EXAMPLE 2 EXAMPLE 2 EXAMP

Olerup SSP[®] 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:	36Y
Expiry date:	2017-October-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:	90+1

CHANGES COMPARED TO THE PREVIOUS HLA-B*35 LOT (02X):

Well	5'-primer	3'-primer	rationale
17	-	Modified	3'-primer modified for increased yield.
33	Moved/ exchanged	Moved/ exchanged	Exchanged primer pair moved to well 90 for decreased tendency of primer oligomer formation.
65	Added	-	5'-primer added for improved HLA-specific amplification of the B*35:148 allele.
80	-	Added	3'-primer added for the B*35:228 allele.
81	-	Added	3'-primer added for the B*35:228 allele.
88	Added	Added	Updated negative control moved to well 91, primer pair added for improved allelic resolution.
89	New	New	New primer pair added for the B*35:259 allele.
90	Added/ exchanged	Added/ exchanged	Exchanged primer pair added from well 33.
91	-	-	Updated negative control.

THE NUMBER OF WELLS is increased from 88 to 91 wells.

ALLELE COVERAGE:

All the HLA-B*35 alleles, i.e. **B*35:01 to B*35:279**, recognized by the HLA Nomenclature Committee in January 2015¹ 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*35:122, 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*35:02:01-35:02:07, the B*35:03:01, 35:03:03-35:03:06, 35:03:08-35:03:10, 35:03:12-35:03:16 and 35:03:19, the B*35:03:12 and 35:03:18, 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 35:08:06-35:08:08, 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 35:15:01 and 35:15:02, the B*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, the B*35:108:01-35:108:02 or the B*35:150:01-35:150:02 alleles.

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

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.

