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Urgent Field Safety Notice	Customer Distribution
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Date of Issue: October 31, 2013

Field Safety Notice Number >

DMR0000542

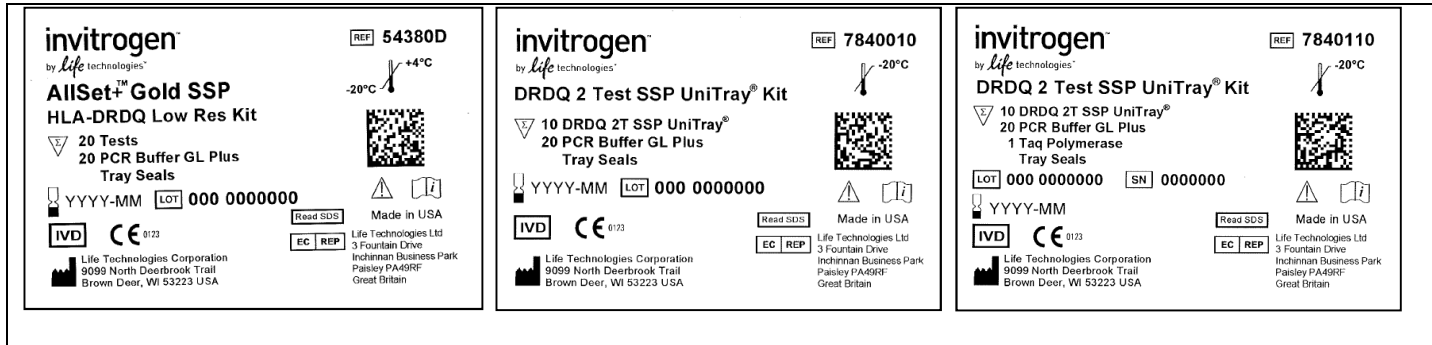
Details on Affected Devices:

Item Code:	Product Name:	Kit Lot/Batch Number (s):	Manufacturing Date:	Expiration Date (s):
54350D	AllSet+™ Gold HLA ABDR LOW RES	036 1255129	01/2013	06/2014
		036 1304515	02/2013	08/2014
		036 1357615	05/2013	10/2014
54360D	AllSet+™ Gold HLA ABDRDQ LOW RES	029 1247232	11/2012	05/2014
		029 1293558	01/2013	06/2014
		029 1306794	02/2013	07/2014
54370D	AllSet+™ Gold HLA DR LOW RES SSP	020 1205205	12/2012	05/2014
		020 1303555	01/2013	07/2014
54380D	AllSet+™ Gold HLA DRDQ LOW RES	030 1216651	12/2012	05/2014
		030 1272183	01/2013	07/2014
		031 1312025	04/2013	10/2014
		031 1377599	06/2013	11/2014
7810010	AB/DR SSP UniTray® 10 TESTS	036 1316325	03/2013	10/2014
7810110	AB/DR SSP UniTray® W/TAQ 10 TS	036 1316325 1409712	06/2013	10/2014
7820010	DR 4T SSP UniTray® 40 TESTS	020 1216655	11/2012	07/2014
7840010	DR/DQ 2T SSP UniTray® 20 TESTS	030 1221267	12/2012	07/2014
		031 1344994	04/2013	12/2014
7840110	DR/DQ 2T SSP UniTray® W/TAQ 20T	030 1221267 1344796	02/2013	01/2014
		030 1221267 1346090	02/2013	01/2014
		030 1221267 1346863	02/2013	01/2014
		030 1221267 1350644	02/2013	01/2014
		030 1221267 1352619	03/2013	01/2014
		030 1221267 1375757	04/2013	01/2014
		030 1221267 1391605	05/2013	01/2014
		030 1221267 1393093	05/2013	07/2014
		030 1221267 1396221	05/2013	07/2014
		030 1221267 1405133	06/2013	07/2014
		030 1221267 1417015	06/2013	07/2014
		030 1221267 1420379	06/2013	07/2014
		030 1221267 1427118	07/2013	07/2014
030 1221267 1429556	07/2013	07/2014		

		030 1221267 1438257	07/2013	07/2014
		031 1344994 1451386	08/2013	12/2014
		031 1344994 1452442	08/2013	12/2014
7850010	AB/DR/DQ SSP UniTray® 10 TESTS	029 1255127	01/2013	07/2014
7850110	AB/DR/DQ SSP UniTray® W/TAQ 10T	029 1255127 1345427	02/2013	01/2014
		029 1255127 1360761	03/2013	01/2014
		029 1255127 1378014	04/2013	01/2014
		029 1255127 1393696	05/2013	01/2014
		029 1255127 1419162	06/2013	07/2014
		029 1255127 1427119	07/2013	07/2014
		029 1255127 1439780	07/2013	07/2014

Product Label:

<p>invitrogen by <i>life technologies</i>[™]</p> <p>AllSet+™ Gold SSP HLA-ABDR Low Res Kit</p> <p>▽ 10 Tests 10 PCR Buffer GL Plus Tray Seals</p> <p>REF 54350D</p> <p>20°C / +4°C</p> <p>Read SDS</p> <p>IVD CE 0123</p> <p>Life Technologies Corporation 9099 North Deerbrook Trail Brown Deer, WI 53223 USA</p>	<p>invitrogen by <i>life technologies</i>[™]</p> <p>ABDR SSP UniTray® Kit</p> <p>▽ 10 ABDR SSP UniTray® 10 PCR Buffer GL Plus Tray Seals</p> <p>REF 7810010</p> <p>-20°C</p> <p>Read SDS</p> <p>IVD CE 0123</p> <p>Life Technologies Corporation 9099 North Deerbrook Trail Brown Deer, WI 53223 USA</p>	<p>invitrogen by <i>life technologies</i>[™]</p> <p>ABDR SSP UniTray® Kit</p> <p>▽ 10 ABDR SSP UniTray® 10 PCR Buffer GL Plus 1 Taq Polymerase Tray Seals</p> <p>REF 7810110</p> <p>-20°C</p> <p>Read SDS</p> <p>IVD CE 0123</p> <p>Life Technologies Corporation 9099 North Deerbrook Trail Brown Deer, WI 53223 USA</p>
<p>invitrogen by <i>life technologies</i>[™]</p> <p>AllSet+™ Gold SSP HLA-ABDRDQ Low Res Kit</p> <p>▽ 10 Tests 10 PCR Buffer GL Plus Tray Seals</p> <p>REF 54360D</p> <p>20°C / +4°C</p> <p>Read SDS</p> <p>IVD CE 0123</p> <p>Life Technologies Corporation 9099 North Deerbrook Trail Brown Deer, WI 53223 USA</p>	<p>invitrogen by <i>life technologies</i>[™]</p> <p>ABDRDQ SSP UniTray® Kit</p> <p>▽ 10 ABDRDQ SSP UniTray® 10 PCR Buffer GL Plus Tray Seals</p> <p>REF 7850010</p> <p>-20°C</p> <p>Read SDS</p> <p>IVD CE 0123</p> <p>Life Technologies Corporation 9099 North Deerbrook Trail Brown Deer, WI 53223 USA</p>	<p>invitrogen by <i>life technologies</i>[™]</p> <p>ABDRDQ SSP UniTray® Kit</p> <p>▽ 10 ABDRDQ SSP UniTray® 10 PCR Buffer GL Plus 1 Taq Polymerase Tray Seals</p> <p>REF 7850110</p> <p>-20°C</p> <p>Read SDS</p> <p>IVD CE 0123</p> <p>Life Technologies Corporation 9099 North Deerbrook Trail Brown Deer, WI 53223 USA</p>
<p>invitrogen by <i>life technologies</i>[™]</p> <p>AllSet+™ Gold SSP HLA-DR Low Res Kit</p> <p>▽ 20 Tests 20 PCR Buffer GL Plus Tray Seals</p> <p>REF 54370D</p> <p>20°C / +4°C</p> <p>Read SDS</p> <p>IVD CE 0123</p> <p>Life Technologies Corporation 9099 North Deerbrook Trail Brown Deer, WI 53223 USA</p>	<p>invitrogen by <i>life technologies</i>[™]</p> <p>DR 4 Test SSP UniTray® Kit</p> <p>▽ 10 DR 4T SSP UniTray® 40 PCR Buffer GL Plus Tray Seals</p> <p>REF 7820010</p> <p>-20°C</p> <p>Read SDS</p> <p>IVD CE 0123</p> <p>Life Technologies Corporation 9099 North Deerbrook Trail Brown Deer, WI 53223 USA</p>	



Description of Problem:

It has been identified that SSP primer mix PMR014G, in the above referenced kits, incorrectly identifies the following alleles as having an expected positive reactivity for this SSP mix: DRB1*11:09/83/87/113, DRB1*13:05:01-05:02/06/26:02/42/56/136.

Internal investigation has confirmed that these alleles should actually have an expected negative reactivity with SSP primer mix PMR014G.

SSP primer mix PMR014G is contained within different lanes depending on the affect kit type utilized:

Product Name	Item Code	Affected Lane (PMR014G)
AllSet+™ Gold ABDR Low Res SSP	54350D	Lane 15
UniTray® ABDR SSP	7810010	Lane 15
UniTray® ABDR SSP w/ Taq	7810110	Lane 15
AllSet+™ Gold ABDRDQ SSP	54360D	Lane 14
UniTray® ABDRDQ SSP	7850010	Lane 14
UniTray® ABDRDQ SSP w/ Taq	7850110	Lane 14
AllSet+™ Gold DR Low Res SSP	54370D	Lane 14
UniTray® DR 4T SSP	7820010	Lane 14
AllSet+™ Gold DRDQ Low Res SSP	54380D	Lane 15
UniTray® DRDQ 2T SSP	7840010	Lane 15
UniTray® DRDQ 2T SSP w/ Taq	7840110	Lane 15

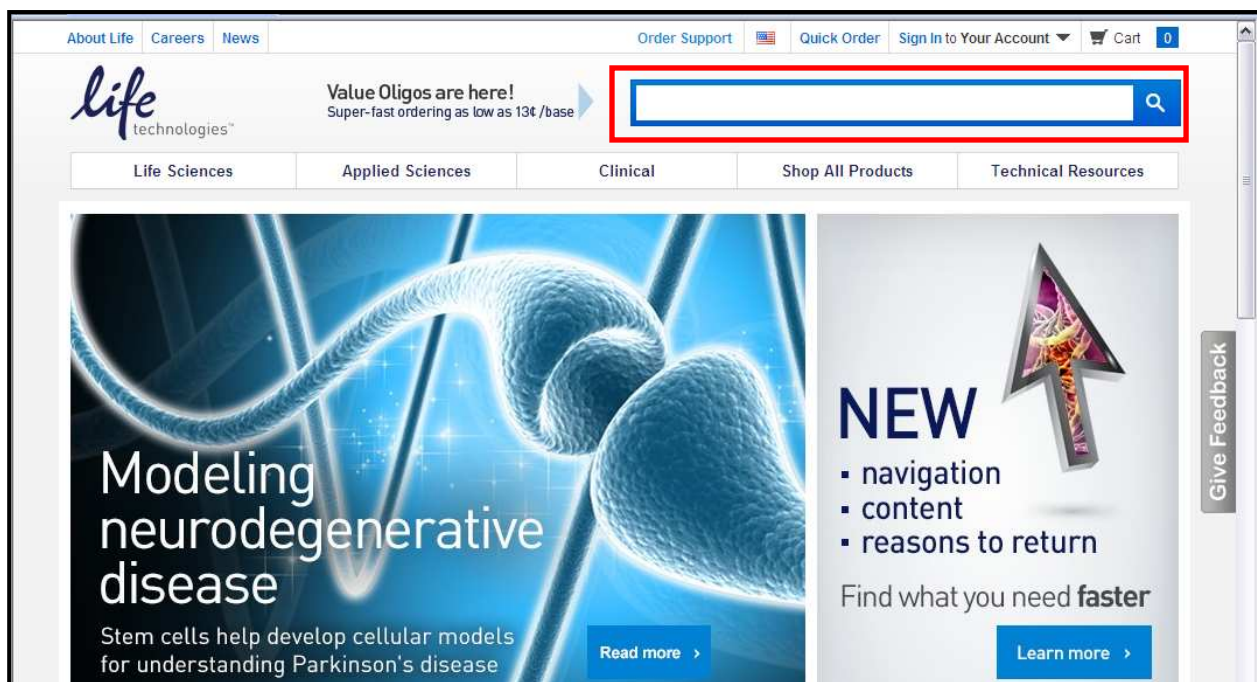
In the presence of any of the alleles mentioned above, there exists the potential for a mis-type or a no-type due to a false negative reaction in any of the above mentioned lanes.

Action to be taken by the user:

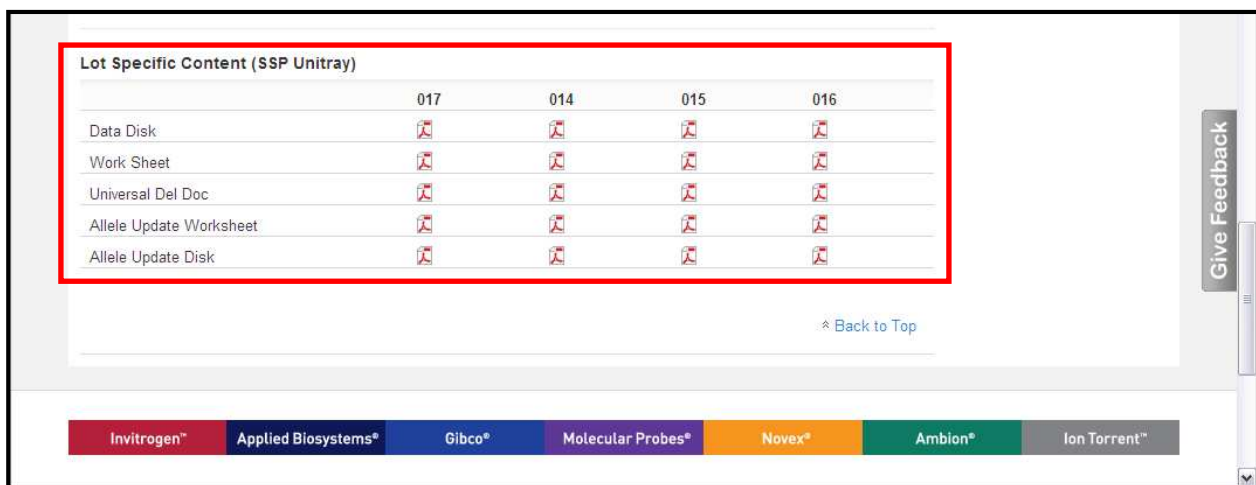
Users are advised to download the updated worksheets and .uch files that have been made available on Life Technologies' website. Additionally, customers are advised to review and confirm previously performed typings for any of the kits mentioned above using the same updated documentation.

Obtaining the corrected documentation can be done by following these steps:

1. In your web browser, navigate to www.lifetechnologies.com.
2. In the Search Bar at the top corner of the page, type in the SKU/Product number that you are seeking documentation for and hit Enter:



3. Once on the product-description page, scroll to the bottom of the page to locate the **Lot Specific Content** section:





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4. SSP Kit Documentation is arranged by lot number. In the Lot Specific Content section, download the specific documentation desired by clicking on the respective PDF icon. The documentation containing the most current allele information can be obtained by downloading the **Allele Update Worksheet** and/or the **Allele Update Disk** (for use with SSP UniMatch® Software).

This notice needs to be passed on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred. Please transfer this notice to other organizations on which this action has an impact. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

For confirmation that this notice was received and read, we kindly ask that you return a completed copy of the Customer Confirmation form provided with this notice. Instructions for returning the form are provided on the form itself.

Correction being undertaken by Life Technologies:

DMR0000542 has been issued. Life Technologies has updated the reactivity from positive to negative for the affected alleles and has made available updated documentation for all affected kits on Life Technologies' website. Users should follow the instructions in the **Actions to be taken by user** section located directly above to obtain this updated documentation.

Contact reference person:

**For users worldwide, If you have any questions
Please contact your local Life Technologies Corporation Representative or
e-mail: HLATechSupport@lifetech.com or call 1-888-821-4443 Option #2**