

LOT SPECIFIC INFORMATION

Product Details

Product Name:	Olerup QTYPE 11 HLA Typing Kit
Product Number:	201.701-10; 201.701-03
Product Lot:	E061
Colour Compensation Lot:	CC61
Number of Tests:	10/3
Number of Wells per Test:	383 + 1
Number of Tests per Plate:	1
Expiry Date:	2024-01-01
Storage:	<div>- PCR Plates</div> <div>- Master mix</div> <div>- PCR Seals</div>
	<div>Dark at -15 °C to -25 °C</div> <div>Dark at -15 °C to -25 °C</div> <div>Room 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

Changes from Olerup QTYPE 11 lot E060 are listed in the table below. 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.

Type	E060 Well	E061 Well	Aim
Inactivation	C24 (FAM)	N/A	The FAM well component will be excluded from analysis. This change leads to one new CWD ambiguity: B*44:18 & B*50:01:01:01/50:04 = B*45:01:01 & B*49:01:01:01.

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 January 2022 (IMGT Release 3.47.0), 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.

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.

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.

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.**

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.

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.**

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
I3	O560	DRB4*03:01N
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
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.
F22	O560	DPB1*21:01, DPB1*36:01, DPB1*44:01, DPB1*58:01, DPB1*114:01, DPB1*265:01, DPB1*384:01, DPB1*394:01, DPB1*550:01, DPB1*563:01, DPB1*630:01, DPB1*746:01, DPB1*961:01, DPB1*1019:01
G22	FAM	B*07:13/07:247/07:270, 39:121, 67:02:01:01, 67:02:01:02
P22	O560	DPB1*34:01:01:01-34:01:02, DPB1*484:01, DPB1*580:01, DPB1*835:01:01:01-835:01:01:03, DPB1*913:01
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, C*07:137:01
O2	FAM	A	B*40:371
P4	FAM	A	C*05:73
B5	FAM	A	C*07:303
K5	FAM	B	C*12:201
L5	FAM	B	C*06:147
M5	FAM	B	C*06:147
D6	FAM	B	C*04:77, C*05:164, C*08:167
E6	FAM	B	C*06:147, C*14:92
G6	FAM	B	C*12:183, C*14:92
H6	FAM	B	C*03:464
K6	FAM	B	C*03:40:03
O6	FAM	B	C*01:32-01:32, C*06:20, C*12:50, C*14:82, C*16:98, C*16:102, C*16:110
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
P8	FAM	B	C*01:73, C*07:414
A9	FAM	B	C*07:01:34/07:401
B9	FAM	B	C*16:85
C9	FAM	B	A*11:262, C*12:184, C*07:546
L9	FAM	B	A*02:01:22/02:06:04/02:40:02, A*23:01:16/23:14:01, A*24:13:02/24:97/24:207/24:315, C*03:77/03:187/03:296:01/03:296:02
J9	FAM	B	C*03:464, C*14:92
K9	FAM	B	C*03:102
H9	FAM	B	C*03:433
A10	FAM	B	C*16:85
K10	O560	B	C*12:168
K10	FAM	B	C*12:183, C*14:92
F10	FAM	B	C*03:384, C*06:207
E11	FAM	C	B*56:37
F11	FAM	C	B*13:13:02
M11	FAM	C	B*15:510
P11	FAM	C	B*39:09:03/39:136
A12	FAM	C	B*08:01:36, B*15:436
E12	FAM	C	B*07:246, B*07:327
P12	FAM	C	B*46:77
G13	FAM	C	B*15:510
H13	FAM	C	B*40:367
J13	FAM	C	B*46:77
L13	FAM	C	B*35:291, B*44:226, B*51:281
M14	FAM	B	C*02:23
O14	FAM	C	B*13:31/13:41
O15	FAM	A	B*55:93, C*03:350
F21	FAM	B	A*01:201, A*26:68/26:100, A*68:56, C*01:32:01/01:32:02, C*02:56, C*04:180:01-04:180:02, C*06:20, C*08:123, C*12:50, C*14:82/14:92
B22	FAM	B	C*01:73
I23	FAM	B	C*01:32:02, C*14:92
D24	FAM	B	C*15:195
E24	FAM	B	C*05:12, C*08:39/08:165
F24	FAM	B	C*07:546

Well	Channel	Main Locus	Cross Reactive Alleles
J24	FAM	B	C*03:161, C*07:516, C*07:521:01/07:521:02, C*15:39/15:130

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
F24	FAM	B	C*07:46

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	2,850	3,325	3,642	3,705

(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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