

URGENT RECALL/CORRECTION/FIELD SAFETY NOTICE

PN# CR170228

Commercial name of the affected product: AllSet+™ Gold SSP

FSCA-identifier: CR170228

Type of action: Review Test Results

27 June 2017

Attention: Distributors and Users

The purpose of this letter is to advise you that One Lambda, Inc., A Thermo Fisher Scientific brand, is conducting a recall/correction of the, AllSet+™ Gold SSP Kits.

Reason for the Voluntary Recall (Description of the problem): The primers PM074D and C15-02A should be negative for the following alleles: , 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, and B*58:73 during analysis. The Lot specific user documents and software UCH files contain the incorrect allele specificity information for these two primer mixes. Please refer to **TABLE 1 - Allele Specificity Impact** for allele information impacted and **TABLE 2 - Corrected Lot Specific User Documents and software UCH files**.

TABLE 1. Allele Specificity Impact

Alleles Removed	Previous Typing to Review
B*07:219	A sample previously typed as an ambiguous B*07:36, B*07:180, may also be 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	A sample previously typed as an ambiguous B*57 (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.) may also be 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 or B*57:82.
B*57:07	A sample having typing results with any of the following conditions may also be B*57:07: - has false negative reaction at lane 74 - includes [B*57:14:01;B*57:14:02] as possible result - typed as [B*44:08;B*44:57]/[B57] allele pair combinations
B*57:09	A sample previously typed as B*57:24 may also be B*57:09.
B*57:12	A sample having typing results with any of the following conditions may also be B*57:12: - has false negative reaction at lane 74 - includes ambiguous [B*57:14:01;B*57:14:02] as possible result - typed as ambiguous [B*15:31;B*15:55;B*15:246N]/[B57] allele pair combinations - typing for [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>A sample having typing results with any of the following conditions may also be B*58:08:01:</p> <ul style="list-style-type: none"> - has false negative reaction at lane 74 - includes [B*51:45] or [B*58:44] as possible result - typing for [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] - typing for [B*58:08:01]/[B*35:28;B*35:226] = [B*58:64]/[B*52:06:01;B*52:06:02] - typing for [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]. For this latter outcome, there is no change to the typing outcome of B58 at intermediate typing level.
B*58:08:02	<p>A sample previously typed as B*58:44 may also be B*58:08:02.</p>
B*58:20	<p>A sample having typing results with any of the following conditions may also be B*58:20:</p> <ul style="list-style-type: none"> - has false negative reaction at lane 74 - includes [B*13:58], [B*38:08], [B*40:109], [B*44:16], [B*44:25], [B*51:148] or [B*52:01:05] as possible typing result - typing for [B*58:20]/[B*37:04:01;B*37:04:02;B*37:21] is [B*37:34]/[B*38:06;B*38:07] - typing for [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] is [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]

27:122;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]
- typing for [B*58:20]/[B*44:02:10;B*44:34:01] is [B*51:45]/[B*44:21;B*44:124]

- typing for [B*58:20]/[B*13:62] is
[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]

- typing for [B*58:20]/[B*51:16;B*51:31;B*51:34;B*51:93] is
[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*51:11

4;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]

- typing for [B*58:20]/[B*57:71] is

[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]

- typing for [B*58:20]/[B*27:30] is

[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;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:

	<p>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>- typing for [B*58:20]/[B*27:75] is [B*27:75]/[B*27:05:23]=[B*27:75]/[B*27:75]</p> <p>- typing for [B*58:20]/[B*38:26] is [B*57:16]/[B*38:26]</p> <p>- typing for [B*58:20]/[B*40:117] is</p> <p>[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>- typing for [B*58:20]/[B*44:62] is [B*52:18]/[B*44:21;B*44:124]</p>
<p>B*58:27</p>	<p>A sample having typing results with any of the following conditions may also be B*58:27:</p> <ul style="list-style-type: none"> - has false negative reaction at lane 74 - includes [B*58:73] or [B*51:81] as possible typing result - typing for [B*58:27]/[B*27:08, B*27:12, B*27:26, B*27:33, B*27:42, B*27:44, B*27:89] is [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] - typing for [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] and [B*58:27]/[B*07:02:32] is [B*27:75]/[B*07:02:32]=[B*27:75]/[B*07:134] - typing for [B*58:27]/[B*08:01:02, B*08:01:13] is [B*27:75]/[B*08:01:24] - typing for [B*58:27]/[B*35:19, B*35:47, B*35:154] is [B*40:19]/[B*35:182] - typing for [B*58:27]/[B*35:137, B*35:147] is [B*40:117]/[B*35:137, B*35:147]=[B*40:117]/[B*35:182] - typing for [B*58:27]/[B*56:17, B*56:33, B*56:42] is [B*51:15]/[B*40:10:01:01, B*40:10:01:02] - typing for [B*58:27]/[B*57:05, B*57:67:01] and [B*58:28:02, B*58:65]/[B*57:13] is [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,

	<p>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] - typing for [B*58:27]/[B*08:155] is [B*40:19]/[B*08:32] - typing for [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] and [B*58:27]/[B*07:02:32] is [B*27:75]/[B*07:02:32]=[B*27:75]/[B*07:134] - typing for [B*58:27]/[B*35:217] is [B*40:19]/[B*35:137, B*35:147] - typing for [B*58:27]/[B*35:274] is [B*40:19]/[B*35:278] - typing for [B*58:27]/[B*50:15] is [B*51:15]/[B*40:24, B*40:120, B*40:148, B*40:161] - typing for [B*58:27]/[B*56:20:02] is [B*27:75]/[B*56:45] - typing for [B*58:27]/[B*58:64] is [B*58:37]/[B*40:10:01:01, B*40:10:01:02]</p>
B*58:28:01	Sample previously typed as ambiguous B*51:148, B*53:14, B*58:59:02 may also be B*58:28:01.
B*58:28:02, B*58:65	A sample previously typed as an ambiguous B*58 (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) may also be B*58:28:02 or B*58:65.

TABLE 2 - Corrected Lot Specific User Documents and software UCH files

Document Number	Incorrect Revision	Corrected Revision	Document Title
ASG-ABC-038-LIM-1101	3	4	AllSet Gold HLA ABC SSP Kit , Lot 038-Resolution Limitations
ASG-ABC-038-PRI-1101	4	5	AllSet Gold HLA ABC SSP Kit , Lot 038-Primer Information
ASG-ABC-038-UCH-1101	3	4	ABC, Lot 038-UCH File
ASG-ABC-038-UCH-1701	1	2	AllSet+™ Gold SSP ABC Low Resolution Kit, Lot 038-UCH File 2017.01
ASG-ABC-038-WS-1101	3	4	AllSet Gold HLA ABC Low Res SSP Kit, Lot 038-Worksheet
ASG-ABC-038-WS-1701	1	2	AllSet Gold HLA ABC Low Res SSP Kit , Lot 038-Worksheet
ASG-CHR-005-LIM-0604	5	6	AllSet Gold HLA C Locus High Res SSP Kit , Lot 005-Resolution Limitations
ASG-CHR-005-PRI-0604	9	10	AllSet Gold HLA C Locus High Res SSP Kit , Lot 005-Primer Information
ASG-CHR-005-UCH-0604	8	9	Cw High Res, Lot 005-UCH File 2006.04
ASG-CHR-005-UCH-1701	1	2	AllSet+™ Gold SSP C Locus High Resolution Kit, Lot 005-UCH File 2017.01
ASG-CHR-005-WS-0604	7	8	AllSet Gold HLA Cw Locus High Res SSP Kit, Lot 005-Worksheet
ASG-CHR-005-WS-1701	1	2	AllSet Gold HLA C Locus High Res SSP Kit , Lot 005-Worksheet
ASG-CLOC-021-LIM-1101	1	2	AllSet Gold HLA C Low Res SSP Kit , Lot 021-Resolution Limitations
ASG-CLOC-021-PRI-1101	0	1	AllSet Gold HLA C Low Res SSP Kit , Lot 021-Primer Information
ASG-CLOC-021-UCH-1101	0	1	C Locus, Lot 021-UCH File
ASG-CLOC-021-UCH-1701	0	1	AllSet+™ Gold SSP C Low Resolution Kit, Lot 021-UCH File 2017.01
ASG-CLOC-021-WS-1101	0	1	AllSet Gold HLA C Low Res SSP Kit, Lot 021-Worksheet
ASG-CLOC-021-WS-1701	0	1	AllSet Gold HLA C Low Res SSP Kit , Lot 021-Worksheet

Risk to Health: There is low risk to the patient or end user as a result of this problem because of the following: The AllSet+™ Gold SSP Instruction for Use (ASG-TRAY-PI-EN-00, rev 11) states that all typing results should be confirmed using another typing method. In addition, clinical decisions for transplant are based on multiple sources. This product is not used as the sole source for typing analysis. Overall risk to the patient is low.

Product and Distribution Information:

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

Action to be taken by the user or distributor: Review test results generated with the above mentioned products, impacted test results may need to be further investigated by HLA Laboratory Director. Other analysis methods may be required to confirm testing results. **TABLE 2 – Corrected Lot Specific User Documents and software UCH files** lists the corrected Worksheets and Documentation. Use the corrected lot specific user documents as listed for data analysis.

End User: Please complete the attached **Acknowledgement Form** and return to One Lambda, Inc.

Distributors – our records indicate that you may have purchased products for re-sale. Please complete the **Acknowledgement Form** in regards to inventory you have received and/or is still in stock. In addition, please contact your affected customers, advise them of the situation and provide them with a copy of this letter. Please insert your information onto the **Acknowledgement Form** and have your end users return the **Acknowledgement Form** back to you.

Type of Action by the Manufacturer: Update to lot specific user documentation to remove allele specificity.

Transmission of this Field Safety Notice: This notice needs to be passed on to all who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Contact reference person: If you have additional questions or concerns regarding this matter, you may contact One Lambda's Customer Support team for assistance at Email: techsupport@onelambda.com or Phone: +1 (818) 702-0042. You may also contact our authorized representative in Germany: MDSS GmbH, Tel.: +49 511 62628630, vigilance@mdss.com

We appreciate your immediate attention to this field correction. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

The undersigned confirms the appropriate Regulatory Agencies have been advised of this Field Safety Notice.



Angela Estany
Director, Regulatory Affairs and Quality

**Field Safety Notice Return Response
ACKNOWLEDGEMENT FORM**

PN# CR170228

Customer Information (Please Complete)

Name:

Address:

Product: AllSet™ Gold SSP

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

I have read and understand the attached Field Safety Notice and instructions and have taken appropriate actions:

_____ (initial)

Any patient death or injury associated with the recalled product? ___ Yes ___ No

If yes please explain:

Return Response: (please provide additional information if applicable)

DISTRIBUTORS:

I have identified and notified my customers that were shipped or may have been shipped product affected by this letter: ___ Yes ___ No

Please sign and date below indicating that all transmission actions have been taken and that this information has been disseminated to all required individuals. Return to One Lambda via fax +1 818-702-6956 or email Vanessa.Powell@thermofisher.com or 1lambda-regulatory@thermofisher.com.

Signature of Receipt by End User/Distributor:

Signature

Date

Print: (please complete)

Name/Title:	
Telephone:	
Email Address:	