

LOT SPECIFIC INFORMATION

Product Details

Product Name:	Olerup QTYPE 11 HLA Typing Kit
Product Number:	201.701-10; 201.701-03
Product Lot:	E063
Colour Compensation Lot:	CC63
Number of Tests:	10/3
Number of Wells per Test:	383 + 1
Number of Tests per Plate:	1
Expiry Date:	2024-05-01
Storage:	<div>- PCR PlatesDark at -15 °C to -25 °C</div> <div>- Master mixDark at -15 °C to -25 °C</div> <div>- PCR SealsRoom temperature</div>
Instructions For Use (IFU)	For further information of using the product, please visit www.caredx.com for Instruction for use

Kit Format

The following components are provided with this kit:

- 10 × PCR plates with pre-aliquoted and dried primer and probe mixes.
- 10 × vials of master mix
- 10 × optically-clear adhesive sealing sheets
- Product insert

Lot-Specific Notes

Changes from Previous Lot

There are no changes from Olerup QTYPE 11 lot E062. Please note that the positions of mixes that are not listed here may also have changed. Refer to SCORE 6 for the full specificity of each mix.

Uniquely Identified Alleles

All HLA-A, B, C, DRB1, DRB3, DRB4, DRB5, DQA1, DQB1, DPA1 and DPB1 alleles, recognised by the HLA Nomenclature Committee in October 2023 (IMGT Release 3.54.0), will be detected by this kit.

The CWD allele C*17:01:01:01 was removed from allele database 3.26 by the IMGT/HLA committee as it is identical to C*17:01:01:02. All results that were previously C*17:01:01:01 will now be listed as C*17:01:01:02, which is now listed as a common allele in SCORE 6.1.

The CWD allele DPA1*02:02:01 was removed from allele database 3.28 by the IMGT/HLA committee as it is identical to DPA1*02:07:01:01. All results that were previously DPA1*02:02:01 will now be listed as DPA1*02:07:01:01, which is now listed as a common allele in SCORE 6.1.

The CWD allele B*47:01:01:01 was removed from allele database 3.33 by the IMGT/HLA committee as it is identical to B*47:01:01:03. All results that were previously B*47:01:01:01 will now be listed as B*47:01:01:03. Please note that B*47:01:01:03 is now listed as a common allele in SCORE 6.1.

The CWD allele B*78:01:01:01 was removed from allele database 3.40 by the IMGT/HLA committee as it is identical to B*78:01:01:02. All results that were previously B*78:01:01:01 will now be listed as B*78:01:01:02. **Please note that B*78:01:01:02 is not listed as a common allele in SCORE 6.1.**

The CWD allele DQB1*02:03:01 was removed from allele database 3.43 by the IMGT/HLA committee as it is identical to DQB1*02:180. All results that were previously DQB1*02:03:01 will now be listed as DQB1*02:180. Please note that DQB1*02:180 is now listed as a common allele in SCORE 6.1.

The CWD allele DRB1*15:02:01:01 was removed from allele database 3.44 by the IMGT/HLA committee as it is identical to DRB1*15:02:01:02. All results that were previously DRB1*15:02:01:01 will now be listed as DRB1*15:02:01:02. **Please note that DRB1*15:02:01:02 is not listed as a common allele in SCORE 6.1.**

Notes on Specific Reactions

The following reactions are designed to amplify rare alleles. No positive DNA samples were available to test these mixes and they have therefore only been proven to be correctly negative with mismatched alleles.

Well	Channel	Reaction Specificity
H9	O560	DPB1*66:01, 76:01, 125:01, 156:01, 264:01, 287:01, 288:01, 385:01, 470:01, 490:01, 503:01, 514:01, 716:01
M10	FAM	B*51:11N
N10	FAM	B*15:01:01:02N.
J15	O560	DRB1*15:14
N16	O560	DRB1*03:08/03:65/03:140, 11:59/11:80/11:83/11:87/11:135/11:142/11:182, DRB3*01:42.
O18	O560	DRB4*02:01N.
F19	O560	DRB1*03:11
G22	FAM	B*07:13/07:247/07:270, 39:121, 67:02:01:01, 67:02:01:02
K24	O560	DPB1*38:01, DPB1*1099:01
N24	O560	DPB1*78:01.
O24	O560	DPB1*59:01, 72:01:01:01-72:01:01:03, 73:01, 95:01, 108:01, 164:01, 179:01, 189:01, 235:01, 306:01, 309:01, 322:01, 355:01, 451:01, 480:01, 508:01, 531:01, 555:01, 574:01, 576:01, 601:01, 620:01, 782:01, DPB1*987:01.

Cross Reactive Class I Wells

SCORE 6 will not consider Class I cross reactive non-CWD alleles during the analysis of tests performed with this lot of Olerup QTYPE 11.

The following wells contain cross reactive non-CWD alleles which will not be included as part of the analysis by SCORE 6:

Well	Channel	Main Locus	Cross Reactive Alleles
N2	FAM	A	C*06:04:02:01, C*06:04:02:02, C*07:01:110, C*07:137:01
O2	FAM	A	B*40:371
P2	FAM	A	B*35:410, B*35:430N, B*52:99
C3	FAM	A	B*15:173, B*15:477, B*44:486, B*50:11, C*03:299
E3	FAM	A	C*16:188
H3	FAM	A	C*12:328
K3	FAM	A	B*15:17:03
P4	FAM	A	C*05:73
B5	FAM	A	C*07:303, C*08:241
K5	FAM	B	C*12:301
L5	FAM	B	C*06:147, C*12:301
M5	FAM	B	C*06:147
C6	FAM	B	C*07:1059
D6	FAM	B	C*04:77, C*05:164, C*08:167
E6	FAM	B	C*06:147, C*12:301
G6	FAM	B	C*12:183, C*14:92, C*07:758
H6	FAM	B	C*03:464
K6	FAM	B	C*03:40:03, C*15:194
O6	FAM	B	C*01:32:01-C*01:32:02, C*06:20, C*12:50, C*14:82, C*16:98:01-C*16:98:02, C*16:102, C*16:110, A*23:128
K7	FAM	B	C*16:85
L7	FAM	B	C*01:124
C8	FAM	B	A*01:201
H8	FAM	B	C*05:184
J8	FAM	B	C*03:464
K8	FAM	B	C*07:626
L8	FAM	B	C*04:188, C*05:70, C*15:51
N8	FAM	B	A*01:201, A*25:66, A*26:68, A*26:100, A*26:200, A*68:56:01-A*68:56:02, C*01:32:01, C*01:32:02, C*02:56, C*04:180:01-C*04:180:02, C*05:217, C*06:20, C*08:123, C*12:50, C*14:82, C*14:92
O8	FAM	B	C*15:117, C*03:609
P8	FAM	B	A*68:233, C*01:73, C*07:414, C*12:301, C*16:151
B9	FAM	B	C*16:85
C9	FAM	B	C*07:546
D9	FAM	B	C*06:147
H9	FAM	B	C*03:433, C*03:514
I9	FAM	B	C*02:60, C*03:386, C*07:850
J9	FAM	B	C*03:464, C*14:92
L9	FAM	B	A*02:147, A*02:555, A*02:743, A*23:52, A*23:129
A10	FAM	B	C*16:85
F10	FAM	B	C*03:384, C*06:207, C*01:30, C*03:51, C*03:161, C*05:216:01:01-C*05:216:01:02, C*08:51, C*08:114 C*08:243, C*12:87, C*14:76, C*15:39, C*15:130, C*15:195, A*33:231
K10	FAM	B	C*12:183, C*14:92, C*07:758, C*03:464
K10	O560	B	C*12:168
E11	FAM	C	B*56:37, B*35:537, B*51:238
F11	FAM	C	B*13:13:02, B*35:578
H11	FAM	C	B*14:02:30
I11	FAM	B	A*01:201, A*03:100, A*25:66, A*26:68, A*26:100, A*26:200, A*29:42, A*30:64, A*32:158, A*33:04, A*33:33, A*68:56:01, A*68:56:02, C*03:102, C*03:263:01, C*03:263:02, C*03:263:03, C*03:514, C*15:126
M11	FAM	C	B*15:510, B*35:475, B*46:84
P11	FAM	C	B*39:09:03, 39:136, B*18:01:48
A12	FAM	C	B*08:01:36, B*15:436, B*55:01:25, B*35:570
B12	FAM	B	C*05:12, C*05:151, C*08:39, C*08:165, C*08:177, C*08:213
D12	FAM	A	C*06:187
E12	FAM	C	B*07:246, B*07:327, B*35:578, B*38:114
I12	FAM	C	B*07:463

Well	Channel	Main Locus	Cross Reactive Alleles
P12	FAM	C	B*46:77, B*46:86
A13	FAM	C	B*35:570, B*39:201
G13	FAM	C	B*15:510, B*35:475, B*46:84
H13	FAM	C	B*40:367
L13	FAM	C	B*35:291, B*44:226, B*51:281
J14	FAM	C	B*46:77, B*35:570
M14	FAM	B	C*02:23
O14	FAM	C	B*13:31, 13:41, B*13:145
B15	FAM	C	A*02:736, A*23:128, A*24:64, B*07:239, B*08:232, B*14:23, B*14:33, B*14:88, B*15:510, B*18:44:01- B*18:44:02, B*35:475, B*40:243, B*44:440, B*46:84, B*57:11, B*58:02:01:02- B*58:02:01:03, B*58:02:02, B*58:02:03, B*58:07, B*58:25, B*58:38, B*58:43, B*58:46, B*58:60, B*58:104, B*58:132
O15	FAM	A	B*55:93, C*03:350, B*38:87
J16	FAM	B	C*01:35, C*01:107, C*03:03:32, C*03:04:27, C*03:04:59, C*03:87:01, C*03:220, C*03:263:01- C*03:263:03, C*01:244
B20	FAM	B	C*15:15, C*15:195
K20	FAM	B	C*07:1059
M21	FAM	B	A*02:147, C*01:101, C*01:102, C*03:245
B22	FAM	B	C*01:73
B23	FAM	B	C*07:758, C*12:183, C*14:92
H23	FAM	B	C*07:1011
I23	FAM	B	C*01:32:02, C*14:92
J23	FAM	B	C*07:850
K23	FAM	B	C*03:102, C*03:263:01, C*03:263:02, C*03:514, C*03:263:03, C*07:81, C*07:168, C*07:450:01, C*07:450:02, C*07:959, C*08:139
B24	FAM	C	B*35:570
D24	FAM	B	C*15:195
F24	FAM	B	C*07:546
J24	FAM	B	C*03:161, C*07:516, C*07:521:01-07:521:02, C*15:39, C*15:130, C*08:243
K24	FAM	B	C*03:102
M24	FAM	B	C*16:85

The following wells contain cross reactive CWD alleles which will be included as part of the analysis by SCORE 6:

Well	Channel	Main Locus	Cross Reactive Alleles
C9	FAM	B	C*07:46
P12	FAM	C	B*07:13, B*67:02:01:01, B*67:02:01:02
B15	FAM	C	B*58:02:01:01, B*58:06
F24	FAM	B	C*07:46

DRB1/3/4/5 Wells

DRB1/3/4/5 are analysed as a group, and some reaction mixes amplify alleles from both DRB1 and DRB3/4/5 in combination. SCORE 6 will not consider some non-CWD alleles during the analysis and tests performed with this lot of Olerup QTYPE 11.

The following wells contain reaction mixes that amplify non-CWD alleles which will not be included as part of the analysis by SCORE 6:

Well	Channel	Main Locus	Alleles that will NOT be included in analysis
D1	O560	DRB1	DRB3*01:14
E1	O560	DRB345	DRB1*03:17, DRB1*03:27, DRB1*03:35, DRB1*03:81, DRB1*03:167, DRB1*03:188, DRB1*04:140, DRB1*11:136, DRB1*14:141, DRB1*14:257
N12	O560	DRB1	DRB3*01:82, DRB3*03:62
M15	O560	DRB1	DRB3*03:01:05
O15	O560	DRB1	DRB5*02:31
A16	O560	DRB1	DRB4*01:03:26
C16	O560	DRB1	DRB3*02:04
E16	O560	DRB1	DRB3*01:71
I16	O560	DRB1	DRB5*01:13, DRB5*01:41
L16	O560	DRB1	DRB3*01:42, DRB3*02:18, DRB5*01:13, DRB5*01:41
M16	O560	DRB1	DRB3*02:18, DRB5*01:13, DRB5*01:41
N16	O560	DRB1	DRB3*01:42
B17	O560	DRB1	DRB3*02:160
O17	O560	DRB1	DRB3*01:14
H18	O560	DRB345	DRB1*03:42, DRB1*03:87, DRB1*11:288, DRB1*12:57, DRB1*14:247
I18	O560	DRB345	DRB1*04:20, DRB1*11:30, DRB1*13:67, DRB1*13:195, DRB1*14:46, DRB1*14:141, DRB1*14:257
K18	O560	DRB345	DRB1*14:141
L18	O560	DRB345	DRB1*12:57, DRB1*13:195, DRB1*14:247
P18	O560	DRB345	DRB1*04:245, DRB1*04:352, DRB1*04:357, DRB1*10:19
E19	O560	DRB1	DRB3*03:56, DRB3*03:59
G19	O560	DRB1	DRB3*01:23, DRB3*01:46, DRB3*02:146
L19	O560	DRB1	DRB3*01:14
M19	O560	DRB1	DRB5*01:73
O19	O560	DRB1	DRB5*01:22:01, DRB5*01:64, DRB5*01:110, DRB5*01:127N
P19	O560	DRB1	DRB3*01:14
K19	O560	DRB1	DRB3*02:111

Please note that the information in this section only applies to SCORE 6.2.

Notes on Bw4/Bw6 Assignment

SCORE 6 assigns the Bw4 and Bw6 status of HLA-B and HLA-A alleles based on the reactivity of mixes that target the Bw4 and Bw6 nucleotide motifs. These mixes will identify the presence or absence of these nucleotide motifs in most Class I alleles. Since there is some redundancy in the nucleotide motifs that code for the Bw amino acid motifs, a subset of alleles will not be detected by these mixes. The following table shows the plate positions of these mixes, and the alleles that are not amplified within their Bw mix (CWD 2.0 alleles shown in **bold**).

Bw Status	Main Locus	Well	Channel	Exceptions
Bw4	A	A4	FAM	A*01:95, A*01:289, A*24:02:96, A*24:02:108, A*24:243, A*24:294Q
Bw4	B	K7	FAM	B*52:04 B*13:02:07, B*13:87, B*27:05:37, B*27:07:03, B*38:01:15, B*38:35, B*38:81, B*44:172, B*44:191, B*44:255, B*51:01:34, B*51:01:54, B*51:28, B*51:67, B*51:178N, B*51:257, B*51:266, B*51:290 B*52:01:25, B*52:87, B*53:01:19, B*53:45, B*53:58, B*57:34, B*57:35, B*57:117 B*58:01:24, B*58:01:25, B*58:25, B*58:54 and B*58:68
Bw6	B	C6 P8	FAM	B*07:13, B*40:22N, B*67:02 B*08:97, B*08:101, B*08:193, B*14:02:05, B*14:34, B*15:01:28, B*15:04:03, B*15:434, B*18:01:24, B*35:01:05, B*35:02:09, B*35:152, B*39:105, B*39:115, B*40:127, B*41:55, B*46:48, B*48:36, B*54:30, B*54:35, B*78:01:02

SCORE 6 also checks the Bw status of HLA-B and HLA-A alleles based on the amino acid sequences at codons 77 and 80-83, in accordance with the following table¹:

Bw Status	Amino Acid Position				
	77	80	81	82	83
Bw4	Asn	Ile	Ala	Leu	Arg
Bw4	Asn	Thr	Ala	Leu	Arg
Bw4	Ser	Ile	Ala	Leu	Arg
Bw4	Ser	Thr	Leu	Leu	Arg
Bw4	Asp	Thr	Leu	Leu	Arg
Bw6	Ser	Asn	Leu	Arg	Gly
Bw6	Gly	Asn	Leu	Arg	Gly

In cases where there is a discrepancy between the Bw mix result and the expected Bw result based on the amino acid sequence for the detected allele(s) (for example, if one of the exceptions in the above table is found, or a null allele is amplified by the Bw mix), SCORE 6 will inform the user that the Bw status has been assigned based on the amino acid sequence.

¹The Bw4 public epitope of HLA-B molecules confers reactivity with natural killer cell clones that express NKB1, a putative HLA receptor Gumperz JE, Litwin V, Phillips JH, Lanier LL, Parham P.1995 Mar 1;181(3):1133-44 <https://www.ncbi.nlm.nih.gov/pubmed/7532677>

Plate Layout

	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	1	17	33	49	65	81	97	113	129	145	161	177	193	209	225	241	257	273	289	305	321	337	353	369
B	2	18	34	50	66	82	98	114	130	146	162	178	194	210	226	242	258	274	290	306	322	338	354	370
C	3	19	35	51	67	83	99	115	131	147	163	179	195	211	227	243	259	275	291	307	323	339	355	371
D	4	20	36	52	68	84	100	116	132	148	164	180	196	212	228	244	260	276	292	308	324	340	356	372
E	5	21	37	53	69	85	101	117	133	149	165	181	197	213	229	245	261	277	293	309	325	341	357	373
F	6	22	38	54	70	86	102	118	134	150	166	182	198	214	230	246	262	278	294	310	326	342	358	374
G	7	23	39	55	71	87	103	119	135	151	167	183	199	215	231	247	263	279	295	311	327	343	359	375
H	8	24	40	56	72	88	104	120	136	152	168	184	200	216	232	248	264	280	296	312	328	344	360	376
I	9	25	41	57	73	89	105	121	137	153	169	185	201	217	233	249	265	281	297	313	329	345	361	377
J	10	26	42	58	74	90	106	122	138	154	170	186	202	218	234	250	266	282	298	314	330	346	362	378
K	11	27	43	59	75	91	107	123	139	155	171	187	203	219	235	251	267	283	299	315	331	347	363	379
L	12	28	44	60	76	92	108	124	140	156	172	188	204	220	236	252	268	284	300	316	332	348	364	380
M	13	29	45	61	77	93	109	125	141	157	173	189	205	221	237	253	269	285	301	317	333	349	365	381
N	14	30	46	62	78	94	110	126	142	158	174	190	206	222	238	254	270	286	302	318	334	350	366	382
O	15	31	47	63	79	95	111	127	143	159	175	191	207	223	239	255	271	287	303	319	335	351	367	383
P	16	32	48	64	80	96	112	128	144	160	176	192	208	224	240	256	272	288	304	320	336	352	368	NTC

The plate layout shows the co-ordinates of each well (row A-P, column 1-24). The reaction number is written in black in each well. The No Template Control (NTC) well is shown in white text on a black background. The double border marks a single test.

The NTC is designed to amplify the same region as the internal control amplification that is present in each well (i.e. a conserved region of a human growth hormone gene), and will therefore be positive if it is contaminated with either human genomic DNA or Olerup QTYPE amplicon. The NTC reaction occurs in the O560 channel.

Instructions for the Preparation of the Reaction Mixture

- Set up the no template control well (in accordance with the instructions for use) before continuing to prepare the reaction mixture. Briefly, the total volume in the NTC should be 10 µl, consisting of 2 µl of master mix and 8 µl water.
- This kit contains mixer tubes, which should be used for preparing the reaction mixtures. Refer to the following table for instructions of how much of each component to add to the mixer tubes, depending on the concentration of the sample DNA:

Component	Volume (µl)			
	For 5 ng/µl DNA stock	For 10 ng/µl DNA stock	For 30 ng/µl DNA stock	For 50 ng/µl DNA stock
Master mix	950	950	950	950
DNA Sample	950	475	158	95
Water	2850	3325	3642	3705

(If calculating different volumes, it is important to ensure that each well contains 2 µl master mix and a total amount of 10 ng DNA. The total well volume should be made up to 10 µl.)

- Briefly vortex the reaction mixture.
- Refer to the Olerup QTYPE Instructions for Use for further information on the test setup.

CONTACT INFORMATION

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