

RICHIAMO/CORREZIONE/AVVISO DI SICUREZZA URGENTE

NP CR170228

Nome commerciale del prodotto interessato: AllSet+™ Gold SSP

Identificativo FSCA: CR170228

Tipo di azione: Revisione dei risultati del test

27 giugno 2017
All'attenzione di: Distributori e utilizzatori

Lo scopo di questa lettera è di informare gli interessati che One Lambda, Inc., un marchio di Thermo Fisher Scientific, sta effettuando un richiamo/una correzione dei Kit AllSet+™ Gold SSP.

Motivo del richiamo volontario (descrizione del problema): I primer PM074D e C15-02A devono essere negativi per i seguenti alleli: , B*07:219, B*57:02:01, , B*57:02:02, , B*57:03:02, , B*57:07, B*57:09, B*57:12, B*57:17, B*57:28N, B*57:39, B*57:42, B*57:46, B*57:57, B*57:63, B*57:66, B*57:70, B*57:80, B*57:82, B*58:08:01, B*58:08:02, B*58:20, B*58:27, B*58:28:01, B*58:28:02, B*58:65 e B*58:73 durante l'analisi. I documenti specifici dell'utente e i file del software UCH del lotto contengono informazioni errate riguardo alla specificità dell'allele per queste due miscele di primer. Fare riferimento alla **TABELLA 1 - Impatto della specificità dell'allele** per le informazioni sugli alleli influenzati e alla **TABELLA 2 - Documenti specifici dell'utente e file di software UCH del lotto corretti**.

TABELLA 1. Impatto della specificità dell'allele

Alleli rimossi	Tipizzazione precedente da rivedere
B*07:219	Un campione precedentemente tipizzato come B*07:36, B*07:180 ambigui, può anche essere B*07:219.
B*57:02:01, B*57:02:02, B*57:03:02, B*57:17, B*57:28N, B*57:39, B*57:42, B*57:46, B*57:57, B*57:63, B*57:66, B*57:70, B*57:80, B*57:82	Un campione precedentemente tipizzato come B*57 ambiguo (B*57:01:01, B*57:01:02, B*57:01:03, B*57:01:04, B*57:01:05, B*57:01:06, B*57:01:08, B*57:01:10, B*57:01:11, B*57:01:12, B*57:01:13, B*57:01:14, B*57:01:15, B*57:01:16, B*57:01:17, B*57:01:18, B*57:01:19, B*57:01:21, B*57:01:22, B*57:04:01, B*57:04:02, B*57:06, B*57:10, B*57:11, B*57:15, B*57:18, B*57:19, B*57:20, B*57:21, B*57:22, B*57:23, B*57:26, B*57:27, B*57:29, B*57:30, B*57:31, B*57:33, B*57:34, B*57:35, B*57:36, B*57:37, B*57:38, B*57:40, B*57:41, B*57:43, B*57:44, B*57:47, B*57:48, B*57:49, B*57:50, B*57:52, B*57:53, B*57:54, B*57:55, B*57:56, B*57:58, B*57:59, B*57:60, B*57:61, B*57:62, B*57:64, B*57:65, B*57:67:02, B*57:68, B*57:72, B*57:73, B*57:74, B*57:75, B*57:76, B*57:77, B*57:78, B*57:79N, B*57:81.) può anche essere B*57:02:01, B*57:02:02, B*57:03:02, B*57:17, B*57:28N, B*57:39, B*57:42, B*57:46, B*57:57, B*57:63, B*57:66, B*57:70, B*57:80 o B*57:82.
B*57:07	Un campione che ha risultati di tipizzazione in una delle seguenti condizioni può anche essere B*57:07: - ha reazione falsamente negativa alla corsia 74 - comprende [B*57:14:01;B*57:14:02] come risultato possibile - tipizzato come combinazioni della coppia di alleli [B*44:08;B*44:57]/[B57]
B*57:09	Un campione precedentemente tipizzato come B*57:24 può anche essere B*57:09.
B*57:12	Un campione che ha risultati di tipizzazione in una delle seguenti condizioni può anche essere B*57:12: - ha reazione falsamente negativa alla corsia 74 - comprende [B*57:14:01;B*57:14:02] ambigui come risultato possibile - tipizzato come combinazioni della coppia di alleli ambigui [B*15:31;B*15:55;B*15:246N]/[B57] - tipizzazione per [B*57:12]/[B*52:06:01;B*52:06:02] = [B*57:01:20]/[B*15:05:01;B*15:05:02;B*15:06;B*15:20;B*15:25:01;B*15:25:02;B*15:25:03;B*15:39:01;B*15:39:02;B*15:42;B*15:65;B*15:84;B*15:86;B*15:107;B*15:155;B*15:185;B*15:188;B*15:195;B*15:199;B*15:204;B*15:219;B*15:224;B*15:237;B*15:240;B*15:250;B*15:271;B*15:288;B*15:300;B*15:310;B*15:322;B*15:332;B*15:348;B*15:360;B*15:364;B*15:366]

B*58:08:01	<p>Un campione che ha risultati di tipizzazione in una delle seguenti condizioni può anche essere B*58:08:01:</p> <ul style="list-style-type: none"> - ha reazione falsamente negativa alla corsia 74 - comprende [B*51:45] o [B*58:44] come risultato possibile - tipizzazione per [B*58:08:01]/[B*15:308;B*35:20:01;B*35:20:02;B*35:26;B*35:82;B*35:95;B*35:212;B*35:294] = [B*53:06]/[B*58:64] - tipizzazione per [B*58:08:01]/[B*35:28;B*35:226] = [B*58:64]/[B*52:06:01;B*52:06:02] - tipizzazione per [B*58:08:01]/[B*15:202] = [B*58:01:01:01;B*58:01:01:02;B*58:01:02;B*58:01:03;B*58:01:04;B*58:01:05;B*58:01:06;B*58:01:07;B*58:01:09;B*58:01:10;B*58:01:11;B*58:01:12;B*58:01:13;B*58:01:14;B*58:01:15;B*58:01:16;B*58:01:17;B*58:01:18;B*58:01:19;B*58:02:01;B*58:02:02;B*58:04;B*58:05;B*58:06;B*58:09;B*58:10N;B*58:11;B*58:12;B*58:13;B*58:14;B*58:15;B*58:16:01;B*58:16:02;B*58:18;B*58:19;B*58:21;B*58:22;B*58:23;B*58:24;B*58:25;B*58:26;B*58:29;B*58:31N;B*58:32;B*58:33;B*58:34;B*58:35;B*58:38;B*58:39N;B*58:40;B*58:41;B*58:42;B*58:43;B*58:45:01;B*58:45:02;B*58:46;B*58:47;B*58:48;B*58:49;B*58:50;B*58:51;B*58:52;B*58:53;B*58:54;B*58:55;B*58:56;B*58:57;B*58:58;B*58:59:01;B*58:60;B*58:61;B*58:62;B*58:63;B*58:66;B*58:67;B*58:68;B*58:69;B*58:70;B*58:71;B*58:72N;B*58:74;B*58:75;B*58:76;B*58:77;B*58:78]/[B*15:32:02]. Per quest'ultimo esito, non ci sono variazioni nell'esito della tipizzazione di B58 a un livello di tipizzazione intermedia.
B*58:08:02	<p>Un campione precedentemente tipizzato come B*58:44 può anche essere B*58:08:02.</p>
B*58:20	<p>Un campione che ha risultati di tipizzazione in una delle seguenti condizioni può anche essere B*58:20:</p> <ul style="list-style-type: none"> - ha reazione falsamente negativa alla corsia 74 - comprende [B*13:58], [B*38:08], [B*40:109], [B*44:16], [B*44:25], [B*51:148] o [B*52:01:05] come risultato possibile di tipizzazione - la tipizzazione per [B*58:20]/[B*37:04:01;B*37:04:02;B*37:21] è [B*37:34]/[B*38:06;B*38:07] - la tipizzazione per [B*58:20]/[B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134] è [B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134]/[B*27:01;B*27:142]=[B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134]/[B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134]=[B*27:03;B*27:05:02;B*27:05:03;B*27:05:04;B*27:05:05;B*27:05:06;B*27:05:07;B*27:05:08;B*27:05:09;B*27:05:10;B*27:05:11;B*27:05:12;B*27:05:13;B*27:05:14;B*27:05:15;B*27:05:16;B*27:05:17;B*27:05:18;B*27:05:19;B*27:05:20;B*27:05:21;B*27:05:22;B*27:05:24;B*27:05:25;B*27:05:26;B*27:05:27;B*27:05:28;B*27:05:29;B*27:05:30;B*27:05:31;B*27:07:01;B*27:07:02;B*27:07:03;B*27:09;B*27:11;B*27:13;B*27:14;B*27:16;B*27:17;B*27:27;B*27:31;B*27:32;B*27:34;B*27:35;B*27:37;B*27:38;B*27:39;B*27:43;B*27:45;B*27:46;B*27:47;B*27:48;B*27:49;B*27:50:01;B*27:50:02;B*27:51;B*27:55;B*27:56;B*27:58;B*27:59N;B*27:60;B*27:61;B*27:64N;B*27:70;B*27:72;B*27:73;B*27:74;B*27:80;B*27:81;B*27:82;B*27:84;B*27:85;B*27:87;B*27:88;B*27:90:02;B*27:90:03;B*27:93;B*27:94N;B*27:96:01;B*27:96:02;B*27:97;B*27:98;B*27:99;B*27:101;B*27:104;B*27:110;B*27:111;B*27:116;B*27:117;B*27:118;B*27:121;B*27:122;B*27:123;B*27:124;B*27:128;B*27:129;B*27:130;B*27:131;B*27:132;B*27:133;B*27:135;B*27:136;B*27:137;B*27:139;B*27:140;B*27:141;B*27:143;B*27:144;B*27:145;B*27:146]/[B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134]=[B*27:05:23]/[B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134]=[B*27:67;B*27:76;B*27:90:01]/[B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134]=[B*27:75]/[B*27:01;B*27:142]=[B*27:75]/[B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134]=[B*27:75]/[B*27:03;B*27:05:02;B*27:05:03;B*27:05:04;B*27:05:05;B*27:05:06;B*27:05:07;B*27:05:08;B*27:05:09;B*27:05:10;B*27:05:11;B*27:05:12;B*27:05:13;B*27:05:14;B*27:05:15;B*27:05:16;B*27:05:17;B*27:05:18;B*27:05:19;B*27:05:20;B*27:05:21;B*27:05:22;B*27:05:24;B*27:05:25;B*27:05:26;B*27:05:27;B*27:05:28;B*27:05:29;B*27:05:30;B*27:05:31;B*27:07:01;B*27:07:02;B*27:07:03;B*27:09;B*27:11;B*27:13;B*27:14;B*27:16;B*27:17;B*27:27;B*27:31;B*27:32;B*27:34;B*27:35;B*27:37;B*27:38;B*27:39;B*27:43;B*27:45;B*27:46;B*27:47;B*27:48;B*27:49;B*27:50:01;B*27:50:02;B*27:51;B*27:55;B*27:56;B*27:58;B*27:59N;B*27:60;B*27:61;B*27:64N;B*27:70;B*27:72;B*27:73;B*27:74;B*27:80;B*27:81;B*27:82;B*27:84;B*27:85;B*27:87;B*27:88;B*27:90:02;B*27:90:03;B*27:93;B*27:94N;B*27:96:01;B*27:96:02;B*27:97;B*27:98;B*27:99;B*27:101;B*27:104;B*27:110;B*27:111;B*27:116;B*27:117;B*27:118;B*27:121;B*27:122;B*27:123;B*27:124;B*27:128;B*27:129;B*27:130;B*27:131;B*27:132;B*27:133;B*27:135;B*27:136;B*27:137;B*27:139;B*27:140;B*27:141;B*27:143;B*27:144;B*27:145;B*27:146]

27:82;B*27:84;B*27:85;B*27:87;B*27:88;B*27:90:02;B*27:90:03;B*27:93;B*27:94N;B*27:96:01;B*27:96:02;B*27:97;B*27:98;B*27:99;B*27:101;B*27:104;B*27:110;B*27:111;B*27:116;B*27:117;B*27:118;B*27:121;B*27:122;B*27:123;B*27:124;B*27:128;B*27:129;B*27:130;B*27:131;B*27:132;B*27:133;B*27:135;B*27:136;B*27:137;B*27:139;B*27:140;B*27:141;B*27:143;B*27:144;B*27:145;B*27:146]=[B*27:75]/[B*27:67;B*27:76;B*27:90:01]=[B*40:117]/[B*27:01;B*27:142]=[B*40:117]/[B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134]=[B*40:117]/[B*27:03;B*27:05:02;B*27:05:03;B*27:05:04;B*27:05:05;B*27:05:06;B*27:05:07;B*27:05:08;B*27:05:09;B*27:05:10;B*27:05:11;B*27:05:12;B*27:05:13;B*27:05:14;B*27:05:15;B*27:05:16;B*27:05:17;B*27:05:18;B*27:05:19;B*27:05:20;B*27:05:21;B*27:05:22;B*27:05:24;B*27:05:25;B*27:05:26;B*27:05:27;B*27:05:28;B*27:05:29;B*27:05:30;B*27:05:31;B*27:07:01;B*27:07:02;B*27:07:03;B*27:09;B*27:11;B*27:13;B*27:14;B*27:16;B*27:17;B*27:27;B*27:31;B*27:32;B*27:34;B*27:35;B*27:37;B*27:38;B*27:39;B*27:43;B*27:45;B*27:46;B*27:47;B*27:48;B*27:49;B*27:50:01;B*27:50:02;B*27:51;B*27:55;B*27:56;B*27:58;B*27:59N;B*27:60;B*27:61;B*27:64N;B*27:70;B*27:72;B*27:73;B*27:74;B*27:80;B*27:81;B*27:82;B*27:84;B*27:85;B*27:87;B*27:88;B*27:90:02;B*27:90:03;B*27:93;B*27:94N;B*27:96:01;B*27:96:02;B*27:97;B*27:98;B*27:99;B*27:101;B*27:104;B*27:110;B*27:111;B*27:116;B*27:117;B*27:118;B*27:121;B*27:122;B*27:123;B*27:124;B*27:128;B*27:129;B*27:130;B*27:131;B*27:132;B*27:133;B*27:135;B*27:136;B*27:137;B*27:139;B*27:140;B*27:141;B*27:143;B*27:144;B*27:145;B*27:146]=[B*40:117]/[B*27:05:23]=[B*40:117]/[B*27:75]=[B*40:188]/[B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134]=[B*40:188]/[B*27:75]

- la tipizzazione per [B*58:20]/[B*44:02:10;B*44:34:01] è [B*51:45]/[B*44:21;B*44:124]

- la tipizzazione per [B*58:20]/[B*13:62] è

[B*52:01:01:01;B*52:01:01:02;B*52:01:01:03;B*52:01:03;B*52:01:06;B*52:01:07;B*52:01:08;B*52:01:11;B*52:01:12;B*52:01:13;B*52:01:14;B*52:01:16;B*52:01:17;B*52:01:18;B*52:01:19;B*52:01:20;B*52:01:21;B*52:01:22;B*52:01:23;B*52:01:24;B*52:01:25;B*52:01:26;B*52:01:27;B*52:01:28;B*52:04;B*52:05;B*52:07;B*52:10:01;B*52:10:02;B*52:11;B*52:12;B*52:13;B*52:17;B*52:19;B*52:22;B*52:23;B*52:26;B*52:27;B*52:28;B*52:29;B*52:30;B*52:31:01;B*52:32;B*52:33;B*52:34;B*52:35;B*52:36;B*52:37;B*52:38;B*52:39;B*52:40;B*52:41;B*52:42;B*52:43;B*52:44;B*52:45;B*52:46;B*52:47;B*52:48;B*52:49N;B*52:50;B*52:51;B*52:52;B*52:53;B*52:55;B*52:56;B*52:57;B*52:58;B*52:59]/[B*13:15]=[B*52:02:02]/[B*13:01:01;B*13:01:02;B*13:01:03;B*13:01:04;B*13:01:05;B*13:01:06;B*13:01:07;B*13:01:08;B*13:01:09;B*13:01:10;B*13:02:01;B*13:02:02;B*13:02:03;B*13:02:04;B*13:02:05;B*13:02:06;B*13:02:07;B*13:02:08;B*13:02:09;B*13:02:10;B*13:02:11;B*13:02:12;B*13:02:13;B*13:02:14;B*13:02:15;B*13:02:16;B*13:02:17;B*13:02:18;B*13:03;B*13:06;B*13:08;B*13:10;B*13:11;B*13:12:01;B*13:12:02;B*13:13:01;B*13:13:02;B*13:14;B*13:16;B*13:17;B*13:18;B*13:19;B*13:20;B*13:22:01;B*13:22:02;B*13:23;B*13:25;B*13:26:01;B*13:26:02;B*13:27;B*13:28;B*13:29;B*13:30;B*13:32;B*13:33;B*13:34;B*13:35;B*13:37;B*13:38;B*13:40;B*13:42;B*13:43;B*13:44;B*13:45;B*13:47;B*13:48;B*13:49N;B*13:50;B*13:52;B*13:53;B*13:54;B*13:55;B*13:56:01N;B*13:56:02N;B*13:57;B*13:59;B*13:60;B*13:61;B*13:63N;B*13:64;B*13:65;B*13:66;B*13:68;B*13:69;B*13:70;B*13:72;B*13:73;B*13:74;B*13:75;B*13:76N;B*13:77;B*13:78;B*13:80;B*13:81;B*13:82;B*13:83;B*13:84;B*13:85;B*13:87]=[B*52:02:02]/[B*13:15]=[B*13:07N]/[B*52:02:02]=[B*52:18]/[B*13:15]

- la tipizzazione per [B*58:20]/[B*51:16;B*51:31;B*51:34;B*51:93] è

[B*51:16;B*51:31;B*51:34;B*51:93]/[B*51:01:01:01;B*51:01:01:02;B*51:01:02;B*51:01:03;B*51:01:04;B*51:01:05;B*51:01:06;B*51:01:07;B*51:01:08;B*51:01:10;B*51:01:11;B*51:01:12;B*51:01:13;B*51:01:14;B*51:01:15;B*51:01:16;B*51:01:17;B*51:01:18;B*51:01:19;B*51:01:20;B*51:01:22;B*51:01:23;B*51:01:24;B*51:01:26;B*51:01:27;B*51:01:28;B*51:01:29;B*51:01:30;B*51:01:31;B*51:01:32;B*51:01:33;B*51:01:34;B*51:01:35;B*51:01:36;B*51:01:37;B*51:01:38;B*51:01:39;B*51:01:40;B*51:01:41;B*51:01:42;B*51:01:43;B*51:01:44;B*51:01:45;B*51:01:46;B*51:01:47;B*51:01:48;B*51:01:49;B*51:01:50;B*51:01:51;B*51:01:52;B*51:01:53;B*51:02:02;B*51:02:03;B*51:02:04;B*51:02:05;B*51:03;B*51:06:01;B*51:06:02;B*51:06:03;B*51:07:01;B*51:07:02;B*51:09:01;B*51:09:02;B*51:09:03;B*51:11N;B*51:12;B*51:14;B*51:17;B*51:18;B*51:21;B*51:22;B*51:24:01;B*51:24:05;B*51:26;B*51:27N;B*51:28;B*51:30;B*51:32;B*51:33;B*51:35;B*51:37;B*51:38;B*51:39;B*51:40;B*51:41N;B*51:43;B*51:48;B*51:49;B*51:50;B*51:51;B*51:52;B*51:53;B*51:55;B*51:58;B*51:59;B*51:60;B*51:65;B*51:66;B*51:67;B*51:69;B*51:70;B*51:71;B*51:72;B*51:73;B*51:74;B*51:75;B*51:77;B*51

:79;B*51:80;B*51:83;B*51:84;B*51:86;B*51:87;B*51:88;B*51:89;B*51:90;B*51:91;B*51:94;B*51:95;B*51:96;B*51:98N;B*51:99;B*51:100;B*51:102;B*51:105;B*51:107;B*51:109;B*51:110N;B*51:111;B*51:113;B*51:114;B*51:115;B*51:117;B*51:118N;B*51:119;B*51:120;B*51:121;B*51:122;B*51:123;B*51:124;B*51:125;B*51:126;B*51:127;B*51:128;B*51:129;B*51:130;B*51:131;B*51:132;B*51:133;B*51:134;B*51:135;B*51:136;B*51:137;B*51:138;B*51:140;B*51:142;B*51:143;B*51:144;B*51:145;B*51:146;B*51:147;B*51:149N;B*51:150;B*51:151;B*51:152;B*51:154;B*51:155;B*51:156;B*51:158:01;B*51:158:02;B*51:159;B*51:160;B*51:161;B*51:162;B*51:163;B*51:164;B*51:165;B*51:166;B*51:167;B*51:168;B*51:169;B*51:170;B*51:171;B*51:173Q;B*51:175;B*51:177;B*51:178N;B*51:179;B*51:180;B*51:181;B*51:182;B*51:183;B*51:184N;B*51:185;B*51:186;B*51:187;B*51:188;B*51:189;B*51:190;B*51:191;B*51:192;B*51:193;B*51:194;B*51:195;B*51:196;B*51:198;B*51:199]=[B*51:16;B*51:31;B*51:34;B*51:93]/[B*51:16;B*51:31;B*51:34;B*51:93]=[B*51:45]/[B*51:16;B*51:31;B*51:34;B*51:93]=[B*51:78:01;B*51:78:02]/[B*51:16;B*51:31;B*51:34;B*51:93]=[B*59:04;B*59:09]/[B*51:01:01:01;B*51:01:01:02;B*51:01:02;B*51:01:03;B*51:01:04;B*51:01:05;B*51:01:06;B*51:01:07;B*51:01:08;B*51:01:10;B*51:01:11;B*51:01:12;B*51:01:13;B*51:01:14;B*51:01:15;B*51:01:16;B*51:01:17;B*51:01:18;B*51:01:19;B*51:01:20;B*51:01:22;B*51:01:23;B*51:01:24;B*51:01:26;B*51:01:27;B*51:01:28;B*51:01:29;B*51:01:30;B*51:01:31;B*51:01:32;B*51:01:33;B*51:01:34;B*51:01:35;B*51:01:36;B*51:01:37;B*51:01:38;B*51:01:39;B*51:01:40;B*51:01:41;B*51:01:42;B*51:01:43;B*51:01:44;B*51:01:45;B*51:01:46;B*51:01:47;B*51:01:48;B*51:01:49;B*51:01:50;B*51:01:51;B*51:01:52;B*51:01:53;B*51:02:02;B*51:02:03;B*51:02:04;B*51:02:05;B*51:03;B*51:06:01;B*51:06:02;B*51:06:03;B*51:07:01;B*51:07:02;B*51:09:01;B*51:09:02;B*51:09:03;B*51:11N;B*51:12;B*51:14;B*51:17;B*51:18;B*51:21;B*51:22;B*51:24:01;B*51:24:05;B*51:26;B*51:27N;B*51:28;B*51:30;B*51:32;B*51:33;B*51:35;B*51:37;B*51:38;B*51:39;B*51:40;B*51:41N;B*51:43;B*51:48;B*51:49;B*51:50;B*51:51;B*51:52;B*51:53;B*51:55;B*51:58;B*51:59;B*51:60;B*51:65;B*51:66;B*51:67;B*51:69;B*51:70;B*51:71;B*51:72;B*51:73;B*51:74;B*51:75;B*51:77;B*51:79;B*51:80;B*51:83;B*51:84;B*51:86;B*51:87;B*51:88;B*51:89;B*51:90;B*51:91;B*51:94;B*51:95;B*51:96;B*51:98N;B*51:99;B*51:100;B*51:102;B*51:105;B*51:107;B*51:109;B*51:110N;B*51:111;B*51:113;B*51:114;B*51:115;B*51:117;B*51:118N;B*51:119;B*51:120;B*51:121;B*51:122;B*51:123;B*51:124;B*51:125;B*51:126;B*51:127;B*51:128;B*51:129;B*51:130;B*51:131;B*51:132;B*51:133;B*51:134;B*51:135;B*51:136;B*51:137;B*51:138;B*51:140;B*51:142;B*51:143;B*51:144;B*51:145;B*51:146;B*51:147;B*51:149N;B*51:150;B*51:151;B*51:152;B*51:154;B*51:155;B*51:156;B*51:158:01;B*51:158:02;B*51:159;B*51:160;B*51:161;B*51:162;B*51:163;B*51:164;B*51:165;B*51:166;B*51:167;B*51:168;B*51:169;B*51:170;B*51:171;B*51:173Q;B*51:175;B*51:177;B*51:178N;B*51:179;B*51:180;B*51:181;B*51:182;B*51:183;B*51:184N;B*51:185;B*51:186;B*51:187;B*51:188;B*51:189;B*51:190;B*51:191;B*51:192;B*51:193;B*51:194;B*51:195;B*51:196;B*51:198;B*51:199]=[B*59:04;B*59:09]/[B*51:16;B*51:31;B*51:34;B*51:93]=[B*59:04;B*59:09]/[B*51:45]

- la tipizzazione per [B*58:20]/[B*57:71] è
[B*57:71]/[B*13:07N]=[B*57:01:01;B*57:01:02;B*57:01:03;B*57:01:04;B*57:01:05;B*57:01:06;B*57:01:08;B*57:01:10;B*57:01:11;B*57:01:12;B*57:01:13;B*57:01:14;B*57:01:15;B*57:01:16;B*57:01:17;B*57:01:18;B*57:01:19;B*57:01:21;B*57:01:22;B*57:04:01;B*57:04:02;B*57:06;B*57:10;B*57:11;B*57:15;B*57:18;B*57:19;B*57:20;B*57:21;B*57:22;B*57:23;B*57:26;B*57:27;B*57:29;B*57:30;B*57:31;B*57:33;B*57:34;B*57:35;B*57:36;B*57:37;B*57:38;B*57:40;B*57:41;B*57:43;B*57:44;B*57:47;B*57:48;B*57:49;B*57:50;B*57:52;B*57:53;B*57:54;B*57:55;B*57:56;B*57:58;B*57:59;B*57:60;B*57:61;B*57:62;B*57:64;B*57:65;B*57:67:02;B*57:68;B*57:72;B*57:73;B*57:74;B*57:75;B*57:76;B*57:77;B*57:78;B*57:79N;B*57:81]/[B*13:07N]

- la tipizzazione per [B*58:20]/[B*27:30] è
[B*27:19;B*27:29;B*27:36;B*27:125]/[B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134]=[B*27:30]/[B*27:01;B*27:142]=[B*27:30]/[B*27:02:02;B*27:53;B*27:57;B*27:65N;B*27:77;B*27:83;B*27:95;B*27:102;B*27:119;B*27:126;B*27:134]=[B*27:30]/[B*27:03;B*27:05:02;B*27:05:03;B*27:05:04;B*27:05:05;B*27:05:06;B*27:05:07;B*27:05:08;B*27:05:09;B*27:05:10;B*27:05:11;B*27:05:12;B*27:05:13;B*27:05:14;B*27:05:15;B*27:05:16;B*27:05:17;B*27:05:18;B*27:05:19;B*27:05:20;B*27:05:21;B*27:05:22;B*27:05:24;B*27:05:25;B*27:05:26;B*27:05:27;B*27:05:28;B*27:05:29;B*27:05:30;B*27:05:31;B*27:07:01;B*27:07:02;B*27:07:03;B*27:09;B*27:11;B*27:13;B*27:14;B*27:16;B*27:17;B*27:27;B*27:31;B*27:32;B*27:34;B*27:35;B*27:37;B*27:38;B*27:39;B*27:43;B*27:45;B*27:46;B*27:47;B*27:48;B*27:49;B*27:50:01;B*27:50:02;B*27:51;B*27:55;B*27:56;B*27:58;B*27:59N;B*27:60;B*27:61;B*27:64N;B*27:70;

	<p>B*27:72;B*27:73;B*27:74;B*27:80;B*27:81;B*27:82;B*27:84;B*27:85;B*27:87;B*27:88;B*27:90:02;B*27:90:03;B*27:93;B*27:94N;B*27:96:01;B*27:96:02;B*27:97;B*27:98;B*27:99;B*27:101;B*27:104;B*27:110;B*27:111;B*27:116;B*27:117;B*27:118;B*27:121;B*27:122;B*27:123;B*27:124;B*27:128;B*27:129;B*27:130;B*27:131;B*27:132;B*27:133;B*27:135;B*27:136;B*27:137;B*27:139;B*27:140;B*27:141;B*27:143;B*27:144;B*27:145;B*27:146]=[B*27:30]/[B*27:05:23]=[B*27:30]/[B*27:19;B*27:29;B*27:36;B*27:125]=[B*27:30]/[B*27:30]=[B*27:67;B*27:76;B*27:90:01]/[B*27:30]=[B*27:75]/[B*27:19;B*27:29;B*27:36;B*27:125]=[B*27:75]/[B*27:30]=[B*40:117]/[B*27:19;B*27:29;B*27:36;B*27:125]=[B*40:117]/[B*27:30]=[B*40:188]/[B*27:30]</p> <p>- la tipizzazione per [B*58:20]/[B*27:75] è [B*27:75]/[B*27:05:23]=[B*27:75]/[B*27:75]</p> <p>- la tipizzazione per [B*58:20]/[B*38:26] è [B*57:16]/[B*38:26]</p> <p>- la tipizzazione per [B*58:20]/[B*40:117] è [B*40:117]/[B*27:67;B*27:76;B*27:90:01]=[B*40:117]/[B*40:117]=[B*40:188]/[B*40:117]</p> <p>- la tipizzazione per [B*58:20]/[B*44:62] è [B*52:18]/[B*44:21;B*44:124]</p>
B*58:27	<p>Un campione che ha risultati di tipizzazione in una delle seguenti condizioni può anche essere B*58:27:</p> <ul style="list-style-type: none"> - ha reazione falsamente negativa alla corsia 74 - comprende [B*58:73] o [B*51:81] come risultato possibile di tipizzazione - la tipizzazione per [B*58:27]/[B*27:08, B*27:12, B*27:26, B*27:33, B*27:42, B*27:44, B*27:89] è [B*27:02:02, B*27:53, B*27:57, B*27:65N, B*27:77, B*27:83, B*27:95, B*27:102, B*27:119, B*27:126, B*27:134]/[B*35:72, B*35:135] - la tipizzazione per [B*58:27]/[B*07:02:02, B*07:02:03, B*07:02:04, B*07:02:05, B*07:02:06, B*07:02:08, B*07:02:09, B*07:02:10, B*07:02:12, B*07:02:13, B*07:02:15, B*07:02:16, B*07:02:17, B*07:02:18, B*07:02:19, B*07:02:20, B*07:02:21, B*07:02:22, B*07:02:23, B*07:02:24, B*07:02:25, B*07:02:26, B*07:02:27, B*07:02:28, B*07:02:29, B*07:02:30, B*07:02:31, B*07:02:33, B*07:02:34, B*07:02:36, B*07:02:37, B*07:02:38, B*07:02:39, B*07:02:40, B*07:02:41, B*07:02:42, B*07:02:43, B*07:02:44, B*07:02:45, B*07:02:46, B*07:02:47, B*07:02:48, B*07:03, B*07:05:02, B*07:05:04, B*07:05:05, B*07:05:06, B*07:05:07, B*07:05:08, B*07:09, B*07:10, B*07:15, B*07:16, B*07:17, B*07:21, B*07:22:01, B*07:22:02, B*07:23, B*07:26, B*07:28, B*07:30, B*07:35, B*07:37, B*07:39, B*07:41, B*07:42, B*07:46, B*07:47, B*07:49N, B*07:52, B*07:54, B*07:56:01, B*07:56:02, B*07:58, B*07:59, B*07:61, B*07:62, B*07:63, B*07:64, B*07:66, B*07:67N, B*07:68:03, B*07:69, B*07:70, B*07:71, B*07:72, B*07:74, B*07:76, B*07:79, B*07:80, B*07:82, B*07:85, B*07:86, B*07:87, B*07:88, B*07:89, B*07:90, B*07:91, B*07:92, B*07:93, B*07:94, B*07:95, B*07:96:01, B*07:96:02, B*07:97, B*07:98, B*07:99, B*07:101, B*07:102, B*07:103, B*07:104, B*07:105, B*07:106, B*07:107, B*07:108, B*07:109, B*07:110, B*07:111N, B*07:112, B*07:113, B*07:114, B*07:115, B*07:116, B*07:117, B*07:118, B*07:119, B*07:120, B*07:121, B*07:123, B*07:124, B*07:125, B*07:126, B*07:127, B*07:128, B*07:129, B*07:130, B*07:132, B*07:135N, B*07:136:01, B*07:136:02, B*07:138, B*07:139, B*07:141, B*07:142, B*07:143, B*07:144, B*07:145, B*07:147, B*07:148, B*07:150, B*07:151:01, B*07:151:02, B*07:152, B*07:154, B*07:155, B*07:156, B*07:157, B*07:158, B*07:159, B*07:160, B*07:161N, B*07:166, B*07:167N, B*07:168, B*07:169, B*07:170, B*07:171, B*07:172, B*07:173, B*07:175, B*07:176, B*07:177, B*07:178, B*07:179, B*07:181N, B*07:183, B*07:184, B*07:185, B*07:187, B*07:188, B*07:189, B*07:190, B*07:191, B*07:194, B*07:195, B*07:196, B*07:197, B*07:198, B*07:199, B*07:200, B*07:201N, B*07:203, B*07:204, B*07:205, B*07:206, B*07:208, B*07:210, B*07:211, B*07:212, B*07:213, B*07:215, B*07:216, B*07:217, B*07:221, B*07:224, B*07:225, B*07:229, B*07:230, B*07:231N, B*07:232, B*07:233, B*07:234, B*07:238, B*07:241, B*07:242, B*07:243, B*07:244, B*07:245, B*07:246, B*07:249, B*07:250, B*07:251N, B*07:252, B*07:254, B*07:256, B*07:257, B*07:258, B*07:259, B*07:260, B*07:263, B*07:264, B*07:265] e [B*58:27]/[B*07:02:32] è [B*27:75]/[B*07:02:32]=[B*27:75]/[B*07:134] - la tipizzazione per [B*58:27]/[B*08:01:02, B*08:01:13] è [B*27:75]/[B*08:01:24] - la tipizzazione per [B*58:27]/[B*35:19, B*35:47, B*35:154] è [B*40:19]/[B*35:182] - la tipizzazione per [B*58:27]/[B*35:137, B*35:147] è [B*40:117]/[B*35:137, B*35:147]=[B*40:117]/[B*35:182] - la tipizzazione per [B*58:27]/[B*56:17, B*56:33, B*56:42] è [B*51:15]/[B*40:10:01:01, B*40:10:01:02] - la tipizzazione per [B*58:27]/[B*57:05, B*57:67:01] e [B*58:28:02, B*58:65]/[B*57:13] è [B*58:01:01:01, B*58:01:01:02, B*58:01:02, B*58:01:03, B*58:01:04, B*58:01:05, B*58:01:06, B*58:01:07, B*58:01:09, B*58:01:10, B*58:01:11, B*58:01:12, B*58:01:13, B*58:01:14, B*58:01:15, B*58:01:16, B*58:01:17, B*58:01:18, B*58:01:19, B*58:02:01, B*58:02:02, B*58:04, B*58:05, B*58:06, B*58:09, B*58:10N, B*58:11, B*58:12, B*58:13, B*58:14, B*58:15, B*58:16:01, B*58:16:02, B*58:18, B*58:19, B*58:21, B*58:22, B*58:23, B*58:24, B*58:25, B*58:26, B*58:29, B*58:31N, B*58:32, B*58:33, B*58:34, B*58:35, B*58:38, B*58:39N,

	<p>B*58:40, B*58:41, B*58:42, B*58:43, B*58:45:01, B*58:45:02, B*58:46, B*58:47, B*58:48, B*58:49, B*58:50, B*58:51, B*58:52, B*58:53, B*58:54, B*58:55, B*58:56, B*58:57, B*58:58, B*58:59:01, B*58:60, B*58:61, B*58:62, B*58:63, B*58:66, B*58:67, B*58:68, B*58:69, B*58:70, B*58:71, B*58:72N, B*58:74, B*58:75, B*58:76, B*58:77, B*58:78]/[B*57:13]=[B*58:17N]/[B*57:13]=[B*58:37]/[B*57:01:07]=[B*58:37]/[B*57:13]</p> <p>- la tipizzazione per [B*58:27]/[B*08:155] è [B*40:19]/[B*08:32]</p> <p>- la tipizzazione per [B*58:27]/[B*07:02:02, B*07:02:03, B*07:02:04, B*07:02:05, B*07:02:06, B*07:02:08, B*07:02:09, B*07:02:10, B*07:02:12, B*07:02:13, B*07:02:15, B*07:02:16, B*07:02:17, B*07:02:18, B*07:02:19, B*07:02:20, B*07:02:21, B*07:02:22, B*07:02:23, B*07:02:24, B*07:02:25, B*07:02:26, B*07:02:27, B*07:02:28, B*07:02:29, B*07:02:30, B*07:02:31, B*07:02:33, B*07:02:34, B*07:02:36, B*07:02:37, B*07:02:38, B*07:02:39, B*07:02:40, B*07:02:41, B*07:02:42, B*07:02:43, B*07:02:44, B*07:02:45, B*07:02:46, B*07:02:47, B*07:02:48, B*07:03, B*07:05:02, B*07:05:04, B*07:05:05, B*07:05:06, B*07:05:07, B*07:05:08, B*07:09, B*07:10, B*07:15, B*07:16, B*07:17, B*07:21, B*07:22:01, B*07:22:02, B*07:23, B*07:26, B*07:28, B*07:30, B*07:35, B*07:37, B*07:39, B*07:41, B*07:42, B*07:46, B*07:47, B*07:49N, B*07:52, B*07:54, B*07:56:01, B*07:56:02, B*07:58, B*07:59, B*07:61, B*07:62, B*07:63, B*07:64, B*07:66, B*07:67N, B*07:68:03, B*07:69, B*07:70, B*07:71, B*07:72, B*07:74, B*07:76, B*07:79, B*07:80, B*07:82, B*07:85, B*07:86, B*07:87, B*07:88, B*07:89, B*07:90, B*07:91, B*07:92, B*07:93, B*07:94, B*07:95, B*07:96:01, B*07:96:02, B*07:97, B*07:98, B*07:99, B*07:101, B*07:102, B*07:103, B*07:104, B*07:105, B*07:106, B*07:107, B*07:108, B*07:109, B*07:110, B*07:111N, B*07:112, B*07:113, B*07:114, B*07:115, B*07:116, B*07:117, B*07:118, B*07:119, B*07:120, B*07:121, B*07:123, B*07:124, B*07:125, B*07:126, B*07:127, B*07:128, B*07:129, B*07:130, B*07:132, B*07:135N, B*07:136:01, B*07:136:02, B*07:138, B*07:139, B*07:141, B*07:142, B*07:143, B*07:144, B*07:145, B*07:147, B*07:148, B*07:150, B*07:151:01, B*07:151:02, B*07:152, B*07:154, B*07:155, B*07:156, B*07:157, B*07:158, B*07:159, B*07:160, B*07:161N, B*07:166, B*07:167N, B*07:168, B*07:169, B*07:170, B*07:171, B*07:172, B*07:173, B*07:175, B*07:176, B*07:177, B*07:178, B*07:179, B*07:181N, B*07:183, B*07:184, B*07:185, B*07:187, B*07:188, B*07:189, B*07:190, B*07:191, B*07:194, B*07:195, B*07:196, B*07:197, B*07:198, B*07:199, B*07:200, B*07:201N, B*07:203, B*07:204, B*07:205, B*07:206, B*07:208, B*07:210, B*07:211, B*07:212, B*07:213, B*07:215, B*07:216, B*07:217, B*07:221, B*07:224, B*07:225, B*07:229, B*07:230, B*07:231N, B*07:232, B*07:233, B*07:234, B*07:238, B*07:241, B*07:242, B*07:243, B*07:244, B*07:245, B*07:246, B*07:249, B*07:250, B*07:251N, B*07:252, B*07:254, B*07:256, B*07:257, B*07:258, B*07:259, B*07:260, B*07:263, B*07:264, B*07:265] e [B*58:27]/[B*07:02:32] è [B*27:75]/[B*07:02:32]=[B*27:75]/[B*07:134]</p> <p>- la tipizzazione per [B*58:27]/[B*35:217] è [B*40:19]/[B*35:137, B*35:147]</p> <p>- la tipizzazione per [B*58:27]/[B*35:274] è [B*40:19]/[B*35:278]</p> <p>- la tipizzazione per [B*58:27]/[B*50:15] è [B*51:15]/[B*40:24, B*40:120, B*40:148, B*40:161]</p> <p>- la tipizzazione per [B*58:27]/[B*56:20:02] è [B*27:75]/[B*56:45]</p> <p>- la tipizzazione per [B*58:27]/[B*58:64] è [B*58:37]/[B*40:10:01:01, B*40:10:01:02]</p>
B*58:28:01	Un campione precedentemente tipizzato come B*51:148 ambiguo, B*53:14, B*58:59:02 può anche essere B*58:28:01.
B*58:28:02, B*58:65	Un campione precedentemente tipizzato come B*58 ambiguo (B*58:01:01:01, B*58:01:01:02, B*58:01:02, B*58:01:03, B*58:01:04, B*58:01:05, B*58:01:06, B*58:01:07, B*58:01:09, B*58:01:10, B*58:01:11, B*58:01:12, B*58:01:13, B*58:01:14, B*58:01:15, B*58:01:16, B*58:01:17, B*58:01:18, B*58:01:19, B*58:02:01, B*58:02:02, B*58:04, B*58:05, B*58:06, B*58:09, B*58:10N, B*58:11, B*58:12, B*58:13, B*58:14, B*58:15, B*58:16:01, B*58:16:02, B*58:18, B*58:19, B*58:21, B*58:22, B*58:23, B*58:24, B*58:25, B*58:26, B*58:29, B*58:31N, B*58:32, B*58:33, B*58:34, B*58:35, B*58:38, B*58:39N, B*58:40, B*58:41, B*58:42, B*58:43, B*58:45:01, B*58:45:02, B*58:46, B*58:47, B*58:48, B*58:49, B*58:50, B*58:51, B*58:52, B*58:53, B*58:54, B*58:55, B*58:56, B*58:57, B*58:58, B*58:59:01, B*58:60, B*58:61, B*58:62, B*58:63, B*58:66, B*58:67, B*58:68, B*58:69, B*58:70, B*58:71, B*58:72N, B*58:74, B*58:75, B*58:76, B*58:77, B*58:78) può anche essere B*58:28:02 o B*58:65.

TABELLA 2 - Documenti specifici dell'utente e file di software UCH del lotto corretti

Numero del documento	Revisione errata	Revisione corretta	Titolo del documento
ASG-ABC-038-LIM-1101	3	4	Kit AllSet Gold HLA ABC SSP, Lotto 038-Limiti di risoluzione
ASG-ABC-038-PRI-1101	4	5	Kit AllSet Gold HLA ABC SSP, Lotto 038-Informazioni sul primer
ASG-ABC-038-UCH-1101	3	4	ABC, Lotto 038-File UCH
ASG-ABC-038-UCH-1701	1	2	Kit a bassa risoluzione AllSet+™ Gold SSP ABC, Lotto 038-File UCH 2017.01
ASG-ABC-038-WS-1101	3	4	Kit a bassa ris. AllSet Gold HLA ABC SSP, Lotto 038-Scheda di lavoro
ASG-ABC-038-WS-1701	1	2	Kit a bassa ris. AllSet Gold HLA ABC SSP, Lotto 038-Scheda di lavoro
ASG-CHR-005-LIM-0604	5	6	Kit ad alta ris. AllSet Gold HLA C Locus SSP, Lotto 005-Limiti di risoluzione
ASG-CHR-005-PRI-0604	9	10	Kit ad alta ris. AllSet Gold HLA C Locus SSP, Lotto 005-Informazioni sul primer
ASG-CHR-005-UCH-0604	8	9	Cw High Res, Lotto 005-File UCH 2006.04
ASG-CHR-005-UCH-1701	1	2	AllSet+™ Gold SSP C Locus High Resolution Kit, Lotto 005-File UCH 2017.01
ASG-CHR-005-WS-0604	7	8	AllSet Gold HLA Cw Locus High Res SSP Kit, Lotto 005-Scheda di lavoro
ASG-CHR-005-WS-1701	1	2	AllSet Gold HLA C Locus High Res SSP Kit, Lotto 005-Scheda di lavoro
ASG-CLOC-021-LIM-1101	1	2	AllSet Gold HLA C Low Res SSP Kit, Lotto 021-Limiti di risoluzione
ASG-CLOC-021-PRI-1101	0	1	AllSet Gold HLA C Low Res SSP Kit, Lotto 021-Informazioni sul primer
ASG-CLOC-021-UCH-1101	0	1	C Locus, Lotto 021-File UCH
ASG-CLOC-021-UCH-1701	0	1	AllSet+™ Gold SSP C Low Resolution Kit, Lotto 021-File UCH 2017.01
ASG-CLOC-021-WS-1101	0	1	AllSet Gold HLA C Low Res SSP Kit, Lotto 021-Scheda di lavoro
ASG-CLOC-021-WS-1701	0	1	AllSet Gold HLA C Low Res SSP Kit, Lotto 021-Scheda di lavoro

Rischio per la salute: c'è un basso rischio per il paziente o per l'utente finale come risultato di questo problema per i seguenti motivi: nelle istruzioni per l'uso di AllSet+™ Gold SSP (ASG-TRAY-PI-EN-00, rev. 11) è dichiarato che tutti i risultati di tipizzazione devono essere confermati utilizzando un altro metodo di tipizzazione. Inoltre, le decisioni cliniche per i trapianti sono basate su più fonti. Questo prodotto non è l'unica fonte usata per l'analisi di tipizzazione. Il rischio complessivo per i pazienti è minimo.

Informazioni sul prodotto e sulla distribuzione:

ID di catalogo: 54340D	Lotto: 038	
		Data di scadenza: 30/06/2017
	Lotto: 0381649364	16/09/2017
	0000090151	01/06/2018
	0000101440	15/09/2018
	0000117687	
ID di catalogo: 54030D	Lotto: 005	
		Data di scadenza: 21/03/2018
	Lotto: 0000090149	27/04/2018
	0000100555	02/08/2018
	0000115881	02/11/2018
	0000129631	09/02/2019
	0000171299	
ID di catalogo: 54330D	Lotto: 021	
		Data di scadenza: 17/03/2018
	Lotto: 0000090150	07/06/2018
	0000101444	22/09/2018
	0000123224	

Azione da intraprendere a cura dell'utilizzatore o del distributore: esaminare i risultati dei test generati con i prodotti suindicati; i risultati dei test interessati potrebbero richiedere l'ulteriore analisi da parte del direttore del laboratorio HLA. Per confermare i risultati dei test potrebbero essere necessari altri metodi di analisi. **La TABELLA 2 - Documenti specifici dell'utente e file di software UCH del lotto** elenca le schede di lavoro e la documentazione corrette. Utilizzare i documenti specifici dell'utente del lotto come elencati per l'analisi dei dati.

Utilizzatore finale: compilare il **Modulo di conferma** allegato e restituirlo a One Lambda, Inc.

Distributori: i dati in nostro possesso indicano che potrebbero essere stati acquistati prodotti per la rivendita. Compilare il **Modulo di conferma** relativamente all'inventario dei prodotti ricevuti e/o ancora in magazzino. Contattare, inoltre, i clienti interessati, informarli della situazione e fornire loro una copia della presente lettera. Inserire le proprie informazioni nel **Modulo di conferma** e chiedere agli utilizzatori finali di restituire il **Modulo di conferma** debitamente compilato.

Tipo di azione da parte del produttore: aggiornare la documentazione relativa al lotto interessato per rimuovere la specificità dell'allele.

Trasmissione del presente avviso di sicurezza: questo avviso deve essere trasmesso a tutti coloro che necessitano di essere informati all'interno della vostra organizzazione o a qualsiasi organizzazione alla quale potrebbero essere stati trasferiti i dispositivi potenzialmente interessati.

Persona di riferimento da contattare: per ulteriori domande o dubbi riguardanti questo problema, è possibile contattare il team di supporto clienti di One Lambda per assistenza all'indirizzo e-mail: techsupport@onelambda.com o telefonicamente al numero: +1 (818) 702-0042. È anche possibile contattare il nostro rappresentante autorizzato in Germania: MDSS GmbH, Tel.: +49 511 62628630, vigilance@mdss.com

Grazie per la vostra immediata attenzione alla presente correzione. Ci scusiamo per l'inconveniente causato e vi ringraziamo in anticipo per la comprensione dimostrata verso l'azione correttiva necessaria da noi intrapresa al fine di garantire la sicurezza e la soddisfazione dei clienti.

La sottoscritta conferma che gli organi di regolamentazione preposti sono stati informati in merito al presente avviso di sicurezza.

[Firma]

Angela Estany
Affari regolatori e Qualità, Direttore

**Risposta di ritorno dell'avviso di sicurezza
MODULO DI CONFERMA**

NP CR170228

Informazioni sul cliente (compilare)

Nome:

Indirizzo:

Prodotto: AllSet™ Gold SSP

ID di catalogo: 54340D	Lotto: 038	Data di scadenza: 30/06/2017
	Lotto: 0381649364	16/09/2017
	0000090151	01/06/2018
	0000101440	15/09/2018
ID di catalogo: 54030D	Lotto: 005	Data di scadenza: 21/03/2018
	Lotto: 0000090149	27/04/2018
	0000100555	02/08/2018
	0000115881	02/11/2018
ID di catalogo: 54330D	Lotto: 021	Data di scadenza: 17/03/2018
	Lotto: 0000090150	07/06/2018
	0000101444	22/09/2018
	0000123224	

Confermo di aver letto e compreso il presente avviso di sicurezza e le relative istruzioni e di aver intrapreso le azioni appropriate:

_____ (iniziali)

Al prodotto richiamato risultano associati decessi di pazienti o lesioni? ____ **Sì** ____ **No**

In caso di risposta affermativa, fornire una spiegazione:

--

Risposta di ritorno: (se applicabile, fornire ulteriori informazioni)

--

DISTRIBUTORI:

Ho individuato e avvisato i miei clienti a cui sono o potrebbero essere stati spediti prodotti interessati da questa lettera: ____ **Sì** ____ **No**

Si prega di firmare e inserire la data di seguito, indicando che sono state intraprese tutte le azioni di notifica e che le informazioni in questione sono state comunicate a tutti i soggetti interessati. Restituire a One Lambda tramite fax +1 818-702-6956 o e-mail a Vanessa.Powell@thermofisher.com oppure a 1lambda-regulatory@thermofisher.com.

Firma di avvenuta ricezione da parte dell'utilizzatore finale/del distributore:

Firma

Data

Stampa: (compilare)

Nome/Titolo:	
Telefono:	
Indirizzo e-mail:	