•LERUPSSP<sup>®</sup> HLA-B\*35 101.522-24/03 – including *Taq* polymerase 101.522-24u/03u – without *Taq* polymerase Lot No.: **02X** 

## **Olerup SSP<sup>®</sup> HLA-B\*35**

| Product number:           | 101.522-24/03 – including <i>Taq</i> pol. |  |
|---------------------------|---|--|
|                           | 101.522-24u/03u – without <i>Taq</i> pol. |  |
| Lot number:               | 02X                                       |  |
| Expiry date:              | 2017-January-01                           |  |
| Number of tests:          | 24 tests – Product No. 101.522-24/24u     |  |
|                           | 3 tests – Product No. 101.522-03/03u      |  |
| Number of wells per test: | 87+1                                      |  |

### CHANGES COMPARED TO THE PREVIOUS HLA-B\*35 LOT (54S):

| Well | 5'-primer | 3'-primer | rationale   |
|------|-----------|-----------|---|
| 1    | -         | Added     | 3'-primer added for the B*35:02:06 allele.  |
| 34   | Added     | -         | 5'-primer added for the B*35:214 allele.  |
| 41   | Moved     | Moved     | Primer pair moved to well 84 for decreased tendency of primer oligomer formation. |
| 51   | Added     | -         | 5'-primer added for the B*35:214 allele.  |
| 77   | -         | Added     | 3'-primer added for the B*35:245 allele.  |
| 80   | New       | New       | New primer pair added for the B*35:194 allele.                                    |
| 81   | New       | New       | New primer pair added for the B*35:219 allele.                                    |
| 82   | New       | New       | New primer pair added for the B*35:225 allele.                                    |
| 83   | New       | New       | New primer pairs added for the B*35:245 and B*35:250 alleles.                     |
| 84   | Added     | Added     | Primer pairs added from well 41.  |
| 85   | New       | New       | New primer pair for the B*35:42:01 allele.  |
| 86   | New       | New       | New primer pair for the B*35:42:02 allele.  |
| 87   | New       | New       | New primer pair for the B*35:241 allele.  |
| 88   | -         | -         | Negative Control.   |

THE NUMBER OF WELLS is increased from 79 to 88 wells.

#### ALLELE COVERAGE:

All the HLA-B\*35 alleles, i.e. **B\*35:01 to B\*35:254**, recognized by the HLA Nomenclature Committee in April 2014<sup>1</sup> will be amplified by the primers in the HLA-B\*35 subtyping kit.

The HLA-B\*35 kit enables separation of the confirmed HLA-B\*35 alleles as listed in the IMGT/HLA database. An HLA allele is listed as confirmed by IMGT/HLA if it has been sequenced by more than a single laboratory or from multiple sources.



The HLA-B\*35 kit also enables identification of polymorphisms in exons outside of the region encoding the peptide binding domain and of null and alternatively expressed alleles.

The following HLA-B\*35 alleles can be distinguished by the different sizes of the HLA-specific PCR product:

| Alleles            | Primer mix |
|--------------------|------------|
| B*35:55, 53:31     | 44         |
| B*35:122, 35:123   | 61         |
| B*35:130N, 35:134N | 64         |
| B*35:132, 35:144   | 62         |

The HLA-B\*35 subtyping kit cannot distinguish the following silent mutations: the B\*35:01:01:01-35:01:03, 35:01:05-35:01:16, 35:01:18-35:01:22, 35:01:24-35:01:27, 35:01:29-35:01:33 and 35:01:35-35:01:41, the B\*35:02:01-35:02:06, the B\*35:03:01, 35:03:03-35:03:06, 35:03:08-35:03:10 and 35:03:12-35:03:14, the B\*35:04:01-35:04:02, the B\*35:05:01-35:05:03, the B\*35:08:01-35:08:02, 35:08:04 and 35:08:06-35:08:07, the B\*35:09:02-35:09:03, the B\*35:11:01 and B\*35:11:03, the B\*35:12:01-35:12:03, the 35:17:01-35:17:02, the B\*35:20:01-35:20:02, the B\*35:24:01-35:24:02, the B\*35:29:01-35:29:02, the B\*35:32:01-35:32:02, the B\*35:101:01-35:101:02 or the B\*35:108:01-35:108:02 alleles.

<sup>1</sup>Alleles that have been deleted from or renamed in the official WHO HLA Nomenclature up to and including the last IMGT/HLA database release can be retrieved from web page <u>http://hla.alleles.org/alleles/deleted.html</u>.

## RESOLUTION IN HLA-B\*35 HOMO- AND HETEROZYGOTES:

Good.

# INFLUENCE ON THE INTERPRETATION OF HLA-B\*35 SUBTYPINGS BY NON-HLA-B\*35 ALLELES:

The interpretation of HLA-B\*35 subtypings is influenced by many other HLA-B alleles.

## MODIFICATIONS MADE DUE TO COMMENTS FROM CUSTOMERS:

No comments received.

