



Customer Notification
Urgent Medical Device Correction

DMR0000671

Date: 14-Aug-2014

Dear Valued AllSet+™ Gold and Unitray® Customer:

We appreciate your utilization of Thermo Fisher Scientific's DPB1 SSP products and want to notify you of some primer mix reactivity updates with respect to the kits listed in the table below.

For the affected kits, primer mix DPB027B (lane 27) and DPB039A (lane 39) have been shown to produce a negative reaction in the presence of samples containing the DPB1*33:01 allele. Current documentation states that this allele should produce a positive reaction with these two primer mixes, therefore samples containing the DPB1*33:01 allele have the potential to be mis-typed.

Root cause of this error is incorrect reactivity prediction due to undefined sequence at the primer binding site. Primers in mixes DPB027B and DPB039A target undefined sequence in exons 1 and 4 for the DPB1*33:01 allele. As stated on the **Quality Control Comments** form that accompanies this kit, reactivity for both of these primer mixes is predicted for alleles containing undefined sequence at the primer binding sites.

The products affected by this issue are:

SKU	Description	Lot/Serial	Expiration Date
210101	AmbiSolv® TUBE FORMAT 40 TESTS	1344877	10/21/2014
451606D	DPB1 SSP UniTray® 12 TESTS	008 1154360	1/31/2014
451606D	DPB1 SSP UniTray® 12 TESTS	008 1190373	03/31/2014
451606D	DPB1 SSP UniTray® 12 TESTS	008 1220578	4/30/2014
451606D	DPB1 SSP UniTray® 12 TESTS	008 1289713	9/30/2014
451606D	DPB1 SSP UniTray® 12 TESTS	009 1415057	2/28/2015
451606D	DPB1 SSP UniTray® 12 TESTS	009 1464121	7/30/2015
451606D	DPB1 SSP UniTray® 12 TESTS	009 1568516	12/31/2015

451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1154360 1215146	1/31/2014
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1154360 1216922	1/31/2014
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1190373 1272060	3/31/2013
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1190373 1273532	3/31/2014
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1190373 1292635	3/31/2014
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1220578 1318513	4/30/2014
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1220578 1320417	4/30/2014
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1220578 1373001	4/30/2014
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1220578 1390474	4/30/2014
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1220578 1407453	4/30/2014
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1220578 1417009	4/30/2014
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	008 1289713 1453657	1/31/2014
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	009 1415057 1501838	2/28/2015
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	009 1415057 1539250	2/28/2015
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	009 1415057 1548815	2/28/2015
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	009 1464121 1586647	7/31/2015
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	009 1464121 1588077	7/31/2015
451616D	DPB1 SSP UniTray® W/TAQ 12 TEST	009 1464121 1606607	7/31/2015
54070D	AllSet+™ Gold DPB1 HIGH RES SSP	008 1204422	2/22/2014
54070D	AllSet+™ Gold DPB1 HIGH RES SSP	008 1256851	6/21/2014
54070D	AllSet+™ Gold DPB1 HIGH RES SSP	009 1377591	12/31/2014
54070D	AllSet+™ Gold DPB1 HIGH RES SSP	009 1450550	3/31/2015
54070D	AllSet+™ Gold DPB1 HIGH RES SSP	009 1544263	9/30/2015

Please take the following action(s):

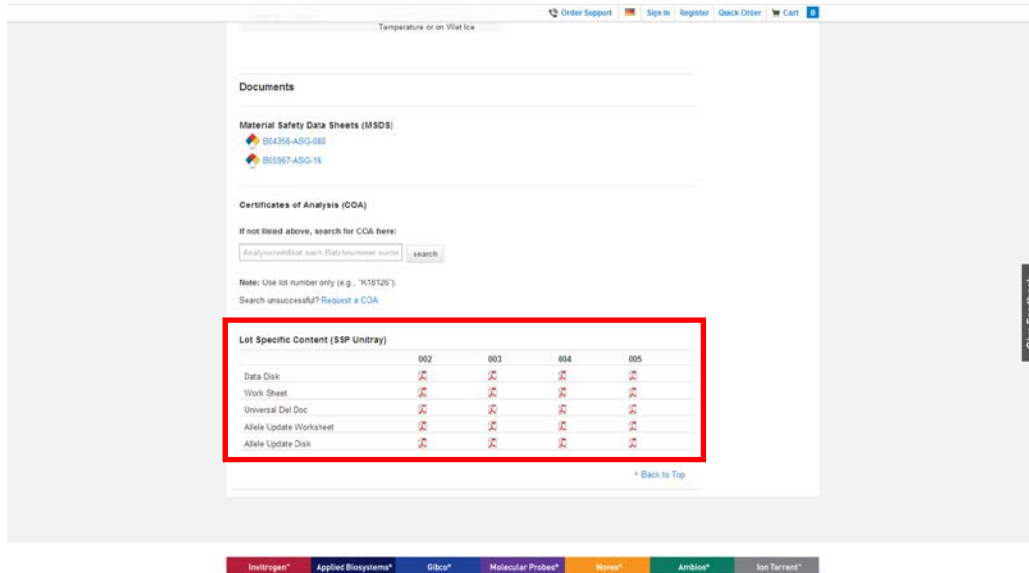
Product documentation has been updated for primer mix DPB027B (lane 27) and DPB039A (lane 39) to reflect the negative reactivity for the DPB1*33:01 allele. Corrected worksheets and .uch files are now available on the Life Technologies website. Customers are advised to download the corrected documentation and to review and confirm previously performed typings using the corrected documentation for any test carried out with the above mentioned products.

Steps to download corrected documentation:

1. In your web browser, navigate to www.lifetechnologies.com.
2. In the Search Bar at the top of the 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:



- 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).

Thank you for your continued support of Thermo Fisher Scientific. If you have questions or require more information regarding these updates, please contact HLA Technical Support:

Phone:

1-888-821-4443, option #2 (US)

00-800-5345-5345 (EMEA)

E-mail:

HLATechSupport@lifetech.com

Sincerely,

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CUSTOMER CONFIRMATION

For all users worldwide, please fill out and return this confirmation form back to Life Technologies HLA Technical Support by using the "Submit via Email" button at the top right corner of this page OR complete and fax to our US Fax Number: +1 414-214-4001.

It is important to us that we are able to confirm that you have received the information in the Customer Notification that accompanies this form. By checking the box below, you are acknowledging and representing that you have received the Customer Notification referenced in the top left of this form and that you understand and have taken the necessary actions recommended in the Customer Notification.

I acknowledge and agree with the above statement. Checking this box constitutes as my signature.

Institution Name:

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