+ ------+- -------    *04:12, *04:95N = *04:52, *04:95N
+++----- --+-+--- -+------ +------ ------- -------    *04:12, *04:94:01 = *04:52, *04:94:01
+++----- --+-+--- +--+---- ------- ------- -------    *04:12, *04:17 = *04:17, *04:52
+++----- --+-+--+ --+----- ------- ------- -------    *04:12, *04:37 = *04:37, *04:52
+++----- --+-+-+- ------- ------- -+----- -------     *04:12, *04:68 = *04:52, *04:68
```

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**101.612-12u– without *Taq* pol.**　　　　　　　**"Instructions for Use" (IFU)**

**Lot No.: 79N**　　　　　　　**Lot-specific information**

```
+++----- --+-++-- ------- ------- -------- ----+--   *04:12, *04:16 = *04:16, *04:52
+++----- --+++--- ------- ------- ----++-- -------   *04:29, *04:74 = *04:33, *04:74
+++----- --+++--- ------- ------- ---++--- -------   *04:29, *04:63 = *04:33, *04:63
+++----- --+++--- ------- ------+- ------+- -------   *04:29, *04:95N = *04:33, *04:95N
+++----- --+++--- -+----- +------- -------- -------   *04:29, *04:94:01 = *04:33, *04:94:01
+++----- --+++--- +--+---- -------- -------- -------   *04:17, *04:29 = *04:17, *04:33
+++----- --+++--+ --+----- -------- -------- -------   *04:29, *04:37 = *04:33, *04:37
+++----- --++-+-- ------- ------- -+------ -------   *04:29, *04:68 = *04:33, *04:68
+++----- --++-+-- ------- ------- -------- ----+--   *04:16, *04:29 = *04:16, *04:33
+++----- -++++--- ------- ------- ----++-- -------   *04:10, *04:74 = *04:31, *04:74
+++----- -++++--- ------- ------- ---++--- -------   *04:10, *04:63 = *04:31, *04:63
+++----- -++++--- ------- ------+- ------+- -------   *04:10, *04:95N = *04:31, *04:95N
+++----- -++++--- -+----- +------- -------- -------   *04:10, *04:94:01 = *04:31, *04:94:01
+++----- -++++--- +--+---- -------- -------- -------   *04:10, *04:17 = *04:17, *04:31
+++----- -++++--+ --+----- -------- -------- -------   *04:10, *04:37 = *04:31, *04:37
+++----- -++-+--- ------- ------- -+------ -------   *04:10, *04:68 = *04:31, *04:68
+++----- -++++--- ------- ------- -------- ------+   *04:11, *04:84 = *04:36, *04:84
+++----- -++++--- ------- ------- -------- -----+-   *04:11, *04:67 = *04:36, *04:67
+++----- -++++--- ------- ------- -------- ----+--   *04:11, *04:66 = *04:36, *04:66
+++----- -++++--- ------- ------- -------- ---+---   *04:11, *04:60 = *04:36, *04:60
+++----- -++++--- ------- ------- -------- --+----   *04:11, *04:81 = *04:36, *04:81
+++----- -++++--- ------- ------- -------- -+-----   *04:11, *04:69 = *04:36, *04:69
+++----- -++++--- ------- ------- -------- +------   *04:11, *04:54 = *04:36, *04:54
+++----- -++++--- ------- ------- -------+ -------   *04:11, *04:56 = *04:36, *04:56
+++----- -++++--- ------- ------- ------+- -------   *04:11, *04:79 = *04:36, *04:79
+++----- -++++--- ------- ------- -----+-- -------   *04:11, *04:83 = *04:36, *04:83
+++----- -++++--- ------- ------- ----+--- -------   *04:11, *04:73 = *04:36, *04:73
+++----- -++++--- ------- ------- ---+---- -------   *04:11, *04:57 = *04:36, *04:57
+++----- -++++--- ------- ------- --+----- -------   *04:11, *04:62 = *04:36, *04:62
+++----- -++++--- ------- ------- -+------ -------   *04:11, *04:61 = *04:36, *04:61
+++----- -++++--- ------- ------- +------- -------   *04:11, *04:65 = *04:36, *04:65
+++----- -++++--- ------- ------+ -------- -------   *04:11, *04:59Q = *04:36, *04:59Q
+++----- -++++--- ------- ------+- -------- -------   *04:11, *04:51 = *04:36, *04:51
+++----- -++++--- ------- -----+-- -------- -------   *04:11, *04:53 = *04:36, *04:53
+++----- -++++--- ------- ----+--- -------- -------   *04:11, *04:49 = *04:36, *04:49
+++----- -++++--- ------- ---+---- -------- -------   *04:11, *04:48 = *04:36, *04:48
+++----- -++++--- ------- --+----- -------- -------   *04:11, *04:46 = *04:36, *04:46
+++----- -++++--- ------- -+------ -------- -------   *04:11, *04:45 = *04:36, *04:45
+++----- -++++--- ------- +------- -------- -------   *04:11, *04:43 = *04:36, *04:43
+++----- -++++--- ------+ -------- -------- -------   *04:11, *04:26 = *04:26, *04:36
+++----- -++++--- ------+- -------- -------- -------   *04:11, *04:25 = *04:25, *04:36
+++----- -++++--- -----+-- -------- -------- -------   *04:11, *04:24 = *04:24, *04:36
+++----- -++++--- ----+--- -------- -------- -------   *04:11, *04:23 = *04:23, *04:36
+++----- -++++--- ---+---- -------- -------- -------   *04:11, *04:15:02 = *04:15:02, *04:36
+++----- -++++--- --+----- -------- -------- -------   *04:11, *04:20 = *04:20, *04:36
+++----- -++++--- -+------ -------- -------- -------   *04:11, *04:19/04:70 = *04:19/04:70, *04:36
+++----- -++++--+ -------- -------- -------- -------   *04:11, *04:15:01 = *04:15:01, *04:36
+++----- -++++--+- -------- -------- -------- -------   *04:11, *04:14 = *04:11, *04:28 = *04:14, *04:36 = *04:28, *04:36
+++----- -++++-+- -------- -------- -------- -------   *04:11, *04:18 = *04:18, *04:36
+++----- -++++--- -------- -------- -------- -------   *04:01:01:01, *04:55 = *04:11, *04:12 = *04:12, *04:36 = *04:12,
                                                      *04:55 = *04:29, *04:55 = *04:31, *04:55 = *04:36, *04:52 = *04:55,
                                                      *04:87 = *04:55, *04:111
+++----- +-+---+- -------+ -------- -------- ----+--   *04:30, *04:66 = *04:30, *04:103
+++----- +-+---+- -------+ -------- ------+- -------   *04:30, *04:71 = *04:30, *04:79
+++----- +-+---+- --+----- -------- -------- ----+--   *04:35, *04:66 = *04:35, *04:103
+++----- +-+---+- --+----- -------- ------+- -------   *04:35, *04:71 = *04:35, *04:79
+++----- +-+----+ --+----- -------- -------- -------   *04:20, *04:30 = *04:26, *04:35 = *04:30, *04:35 = *04:35, *04:42
+++----- +-+---+ --+----- -------- -------- -------   *04:09N, *04:37 = *04:15:01, *04:35 = *04:35, *04:37
+++----- +-+---+- -------+ -------- -------- -------   *04:14, *04:30 = *04:28, *04:30
+++----- +-+---+- --+----- -------- -------- -------   *04:14, *04:35 = *04:28, *04:35
+++----- +-+-+--- -------+ -------- -------- -------   *04:12, *04:30 = *04:30, *04:52
+++----- +-+-+--- --+----- -------- -------- -------   *04:12, *04:35 = *04:35, *04:52
+++----- +-++---- -------+ -------- -------- -------   *04:29, *04:30 = *04:30, *04:33
+++----- +-++---- --+----- -------- -------- -------   *04:29, *04:35 = *04:33, *04:35
+++----- +++++--- -------+ -------- -------- -------   *04:10, *04:30 = *04:30, *04:31
+++----- +++++--- --+----- -------- -------- -------   *04:10, *04:35 = *04:31, *04:35
+++----- +++++--- -------- -------- -------- -------   *04:09N, *04:11 = *04:09N, *04:36
+++----+ -++++--- -------- -------- -------- -------   *04:08, *04:11 = *04:08, *04:36
+++---+- --+-+--- ------- ------- ----++-- -------   *04:07, *04:74 = *04:27, *04:74 = *04:32, *04:74
+++---+- --+-+--- ------- ------- ---++--- -------   *04:07, *04:63 = *04:27, *04:63 = *04:32, *04:63
+++---+- --+-+--- ------- -------+ -------- ----+--   *04:66, *04:77 = *04:77, *04:103
```

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Lot No.: **79N**                      Lot-specific information

```
+++---+- --+----- ------- ------+ ------+- ------   *04:71, *04:77 = *04:77, *04:79
+++---+- --+----- ------- ------+- ------+- -------  *04:07, *04:95N = *04:27, *04:95N = *04:32, *04:95N
+++---+- --+----- ------+ ------+ -------- -------   *04:26, *04:77 = *04:42, *04:77
+++---+- --+----- -+----- +------ -------- -------   *04:07, *04:94:01 = *04:27, *04:94:01 = *04:32, *04:94:01
+++---+- --+----- +--+---- ------- -------- -------  *04:07, *04:17 = *04:17, *04:27 = *04:17, *04:32
+++---+- --+---+ --+----- ------- -------- -------   *04:07, *04:37 = *04:27, *04:37 = *04:32, *04:37
+++---+- --+---+- ------- -------- -+----- -------   *04:07, *04:68 = *04:27, *04:68 = *04:32, *04:68
+++---+- --+----- ------- -------+ -------- -------  *04:14, *04:77 = *04:28, *04:77
+++---+- --+-+--- ------- -------+ -------- -------  *04:12, *04:77 = *04:52, *04:77
+++---+- --++---- ------- -------+ -------- -------  *04:29, *04:77 = *04:33, *04:77
+++---+- -++----- ------- -------+ -------- -------  *04:10, *04:77 = *04:31, *04:77
+++---+- -+++---- ------- -------- -------- -------  *04:07, *04:11 = *04:07, *04:36 = *04:11, *04:32 = *04:27, *04:36 =
                                                     *04:32, *04:36
+++---+- +-+----- ------+ -------- -------- -------  *04:07, *04:30 = *04:27, *04:30 = *04:30, *04:32
+++---+- +-+----- --+---- -------- -------- -------  *04:07, *04:35 = *04:27, *04:35 = *04:32, *04:35
+++--+-- -+++---- ------- -------- -------- -------  *04:05, *04:11 = *04:05, *04:36
+++-+--- --+--+-- ------- -------- -+----- -------   *04:01:01:01, *04:13 = *04:01:10, *04:13 = *04:01:28, *04:13 =
                                                     *04:13, *04:18 = *04:13, *04:61 = *04:13, *04:87
+++-+--- -+++---- ------- -------- -------- -------  *04:04:01, *04:11 = *04:04:01, *04:36
+++-+--+ --+----- ------- -------- -------- ----+--  *04:34, *04:66 = *04:34, *04:103
+++-+--+ --+----- ------- -------- ------+- ------   *04:34, *04:71 = *04:34, *04:79
+++-+--+ --+----- ------+ -------- -------- -------  *04:26, *04:34 = *04:34, *04:42
+++-+--+ --+-+--- ------- -------- -------- -------  *04:12, *04:34 = *04:34, *04:52
+++-+--+ --++---- ------- -------- -------- -------  *04:29, *04:34 = *04:33, *04:34
+++-+--+ -++----- ------- -------- -------- -------  *04:10, *04:34 = *04:31, *04:34
+++-+-++ --+----- ------- -------- -------- -------  *04:07, *04:34 = *04:27, *04:34 = *04:32, *04:34
+++++--- --+----- ------- -------- ----++-- -------  *04:03, *04:74 = *04:74, *04:107
+++++--- --+----- ------- -------- ---++--- -------  *04:03, *04:63 = *04:63, *04:107
+++++--- --+----- ------- ------+- -------+- ------  *04:03, *04:95N = *04:95N, *04:107
+++++--- --+----- -+----- +------ -------- -------   *04:03, *04:94:01 = *04:94:01, *04:107
+++++--- --+----- +--+---- ------- -------- -------  *04:03, *04:17 = *04:15:02, *04:80 = *04:17, *04:80 = *04:17, *04:107
+++++--- --+---+ --+----- ------- -------- -------   *04:03, *04:37 = *04:37, *04:107
+++++--- --+---+- ------- -------- -+----- -------   *04:03, *04:68 = *04:68, *04:107
+++++--- --+-+--- +------ -------- -------- -------  *04:14, *04:80 = *04:28, *04:80
+++++--- --+-+--- +------ -------- -------- -------  *04:12, *04:80 = *04:52, *04:80
+++++--- --++---- +------ -------- -------- -------  *04:29, *04:80 = *04:33, *04:80
+++++--- +-+----- ------+ -------- -------- -------  *04:03, *04:30 = *04:30, *04:107
+++++--- +-+----- --+---- -------- -------- -------  *04:03, *04:35 = *04:35, *04:107
+++++-+- --+-+--- ------- ------+ -------- -------   *04:03, *04:77 = *04:77, *04:107
+++++--- --+-+--- ------- -------- -------- -------  *04:06, *04:12 = *04:06, *04:52
+++++--- --+----- ------- -------- -------- -------  *04:06, *04:29 = *04:06, *04:33
+++++--+ --+----- ------- -------- -------- -------  *04:03, *04:34 = *04:06, *04:08 = *04:34, *04:107
-+++-+--- --+--++- ------- -------- ++----- -------  *04:14, *04:58 = *04:58, *04:68
+++----- -+++---- ------- -------- ----++-- -------  *04:11, *04:74 = *04:36, *04:74
+++----- -+++---- ------- -------- ---++--- -------  *04:11, *04:63 = *04:36, *04:63
+++----- -+++---- ------- ------+- -------+- ------  *04:11, *04:95N = *04:36, *04:95N
+++----- -+++---- -+----- +------ -------- -------   *04:11, *04:94:01 = *04:36, *04:94:01
+++----- -+++---- +--+---- ------- -------- -------  *04:11, *04:17 = *04:17, *04:36
+++----- -+++---+ --+----- ------- -------- -------  *04:11, *04:37 = *04:36, *04:37
+++----- -+++--+- ------- -------- -+----- -------   *04:11, *04:68 = *04:36, *04:68
+++----- -++++-+- ------- -------- -------- -------  *04:14, *04:55 = *04:28, *04:55
+++----- ++++---- ------+ -------- -------- -------  *04:11, *04:30 = *04:30, *04:36
+++----- ++++---- --+---- -------- -------- -------  *04:11, *04:35 = *04:35, *04:36
+++----+- -+++---- ------- -------- -------+ -------  *04:11, *04:77 = *04:36, *04:77
+++--+-- -++++--- ------- -------- -------- -------  *04:07, *04:55 = *04:32, *04:55
+++-+--- --+--+-- ------- -------- -+----- ----+--  *04:13, *04:16 = *04:13, *04:66 = *04:13, *04:103
+++-+--- --+--+-- ------- -------- -+----+- ------   *04:13, *04:71 = *04:13, *04:79
+++-+--- --+--+-- ------- -------- ++----- -------   *04:01:01:01, *04:58 = *04:01:10, *04:58 = *04:01:28, *04:58 =
                                                     *04:13, *04:65 = *04:18, *04:58 = *04:58, *04:61 = *04:58, *04:65 =
                                                     *04:58, *04:87
+++-+--- --+--+-- ------+ -------- -+----- -------   *04:13, *04:26 = *04:13, *04:42
+++-+--- --+-++-- ------- -------- -+----- -------   *04:12, *04:13 = *04:13, *04:52
+++-+--- --++-+-- ------- -------- -+----- -------   *04:13, *04:29 = *04:13, *04:33
+++-+--- -++-+--- ------- -------- -+----- -------   *04:10, *04:13 = *04:13, *04:31
+++-+--+ -+++---- ------- -------- -------- -------  *04:11, *04:34 = *04:34, *04:36
+++-+-+- --+--+-- ------- -------- -+----- -------   *04:07, *04:13 = *04:13, *04:27 = *04:13, *04:32
+++++--- --+-+--- ------- -------- -+----- -------   *04:03, *04:13 = *04:13, *04:107
+++-+--- --+--+-- ------- -------- ++----- ----+--  *04:16, *04:58 = *04:58, *04:66 = *04:58, *04:103
+++-+--- --+--+-- ------- -------- ++----+- ------   *04:58, *04:71 = *04:58, *04:79
+++-+--- --+--+-- ------+ -------- ++----- -------   *04:26, *04:58 = *04:42, *04:58
+++-+--- --+-++-- ------- -------- ++----- -------   *04:12, *04:58 = *04:52, *04:58
```

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**Lot No.: 79N**                    **Lot-specific information**

```
+++-+--- --++-+-- -------- -------- ++------ -------   *04:29, *04:58 = *04:33, *04:58
+++-+--- -+++-+-- -------- -------- ++------ -------   *04:10, *04:58 = *04:31, *04:58
+++-+--- -+++-+-- -------- -------- -+------ -------   *04:11, *04:13 = *04:13, *04:36
+++-+-+- --+-+-- -------- -------- ++------ -------   *04:07, *04:58 = *04:27, *04:58 = *04:32, *04:58
+++++--- --+-+-- -------- -------- ++------ -------   *04:03, *04:58 = *04:58, *04:107
+++-+--- -+++-+-- -------- -------- ++------ -------   *04:11, *04:58 = *04:36, *04:58
```

*04:01:01:01 = *04:01:01:01-04:01:09, 04:01:11-04:01:22, 04:01:24-04:01:27 and 04:01:29-
04:01:37 and 04:85-04:86, 04:90-04:92, 04:97-04:99, 04:101-04:102, 04:104, 04:109-04:110
and 04:112
*04:01:10 = *04:01:10 and 04:01:23
*04:04:01 = *04:04:01-04:04:02
*04:07 = *04:07 and04:89
*04:15:01 = *04:15:01 and 04:15:03
*04:15:02 = *04:15:02, 04:44 and 04:47
*04:17 = *04:17 and 04:100
*04:23 = *04:23, 04:38-04:39 and 04:108
*04:25 = *04:25, 04:40 and 04:41
*04:46 = *04:46 and 04:50
*04:48 = *04:48 and 04:75
*04:54  = *04:54 and 04:105N
*04:56 = *04:56 and 04:64
*04:59Q = *04:59Q and 04:78
*04:61  = *04:61 and 04:96
*04:62 = *04:62 and 04:76
*04:65 = *04:65 and 04:72
*04:67  = *04:67 and 04:93N
*04:69 = *04:69 and 04:82
*04:81  = *04:81 and 04:88N
*04:84  = *04:84 and 04:106
*04:94:01  = *04:94:01-04:94:02

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**Lot No.: 79N**  Lot-specific information
# SPECIFICITY TABLE

## HLA-C*04 SSP subtyping

**Specificities and sizes of the PCR products of the 47 primer mixes used for HLA-C*04 SSP subtyping**

| Primer Mix | Size of spec. PCR product[1] | Size of control band[2] | Amplified HLA-C*04 alleles[3] | Other amplified HLA Class I alleles[4] |
|---|---|---|---|---|
| 1 | 250 bp | **800 bp** | *04:01:01:01-04:01:37, 04:03, 04:05, 04:07-04:12, 04:15:01-04:18, 04:19[w], 04:20, 04:23-04:33, 04:35-04:57, 04:59Q-04:67, 04:69-04:94:02, 04:95N[w], 04:96-04:109, 04:110[?], 04:112 | *01:02:01-01:21, 01:23-01:34, 01:36-01:66, 02:02:01-02:02:03, 02:02:05-02:02:22, 02:04-02:15, 02:17, 02:19-02:40, 02:42-02:56, 05:01:01:01-05:01:18, 05:03-05:10, 05:12-05:16, 05:18:01-05:26, 05:28-05:50, 05:52-05:61, 05:63-05:67, 05:69, 05:71-05:74, 06:02:01:01-06:02:01:02, 06:02:03-06:03:02, 06:05-06:39, 06:41-06:76, 08:02:01-08:02:07, 08:05, 08:07, 08:12, 08:15:01-08:15:02, 08:17-08:19, 08:23, 08:25, 08:27-08:35, 08:37, 08:43, 08:45, 08:47-08:49, 08:51-08:53, 08:55N, 12:02:01-12:13, 12:15-12:17, 12:21-12:76, 14:02:01-14:05, 14:07N-14:14, 14:16-14:37, 15:08, 16:04, 16:29, 16:33, 16:42, 18:01-18:05 |
| 2 | 220 bp | 1070 bp | *04:01:01:01-04:01:27, 04:01:29-04:01:37, 04:04:01-04:05, 04:07-04:09N, 04:12[w], 04:13-04:15:03, 04:17-04:20, 04:23-04:35, 04:37-04:41, 04:43-04:54, 04:56-04:70, 04:72-04:79, 04:81-04:102, 04:104-04:106, 04:108-04:112 | *07:64 |
| 3 | 145 bp | 1070 bp | *04:01:01:01-04:01:37, 04:04:01-04:05, 04:08-04:15:03, 04:17-04:20, 04:23-04:26, 04:28-04:41, 04:43-04:79, 04:81-04:86, 04:88N, | |

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| | | | | |
|---|---|---|---|---|
| | | | 04:90-04:102, 04:104-04:106, 04:108-04:112 | |
| **4** | 210 bp | 1070 bp | *04:03, 04:06, 04:80, 04:107 | *02:12, 02:49, 02:55 |
| **5** | 250 bp | 1070 bp | *04:04:01-04:04:02, 04:06, 04:13, 04:34, 04:58 | *01:22, 01:35, 02:03, 02:16:01-02:16:02, 02:18, 05:11, 05:17, 05:27, 05:68, 06:04, 08:01:01-08:01:05, 08:03:01-08:04:02, 08:06, 08:08-08:11, 08:13-08:14, 08:16:01-08:16:02, 08:20-08:22, 08:24, 08:26N, 08:36N, 08:38-08:42, 08:44, 08:46, 08:50, 08:54, 08:56-08:60, 12:14:01-12:14:02, 12:18:01-12:18:02, 12:20, 14:06, 14:15, 15:02:01-15:07, 15:09-15:13, 15:15-15:24, 15:26-15:50, 15:52-15:60, 16:35, 16:40, 17:01:01:01-17:11, **B*58:02** |
| **6**[5] | 95 bp | 1070 bp | *04:05 | |
| **7**[6] | 145 bp | 1070 bp | *04:07, 04:27, 04:32, 04:77, 04:89 | *03:34, 03:142, 07:64, 14:25, 15:36, 18:03 |
| **8** | 270 bp | 1070 bp | *04:08, 04:34 | *01:35, 05:27, 05:39, 08:41, 14:20, 15:15, 17:07, **B*58:02** |
| | | | | |
| **9**[5,9] | 110 bp, 180 bp, 220 bp | 1070 bp | *04:09N, 04:30, 04:35 | |
| **10**[10] | 195 bp, 220 bp | 1070 bp | *04:10-04:11, 04:31, 04:36, 04:55 | *15:36 |
| **11** | 180 bp | 1070 bp | *04:01:01:01-04:01:09, 04:01:11-04:01:22, 04:01:24-04:01:37, 04:03-04:10, 04:12-04:20, 04:23-04:26, 04:28-04:32, 04:34-04:51, 04:53-04:54, 04:56-04:106, 04:108-04:112 | *02:49, 05:25, 05:42, 06:05, 07:02:09, 08:28, 12:28, 15:25, 16:26 |
| **12**[5,11] | 125 bp, 165 bp | 1070 bp | *04:11, 04:29, 04:33, 04:36, 04:55 | *07:125 |
| **13**[12] | 225 bp, 270 bp | 1070 bp | *04:12, 04:52, 04:55 | |
| **14**[6,13] | 155 bp, 190 bp | 1070 bp | *04:13, 04:16, 04:18, 04:58 | *07:08, 07:108 |
| **15** | 180 bp | 1070 bp | *04:14, 04:28, 04:68 | *16:45, **A*24:96, A*24:146** |

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| | | | | |
|---|---|---|---|---|
| **16** | 130 bp | 1070 bp | *04:15:01, 04:15:03, 04:37 | *03:05, 03:25, 03:27, 03:135, 14:09, **B\*15:78:03** |
| | | | | |
| **17** | 320 bp | 1070 bp | *04:17, 04:80, 04:100 | *01:50 |
| **18**[5,14] | 125 bp, 220 bp | 1070 bp | *04:19, 04:70, 04:94:01-04:94:02 | *12:10:01-12:10:02, 18:03, **B\*15:27:01-15:27:03, B\*15:109** |
| **19**[5,15] | 120 bp, 155 bp | 1070 bp | *04:20, 04:35, 04:37 | *03:135 |
| **20**[16] | 165 bp, 250 bp, 545 bp | 1070 bp | *04:15:02, 04:17, 04:44, 04:47, 04:100 | *15:36, **A\*33:52** |
| **21**[5,6,17] | 85 bp, 145 bp, 240 bp | 1070 bp | *04:23, 04:38-04:39, 04:108 | |
| **22** | 130 bp | 1070 bp | *04:24 | |
| **23**[5,18] | 85 bp, 145 bp, 215 bp | 1070 bp | *04:25, 04:40-04:41 | |
| **24**[6] | 170 bp | 1070 bp | *04:26, 04:30, 04:42 | *07:125 |
| | | | | |
| **25** | 200 bp | 1070 bp | *04:43, 04:94:01-04:94:02 | *12:10:01-12:10:02, 18:03, **B\*15:27:01-15:27:03, B\*15:109** |
| **26**[7] | 215 bp | **800 bp** | *04:45 | |
| **27**[5,19] | 125 bp, 285 bp | **800 bp** | *04:46, 04:50 | |
| **28**[5,20] | 120 bp, 215 bp | 1070 bp | *04:48, 04:75 | |
| **29** | 185 bp | 1070 bp | *04:49 | |
| **30**[5] | 75 bp | 1070 bp | *04:53 | *05:49, **B\*07:90** |
| **31**[21] | 130 bp, 180 bp | 1070 bp | *04:51, 04:95N | |
| **32**[5,22] | 105 bp, 235 bp, 275 bp | 1070 bp | *04:59Q, 04:77-04:78 | **B\*40:100** |
| | | | | |
| **33**[5,23] | 80 bp, 180 bp | 1070 bp | *04:58, 04:65, 04:72 | *07:08, 07:108, B\*40:100 |
| **34**[5,24] | 75 bp, 200 bp | 1070 bp | *04:13, 04:58, 04:61, 04:68, 04:96 | *07:08, 07:108 |
| **35**[5,25] | 85 bp, 175 bp | 1070 bp | *04:62, 04:76 | |
| **36**[5] | 115 bp | 1070 bp | *04:57, 04:63 | |
| **37**[5,26] | 110 bp, 135 bp | 1070 bp | *04:63, 04:73-04:74 | |
| **38**[5,27] | 105 bp, 135 bp | 1070 bp | *04:74, 04:83 | |

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| | | | | |
|---|---|---|---|---|
| **39**[28] | 135 bp, 330 bp | 1070 bp | *04:71, 04:79, 04:95N | *01:21 |
| **40**[29] | 140 bp, 270 bp | **800 bp** | *04:56, 04:64 | |
| **41**[6,30] | 135 bp, 280 bp | 1070 bp | *04:54, 04:105N | *01:04, 01:54, 14:02:01-14:25, 14:27-14:37 |
| **42**[5,8] | 85 bp | 1070 bp | *04:69 | *16:12 |
| **43**[7,31] | 170 bp, 260 bp | 1070 bp | *04:81, 04:88N | |
| **44** | 135 bp | 1070 bp | *04:60 | |
| **45**[32] | 135 bp, 160 bp | 1070 bp | *04:16, 04:66, 04:103 | |
| **46**[5,33] | 125 bp, 300 bp | 1070 bp | *04:67, 04:93N | |
| **47**[6,7,34] | 155 bp, 240 bp | 1070 bp | *04:84, 04:106 | *07:167 |

[1]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 HLA-C*04 SSP typings.

When the primers in a primer mix can give rise to specific PCR products of more than one length this is indicated if the size difference is 20 base pairs or more. Size differences shorter than 20 base pairs are not given. For high resolution SSP kits the respective lengths of the specific PCR product(s) of the alleles amplified by these primer mixes are given.

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

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

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

Some primers may give rise to primer oligomer artifacts. Sometimes this phenomenon is an inherit 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.

[2]The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.

Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-C*04 subtyping.

In addition, wells number 26, 27 and 40 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

In the presence of a specific amplification the intensity of the control band often decreases.

[3]For several HLA-C*04 alleles 4th to 7th exon or 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. We assume that unknown sequences in these areas are conserved within allelic groups.

[4]Due to the sharing of sequence motifs between HLA-C alleles non-HLA-C*04 alleles will be amplified by primer mixes 1, 2, 4, 5, 7, 8, 10 to 12, 14 to 20, 24, 25, 30, 33, 34, 39, 41, 42 and 47. In addition, the A*24:96 and A*24:146 alleles will be amplified by primer mix 15, the A*33:52 allele will be amplified by primer mix 20, the B*07:90 allele will be amplified by primer mix 30, the B*15:27:01-15:27:03 and 15:109 alleles will be amplified by primer mixes 18 and 25, the

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B*15:78:03 allele will be amplified by primer mix 16, the B*40:100 allele will be amplified by primer mixes 32 and 33 and the B*58:02 allele will be amplified by primer mixes 5 and 8.

[5]Short specific PCR fragments are less intense and not as sharp as longer specific bands.

[6]Primer mixes 7, 14, 21, 24, 41 and 47 may give rise to primer oligomer formation.

[7]Primer mixes 26, 43 and 47 may have tendencies of unspecific amplification.

[8]Primer mix 42 may give rise to a long unspecific amplification product of approximately 525 bp. This should be disregarded when interpreting the C*04 typings.

[9]Primer mix 9: Specific PCR fragment of 110 bp in the C*04:35 allele. Specific PCR fragment of 180 bp in the C*04:30 allele. Specific PCR fragment of 220 bp in the C*04:09N allele.

[10]Primer mix 10: Specific PCR fragment of 195 bp in the C*04:31 allele. Specific PCR fragment of 220 bp in the C*04:10-04:11, 04:36 and 04:55 and the C*15:36 alleles.

[11]Primer mix 12: Specific PCR fragment of 125 bp in the C*04:29, 04:36 and 04:55 and the C*07:125 alleles. Specific PCR fragment of 165 bp in the C*04:33 allele. Specific PCR fragment of 125 and 165 bp in the C*04:11 allele.

[12]Primer mix 13: Specific PCR fragment of 225 bp in the C*04:12 allele. Specific PCR fragment of 270 bp in the C*04:52 and 04:55 alleles.

[13]Primer mix 14: Specific PCR fragment of 155 bp in the C*04:16 allele. Specific PCR fragment of 190 bp in the C*04:13, 04:18 and 04:58 and the C*07:08 and 07:108 alleles.

[14]Primer mix 18: Specific PCR fragment of 125 bp in the C*04:70 allele. Specific PCR fragment of 220 bp in the C*04:19 and 04:94:01-04:94:02 and the C*12:10:01-12:10:02 and 18:03 and in the B*15:27:01-15:27:03 and B*15:109 alleles.

[15]Primer mix 19: Specific PCR fragment of 120 bp in the C*04:35 and 04:37 alleles. Specific PCR fragment of 155 bp in the C*04:20 and the C*03:135 alleles.

[16]Primer mix 20: Specific PCR fragment of 165 bp in the C*04:44 allele. Specific PCR fragment of 250 bp in the C*04:47 allele. Specific PCR fragment of 545 bp in the C*04:15:02, 04:17 and 04:100 and the C*15:36 and the A*33:52 alleles.

[17]Primer mix 21: Specific PCR fragment of 85 bp in the C*04:23 and 04:108 alleles. Specific PCR fragment of 145 bp in the C*04:38 allele. Specific PCR fragment of 240 bp in the C*04:39 allele.

[18]Primer mix 23: Specific PCR fragment of 85 bp in the C*04:25 allele. Specific PCR fragment of 145 bp in the C*04:40 allele. Specific PCR fragment of 215 bp in the C*04:41 allele.

[19]Primer mix 27: Specific PCR fragment of 125 bp in the C*04:50 allele. Specific PCR fragment of 285 bp in the C*04:46 allele.

[20]Primer mix 28: Specific PCR fragment of 120 bp in the C*04:75 allele. Specific PCR fragment of 215 bp in the C*04:48 allele.

[21]Primer mix 31: Specific PCR fragment of 130 bp in the C*04:95N allele. Specific PCR fragment of 180 bp in the C*04:51 allele.

[22]Primer mix 32: Specific PCR fragment of 105 bp in the C*04:78 allele. Specific PCR fragment of 235 bp in the C*04:59Q allele. Specific PCR fragment of 275 bp in the C*04:77 and in the B*40:100 alleles.

[23]Primer mix 33: Specific PCR fragment of 80 bp in the C*04:72 allele. Specific PCR fragment of 180 bp in the C*04:58 and 04:65 and the C*07:08 and 07:108 and in the B*40:100 alleles.

[24]Primer mix 34: Specific PCR fragment of 75 bp in the C*04:96 allele. Specific PCR fragment of 200 bp in the C*04:13, 04:58, 04:61 and 04:68 and the C*07:08 and 07:108 alleles.

[25]Primer mix 35: Specific PCR fragment of 85 bp in the C*04:62 allele. Specific PCR fragment of 175 bp in the C*04:76 allele.

[26]Primer mix 37: Specific PCR fragment of 110 bp in the C*04:63 and 04:73 alleles. Specific PCR fragment of 135 bp in the C*04:74 allele.

[27]Primer mix 38: Specific PCR fragment of 105 bp in the C*04:83 allele. Specific PCR fragment of 135 bp in the C*04:74 allele.

[28]Primer mix 39: Specific PCR fragment of 135 bp in the C*04:71 and 04:95N and the C*01:21 alleles. Specific PCR fragment of 330 bp in the C*04:79 allele.

[29]Primer mix 40: Specific PCR fragment of 140 bp in the C*04:56 allele. Specific PCR fragment of 270 bp in the C*04:64 allele.

[30]Primer mix 41: Specific PCR fragment of 135 bp in the C*04:105N allele. Specific PCR fragment of 280 bp in the C*04:54 and the C*01:04, 01:54, 14:02:01-14:25 and 14:27-14:37 alleles.

[31]Primer mix 43: Specific PCR fragment of 170 bp in the C*04:81 allele. Specific PCR fragment of 260 bp in the C*04:88N allele.

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[32]Primer mix 45: Specific PCR fragment of 135 bp in the C*04:66 allele. Specific PCR fragment of 160 bp in the C*04:16 and 04:103 alleles.

[33]Primer mix 46: Specific PCR fragment of 125 bp in the C*04:93N allele. Specific PCR fragment of 300 bp in the C*04:67 allele.

[34]Primer mix 47: Specific PCR fragment of 155 bp in the C*04:84 and the C*07:167 alleles. Specific PCR fragment of 240 bp in the C*04:106 allele.

'w', may be weakly amplified.

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## INTERPRETATION TABLE
## HLA-C*04 SSP subtyping
### Amplification patterns of the C*04:01 to C*04:112 alleles

| | Well[22] | | | | | | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| **Length of spec.** | 250 | 220 | 145 | 210 | 250 | 95 | 145 | 270 | 110 | 195 | 180 | 125 | 225 | 155 | 180 | 130 | 320 | 125 | 120 | 165 | 85 | 130 | 85 | 170 |
| **PCR product(s)** | | | | | | | | | 180 | 220 | | 165 | 270 | 190 | | | | 220 | 155 | 250 | 145 | | 145 | |
| | | | | | | | | | 220 | | | | | | | | | | | 545 | 240 | | 215 | |
| **Length of int.** | 800 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 |
| **pos. control[1]** | | | | | | | | | | | | | | | | | | | | | | | | |
| **5'-primer(s)[2]** | 2nd \| 5'-CCA 3' | 112 5'-CCT 3' | 112 5'-CCT 3' | 118 5'-CCA 3' | 2nd \| 5'-CCA 3' | 98 5'-CTC 3' | 112 5'-CCT 3' | 2nd \| 5'-CCA 3' | 391 5'-ACC 3' | 112 5'-CCT 3' | 201 5'-CCA 3' | 218 5'-ggA 3' | 112 5'-CCT 3' | 105 5'-gCT 3' | 412 5'-ATA 3' | 368 5'-gTg 3' | 379 5'-ACg 3' | 228 5'-ATg 3' | 347 5'-gTA 3' | 112 5'-CCT 3' | 368 5'-gTT 3' | 127 5'-ggA 3' | 172 5'-TCC 3' | 89 5'-gAT 3' |
| | | | | | | | 459 5'-gAT 3' | | 1018 5'-gTg 3' | 368 5'-gTT 3' | | | | 368 5'-gTT 3' | 697 5'-TCC 3' | 369 5'-TAC 3' | | 368 5'-gTT 3' | 368 5'-gTg 3' | | | | 355 5'-CCT 3' | 97 5'-TCg 3' |
| | | | | | | | | | | | | | | | | | | 391 5'-ACC 3' | | | | | 670 5'-CCg 3' | 1018 5'-gTg 3' |
| **3'-primer(s)[3]** | 539 5'-TCC 3' | 289 5'-AgC 3' | 218 5'-gCT 3' | 289 5'-AgC 3' | 539 5'-TCA 3' | 154 5'-CAg 3' | 218 5'-gCg 3' | 559 5'-CAg 3' | 459 5'-AgA 3' | 289 5'-AgT 3' | 341 5'-CgT 3' | 302 5'-ggC 3' | 295 5'-TCC 3' | 218 5'-gCT 3' | 539 5'-TCT 3' | 459 5'-AgA 3' | 3rd \| 5'-ACg 3' | 312 5'-AgT 3' | 459 5'-AgA 3' | 238 5'-CCA 3' | 412 5'-gTC 3' | 218 5'-gCT 3' | 218 5'-gCT 3' | 218 5'-gCT 3' |
| | | 289 5'-AgC 3' | | 289 5'-AgC 3' | | | 559 5'-CTC 3' | | 1052 5'-Tgg 3' | 289 5'-AgT 3' | | 341 5'-Cgg 3' | 343 5'-T 3' | 514 5'-CTT 3' | 846 5'-CAC 3' | | | 538 5'-CCA 3' | 319 5'-gCT 3' | 472 5'-ggC 3' | | 459 5'-AgA 3' | 1052 5'-Tgg 3' | |
| | | | | | | | | | 1092 5'-TTA 3' | 521 5'-ggA 3' | | | | 527 5'-CCg 3' | | | | 550 5'-CAT 3' | 368 5'-CAT 3' | 568 5'-CTg 3' | | 846 5'-CAC 3' | | |
| **Well No.** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| **HLA-C allele[4,5]** | | | | | | | | | | | | | | | | | | | | | | | | |

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**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

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**Lot No.: 79N**  Lot-specific information

## INTERPRETATION TABLE
## HLA-C*04 SSP subtyping
### Amplification patterns of the C*04:01 to C*04:112 alleles

| | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | Well[22] |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| Length of spec. PCR product(s) | 200 | 215 | 125 | 120 | 185 | 75 | 130 | 105 | 80 | 75 | 85 | 115 | 110 | 105 | 135 | 140 | 135 | 85 | 170 | 135 | 135 | 125 | 155 | |
| | | | 285 | 215 | | | 180 | 235 | 180 | 200 | 175 | | 135 | 135 | 330 | 270 | 280 | | 260 | | 160 | 300 | 240 | |
| | | | | | | | | 275 | | | | | | | | | | | | | | | | |
| Length of int. pos. control[1] | 1070 | 800 | 800 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 800 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | 1070 | |
| 5'-primer(s)[2] | 368 | 112 | 368 | 232 | 112 | 503 | 81 | 368 | 368 | 368 | 112 | 383 | 364 | 364 | 98 | 112 | 249 | 256 | 112 | 364 | 98 | 83 | 3rd | |
| | 5'-gTT 3' | 5'-CCT 3' | 5'-gTT 3' | 5'-Agg 3' | 5'-CCT 3' | 5'-CCg 3' | 5'-CAg 3' | 5'-gTT 3' | 5'-gTT 3' | 5'-gTT 3' | 5'-CCT 3' | 5'-ggC 3' | 5'-ggT 3' | 5'-ggT 3' | 5'-CTT 3' | 5'-CCT 3' | 5'-TAg 3' | 5'-ACg 3' | 5'-CCT 3' | 5'-ggg 3' | 5'-CTA 3' | 5'-CTA 3' | 5'-Cgg 3' | |
| | | | 368 | | | | 459 | | | | | 386 | 386 | 395 | 459 | 368 | 419 | 972 | | | 124 | 375 | | |
| | | | 5'-gTT 3' | | | | 5'-gAT 3' | | | | | 5'-gCA 3' | 5'-gCA 3' | 5'-gCT 3' | 5'-gAT 3' | 5'-gTT 3' | 5'-gTC 3' | 5'-CTA 3' | | | 5'-gCT 3' | 5'-TgA 3' | | |
| | | | | | | | | | | | | | 392 | | 3rd | | | | | | | | | |
| | | | | | | | | | | | | | 5'-CgC 3' | | 5'-Cgg 3' | | | | | | | | | |
| 3'-primer(s)[3] | 518 | 284 | 454 | 312 | 256 | 539 | 218 | 430 | 407 | 403 | 154 | 459 | 459 | 459 | 201 | 212 | 341 | 302 | 239 | 459 | 218 | 341 | 704 | |
| | 5'-CCA 3' | 5'-gTA 3' | 5'-CTg 3' | 5'-AgT 3' | 5'-CCA 3' | 5'-TCC 3' | 5'-gCT 3' | 5'-gCA 3' | 5'-ACg 3' | 5'-gCA 3' | 5'-CAT 3' | 5'-AgA 3' | 5'-AgA 3' | 5'-AgA 3' | 5'-CTT 3' | 5'-gCC 3' | 5'-CgT 3' | 5'-ggT 3' | 5'-gCT 3' | 5'-AgA 3' | 5'-gCT 3' | 5'-CgT 3' | 5'-CCA 3' | |
| | 538 | | 613 | 544 | | 549 | 563 | 505 | 527 | 247 | | | | | 549 | 595 | 3rd | 1016 | 331 | | | 459 | 787 | |
| | 5'-CCA 3' | | 5'-gCA 3' | 5'-ggg 3' | | 5'-AgT 3' | 5'-CgT 3' | 5'-gCT 3' | 5'-CCg 3' | 5'-ATT 3' | | | | | 5'-AgT 3' | 5'-CCT 3' | 5'-ACg 3' | 5'-CAC 3' | 5'-CTA 3' | | | 5'-AgA 3' | 5'-TCT 3' | |
| | | | | | | | | 603 | 512 | | | | | | 878 | | | | | | | | | |
| | | | | | | | | 5'-TTg 3' | 5'-CCA 3' | | | | | | 5'-ggA 3' | | | | | | | | | |
| | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | Well No. |
| | | | | | | | | | | | | | | | | | | | | | | | | HLA-C allele[4,5] |

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**Lot No.: 79N**   **Lot-specific information**

| Length of spec. | 250 | 220 | 145 | 210 | 250 | 95 | 145 | 270 | 110 | 195 | 180 | 125 | 225 | 155 | 180 | 130 | 320 | 125 | 120 | 165 | 85 | 130 | 85 | 170 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PCR product(s) | | | | | | | | | 180 | 220 | | 165 | 270 | 190 | | | | 220 | 155 | 250 | 145 | | 145 | |
| | | | | | | | | | 220 | | | | | | | | | | | 545 | 240 | | 215 | |
| **Well No.** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** |
| **HLA-C allele[4,5]** | | | | | | | | | | | | | | | | | | | | | | | | |
| **\*04:01:01:01-04:01:09, 04:01:11-**04:01:22, 04:01:24-04:01:27, 04:01:29-04:01:37, 04:82, 04:85-04:86, 04:90-04:92, 04:97-04:99, 04:101-04:102, 04:104, 04:109, 04:112 | **1** | **2** | **3** | | | | | | | | **11** | | | | | | | | | | | | | |
| **\*04:01:10,** 04:01:23 | **1** | **2** | **3** | | | | | | | | | | | | | | | | | | | | | |
| **\*04:01:28** | **1** | | **3** | | | | | | | | **11** | | | | | | | | | | | | | |
| **\*04:03,** 02:49[6] | **1** | | | **4** | | | | | | | **11** | | | | | | | | | | | | | |
| **\*04:04:01-**04:04:02 | | **2** | **3** | | **5** | | | | | | **11** | | | | | | | | | | | | | |
| \*04:05 | **1** | **2** | **3** | | | **6** | | | | | **11** | | | | | | | | | | | | | |
| **\*04:06** | | | | **4** | **5** | | | | | | **11** | | | | | | | | | | | | | |
| **\*04:07,** 04:89 | **1** | **2** | | | | | **7** | | | | **11** | | | | | | | | | | | | | |
| **\*04:08** | **1** | **2** | **3** | | | | | **8** | | | **11** | | | | | | | | | | | | | |
| **\*04:09N** | **1** | **2** | **3** | | | | | | **9** | | **11** | | | | | | | | | | | | | |
| **\*04:10** | **1** | | **3** | | | | | | | **10** | **11** | | | | | | | | | | | | | |
| **\*04:11** | **1** | | **3** | | | | | | | **10** | | **12** | | | | | | | | | | | | |
| \*04:12 | **1** | **w** | **3** | | | | | | | | **11** | | **13** | | | | | | | | | | | |
| **\*04:13** | | **2** | **3** | | **5** | | | | | | **11** | | | **14** | | | | | | | | | | |
| **\*04:14** | | **2** | **3** | | | | | | | | **11** | | | | **15** | | | | | | | | | |
| \*04:15:01, 04:15:03 | **1** | **2** | **3** | | | | | | | | **11** | | | | | **16** | | | | | | | | |
| **\*04:15:02,** 04:44, **04:47[8]** | **1** | **2** | **3** | | | | | | | | **11** | | | | | | | | | **20** | | | | |
| **\*04:16** | **1** | | | | | | | | | | **11** | | | **14** | | | | | | | | | | |
| \*04:17, 04:100 | **1** | **2** | **3** | | | | | | | | **11** | | | | | | **17** | | | **20** | | | | |
| \*04:18 | **1** | **2** | **3** | | | | | | | | **11** | | | **14** | | | | | | | | | | |
| \*04:19 | **w** | **2** | **3** | | | | | | | | **11** | | | | | | | **18** | | | | | | |
| \*04:20 | **1** | **2** | **3** | | | | | | | | **11** | | | | | | | | **19** | | | | | |
| \*04:23, **04:38, 04:39,** 04:108[9] | **1** | **2** | **3** | | | | | | | | **11** | | | | | | | | | | **21** | | | |
| \*04:24 | **1** | **2** | **3** | | | | | | | | **11** | | | | | | | | | | | **22** | | |
| \*04:25, **04:40,** 04:41[10] | **1** | **2** | **3** | | | | | | | | **11** | | | | | | | | | | | | **23** | |
| **\*04:26** | **1** | **2** | **3** | | | | | | | | **11** | | | | | | | | | | | | | **24** |
| **\*04:27** | **1** | **2** | | | | | **7** | | | | | | | | | | | | | | | | | |
| \*04:28 | **1** | **2** | **3** | | | | | | | | **11** | | | | **15** | | | | | | | | | |
| **\*04:29** | **1** | **2** | **3** | | | | | | | | **11** | **12** | | | | | | | | | | | | |
| \*04:30 | **1** | **2** | **3** | | | | | | **9** | | **11** | | | | | | | | | | | | | **24** |
| \*04:31 | **1** | **2** | **3** | | | | | | | **10** | **11** | | | | | | | | | | | | | |
| **\*04:32** | **1** | **2** | **3** | | | | **7** | | | | **11** | | | | | | | | | | | | | |
| **\*04:33** | **1** | **2** | **3** | | | | | | | | | **12** | | | | | | | | | | | | |
| \*04:34 | | **2** | **3** | | **5** | | | **8** | | | **11** | | | | | | | | | | | | | |
| **Well No.** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** |

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October 2013
Rev. No.: 01

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**Lot No.: 79N**     **Lot-specific information**

| 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | Length of spec. |
|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 200 | 215 | 125 | 120 | 185 | 75 | 130 | 105 | 80 | 75 | 85 | 115 | 110 | 105 | 135 | 140 | 135 | 85 | 170 | 135 | 135 | 125 | 155 | |
| | | 285 | 215 | | | 180 | 235 | 180 | 200 | 175 | | 135 | 135 | 330 | 270 | 280 | | 260 | | 160 | 300 | 240 | **PCR product(s)** |
| | | | | | | | 275 | | | | | | | | | | | | | | | | |
| **25** | **26** | **27** | **28** | **29** | **30** | **31** | **32** | **33** | **34** | **35** | **36** | **37** | **38** | **39** | **40** | **41** | **42** | **43** | **44** | **45** | **46** | **47** | **Well No.** |
| | | | | | | | | | | | | | | | | | | | | | | | **HLA-C allele[4,5]** |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:01:01:01-04:01:09, 04:01:11-**04:01:22, 04:01:24-04:01:27, 04:01:29-04:01:37, 04:82, 04:85-04:86, 04:90-04:92, 04:97-04:99, 04:101-04:102, 04:104, 04:109, 04:112 |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:01:10,** 04:01:23 |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:01:28** |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:03,** 02:49[6] |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:04:01-**04:04:02 |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:05 |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:06** |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:07,** 04:89 |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:08** |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:09N** |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:10** |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:11 |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:12 |
| | | | | | | | | | | 34 | | | | | | | | | | | | | **\*04:13** |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:14** |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:15:01, 04:15:03 |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:15:02,** 04:44, **04:47[8]** |
| | | | | | | | | | | | | | | | | | | | | 45 | | | **\*04:16** |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:17, 04:100 |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:18 |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:19 |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:20 |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:23, **04:38, 04:39,** 04:108[9] |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:24 |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:25, **04:40,** 04:41[10] |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:26** |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:27** |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:28 |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:29** |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:30 |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:31 |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:32** |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:33** |
| | | | | | | | | | | | | | | | | | | | | | | | \*04:34 |
| **25** | **26** | **27** | **28** | **29** | **30** | **31** | **32** | **33** | **34** | **35** | **36** | **37** | **38** | **39** | **40** | **41** | **42** | **43** | **44** | **45** | **46** | **47** | **Well No.** |

October 2013
Rev. No.: 01

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**101.612-12u– without *Taq* pol.**　　　　　　　**"Instructions for Use" (IFU)**

Lot No.: **79N**　　　　　　　Lot-specific information

| Length of spec. | 250 | 220 | 145 | 210 | 250 | 95 | 145 | 270 | 110 180 220 | 195 220 | 180 | 125 165 | 225 270 | 155 190 | 180 | 130 | 320 | 125 220 | 120 155 545 | 165 250 240 | 85 145 | 130 | 85 145 215 | 170 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| **PCR product(s) / Well No.** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |
| *04:35 | 1 | 2 | 3 | | | | | | 9 | | 11 | | | | | | | | 19 | | | | | |
| **\*04:36** | 1 | | 3 | | | | | | | 10 | 11 | 12 | | | | | | | | | | | | |
| **\*04:37** | 1 | 2 | 3 | | | | | | | | 11 | | | | | 16 | | | 19 | | | | | |
| *04:42 | 1 | | | | | | | | | | 11 | | | | | | | | | | | | | 24 |
| **\*04:43** | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:45** | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:46, 04:50[11] | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:48,** 04:75[12] | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:49 | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:51 | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:52** | 1 | 2 | 3 | | | | | | | | | | 13 | | | | | | | | | | | |
| *04:53 | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:54,** 04:105N[13] | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:55 | 1 | | 3 | | | | | | | 10 | | 12 | 13 | | | | | | | | | | | |
| **\*04:56,** 04:64[14] | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:57 | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:58** | | 2 | 3 | | 5 | | | | | | 11 | | | 14 | | | | | | | | | | |
| **\*04:59Q,** 04:78[15] | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:60 | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:61, 04:96[16]** | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:62,** 04:76[17] | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:63** | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:65,** 04:72[18] | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:66 | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:67, 04:93N[19] | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:68** | | 2 | 3 | | | | | | | | 11 | | | | 15 | | | | | | | | | |
| **\*04:69** | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:70 | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | 18 | | | | | | |
| *04:71 | 1 | | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:73 | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:74** | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:77** | 1 | 2 | 3 | | | | 7 | | | | 11 | | | | | | | | | | | | | |
| *04:79 | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:80 | 1 | | | 4 | | | | | | | 11 | | | | | | 17 | | | | | | | |
| **\*04:81,** 04:88N[20] | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:83** | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:84, 04:106[21] | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:87 | 1 | 2 | | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:94:01-**04:94:02 | 1 | 2 | 3 | | | | | | | | 11 | | | | | | | 18 | | | | | | |
| *04:95N | w | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| **\*04:103** | 1 | | | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:107, 02:12, 02:55[7] | 1 | | | 4 | | | | | | | | | | | | | | | | | | | | |
| **Well No.** | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 |

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

Lot No.: **79N**          **Lot-specific information**

| 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | Length of spec. |
|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|
| 200 | 215 | 125 | 120 | 185 | 75 | 130 | 105 | 80 | 75 | 85 | 115 | 110 | 105 | 135 | 140 | 135 | 85 | 170 | 135 | 135 | 125 | 155 | |
| | | 285 | 215 | | | 180 | 235 | 180 | 200 | 175 | | 135 | 135 | 330 | 270 | 280 | | 260 | | 160 | 300 | 240 | PCR product(s) |
| | | | | | | | 275 | | | | | | | | | | | | | | | | |
| **25** | **26** | **27** | **28** | **29** | **30** | **31** | **32** | **33** | **34** | **35** | **36** | **37** | **38** | **39** | **40** | **41** | **42** | **43** | **44** | **45** | **46** | **47** | **Well No.** |
| | | | | | | | | | | | | | | | | | | | | | | | *04:35 |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:36** |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:37** |
| | | | | | | | | | | | | | | | | | | | | | | | *04:42 |
| 25 | | | | | | | | | | | | | | | | | | | | | | | **\*04:43** |
| | 26 | | | | | | | | | | | | | | | | | | | | | | **\*04:45** |
| | | 27 | | | | | | | | | | | | | | | | | | | | | *04:46, 04:50[11] |
| | | | 28 | | | | | | | | | | | | | | | | | | | | **\*04:48**, 04:75[12] |
| | | | | 29 | | | | | | | | | | | | | | | | | | | *04:49 |
| | | | | | | 31 | | | | | | | | | | | | | | | | | *04:51 |
| | | | | | | | | | | | | | | | | | | | | | | | **\*04:52** |
| | | | | | 30 | | | | | | | | | | | | | | | | | | *04:53 |
| | | | | | | | | | | | | | | | | 41 | | | | | | | **\*04:54**, 04:105N[13] |
| | | | | | | | | | | | | | | | | | | | | | | | *04:55 |
| | | | | | | | | | | | | | | | 40 | | | | | | | | **\*04:56**, 04:64[14] |
| | | | | | | | | | | | 36 | | | | | | | | | | | | *04:57 |
| | | | | | | | | 33 | 34 | | | | | | | | | | | | | | **\*04:58** |
| | | | | | | | 32 | | | | | | | | | | | | | | | | *04:59Q, 04:78[15] |
| | | | | | | | | | | | | | | | | | | | 44 | | | | *04:60 |
| | | | | | | | | | 34 | | | | | | | | | | | | | | **\*04:61, 04:96**[16] |
| | | | | | | | | | | 35 | | | | | | | | | | | | | **\*04:62**, 04:76[17] |
| | | | | | | | | | | | 36 | 37 | | | | | | | | | | | **\*04:63** |
| | | | | | | | | 33 | | | | | | | | | | | | | | | **\*04:65**, 04:72[18] |
| | | | | | | | | | | | | | | | | | | | | 45 | | | *04:66 |
| | | | | | | | | | | | | | | | | | | | | | 46 | | *04:67, 04:93N[19] |
| | | | | | | | | | 34 | | | | | | | | | | | | | | **\*04:68** |
| | | | | | | | | | | | | | | | | | 42 | | | | | | **\*04:69** |
| | | | | | | | | | | | | | | | | | | | | | | | *04:70 |
| | | | | | | | | | | | | | | 39 | | | | | | | | | *04:71 |
| | | | | | | | | | | | | 37 | | | | | | | | | | | *04:73 |
| | | | | | | | | | | | | 37 | 38 | | | | | | | | | | **\*04:74** |
| | | | | | | | 32 | | | | | | | | | | | | | | | | **\*04:77** |
| | | | | | | | | | | | | | | 39 | | | | | | | | | *04:79 |
| | | | | | | | | | | | | | | | | | | | | | | | *04:80 |
| | | | | | | | | | | | | | | | | | | 43 | | | | | **\*04:81**, 04:88N[20] |
| | | | | | | | | | | | | | 38 | | | | | | | | | | **\*04:83** |
| | | | | | | | | | | | | | | | | | | | | | | 47 | *04:84, 04:106[21] |
| | | | | | | | | | | | | | | | | | | | | | | | *04:87 |
| 25 | | | | | | | | | | | | | | | | | | | | | | | **\*04:94:01**-04:94:02 |
| | | | | | | 31 | | | | | | | | 39 | | | | | | | | | *04:95N |
| | | | | | | | | | | | | | | | | | | | | 45 | | | **\*04:103** |
| | | | | | | | | | | | | | | | | | | | | | | | *04:107, 02:12, 02:55[7] |
| **25** | **26** | **27** | **28** | **29** | **30** | **31** | **32** | **33** | **34** | **35** | **36** | **37** | **38** | **39** | **40** | **41** | **42** | **43** | **44** | **45** | **46** | **47** | **Well No.** |

CE

For In Vitro Diagnostic Use

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

Visit www.olerup-ssp.com for
**"Instructions for Use" (IFU)**

**Lot No.: 79N**                **Lot-specific information**

| Length of spec. | 250 | 220 | 145 | 210 | 250 | 95 | 145 | 270 | 110 | 195 | 180 | 125 | 225 | 155 | 180 | 130 | 320 | 125 | 120 | 165 | 85 | 130 | 85 | 170 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PCR product(s) | | | | | | | | | 180 | 220 | | 165 | 270 | 190 | | | | 220 | 155 | 250 | 145 | | 145 | |
| | | | | | | | | | 220 | | | | | | | | | | | 545 | 240 | | 215 | |
| **Well No.** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** |
| *04:110 | ? | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *04:111 | | 2 | 3 | | | | | | | | 11 | | | | | | | | | | | | | |
| *01:02:01-01:03, 01:05-01:20, 01:23-01:34, 01:36-01:49, 01:51-01:53, 01:55-01:66, 02:02:01-02:02:03, 02:02:05-02:02:22, 02:04-02:11, 02:13-02:15, 02:17, 02:19-02:40, 02:42-02:48, 02:50-02:54, 02:56, 05:01:01:01-05:01:18, 05:03-05:10, 05:12-05:16, 05:18:01-05:24, 05:26, 05:28-05:38, 05:40-05:41, 05:43-05:48N, 05:50, 05:52-05:61, 05:63-05:67, 05:69, 05:71-05:74, 06:02:01:01-06:02:01:02, 06:02:03-06:03:02, 06:06-06:39, 06:41-06:76, 08:02:01-08:02:07, 08:05, 08:07, 08:12, 08:15:01-08:15:02, 08:17-08:19, 08:23, 08:25, 08:27, 08:29-08:35, 08:37, 08:43, 08:45, 08:47-08:49, 08:51-08:53, 08:55N, 12:02:01-12:09, 12:11-12:13, 12:15-12:17, 12:21-12:27, 12:29-12:76, 14:26, 15:08, 16:04, 16:29, 16:33, 16:42, 18:01-18:02, 18:04-18:05 | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| *01:04, 01:54, 14:02:01-14:05, 14:07N-14:08, 14:10-14:14, 14:16-14:19, 14:21N-14:24, 14:27-14:37 | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| *01:21 | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| **Well No.** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** |

CE

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

Lot No.: **79N**          **Lot-specific information**

| 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | Length of spec. |
|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----------------|
| 200 | 215 | 125 | 120 | 185 | 75 | 130 | 105 | 80 | 75 | 85 | 115 | 110 | 105 | 135 | 140 | 135 | 85 | 170 | 135 | 135 | 125 | 155 | Length of spec. |
|  |  | 285 | 215 |  |  | 180 | 235 | 180 | 200 | 175 |  | 135 | 135 | 330 | 270 | 280 |  | 260 |  | 160 | 300 | 240 | PCR product(s) |
|  |  |  |  |  |  |  | 275 |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| **25** | **26** | **27** | **28** | **29** | **30** | **31** | **32** | **33** | **34** | **35** | **36** | **37** | **38** | **39** | **40** | **41** | **42** | **43** | **44** | **45** | **46** | **47** | **Well No.** |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | *04:110 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | *04:111 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | *01:02:01-01:03, 01:05-01:20, 01:23-01:34, 01:36-01:49, 01:51-01:53, 01:55-01:66, 02:02:01-02:02:03, 02:02:05-02:02:22, 02:04-02:11, 02:13-02:15, 02:17, 02:19-02:40, 02:42-02:48, 02:50-02:54, 02:56, 05:01:01:01-05:01:18, 05:03-05:10, 05:12-05:16, 05:18:01-05:24, 05:26, 05:28-05:38, 05:40-05:41, 05:43-05:48N, 05:50, 05:52-05:61, 05:63-05:67, 05:69, 05:71-05:74, 06:02:01:01-06:02:01:02, 06:02:03-06:03:02, 06:06-06:39, 06:41-06:76, 08:02:01-08:02:07, 08:05, 08:07, 08:12, 08:15:01-08:15:02, 08:17-08:19, 08:23, 08:25, 08:27, 08:29-08:35, 08:37, 08:43, 08:45, 08:47-08:49, 08:51-08:53, 08:55N, 12:02:01-12:09, 12:11-12:13, 12:15-12:17, 12:21-12:27, 12:29-12:76, 14:26, 15:08, 16:04, 16:29, 16:33, 16:42, 18:01-18:02, 18:04-18:05 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | **41** |  |  |  |  |  |  | *01:04, 01:54, 14:02:01-14:05, 14:07N-14:08, 14:10-14:14, 14:16-14:19, 14:21N-14:24, 14:27-14:37 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  | **39** |  |  |  |  |  |  |  |  | *01:21 |
| **25** | **26** | **27** | **28** | **29** | **30** | **31** | **32** | **33** | **34** | **35** | **36** | **37** | **38** | **39** | **40** | **41** | **42** | **43** | **44** | **45** | **46** | **47** | **Well No.** |

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

Visit www.olerup-ssp.com for
**"Instructions for Use" (IFU)**

Lot No.: **79N**          **Lot-specific information**

| Length of spec. | 250 | 220 | 145 | 210 | 250 | 95 | 145 | 270 | 110 | 195 | 180 | 125 | 225 | 155 | 180 | 130 | 320 | 125 | 120 | 165 | 85 | 130 | 85 | 170 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PCR product(s) | | | | | | | | | 180 | 220 | | 165 | 270 | 190 | | | | 220 | 155 | 250 | 145 | | 145 | |
| | | | | | | | | | 220 | | | | | | | | | | | 545 | 240 | | 215 | |
| **Well No.** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** |
| *01:22, 02:03, 02:16:01-02:16:02, 02:18, 05:11, 05:17, 05:68, 06:04, 08:01:01-08:01:05, 08:03:01-08:04:02, 08:06, 08:08-08:11, 08:13-08:14, 08:16:01-08:16:02, 08:20-08:22, 08:24, 08:26N, 08:36N, 08:38-08:40, 08:42, 08:44, 08:46, 08:50, 08:54, 08:56-08:60, 12:14:01-12:14:02, 12:18:01-12:18:02, 12:20, 15:02:01-15:07, 15:09-15:13, 15:16-15:24, 15:26-15:35, 15:37-15:50, 15:52-15:60, 16:35, 16:40, 17:01:01:01-17:06, 17:08-17:11 | | | | | 5 | | | | | | | | | | | | | | | | | | | |
| *01:35, 05:27, 08:41, 15:15, 17:07, *B*58:02* | | | | | 5 | | | 8 | | | | | | | | | | | | | | | | |
| *01:50 | 1 | | | | | | | | | | | | | | | | 17 | | | | | | | |
| *03:05, 03:25, 03:27, *B*15:78:03* | | | | | | | | | | | | | | | | 16 | | | | | | | | |
| *03:34, 03:142 | | | | | | | 7 | | | | | | | | | | | | | | | | | |
| *03:135 | | | | | | | | | | | | | | | | 16 | | | 19 | | | | | |
| *05:25, 05:42, 06:05, 08:28, 12:28 | 1 | | | | | | | | | | 11 | | | | | | | | | | | | | |
| *05:39 | 1 | | | | | | | 8 | | | | | | | | | | | | | | | | |
| *05:49 | 1 | | | | | | | | | | | | | | | | | | | | | | | |
| *07:02:09, 15:25, 16:26 | | | | | | | | | | | 11 | | | | | | | | | | | | | |
| *07:08, 07:108 | | | | | | | | | | | | | | 14 | | | | | | | | | | |
| *07:64 | | 2 | | | | | 7 | | | | | | | | | | | | | | | | | |
| *07:125 | | | | | | | | | | | | 12 | | | | | | | | | | | | 24 |
| *07:167 | | | | | | | | | | | | | | | | | | | | | | | | |
| *12:10:01-12:10:02 | 1 | | | | | | | | | | | | | | | | | 18 | | | | | | |
| *14:06, 14:15 | | | | | 5 | | | | | | | | | | | | | | | | | | | |
| *14:09 | 1 | | | | | | | | | | | | | | | 16 | | | | | | | | |
| *14:20 | 1 | | | | | | | 8 | | | | | | | | | | | | | | | | |
| *14:25 | 1 | | | | | | 7 | | | | | | | | | | | | | | | | | |
| *15:36 | | | | | 5 | | 7 | | | 10 | | | | | | | | | | 20 | | | | |
| *16:12 | | | | | | | | | | | | | | | | | | | | | | | | |
| *16:45, *A*24:96, A*24:146* | | | | | | | | | | | | | | | 15 | | | | | | | | | |
| *18:03 | 1 | | | | | | 7 | | | | | | | | | | | 18 | | | | | | |
| **Well No.** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** |

CE

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

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**"Instructions for Use" (IFU)**

**Lot No.: 79N**      **Lot-specific information**

| 200 | 215 | 125 | 120 | 185 | 75 | 130 | 105 | 80 | 75 | 85 | 115 | 110 | 105 | 135 | 140 | 135 | 85 | 170 | 135 | 135 | 125 | 155 | Length of spec. |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 285 | 215 | | | 180 | 235 | 180 | 200 | 175 | | 135 | 135 | 330 | 270 | 280 | | 260 | | 160 | 300 | 240 | PCR product(s) |
| | | | | | | | 275 | | | | | | | | | | | | | | | | |
| 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | Well No. |
| | | | | | | | | | | | | | | | | | | | | | | | *01:22, 02:03, 02:16:01-02:16:02, 02:18, 05:11, 05:17, 05:68, 06:04, 08:01:01-08:01:05, 08:03:01-08:04:02, 08:06, 08:08-08:11, 08:13-08:14, 08:16:01-08:16:02, 08:20-08:22, 08:24, 08:26N, 08:36N, 08:38-08:40, 08:42, 08:44, 08:46, 08:50, 08:54, 08:56-08:60, 12:14:01-12:14:02, 12:18:01-12:18:02, 12:20, 15:02:01-15:07, 15:09-15:13, 15:16-15:24, 15:26-15:35, 15:37-15:50, 15:52-15:60, 16:35, 16:40, 17:01:01:01-17:06, 17:08-17:11 |
| | | | | | | | | | | | | | | | | | | | | | | | *01:35, 05:27, 08:41, 15:15, 17:07, *B*58:02* |
| | | | | | | | | | | | | | | | | | | | | | | | *01:50 |
| | | | | | | | | | | | | | | | | | | | | | | | *03:05, 03:25, 03:27, *B*15:78:03* |
| | | | | | | | | | | | | | | | | | | | | | | | *03:34, 03:142 |
| | | | | | | | | | | | | | | | | | | | | | | | *03:135 |
| | | | | | | | | | | | | | | | | | | | | | | | *05:25, 05:42, 06:05, 08:28, 12:28 |
| | | | | | | | | | | | | | | | | | | | | | | | *05:39 |
| | | | | | 30 | | | | | | | | | | | | | | | | | | *05:49 |
| | | | | | | | | | | | | | | | | | | | | | | | *07:02:09, 15:25, 16:26 |
| | | | | | | | | 33 | 34 | | | | | | | | | | | | | | *07:08, 07:108 |
| | | | | | | | | | | | | | | | | | | | | | | | *07:64 |
| | | | | | | | | | | | | | | | | | | | | | | | *07:125 |
| | | | | | | | | | | | | | | | | | | | | | | 47 | *07:167 |
| 25 | | | | | | | | | | | | | | | | | | | | | | | *12:10:01-12:10:02 |
| | | | | | | | | | | | | | | | | 41 | | | | | | | *14:06, 14:15 |
| | | | | | | | | | | | | | | | | 41 | | | | | | | *14:09 |
| | | | | | | | | | | | | | | | | 41 | | | | | | | *14:20 |
| | | | | | | | | | | | | | | | | 41 | | | | | | | *14:25 |
| | | | | | | | | | | | | | | | | | | | | | | | *15:36 |
| | | | | | | | | | | | | | | | | | 42 | | | | | | *16:12 |
| | | | | | | | | | | | | | | | | | | | | | | | *16:45, *A*24:96, A*24:146* |
| 25 | | | | | | | | | | | | | | | | | | | | | | | *18:03 |
| 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | Well No. |

CE

**101.612-12 – including *Taq* pol.**          Visit www.olerup-ssp.com for
**101.612-12u– without *Taq* pol.**          **"Instructions for Use" (IFU)**

Lot No.: **79N**                    Lot-specific information

| Length of spec. | 250 | 220 | 145 | 210 | 250 | 95 | 145 | 270 | 110 | 195 | 180 | 125 | 225 | 155 | 180 | 130 | 320 | 125 | 120 | 165 | 85 | 130 | 85 | 170 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| PCR product(s) | | | | | | | | | 180 | 220 | | 165 | 270 | 190 | | | | 220 | 155 | 250 | 145 | | 145 | |
| | | | | | | | | | 220 | | | | | | | | | | | 545 | 240 | | 215 | |
| **Well No.** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** |
| *A*33:52 | | | | | | | | | | | | | | | | | | | | 20 | | | | |
| *B*07:90 | | | | | | | | | | | | | | | | | | | | | | | | |
| *B*15:27:01-15:27:03, A*15:109 | | | | | | | | | | | | | | | | | | 18 | | | | | | |
| *B*40:100 | | | | | | | | | | | | | | | | | | | | | | | | |
| **HLA-C allele**[4,5] | | | | | | | | | | | | | | | | | | | | | | | | |
| **Well No.** | **1** | **2** | **3** | **4** | **5** | **6** | **7** | **8** | **9** | **10** | **11** | **12** | **13** | **14** | **15** | **16** | **17** | **18** | **19** | **20** | **21** | **22** | **23** | **24** |

[1]The internal positive control primer pairs amplify segments of the human growth hormone gene. The two different control primer pairs give rise to either an internal positive control band of 1070 base pairs, for most wells, or a band of 800 base pairs, for some wells.
Well number 1 contains the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to help in the correct orientation of the HLA-C*04 subtyping. .
In addition, wells number 26, 27 and 40 contain the primer pair giving rise to the shorter, 800 bp, internal positive control band in order to allow kit identification.

[2]The nucleotide position, in the 2nd, 3rd, 4th, 5th or 6th, exon or in the 2nd and 3rd intron, 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.

[3]The nucleotide position, in the 2nd, 3rd, 4th, 6th or 7th exon or in the 3rd intron, 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.

[4]The nucleotide sequence of the Cw*0402 allele has been shown to be identical to C*04:01:01:01. The nucleotide sequence of the Cw*0421 allele has been renamed C*04:15:02.
The nucleotide sequence of the Cw*0422 allele has been shown to be identical to C*04:21.

[5]HLA-C*04 alleles in bold lettering are listed as confirmed alleles on the IMGT/HLA web page www.ebi.ac.uk/imgt/hla, release 3.8.0, April 2012.

[6]The HLA-C*04 primer set cannot separate the C*04:03 and 02:49 alleles. These alleles can be distinguished by the HLA-C low resolution kit and/or the HLA-C*02 high resolution kit.

[7]The HLA-C*04 primer set cannot separate the C*04:107 and the C*02:12 and 02:55 alleles. These alleles can be distinguished by the HLA-C low resolution kit and/or the HLA-C*02 high resolution kit.

[8]The C*04:15:02, C*04:44 and C*04:47alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 20.

[9]The C*04:23, C*04:38 and C*04:39 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 21.

[10]The C*04:25, C*04:40 and C*04:41 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 23.

[11]The C*04:46 and C*04:50 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 27.

[12]The C*04:48 and C*04:75 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 28.

[13]The C*04:54 and C*04:105N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 41.

[14]The C*04:56 and C*04:64 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 40.

[15]The C*04:59Q and C*04:78 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 32.

CE

October 2013                                                     For In Vitro Diagnostic Use
Rev. No.: 01

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

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**"Instructions for Use" (IFU)**

**Lot No.: 79N**   **Lot-specific information**

| 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 | |
|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|---|
| 200 | 215 | 125 | 120 | 185 | 75 | 130 | 105 | 80 | 75 | 85 | 115 | 110 | 105 | 135 | 140 | 135 | 85 | 170 | 135 | 135 | 125 | 155 | **Length of spec.** |
| | | 285 | 215 | | 180 | | 235 | 180 | 200 | 175 | | 135 | 135 | 330 | 270 | 280 | | 260 | | 160 | 300 | 240 | **PCR product(s)** |
| | | | | | | | 275 | | | | | | | | | | | | | | | | |
| **25** | **26** | **27** | **28** | **29** | **30** | **31** | **32** | **33** | **34** | **35** | **36** | **37** | **38** | **39** | **40** | **41** | **42** | **43** | **44** | **45** | **46** | **47** | **Well No.** |
| | | | | | | | | | | | | | | | | | | | | | | | *A\*33:52* |
| | | | | | 30 | | | | | | | | | | | | | | | | | | *B\*07:90* |
| 25 | | | | | | | | | | | | | | | | | | | | | | | *B\*15:27:01-15:27:03, A\*15:109* |
| | | | | | | | 32 | 33 | | | | | | | | | | | | | | | *B\*40:100* |
| | | | | | | | | | | | | | | | | | | | | | | | **HLA-C allele[4,5]** |
| **25** | **26** | **27** | **28** | **29** | **30** | **31** | **32** | **33** | **34** | **35** | **36** | **37** | **38** | **39** | **40** | **41** | **42** | **43** | **44** | **45** | **46** | **47** | **Well No.** |

[16]The C\*04:61 and C\*04:96 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 34.

[17]The C\*04:62 and C\*04:76 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 35.

[18]The C\*04:65 and C\*04:72 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 33.

[19]The C\*04:67 and C\*04:93N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 46.

[20]The C\*04:81 and C\*04:88N alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 43.

[21]The C\*04:84 and C\*04:106 alleles can be distinguished by the different sizes of the specific PCR products generated by primer mix 47.

[22]Primer mix 9: Specific PCR fragment of 110 bp in the C\*04:35 allele. Specific PCR fragment of 180 bp in the C\*04:30 allele. Specific PCR fragment of 220 bp in the C\*04:09N allele.

Primer mix 10: Specific PCR fragment of 195 bp in the C\*04:31 allele. Specific PCR fragment of 220 bp in the C\*04:10-04:11, 04:36 and 04:55 and the C\*15:36 alleles.

Primer mix 12: Specific PCR fragment of 125 bp in the C\*04:29, 04:36 and 04:55 and the C\*07:125 alleles. Specific PCR fragment of 165 bp in the C\*04:33 allele. Specific PCR fragment of 125 and 165 bp in the C\*04:11 allele.

Primer mix 13: Specific PCR fragment of 225 bp in the C\*04:12 allele. Specific PCR fragment of 270 bp in the C\*04:52 and 04:55 alleles.

Primer mix 14: Specific PCR fragment of 155 bp in the C\*04:16 allele. Specific PCR fragment of 190 bp in the C\*04:13, 04:18 and 04:58 and the C\*07:08 and 07:108 alleles.

Primer mix 18: Specific PCR fragment of 125 bp in the C\*04:70 allele. Specific PCR fragment of 220 bp in the C\*04:19 and 04:94:01-04:94:02 and the C\*12:10:01-12:10:02 and 18:03 and in the B\*15:27:01-15:27:03 and B\*15:109 alleles.

Primer mix 19: Specific PCR fragment of 120 bp in the C\*04:35 and 04:37 alleles. Specific PCR fragment of 155 bp in the C\*04:20 and the C\*03:135 alleles.

Primer mix 20: Specific PCR fragment of 165 bp in the C\*04:44 allele. Specific PCR fragment of 250 bp in the C\*04:47 allele. Specific PCR fragment of 545 bp in the C\*04:15:02, 04:17 and 04:100 and the C\*15:36 and the A\*33:52 alleles.

Primer mix 21: Specific PCR fragment of 85 bp in the C\*04:23 and 04:108 alleles. Specific PCR fragment of 145 bp in the C\*04:38 allele. Specific PCR fragment of 240 bp in the C\*04:39 allele.

Primer mix 23: Specific PCR fragment of 85 bp in the C\*04:25 allele. Specific PCR fragment of 145 bp in the C\*04:40 allele. Specific PCR fragment of 215 bp in the C\*04:41 allele.

Primer mix 27: Specific PCR fragment of 125 bp in the C\*04:50 allele. Specific PCR fragment of 285 bp in the C\*04:46 allele.

Primer mix 28: Specific PCR fragment of 120 bp in the C\*04:75 allele. Specific PCR fragment of 215 bp in the C\*04:48 allele.

Primer mix 31: Specific PCR fragment of 130 bp in the C\*04:95N allele. Specific PCR fragment of 180 bp in the C\*04:51 allele.

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**Lot No.: 79N**                    **Lot-specific information**

Primer mix 32: Specific PCR fragment of 105 bp in the C*04:78 allele. Specific PCR fragment of 235 bp in the C*04:59Q allele. Specific PCR fragment of 275 bp in the C*04:77 and in the B*40:100 alleles.

Primer mix 33: Specific PCR fragment of 80 bp in the C*04:72 allele. Specific PCR fragment of 180 bp in the C*04:58 and 04:65 and the C*07:08 and 07:108 and in the B*40:100 alleles.

Primer mix 34: Specific PCR fragment of 75 bp in the C*04:96 allele. Specific PCR fragment of 200 bp in the C*04:13, 04:58, 04:61 and 04:68 and the C*07:08 and 07:108 alleles.

Primer mix 35: Specific PCR fragment of 85 bp in the C*04:62 allele. Specific PCR fragment of 175 bp in the C*04:76 allele.

Primer mix 37: Specific PCR fragment of 110 bp in the C*04:63 and 04:73 alleles. Specific PCR fragment of 135 bp in the C*04:74 allele.

Primer mix 38: Specific PCR fragment of 105 bp in the C*04:83 allele. Specific PCR fragment of 135 bp in the C*04:74 allele.

Primer mix 39: Specific PCR fragment of 135 bp in the C*04:71 and 04:95N and the C*01:21 alleles. Specific PCR fragment of 330 bp in the C*04:79 allele.

Primer mix 40: Specific PCR fragment of 140 bp in the C*04:56 allele. Specific PCR fragment of 270 bp in the C*04:64 allele.

Primer mix 41: Specific PCR fragment of 135 bp in the C*04:105N allele. Specific PCR fragment of 280 bp in the C*04:54 and the C*01:04, 01:54, 14:02:01-14:25 and 14:27-14:37 alleles.

Primer mix 43: Specific PCR fragment of 170 bp in the C*04:81 allele. Specific PCR fragment of 260 bp in the C*04:88N allele.

Primer mix 45: Specific PCR fragment of 135 bp in the C*04:66 allele. Specific PCR fragment of 160 bp in the C*04:16 and 04:103 alleles.

Primer mix 46: Specific PCR fragment of 125 bp in the C*04:93N allele. Specific PCR fragment of 300 bp in the C*04:67 allele.

Primer mix 47: Specific PCR fragment of 155 bp in the C*04:84 and the C*07:167 alleles. Specific PCR fragment of 240 bp in the C*04:106 allele.

 'w', may be weakly amplified.

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**101.612-12u– without *Taq* pol.**

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**Lot No.: 79N**       **Lot-specific information**

## CELL LINE VALIDATION SHEET
### HLA-C*04 SSP subtyping kit

| # | IHWC cell line | | C* | | Prod. No.: | 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 | 16 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 201070201 | 201070202 | 201070203 | 201201804 | 201070205 | 201070206 | 201070207 | 201070208 | 201070209 | 201201810 | 201070211 | 201070212 | 201070213 | 201205414 | 201070215 | 201070216 |
| 1 | 9001 | SA | *07:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 2 | 9280 | LK707 | *07:01 | *15:05 | | - | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - |
| 3 | 9011 | E4181324 | *12:02 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 4 | 9275 | GU373 | *03:04 | *04:01 | | + | + | + | - | - | - | - | - | - | - | + | - | - | - | - | - |
| 5 | 9009 | KAS011 | *06:02 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 6 | 9353 | SM | *03:04 | *07:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 7 | 9020 | QBL | *05:01 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 8 | 9025 | DEU | *04:01 | | | + | + | + | - | - | - | - | - | - | - | + | - | - | - | - | - |
| 9 | 9026 | YAR | *12:03 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 10 | 9107 | LKT3 | *01:02 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 11 | 9051 | PITOUT | *16:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 12 | 9052 | DBB | *06:02 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 13 | 9004 | JESTHOM | *01:02 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 14 | 9071 | OLGA | *01:02 | *03:04 | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 15 | 9075 | DKB | *03:04 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 16 | 9037 | SWEIG007 | *02:02 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 17 | 9282 | CTM3953540 | *03:03 | *07:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 18 | 9257 | 32367 | *01:02 | *07:05 | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 19 | 9038 | BM16 | *07:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 20 | 9059 | SLE005 | *03:04 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 21 | 9064 | AMALA | *03:03 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 22 | 9056 | KOSE | *12:03 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 23 | 9124 | IHL | *01:02 | *15:02 | | + | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - |
| 24 | 9035 | JBUSH | *12:03 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 25 | 9049 | IBW9 | *08:02 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 26 | 9285 | WT49 | *07:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 27 | 9191 | CH1007 | *07:04 | *15:05 | | - | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - |
| 28 | 9320 | BEL5GB | *05:01 | *16:01 | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 29 | 9050 | MOU | *16:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 30 | 9021 | RSH | *17:01 | | | - | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - |
| 31 | 9019 | DUCAF | *05:01 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 32 | 9297 | HAG | *17:01 | *17:03 | | - | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - |
| 33 | 9098 | MT14B | *03:04 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 34 | 9104 | DHIF | *12:03 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 35 | 9302 | SSTO | *05:01 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 36 | 9024 | KT17 | *03:03 | *04:01 | | + | + | + | - | - | - | - | - | - | - | + | - | - | - | - | - |
| 37 | 9065 | HHKB | *07:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 38 | 9099 | LZL | *03:03 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 39 | 9315 | CML | *02:02 | *07:01 | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 40 | 9134 | WHONP199 | *01:02 | *06:02 | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 41 | 9055 | H0301 | *08:02 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 42 | 9066 | TAB089 | *01:02 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 43 | 9076 | T7526 | *01:02 | *08:01 | | + | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - |
| 44 | 9057 | TEM | *12:03 | | | + | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 45 | 9239 | SHJO | *06:02 | *17:01 | | + | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - |
| 46 | 9013 | SCHU | *07:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 47 | 9045 | TUBO | *07:04 | *15:02 | | - | - | - | - | + | - | - | - | - | - | - | - | - | - | - | - |
| 48 | 9303 | TER-ND | *04:01 | *16:01 | | + | + | + | - | - | - | - | - | - | - | + | - | - | - | - | - |

CE

**101.612-12 – including *Taq* pol.**
**101.612-12u– without *Taq* pol.**

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**Lot No.: 79N**       **Lot-specific information**

## CELL LINE VALIDATION SHEET
### HLA-C*04 SSP subtyping kit

| # | IHWC cell line | | C* | | Prod. No.: | 17 | 18 | 19 | 20 | 21 | 22 | 23 | 24 | 25 | 26 | 27 | 28 | 29 | 30 | 31 | 32 |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | 201185317 | 201201818 | 201070219 | 201070220 | 201070221 | 201070222 | 201070223 | 201070224 | 201201825 | 201070226 | 201070227 | 201185328 | 201070229 | 201070230 | 201201831 | 201205432 |
| 1 | 9001 | SA | *07:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 2 | 9280 | LK707 | *07:01 | *15:05 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 3 | 9011 | E4181324 | *12:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 4 | 9275 | GU373 | *03:04 | *04:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 5 | 9009 | KAS011 | *06:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 6 | 9353 | SM | *03:04 | *07:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 7 | 9020 | QBL | *05:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 8 | 9025 | DEU | *04:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 9 | 9026 | YAR | *12:03 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 10 | 9107 | LKT3 | *01:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 11 | 9051 | PITOUT | *16:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 12 | 9052 | DBB | *06:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 13 | 9004 | JESTHOM | *01:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 14 | 9071 | OLGA | *01:02 | *03:04 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 15 | 9075 | DKB | *03:04 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 16 | 9037 | SWEIG007 | *02:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 17 | 9282 | CTM3953540 | *03:03 | *07:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 18 | 9257 | 32367 | *01:02 | *07:05 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 19 | 9038 | BM16 | *07:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 20 | 9059 | SLE005 | *03:04 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 21 | 9064 | AMALA | *03:03 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 22 | 9056 | KOSE | *12:03 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 23 | 9124 | IHL | *01:02 | *15:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 24 | 9035 | JBUSH | *12:03 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 25 | 9049 | IBW9 | *08:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 26 | 9285 | WT49 | *07:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 27 | 9191 | CH1007 | *07:04 | *15:05 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 28 | 9320 | BEL5GB | *05:01 | *16:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 29 | 9050 | MOU | *16:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 30 | 9021 | RSH | *17:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 31 | 9019 | DUCAF | *05:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 32 | 9297 | HAG | *17:01 | *17:03 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 33 | 9098 | MT14B | *03:04 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 34 | 9104 | DHIF | *12:03 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 35 | 9302 | SSTO | *05:01 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 36 | 9024 | KT17 | *03:03 | *04:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 37 | 9065 | HHKB | *07:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 38 | 9099 | LZL | *03:03 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 39 | 9315 | CML | *02:02 | *07:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 40 | 9134 | WHONP199 | *01:02 | *06:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 41 | 9055 | H0301 | *08:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 42 | 9066 | TAB089 | *01:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 43 | 9076 | T7526 | *01:02 | *08:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 44 | 9057 | TEM | *12:03 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 45 | 9239 | SHJO | *06:02 | *17:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 46 | 9013 | SCHU | *07:02 | | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 47 | 9045 | TUBO | *07:04 | *15:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 48 | 9303 | TER-ND | *04:01 | *16:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |

CE

October 2013        For In Vitro Diagnostic Use
Rev. No.: 01

**101.612-12 – including *Taq* pol.**          Visit www.olerup-ssp.com for
**101.612-12u– without *Taq* pol.**          **"Instructions for Use" (IFU)**

**Lot No.: 79N**          **Lot-specific information**

| | | | | | Well | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | 33 | 34 | 35 | 36 | 37 | 38 | 39 | 40 | 41 | 42 | 43 | 44 | 45 | 46 | 47 |
| | | | | Prod. No.: | 201185333 | 201201834 | 201205435 | 201185336 | 201205437 | 201205438 | 201201839 | 201185340 | 201201841 | 201205442 | 201201843 | 201185344 | 201201845 | 201205446 | 201201847 |
| | **IHWC cell line** | | **C*** | | | | | | | | | | | | | | | | |
| 1 | 9001 | SA | *07:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 2 | 9280 | LK707 | *07:01 | *15:05 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 3 | 9011 | E4181324 | *12:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 4 | 9275 | GU373 | *03:04 | *04:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 5 | 9009 | KAS011 | *06:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 6 | 9353 | SM | *03:04 | *07:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 7 | 9020 | QBL | *05:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 8 | 9025 | DEU | *04:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 9 | 9026 | YAR | *12:03 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 10 | 9107 | LKT3 | *01:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 11 | 9051 | PITOUT | *16:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 12 | 9052 | DBB | *06:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 13 | 9004 | JESTHOM | *01:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 14 | 9071 | OLGA | *01:02 | *03:04 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 15 | 9075 | DKB | *03:04 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 16 | 9037 | SWEIG007 | *02:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 17 | 9282 | CTM3953540 | *03:03 | *07:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 18 | 9257 | 32367 | *01:02 | *07:05 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 19 | 9038 | BM16 | *07:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 20 | 9059 | SLE005 | *03:04 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 21 | 9064 | AMALA | *03:03 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 22 | 9056 | KOSE | *12:03 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 23 | 9124 | IHL | *01:02 | *15:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 24 | 9035 | JBUSH | *12:03 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 25 | 9049 | IBW9 | *08:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 26 | 9285 | WT49 | *07:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 27 | 9191 | CH1007 | *07:04 | *15:05 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 28 | 9320 | BEL5GB | *05:01 | *16:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 29 | 9050 | MOU | *16:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 30 | 9021 | RSH | *17:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 31 | 9019 | DUCAF | *05:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 32 | 9297 | HAG | *17:01 | *17:03 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 33 | 9098 | MT14B | *03:04 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 34 | 9104 | DHIF | *12:03 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 35 | 9302 | SSTO | *05:01 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 36 | 9024 | KT17 | *03:03 | *04:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 37 | 9065 | HHKB | *07:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 38 | 9099 | LZL | *03:03 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 39 | 9315 | CML | *02:02 | *07:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 40 | 9134 | WHONP199 | *01:02 | *06:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 41 | 9055 | H0301 | *08:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 42 | 9066 | TAB089 | *01:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 43 | 9076 | T7526 | *01:02 | *08:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 44 | 9057 | TEM | *12:03 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 45 | 9239 | SHJO | *06:02 | *17:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 46 | 9013 | SCHU | *07:02 | | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 47 | 9045 | TUBO | *07:04 | *15:02 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |
| 48 | 9303 | TER-ND | *04:01 | *16:01 | - | - | - | - | - | - | - | - | - | - | - | - | - | - | - |

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**101.612-12 – including *Taq* pol.**          Visit www.olerup-ssp.com for
**101.612-12u– without *Taq* pol.**          **"Instructions for Use" (IFU)**

**Lot No.: 79N**          **Lot-specific information**

# CERTIFICATE OF ANALYSIS

## *Olerup* SSP® HLA-C*04 SSP

| | |
|---|---|
| **Product number:** | **101.612-12 – including *Taq* polymerase** |
| | **101.612-12u – without *Taq* polymerase** |
| **Lot number:** | **79N** |
| **Expiry date:** | **2015-January-01** |
| **Number of tests:** | **12** |
| **Number of wells per test:** | **47** |

**Well specifications:**

| Well No. | Production No. | Well No. | Production No. | Well No. | Production No. |
|---|---|---|---|---|---|
| 1 | 2010-702-01 | 17 | 2011-853-17 | 33 | 2011-853-33 |
| 2 | 2010-702-02 | 18 | 2012-018-18 | 34 | 2012-018-34 |
| 3 | 2010-702-03 | 19 | 2010-702-19 | 35 | 2012-054-35 |
| 4 | 2012-018-04 | 20 | 2010-702-20 | 36 | 2011-853-36 |
| 5 | 2010-702-05 | 21 | 2010-702-21 | 37 | 2012-054-37 |
| 6 | 2010-702-06 | 22 | 2010-702-22 | 38 | 2012-054-38 |
| 7 | 2010-702-07 | 23 | 2010-702-23 | 39 | 2012-018-39 |
| 8 | 2010-702-08 | 24 | 2010-702-24 | 40 | 2011-853-40 |
| 9 | 2010-702-09 | 25 | 2012-018-25 | 41 | 2012-018-41 |
| 10 | 2012-018-10 | 26 | 2010-702-26 | 42 | 2012-054-42 |
| 11 | 2010-702-11 | 27 | 2010-702-27 | 43 | 2012-018-43 |
| 12 | 2010-702-12 | 28 | 2011-853-28 | 44 | 2011-853-44 |
| 13 | 2010-702-13 | 29 | 2010-702-29 | 45 | 2012-018-45 |
| 14 | 2012-054-14 | 30 | 2010-702-30 | 46 | 2012-054-46 |
| 15 | 2010-702-15 | 31 | 2012-018-31 | 47 | 2012-018-47 |
| 16 | 2010-702-16 | 32 | 2012-054-32 | | |

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

No DNAs carrying the alleles to be amplified by primer solutions 6, 8, 10, 12, 13, 15, 17, 19 to 24, 26 to 40 and 42 to 47 were available. The specificity of the primers in primer solutions 8, 10, 12, 13, 15, 17, 19 to 21, 24, 28, 31 to 34, 39, 42 and 45 were tested by separately adding one additional 5'-primer, respectively one additional 3'-primer. In primer solutions 6, 26, 27, 29, 35, 40, 43 and 47 it was only possible to test the 5'-primers, the 3'-primers were not possible to test. In primer solutions 22, 23, 30, 36 to 38 and 44 and 46 it was only possible to test the 3'-primers, the 5'-primers were not possible to test. In primer solutions 9, 15, 18, 19, 24, 28, 31, 41, 42 and 45 one or two of the 5'-primers were not possible to test, and in primer solutions 9, 10, 13, 14, 18, 20, 21, 24, 25, 28, 31 to 34 and 39 one or two of the 3'-primers were not possible to test. Additional primers in primer solutions 7, 9, 14, 16, 18 and 41 were tested by separately adding one 5'-primer and/or one 3'-primer.

**101.612-12 – including *Taq* pol.**        Visit www.olerup-ssp.com for
**101.612-12u– without *Taq* pol.**        **"Instructions for Use" (IFU)**

**Lot No.: 79N**        **Lot-specific information**
*Results:*     No false positive or false negative amplifications were obtained.

*Date of approval:*    2012-July-13

*Approved by:*

**Production Quality Control**

**101.612-12 – including *Taq* pol.**               Visit www.olerup-ssp.com for
**101.612-12u– without *Taq* pol.**                 **"Instructions for Use" (IFU)**

Lot No.: **79N**                    Lot-specific information
# Declaration of Conformity

**Product name:**       *Olerup* SSP® HLA-C*04
**Product number:**     101.612-12/12u
**Lot number:**         79N

**Intended use:**       HLA-C*04 high resolution histocompatibility testing

**Manufacturer:**       *Olerup* SSP AB
                        Franzengatan 5
                        SE-112 51 Stockholm, Sweden
                        ***Phone:*** +46-8-717 88 27
                        ***Fax:*** +46-8-717 88 18

We, *Olerup* SSP AB, hereby declare that this product, to which this Declaration of Conformity relates is in conformity with the following Standard(s) and other normative document(s) ISO 9001:2008 and ISO 13485:2003, following the provisions of the 98/79/EC Directive on *in vitro* diagnostic medical devices, Annex III, as transposed into the national laws of the Member States of the European Union.

The Technical Documentation File is maintained at *Olerup* SSP AB, Franzengatan 5, SE-112 51 Stockholm, Sweden.

The Authorized Representative located within the Community is: *Olerup* SSP AB.

Stockholm, Sweden
2012-July-13


Ann-Cathrin Jareman
Head of QA and Regulatory Affairs

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**Lot No.: 79N**                    **Lot-specific information**

October 2013                    $C \in$                    For In Vitro Diagnostic Use
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**101.612-12u– without *Taq* pol.**                    **"Instructions for Use" (IFU)**

Lot No.: **79N**                    **Lot-specific information**

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***Fax:*** +46-8-717 88 18
***E-mail:*** info-ssp@olerup.com
***Web page:*** http://www.olerup-ssp.com

**Distributed by:**
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***Tel:*** +43-1-710 15 00
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***Fax:*** 610-344-7989
***E-mail:*** info.us@olerup.com
***Web page:*** http://www.olerup.com

For information on *Olerup* SSP distributors worldwide, contact **Olerup GmbH**.

CE