

PN# NCR 16-052

URGENT RECALL/CORRECTION/FIELD SAFETY NOTICE

Commercial name of the affected product: LABType DNA Typing Tests

FSCA-identifier: NCR 16-052

Type of action: Review Test Results

29 September 2016

Attention: Distributors and Users

The purpose of this letter is to advise you that One Lambda, Inc., part of Thermo Fisher Scientific, is conducting a recall/correction of the following *LABType DNA Typing Tests*:

- LABType™ SSO Class II DRB1 Typing Test (Catalog ID: RSSO2B1, RS02B1T)
- LABType™ HD Class II DRB1 Typing Test (Catalog ID: RSSOH2B1, RSOH2B1T, RSSOH2B1X)
- LABType™ SSO Class II DQA1/DQB1 Typing Test (Catalog ID: RSSO2Q, RSSO2QX, RSO2QT)
- LABType™ SSO MICA (Catalog ID: RSSOMICA)
- LABType™ SSO Class I Bw4 Supplement Typing Test (Catalog ID: RSSO1S4, RSO1S4T)
- LABType™ XR Class II DRB1 Typing Test (Catalog ID: RSSOX2B1, RSOX2B1T)
- LABType™ CWD Class II DRB1 Typing Test (Catalog ID: RSSOW2B1, RSOW2B1T)

Reason for the Voluntary Recall (Description of the problem): Lot specific user documents and catalog files updated for the January 2016 nomenclature contain incorrect allele specificity information for certain beads for the LABType DNA Typing Trays listed above. If you have used these documents and catalog files, which were accessible between the date period July 29, 2016 to August 22, 2016 you may be impacted. Please refer to **TABLE 1 - Worksheets and Catalog Files Containing Errors** for a list of impacted worksheets, **TABLE 2 - Product List and Allele Specificity Impact** for product and allele information impacted, **TABLE 3 - Product Impacted** for a listing of specific kit batches affected and **TABLE 4 - Corrected Worksheets and Catalog Files** for corrected worksheets and catalog files.

TABLE 1. Worksheets and Catalog Files Containing Errors

Kit Name (CAT ID)	Lot	BPI/PRI	Rev	WS/WS3	Rev	LIM	Rev	Catalog File
LABType SSO Class II DQA1 and DQB1 Typing Test (RSSO2Q, RSO2QT, RSSO2QX)	10	RSSO2Q_010_BPI-00	4	RSSO2Q_010_WS3-00	4	RSSO-002Q-010-LIM-00	4	RSSO2Q_010_05.cat
LABType HD Class II DRB1 Typing Test (RSSOH2B1, RSOH2B1T, RSSOH2B1X)	9	RSSOH2B1_009_BPI-00	8	RSSOH2B1_010_WS3-00	8	RSSO-H2B1-009-LIM-00	8	RSSOH2B1_009_08.cat
	10	RSSOH2B1_010_BPI-00	2	RSSOH2B1_009_WS3-00	2	RSSO-H2B1-010-LIM-00	2	RSSOH2B1_010_02.cat
LABType SSO Class II DRB1 Typing Test (RSSO2B1, RSO2B1T)	18	RSSO2B1_018_BPI-00	5	RSSO2B1_018_WS-00	5	RSSO-02B-018-LIM-00	5	RSSO2B1_018_05.cat
	19	RSSO2B1_019_BPI-00	0	RSSO2B1_019_WS-00	0	RSSO-02B1-019-LIM-00	0	RSSO2B1_019_00.cat
LABType SSO Class I Bw4 Supplement Typing Test (RSSO1S4, RSO1S4T)	7	RSSO1S4_007_BPI-00	3	RSSO1S4_007_WS-00	3	RSSO-01S4-007-LIM-00	3	RSSO1S4_007_03.cat
	8	RSSO1S4_008_BPI-00	1	RSSO1S4_008_WS-00	1	RSSO-01S4-008-LIM-00	1	RSSO1S4_008_01.cat
LABType SSO MICA (RSSOMICA)	7	RSSOMICA_007_BPI-00	5	RSSOMICA_007_WS-00	5	RSSO-MICA-007-LIM-00	5	RSSOMICA_007_06.cat
LABType CWD Class II DRB1 Locus Typing Test (RSSOW2B1, RSOW2B1T)	2	RSSOW2B1_002_BPI-00	3	NA	NA	LTXRCWD-W2B1-002-LIM-00	3	RSSOW2B1_002_03.cat
LABType XR Class II DRB1 Locus Typing Test (RSSOX2B1, RSOX2B1T)	4	RSSOX2B1_004_BPI-00	3	NA	NA	LTXRCWD-X2B1-004-LIM-00	3	RSSOX2B1_004_03.cat

TABLE 2. Product List and Allele Specificity Impact

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSO2B1/ RSO2B1T (Lot 018)	031, 032, 033, 034, 036, 037, 038, 039, 041, 042, 0000057023, 0000057026, 0000059795, 0000060110, 0000062200, 0000062969, 0000063379, 0000066581, 0000070108, 0000071031, 0000076607, 0000077580, 0000078201, 0000079037, 0000079811, 0000080301, 0000087412, 0000087909, 0000089414, 0000097258, 0000103005, 0000107016, 0000114081, 0000114736, 0000120357	Existing allele omitted.	Allele DRB1*04:151 has been added to documentation	A sample previously typed as including [DRB1*04:01:01/ 01:06/ 01:08/ 01:11/ 33/ 38/ 72:01~72:02/ 76/ 111~112/ 119N/ 127/ 130/ 135/ 139/ 155/ 171/ 175/ 179/ 190/ 192/ 196], DRB1*04:13, or [DRB1*04:123/ 200] may also include DRB1*04:151.
		New allele omitted.	Allele DRB1*04:203 has been added to documentation	A sample previously typed as DRB1*04:11:01 may also include DRB1*04:203.
		New allele omitted.	Allele DRB1*04:207 has been added to documentation	A sample previously typed as [DRB1*04:10:01~10:03/ 201] may also include DRB1*04:207.
		Existing allele omitted.	Allele DRB1*04:23 has been added to documentation	A sample previously typed as [DRB1*04:04:01/ 04:03~04:04/ 04:10/ 44/ 56:01/ 70/ 120N~121/ 149/ 157N/ 182/ 193] may also include DRB1*04:23.
		Existing allele omitted.	Allele DRB1*04:49 has been added to documentation	A sample previously typed as including [DRB1*04:06:01~06:02/ 06:05~06:06/ 144] may also include DRB1*04:49.
		Existing allele omitted.	Allele DRB1*04:52 has been added to documentation	A sample previously typed as [DRB1*04:03:01/ 03:03/ 03:05/ 03:07~03:11/ 50~51/ 60/ 71/ 88/ 93/ 96/ 109/ 142N/ 148/ 167/ 181/ 183/ 195/ 198] may also include DRB1*04:52.
		Existing allele omitted.	Allele DRB1*04:66 has been added to documentation	A sample previously typed as [DRB1*04:01:05/ 34/ 64/ 115/ 153] may also include DRB1*04:66.
		Existing allele omitted.	Allele DRB1*07:33 has been added to documentation	A sample previously typed as [DRB1*07:01:01~01:01:02/ 01:03~01:06/ 01:09/ 01:11/ 01:13/ 01:15~03/ 05/ 07/ 09~11/ 13/ 15~18/ 21/ 25~32/ 34/ 38/ 40~43/ 47~53/ 55/ 58N~63/ 65~66/ 68N] may also include DRB1*07:33.

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSO2B1/ RSO2B1T (Lot 018) (continued)	011, 012, 0000053117, 0000055412, 0000055832, 0000063644, 0000064406, 0000071285, 0000084881, 0000085909, 0000112558, 0000117677	Existing allele omitted.	Allele DRB1*07:56 has been added to documentation	A sample previously typed as [DRB1*07:01:14/ 24/ 35] may also include DRB1*07:56.
		New Allele omitted.	Allele DRB1*09:25 has been added to documentation	A sample previously typed as [DRB1*09:01:02~01:03/ 01:10~01:11/ 04~05/ 10~11/ 13/ 16~19/ 21~23/ 25~27] may also include DRB1*09:25.
		Existing alleles omitted.	Alleles DRB1*15:85, DRB1*15:86, DRB1*15:123, DRB1*15:124 have been added to documentation.	A sample previously typed as [DRB1*15:01:01:01~01:01:04/ 01:03/ 01:05/ 01:07~01:17/ 01:19~01:20/ 01:25/ 01:27/ 13/ 16/ 20/ 22/ 32/ 36~37:02/ 41~43/ 46/ 51~53/ 55~56/ 61~62/ 64~65/ 67/ 75~76/ 79/ 83/ 90~93/ 95/ 97~98/ 102/ 106~108/ 111~112/ 114/ 121/ 127/ 129N] may also include DRB1*15:85, DRB1*15:86, DRB1*15:123 or DRB1*15:124.
		Wrong allele added.	Allele DRB1*15:105 has been removed from documentation	A sample previously typed as [DRB1*15:02:02/ 02:05/ 02:15/ 105] should not include DRB1*15:105.
		Existing allele omitted.	Allele DRB1*15:06:02 has been added to documentation.	A sample previously typed as [DRB1*15:06:01/ 06:03/ 09/ 48/ 59/ 77/ 125] may also include DRB1*15:06:02.
		Wrong allele added. Existing allele omitted.	Allele DRB1*16:22 has been removed from documentation. Allele DRB1*16:35 has been added to documentation.	A sample previously typed as [DRB1*16:02:01/ 02:03/ 02:05/ 17/ 19~20/ 22/ 29/ 31] may also include DRB1*16:35 and should not include DRB1*16:22.
RSSO2B1/ RSO2B1T (Lot 019)	0000119913, 0000120363, 0000124377 0000120892	Existing allele omitted.	Allele DRB1*04:151 has been added to documentation.	A sample previously typed as [DRB1*04:13]/ [DRB1*04:04:05/ 32/ 122/ 168], [DRB1*04:13]/ [DRB1*04:13] or as allele pairs including [DRB1*04:01:01/ 01:06/ 01:08/ 01:11/ 33/ 38/ 72:01~72:02/ 76/ 111~112/ 119N/ 127/ 130/ 135/ 139/ 155/ 171/ 175/ 179/ 190/ 192/ 196] may also include DRB1*04:151.
		Existing allele omitted.	Allele DRB1*04:203 has been added to documentation.	A sample previously typed as DRB1*04:11:01 may also include DRB1*04:203.

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSO2B1/ RSO2B1T (Lot 019) (continued)		Existing allele omitted.	Allele DRB1*04:207 has been added to documentation.	A sample previously typed as [DRB1*04:10:01~10:03/ 201] may also include DRB1*04:207.
		Existing allele omitted.	Allele DRB1*04:23 has been added to documentation.	A sample previously typed as [DRB1*04:04:01/ 04:03~04:04/ 04:10/ 44/ 56:01/ 70/ 120N~121/ 149/ 157N/ 182/ 193] may also include DRB1*04:23.
		Existing allele omitted.	Allele DRB1*04:49 has been added to documentation.	A sample previously typed as including [DRB1*04:06:01~06:02/ 06:05~06:06/ 144]/ [DRB1*04:06:01~06:02/ 06:05~06:06/ 144] may also include DRB1*04:49.
		Existing allele omitted.	Allele DRB1*04:52 has been added to documentation.	A sample previously typed as [DRB1*04:03:01/ 03:03/ 03:05/ 03:07~03:11/ 50~51/ 60/ 71/ 88/ 93/ 96/ 109/ 142N/ 148/ 167/ 181/ 183/ 195/ 198] may also include DRB1*04:52.
		Existing allele omitted.	Allele DRB1*04:66 has been added to documentation.	A sample previously typed as [DRB1*04:01:05/ 34/ 64/ 115/ 153] may also include DRB1*04:66.
		Existing allele omitted.	Allele DRB1*07:33 has been added to documentation.	A sample previously typed as [DRB1*07:01:01~01:01:02/ 01:03~01:06/ 01:09/ 01:11/ 01:13/ 01:15~03/ 05/ 07/ 09~11/ 13/ 15~18/ 21/ 25~32/ 34/ 38/ 40~43/ 47~53/ 55/ 58N~63/ 65~66/ 68N] may also include DRB1*07:33.
		Existing allele omitted.	Allele DRB1*07:56 has been added to documentation.	A sample previously typed as [DRB1*07:01:14/ 24/ 35] may also include DRB1*07:56.
		Existing allele omitted.	Allele DRB1*09:25 has been added to documentation.	A sample previously typed as [DRB1*09:01:02~01:03/ 01:10~01:11/ 04~05/ 10~11/ 13/ 16~19/ 21~23/ 25~27] may also include DRB1*09:25.
		Existing alleles omitted.	Alleles DRB1*15:85, DRB1*15:86, DRB1*15:123, DRB1*15:124 have been added to documentation.	A sample previously typed as [DRB1*15:01:01~01:01:04/ 01:03/ 01:05/ 01:07~01:17/ 01:19~01:20/ 01:25/ 01:27/ 13/ 16/ 20/ 22/ 32/ 36~37:02/ 41~43/ 46/ 51~53/ 55~56/ 61~62/ 64~65/ 67/ 75~76/ 79/ 83/ 90~93/ 95/ 97~98/ 102/ 106~108/ 111~112/ 114/ 121/ 127/ 129N] may also include DRB1*15:85, DRB1*15:86, DRB1*15:123 or DRB1*15:124.

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSO2B1/ RSO2B1T (Lot 019) (continued)		Wrong allele added.	Allele DRB1*15:105 has been removed from documentation.	A sample previously typed as [DRB1*15:02:02/ 02:05/ 02:15/ 105] should not include DRB1*15:105.
		Existing allele omitted.	Allele DRB1*15:06:02 has been added to documentation.	A sample previously typed as [DRB1*15:06:01/ 06:03/ 09/ 48/ 59/ 77/ 125] may also include DRB1*15:06:02.
		Wrong allele added. Existing allele omitted.	Allele DRB1*16:22 has been removed from documentation. Allele DRB1*16:35 has been added to documentation.	A sample previously typed as [DRB1*16:02:01/ 02:03/ 02:05/ 17/ 19~20/ 22/ 29/ 31] may also include DRB1*16:35 and should not include DRB1*16:22.
RSSOH2B1/ RSOH2B1T/ RSSOH2B1X (Lot 009)	033, 034, 035, 036, 0000053070, 0000053275, 0000057250, 0000058667, 0000061327, 0000062968, 0000063092, 0000063728, 0000071281, 0000074348, 0000079511, 0000081969, 0000084459, 0000092756, 0000094518 010, 011, 0000054823, 0000064410, 0000064952,	Existing allele omitted.	Allele DRB1*04:151 has been added to documentation.	"A sample previously typed as [DRB1*04:01:01/ 01:06/ 01:08/ 01:11/ 171/ 175/ 190/ 192]/ [DRB1*04:01:01/ 01:06/ 01:08/ 01:11/ 171/ 175/ 190/ 192] or as homozygous DRB1*04:13, DRB1*04:123 or DRB1*04:200, or as including [DRB1*01:01:01/ 01:05/ 01:07~01:10/ 01:12~01:14/ 01:17/ 01:19/ 01:23~01:25/ 01:28/ 50/ 62N/ 64~65:01/ 67/ 70~72] may also include DRB1*04:151."
		New allele omitted.	Allele DRB1*04:203 has been added to documentation.	A sample previously typed as DRB1*04:11:01 may also include DRB1*04:203.
		New allele omitted.	Allele DRB1*04:207 has been added to documentation.	A sample previously typed as [DRB1*04:10:01~10:03/ 201] may also include DRB1*04:207.
		Existing allele omitted.	Allele DRB1*04:23 has been added to documentation.	A sample previously typed as [DRB1*04:04:01/ 04:03~04:04/ 04:10/ 157N/ 182] may also include DRB1*04:23.
		Existing allele omitted.	Allele DRB1*04:49 has been added to documentation.	A sample previously typed as including DRB1*04:71 may also include DRB1*04:49.

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSOH2B1/ RSOH2B1T/ RSSOH2B1X (Lot 009) (continued)	0000066808, 0000089318, 0000064446, 0000070911	Existing allele omitted.	Allele DRB1*04:52 has been added to documentation.	A sample previously typed as [DRB1*04:03:01/ 03:03/ 03:05/ 03:07~03:10/ 181/ 195/ 198] may also include DRB1*04:52.
		Existing allele omitted.	Allele DRB1*04:66 has been added to documentation.	A sample previously typed as including DRB1*04:01:05 paired with one of DRB1*14:60, DRB1*11:194, DRB1*08:23 or DRB1*15:16 may also include DRB1*04:66.
		Existing allele omitted.	Allele DRB1*07:33 has been added to documentation.	A sample previously typed as [DRB1*07:01:01:01~01:01:02/ 01:03~01:06/ 01:09/ 01:11/ 01:13/ 01:15~01:18/ 31/ 34/ 38/ 40~41/ 43/ 48~51/ 55/ 58N~63/ 66/ 68N] may also include DRB1*07:33.
		Existing allele omitted.	Allele DRB1*07:56 has been added to documentation.	A sample previously typed as [DRB1*07:01:14/ 24/ 35] may also include DRB1*07:56.
		New allele omitted.	Allele DRB1*09:25 has been added to documentation.	A sample previously typed as [DRB1*09:01:02~01:03/ 01:10~01:11/ 21] may also include DRB1*09:25.
		Existing allele omitted.	Alleles DRB1*15:85, DRB1*15:86, DRB1*15:123, DRB1*15:124 have been added to documentations.	A sample previously typed as [DRB1*15:01:01:01~01:01:04/ 01:05/ 01:07~01:17/ 01:19~01:20/ 01:25/ 01:27/ 106~108/ 111~112/ 114/ 127] may also include DRB1*15:85, DRB1*15:86, DRB1*15:123, or DRB1*15:124.
		Wrong allele added.	Allele DRB1*15:105 has been removed from documentation.	A sample previously typed as [DRB1*15:02:02/ 02:05/ 105] should not include DRB1*15:105.
		Existing allele omitted.	Allele DRB1*15:06:02 has been added to documentation.	A sample previously typed as [DRB1*15:06:01/ 06:03/ 125] may also include DRB1*15:06:02.

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSOH2B1/ RSOH2B1T/ RSSOH2B1X (Lot 009) (continued)		Wrong allele added. Existing allele omitted.	Allele DRB1*16:22 has been removed from documentation. Allele DRB1*16:35 has been added to documentation.	A sample previously typed as [DRB1*16:02:01/ 22/ 29/ 31] may also include DRB1*16:35 and should not include DRB1*16:22.
RSSOH2B1/ RSOH2B1T/ RSSOH2B1X (Lot 010)	0000110068, 0000110548, 0000114596, 0000115883, 0000118315 0000120362, 0000120642 0000110547 0000111323, 0000124895	Existing allele omitted.	Allele DRB1*04:151 has been added to documentation.	A sample previously typed as typed as including [DRB1*04:01:01/ 01:06/ 01:08/ 01:11/ 171/ 175/ 190/ 192] or typed as DRB1*04:13 paired with one of DRB1*03:76, DRB1*04:13, DRB1*04:67, DRB1*04:100, DRB1*11:153 or DRB1*15:84, may also include DRB1*04:151.
		New allele omitted.	Allele DRB1*04:203 has been added to documentation.	A sample previously typed as DRB1*04:11:01 may also include DRB1*04:203.
		New allele omitted.	Allele DRB1*04:207 has been added to documentation.	A sample previously typed as [DRB1*04:10:01~10:03/ 201] may also include DRB1*04:207.
		Existing allele omitted.	Allele DRB1*04:23 has been added to documentation.	A sample previously typed as [DRB1*04:04:01/ 04:03~04:04/ 04:10/ 157N/ 182] may also include DRB1*04:23.
		Existing allele omitted.	Allele DRB1*04:49 has been added to documentation.	A sample previously typed as including DRB1*04:71 may also include DRB1*04:49.
		Existing allele omitted.	Allele DRB1*04:52 has been added to documentation.	A sample previously typed as [DRB1*04:03:01/ 03:03/ 03:05/ 03:07~03:10/ 181/ 195/ 198] may also include DRB1*04:52.
		Existing allele omitted.	Allele DRB1*04:66 has been added to documentation.	A sample previously typed as including DRB1*04:01:05 paired with one of DRB1*01:05, DRB1*07:22, DRB1*08:23, DRB1*09:12, DRB1*11:194, DRB1*14:60 or DRB1*15:16, may also include DRB1*04:66.
		Existing allele omitted.	Allele DRB1*07:33 has been added to documentation.	A sample previously typed as [DRB1*07:01:01~01:01:02/ 01:03~01:06/ 01:09/ 01:11/ 01:13/ 01:15~01:18/ 31/ 34/ 38/ 40~41/ 43/ 48~51/ 55/ 58N~63/ 66/ 68NN] may also include DRB1*07:33.

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSOH2B1/ RSOH2B1T/ RSSOH2B1X (Lot 010) (continued)		Existing allele omitted.	Allele DRB1*07:56 has been added to documentation.	A sample previously typed as [DRB1*07:01:14/ 35] may also include DRB1*07:56.
		New allele omitted.	Allele DRB1*09:25 has been added to documentation.	A sample previously typed as [DRB1*09:01:02~01:03/ 01:10~01:11/ 21] may also include DRB1*09:25.
		Existing allele omitted.	Alleles DRB1*15:85, DRB1*15:86, DRB1*15:123, DRB1*15:124 have been added to documentation.	A sample previously typed as [DRB1*15:01:01~01:01:04/ 01:05/ 01:07~01:17/ 01:19~01:20/ 01:25/ 01:27/ 106~108/ 111~112/ 114/ 127] may also include DRB1*15:85, DRB1*15:86, DRB1*15:123, or DRB1*15:124.
		Wrong allele added.	Allele DRB1*15:105 has been removed from documentation.	A sample previously typed as [DRB1*15:02:02/ 02:05/ 105] should not include DRB1*15:105.
		Wrong allele added. Existing allele omitted.	Allele DRB1*16:22 has been removed from documentation. Allele DRB1*16:35 has been added to documentation.	A sample previously typed as [DRB1*16:02:01/ 22/ 29/ 31] may also include DRB1*16:35 and should not include DRB1*16:22.
RSSO2Q/ RSO2QT/ RSSO2QX (Lot 010)	002, 003, 004, 005, 006, 007, 008, 009, 0000054593, 0000055231, 0000056058, 0000060053, 0000060784, 0000061599, 0000062603, 0000063652, 0000066921,	Existing allele omitted.	Allele DQA1*03:02 has been added to documentation.	A sample previously typed as [DQA1*03:03:01~03:02] may also include DQA1*03:02.

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSO2Q/ RSO2QT/ RSSO2QX (Lot 010) (continued)	0000070566, 0000076222, 0000077803, 0000078350, 0000079319, 0000079929, 0000081865, 0000083143, 0000084412, 0000085077, 0000087193, 0000087755, 0000091499, 0000097260, 0000101211, 0000102893, 0000105847, 0000107310, 0000108579, 0000116017, 0000118442, 0000124698, 1000094035, 0000054510, 0000056055, 0000060877, 0000063729, 0000064407, 0000066546, 0000083952, 0000085912, 0000096060, 0000102984, 0000107127, 0000117461, 1000094034, 1000095827	Existing allele omitted.	Allele DQB1*05:83(Exon2) has been added to documentation.	A sample previously typed as [DQB1*05:14/ 35/ 87Q/ 100/ 113/ 117] may also include DQB1*05:83

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSOMICA (Lot 007)	008, 0000055120, 0000079450, 0000092263, 0000117730	Existing allele omitted.	Allele MICA*002:03 has been added to documentation.	A sample previously typed as MICA*002:01 may also include MICA*002:03.
RSSO1S4/ RSO1S4T (Lot 007)	0000091890 0000082316, 0000083959, 0000087101, 0000088768	Existing allele omitted.	Allele B*44:180 has been added to documentation.	A sample previously typed as [B*44:02:11/ 03:01:01~03:16/ 03:18~03:25/ 03:27/ 03:29~03:33/ 07/ 13/ 26/ 28:01~28:02/ 32/ 35~36/ 38~40/ 45/ 50:01~50:02/ 57/ 60~61N/ 65/ 69/ 73/ 81/ 85/ 89/ 92/ 94/ 96/ 98/ 103/ 105/ 107~108N/ 110~111/ 114~115/ 122/ 125/ 128:01~128:02/ 130/ 141/ 143/ 147/ 153~157/ 159/ 161/ 164~165/ 167/ 174/ 178/ 181~183/ 186/ 188~189/ 192~194/ 197~199/ 202~205:02/ 207/ 209~210/ 222~224/ 228/ 231~233/ 237N; B*51:42] may also include B*44:180.
RSSO1S4 / RSO1S4T (Lot 008)	0000120382 0000101153, 0000102520, 0000113329, 0000122052, 0000122953	Existing allele omitted	Allele B*44:180 has been added to documentation.	A sample previously typed as [B*44:02:11/ 03:01:01~03:16/ 03:18~03:25/ 03:27/ 03:29~03:33/ 07/ 13/ 26/ 28:01~28:02/ 32/ 35~36/ 38~40/ 45/ 50:01~50:02/ 57/ 60~61N/ 65/ 69/ 73/ 81/ 85/ 89/ 92/ 94/ 96/ 98/ 103/ 105/ 107~108N/ 110~111/ 114~115/ 122/ 125/ 128:01~128:02/ 130/ 141/ 143/ 147/ 153~157/ 159/ 161/ 164~165/ 167/ 174/ 178/ 181~183/ 186/ 188~189/ 192~194/ 197~199/ 202~205:02/ 207/ 209~210/ 222~224/ 228/ 231~233/ 237N; B*51:42] may also include B*44:180.
RSSOX2B1/ RSOX2B1T (Lot 004)	0000060897, 00000110072, 00000120635 0000061768, 0000090564	Existing allele omitted.	Allele DRB1*04:151 has been added to documentation.	A sample previously typed as including [DRB1*04:01:01/ 01:06/ 01:08/ 01:11/ 171/ 190/ 192] or DRB1*04:13 may also include DRB1*04:151.
		New allele omitted.	Allele DRB1*04:203 has been added to documentation.	A sample previously typed as DRB1*04:11:01 may also include DRB1*04:203.
		New allele omitted.	Allele DRB1*04:207 has been added to documentation.	A sample previously typed as [DRB1*04:10:01~10:03/ 201] may also include DRB1*04:207.
		Existing allele omitted.	Allele DRB1*04:23 has been added to documentation.	A sample previously typed as [DRB1*04:04:01/ 04:03~04:04/ 04:10/ 182] may also include DRB1*04:23.

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSOX2B1/ RSOX2B1T (Lot 004) (Continued)		Existing allele omitted.	Allele DRB1*04:49 has been added to documentation.	A sample previously typed with false negative reaction at 555, as DRB1*04 variants ([DRB1*04:06:01~06:02/ 06:06], DRB1*04:06:03, DRB1*04:06:04, DRB1*04:20, DRB1*04:46, DRB1*04:91, DRB1*04:144) paired with one of DRB1*13:103, DRB1*13:160 or DRB1*15:69, may be DRB1*04:49.
		Existing allele omitted.	Allele DRB1*04:52 has been added to documentation.	A sample previously typed as [DRB1*04:03:01/ 03:03/ 03:05/ 03:07~03:10/ 181/ 195/ 198] may also include DRB1*04:52.
		Existing allele omitted.	Allele DRB1*04:66 has been added to documentation.	A sample previously typed as DRB1*04:01:05 paired with one of DRB1*07:22, DRB1*09:12 may also include DRB1*04:66.
		Existing allele omitted.	Allele DRB1*07:33 has been added to documentation.	A sample previously typed as [DRB1*07:01:01:01~01:01:02/ 01:03~01:06/ 01:09/ 01:11/ 01:13/ 01:15~01:18/ 34/ 38/ 40~41/ 43/ 48~51/ 55/ 58N~63/ 66/ 68N] may also include DRB1*07:33.
		Existing allele omitted.	Allele DRB1*07:56 has been added to documentation.	A sample previously typed as [DRB1*07:01:14/ 35] may also include DRB1*07:56.
		New allele omitted.	Allele DRB1*09:25 has been added to documentation.	A sample previously typed as [DRB1*09:01:02~01:03/ 01:10~01:11/ 21] may also include DRB1*09:25.
		Existing alleles omitted.	Alleles DRB1*15:85, DRB1*15:86, DRB1*15:123, DRB1*15:124 have been added to documentation.	A sample previously typed as [DRB1*15:01:01:01~01:01:04/ 01:05/ 01:07~01:17/ 01:19~01:20/ 01:25/ 01:27/ 114/ 127] may also include DRB1*15:85, DRB1*15:86, DRB1*15:123, or DRB1*15:124.
		Wrong allele added.	Allele DRB1*15:105 has been removed from documentation.	A sample previously typed as [DRB1*15:02:02/ 02:05/ 02:15/ 105] should not include DRB1*15:105.
		Existing allele omitted.	Allele DRB1*15:06:02 has been added to documentation.	A sample previously typed as [DRB1*15:06:01/ 06:03/ 125] may also include DRB1*15:06:02.

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSOX2B1/ RSOX2B1T (Lot 004) (Continued)		Wrong allele added. Existing allele omitted.	Allele DRB1*16:22 has been removed from documentation. Allele DRB1*16:35 has been added to documentation.	A sample previously typed as [DRB1*16:02:01/ 22/ 29/ 31] may also include DRB1*16:35 and should not include DRB1*16:22.
RSSOW2B1/ RSOW2B1T (Lot 002)	000006116 0000061791, 00000122205	Existing allele omitted.	Allele DRB1*04:151 has been added to documentation.	A sample previously typed as including [DRB1*04:01:01/ 01:06/ 01:08/ 01:11/ 111~112/ 119N/ 127/ 130/ 135/ 171/ 174~175/ 190/ 192] or DRB1*04:13 may also include DRB1*04:151.
		New allele omitted.	Allele DRB1*04:203 has been added to documentation.	A sample previously typed as DRB1*04:11:01 may also include DRB1*04:203.
		New allele omitted.	Allele DRB1*04:207 has been added to documentation.	A sample previously typed as [DRB1*04:10:01~10:03/ 201] may also include DRB1*04:207.
		Existing allele omitted.	Allele DRB1*04:23 has been added to documentation.	A sample previously typed as [DRB1*04:04:01/ 04:03~04:04/ 04:10/ 56:01/ 120N~121/ 149/ 157N/ 182/ 193] may also include DRB1*04:23.
		Existing allele omitted.	Allele DRB1*04:49 has been added to documentation.	A sample previously typed as including [DRB1*04:06:01~06:02/ 06:06/ 144] may also include DRB1*04:49.
		Existing allele omitted.	Allele DRB1*04:52 has been added to documentation.	A sample previously typed as [DRB1*04:03:01/ 03:03/ 03:05/ 03:07~03:10/ 60/ 71/ 88/ 93/ 96/ 109/ 142N/ 148/ 181/ 195/ 198] may also include DRB1*04:52.
		Existing allele omitted.	Allele DRB1*04:66 has been added to documentation.	A sample previously typed as [DRB1*04:01:05/ 34/ 115/ 153] may also include DRB1*04:66.
		Existing allele omitted.	Allele DRB1*07:33 has been added to documentation.	A sample previously typed as [DRB1*07:01:01~01:01:02/ 01:03~01:06/ 01:09/ 01:11/ 01:13/ 01:15~01:18/ 09/ 15~18/ 21/ 25~28/ 30~31/ 34/ 38/ 40~41/ 43/ 47~53/ 55/ 58N~63/ 66/ 68N] may also include DRB1*07:33.

Cat ID	Batch	Error	Description of Change (Correction)	Impact to prior testing with original Jan 2016 NOM release files
RSSOW2B1/ RSOW2B1T (Lot 002) (continued)		Existing allele omitted.	Allele DRB1*07:56 has been added to documentation.	A sample previously typed as [DRB1*07:01:14/ 35] may also include DRB1*07:56.
		New allele omitted.	Allele DRB1*09:25 has been added to documentation.	A sample previously typed as [DRB1*09:01:02~01:03/ 01:10~01:11/ 11/ 16~19/ 21~23/ 27] may also include DRB1*09:25.
		Existing alleles omitted.	Alleles DRB1*15:85, DRB1*15:86, DRB1*15:123, DRB1*15:124 have been added to documentation.	A sample previously typed as [DRB1*15:01:01:01~01:01:04/ 01:05/ 01:07~01:17/ 01:19~01:20/ 01:25/ 01:27/ 16/ 41~43/ 46/ 51~52/ 55~56/ 64/ 75~76/ 79/ 90~91/ 93/ 95/ 97~98/ 106~108/ 111~112/ 114/ 127/ 129N] may also include DRB1*15:85, DRB1*15:86, DRB1*15:123, or DRB1*15:124.
		Wrong allele added.	Allele DRB1*15:105 has been removed from documentation.	A sample previously typed as [DRB1*15:02:02/ 02:05/ 105] should not include DRB1*15:105.
		Existing allele omitted.	Allele DRB1*15:06:02 has been added to documentation.	A sample previously typed as [DRB1*15:06:01/ 06:03/ 77/ 125] may also include DRB1*15:06:02.
		Wrong allele added.	Allele DRB1*16:22 has been removed from documentation. Allele DRB1*16:35 has been added to documentation.	A sample previously typed as [DRB1*16:02:01/ 20/ 22/ 29/ 31] may also include DRB1*16:35 and should not include DRB1*16:22.
		Existing allele omitted.		

Risk to Health: There is low risk to the patient or end user as a result of this problem.

The HLA alleles that are incorrect on the lot specific user documents are very rare occurring in the population, therefore the probability of occurrence is low. In addition, the HLA alleles resulting in ambiguities/false reactions would need to be resolved prior to assignment based on ASHI and EFI guidelines (Guidelines that govern transplantation testing).

Clinical decisions for transplant are based on multiple sources. This product is not used as the sole source for typing analysis. Test results will be further investigated by the HLA specialist, as part of secondary and confirmatory testing. Overall risk to the patient is low. In addition, test results will be further investigated by the HLA specialist during confirmatory testing per ASHI and EFI regulations.

Product and Distribution Information:

TABLE 3. Product Impacted

Cat ID	Batch	Expiration Date
RSSO2B1 (Lot 018)	031, 32, 33, 34, 36, 37, 38, 39, 40, 41, 42, 0000057023, 0000057026, 0000059795, 0000060110, 0000062200, 0000062969, 0000063379, 0000066581,	11/30/2016
	0000070108, 0000071031, 0000076607, 0000077580, 0000078201, 0000079037, 0000079811, 0000080301, 0000087412, 0000087909, 0000089414	01/31/2017
	0000097258, 0000103005, 0000107016, 0000114081, 0000114736, 0000120357	04/30/2017
RSSO2B1 (Lot 019)	0000120363	04/30/2017
	0000124377	11/30/2017
	0000119913	04/30/2017
RSO2B1T (Lot 018)	011, 012, 0000053117, 0000055412, 0000055832, 0000063644, 0000064406, 0000071285	11/30/2016
	0000084881, 0000085909	01/19/2017
	0000112558	10/07/2017
	0000117677	04/20/2017
RSO2B1T (Lot 019)	0000120892	08/04/2017
RSSOH2B1 (Lot 009)	033, 034, 035, 036	11/2016
	0000053275, 0000057250, 0000058667, 0000061327, 0000062968, 0000063092, 0000063728	1/30/2017
	0000053070, , 0000071281, 0000074348, 0000079511, 0000081969, 0000084459, 0000092756, 0000094518	1/31/2017
RSSOH2B1 (Lot 010)	0000110068, 0000110548, 0000114596, 0000115883, 0000118315, 0000120362	04/30/2017
	0000120642	10/28/2017
RSOH2B1T (Lot 009)	010, 011	11/2016
	0000054823, 0000064410, 0000064952, 0000066808,	11/30/2016
	0000089318	1/19/2017

TABLE 3. Product Impacted (Continued)

Cat ID	Batch	Expiration Date
RSOH2B1T (Lot 010)	0000110547	10/28/2017
RSSOH2B1X (Lot 009)	0000064446, 0000070911	11/30/2016
RSSOH2B1X (Lot 101)	0000111323	01/19/2017
	0000124895	06/04/2017
RSSO2Q (Lot 010)	002, 003, 004, 005, 006, 007, 008, 009	11/2016
	0000054593, 0000055231, 0000056058, 0000060053, 0000060784, 0000061599, 0000062603, 0000063652, 0000066921	11/30/2016
	0000070566, 0000076222, 0000077803, 0000078350, 0000079319, 0000079929, 0000081865, 0000083143, 0000084412, 0000085077, 0000087193, 0000087755, 0000091499	1/31/2017
	0000097260, 00000101211, 0000102893, 0000105847, 0000107310, 0000108579, 0000116017, 0000118442	4/30/2017
	0000124698	11/30/2017
	I000094035	4/30/2017
RSSO2QX (Lot 010)	0000062810, 0000064445, 0000070913	11/30/2016
	0000112688, 0000112690, 0000118313	4/30/2017
RSO2QT (Lot 010)	002, 003, 004, 005, 0000056055, 0000060877, 0000063729, 0000064407, 0000066546	11/30/2016
	0000054510,	11/28/2016
	0000083952, 0000085912, 0000096060, 0000102984	1/19/2017
	0000107127	10/28/2017
	0000117461	4/20/2017
	I000094034, I000095827	1/19/2017
RSSOMICA (Lot 007)	008	11/2016
	0000055120	11/30/2016
	0000079450, 0000092263	1/19/2017
	0000117730	3/12/2017
RSSO1S4 (Lot 007)	0000091890	01/31/2017
RSSO1S4 (Lot 008)	0000120382	04/30/2017
RSO1S4T (Lot 007)	0000082316, 0000083959, 0000087101, 0000088768, 0000100776	01/19/2017

TABLE 3. Product Impacted (Continued)

Cat ID	Batch	Expiration Date
RSO1S4T (Lot 008)	0000101153	04/20/2017
	0000102520	01/19/2017
	0000113329	10/28/2017
	0000122052, 0000122953	04/20/2017
RSSOX2B1 (Lot 004)	0000060897	11/30/2016
	00000110072	01/07/2017
	00000120635	04/30/2017
RSOX2B1T (Lot 004)	0000061768	11/30/2016
	0000090564	01/19/2017
RSSOW2B1 (Lot 002)	0000061161	11/30/2016
RSOW2B1T (Lot 002)	0000061791	11/30/2016
	00000122205	04/20/2017

Action to be taken by the user or distributor: If you have used any impacted products between the date period July 29, 2016 to August 22, 2016 review test results generated with the above-mentioned products using the corrected lot-specific user documents and catalog file; if there is an assignment of one of the affected primer specificities a secondary check for confirmation of that allele is required.

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: Affected Lot specific user documents and catalog files were corrected and updated. **TABLE 4 – Corrected Worksheets** lists the corrected Worksheets. Use the corrected lot specific user documents as listed on the following page:

TABLE 4. Corrected Worksheets and Catalog Files

Product (Catalog #)	Lot	BPI/PRI	Rev	WS/WS3	Rev	LIM	Rev	Catalog File
LABType SSO Class II DQA1 and DQB1 Typing Test (RSSO2Q, RSO2QT, RSSO2QX)	10	RSSO-002Q-010-BPI-00	5	RSSO-002Q-010-WS3-00	5	RSSO-002Q-010-LIM-00	5	RSSO2Q_010_06.cat
LABType HD Class II DRB1 Typing Test (RSSOH2B1, RSOH2B1T, RSSOH2B1X)	9	RSSO-H2B1-009-BPI-00	10	RSSO-H2B1-009-WS3-00	10	RSSO-H2B1-009-LIM-00	10	RSSOH2B1_009_10.cat
	10	RSSO-H2B1-010-BPI-00	4	RSSO-H2B1-010-WS3-00	4	RSSO-H2B1-010-LIM-00	4	RSSOH2B1_010_04.cat
LABType SSO Class II DRB1 Typing Test (RSSO2B1, RSO2B1T)	18	RSSO-02B1-018-BPI-00	7	RSSO-02B1-018-WS-00	7	RSSO-02B1-018-LIM-00	7	RSSO2B1_018_07.cat
	19	RSSO-02B1-019-00	2	RSSO-02B1-019-WS-00	2	RSSO-02B1-019-LIM-00	2	RSSO2B1_019_02.cat
LABType SSO Class I Bw4 Supplement Typing Test (RSSO1S4, RSO1S4T)	7	RSSO-01S4-007-BPI-00	4	RSSO-01S4-007-WS-00	4	RSSO-01S4-007-LIM-000	4	RSSO1S4_007_04.cat
	8	RSSO-01S4-008-BPI-00	2	RSSO-01S4-008-WS-00	2	RSSO-01S4-008-LIM-00	2	RSSO1S4_008_02.cat
LABType SSO MICA (RSSOMICA)	7	RSSO-MICA-007-BPI-00	6	RSSO-MICA-007-WS-00	6	RSSO-MICA-007-LIM-00	6	RSSOMICA_007_07.cat
LABType CWD Class II DRB1 Locus Typing Test (RSSOW2B1, RSOW2B1T)	2	LTXRCWD-W2B1-002-BPI-00	5	N/A	N/A	LTXRCWD-W2B1-002-LIM-00	5	RSSOW2B1_002_05.cat
LABType XR Class II DRB1 Locus Typing Test (RSSOX2B1, RSOX2B1T)	4	LTXRCWD-X2B1-004-BPI-00	5	N/A	N/A	LTXRCWD-X2B1-004-LIM-00	5	RSSOX2B1_004_05.cat

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 System

Field Safety Notice Return Response
ACKNOWLEDGEMENT FORM

Customer Information (Please Complete)

Name:

Address:

Product/Catalog ID: – Reference TABLE 3 - Product Impacted from URGENT RECALL/CORRECTION/FIELD SAFETY NOTICE

I have read and understand the attached Field Safety Notice and instructions **and have taken appropriate actions to review test results:** _____ **(initial)**

Any adverse events associated with the recalled product? ____ **Yes** ____ **No**

If yes please explain:

Return Response: (please provide additional information if applicable)

DISTRIBUTORS:

Inventory does not need to be quarantined. Action is to review test results with revised documentation.

I have identified and notified my customers that were shipped or may have been shipped product affected by this letter by [specify date and method of notification – attach additional sheets if necessary]:

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 raul.arevalo@thermofisher.com

Signature of Receipt by End User/Distributor:

Signature

Date

Print: (please complete)

Name/Title:	
Telephone:	
Email Address:	