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URGENT MEDICAL DEVICE RECALL
Richard Allan Scientific Company

Shandon Rapid Chrome Kwik-Diff Kit Part Number: 9990700
Lot Number S-645, S-646 and S-647
Manufactured on 12/2016, Distributed 12/2016

Shandon Rapid Chrome Kwik-Diff Reagent #3 Part Number 9990707
Lot: 234, 235, and 236
Manufactured on 12/2016, Distributed 1/2017

[Insert date]

[Insert Customer name
Attn:
Customer address]

Dear <insert Customer name

The purpose of this letter is to advise you that Richard Allan Scientific Company, part of Thermo Fisher Scientific, is voluntarily recalling Shandon Rapid Chrome Kwik –Diff Kit Part Number 9990700 lot numbers S-645, S-646 and S-647, and Shandon Rapid Chrome Kwik-Diff Reagent #3, Part Number 9990707 lot number 234, 235, and 236.

Shandon Rapid Chrome Kwik Diff Kit is intended for use to for use as a kit in special stain techniques in use for differential staining of blood smears, FNA's , bone marrow and blood parasites. To clearly define individual cells, their nuclear detail, and the cytoplasmic structure for microscopic examination.

Shandon Rapid Chrome Kwik-Diff Kit, Part Number 9990700 is sold as a kit in 500ml bottles. Shandon Rapid Chrome Kwik-Diff Kit, Part Number 9990707 is sold as a reagent in a 4L bottle.

REASON FOR VOLUNTARY RECALL:

Complaints for the Shandon Rapid Chrome Kwik Diff Kit starting being initiated in January 16, 2017. An investigation was initiated and indicated that the Methylene Blue, Solution #3 in the Kwik Diff Kit was not Methylene Blue but Crystal Violet. During investigation, it was verified that the contract manufacture had labeled the Methylene Blue Solution #3 incorrectly in the kits.

- No adverse events have been reported due to the incorrect labeling.

RISK TO HEALTH:

No adverse health consequences are anticipated with product use.

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The Shandon Rapid Chrome Kwik-Diff Staining Kit is used by clinical laboratories for staining blood smears, FNAs, and bone marrow. The combination of eosin and methylene blue stains generate a distinctive and highly recognizable and reproduce able cell staining pattern, which aids in straightforward and rapid determination of staining quality by clinical laboratory technicians and pathologists.

Use of the product is not expected to generate erroneous patient results. A limited delay in repeat slide preparation (following completion of troubleshooting measures) using additional patient specimen is not expected to adversely impact timely patient diagnosis or clinical decision-making.

PRODUCT AND DISTRIBUTION INFORMATION:

Product Names	Manufacturer's Product No. / Catalog No.	Lot/Serial Number	Manufacturing/ Distribution Dates	Expiration Date (mm/dd/yyyy)	Quantity
Shandon Rapid Chrome Kwik-Diff Kit	Item **9990700**	**S645**	MFG Date: 12/2016 Distributed : 12/2016	12/01/2018	40 Kits
Shandon Rapid Chrome Kwik-Diff Kit	Item **9990700**	**S646**	MFG Date: 12/2016 Distributed : 12/2016	8/18/2018	35 Kits
Shandon Rapid Chrome Kwik-Diff Kit	Item **9990700**	**S647**	MFG Date: 12/2016 Distributed : 12/2016	11/11/2018	44 Kits
Shandon Rapid Chrome Kwik-Diff Reagent #3	Item **9990707**	**234**	MFG Date: 12/2016 Distributed 01/2017	9/11/2018	1/ 4L Bottles
Shandon Rapid Chrome Kwik-Diff Reagent #3	Item **9990707**	**235**	MFG Date: 12/2016 Distributed 01/2017	11/20/2018	42 / 4L Bottles

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Shandon Rapid Chrome Kwik-Diff Reagent #3	Item **9990707**	**236**	MFG Date: 12/2016 Distributed 01/2017	12/10/2018	7/ 4L Bottles

ACTIONS TO BE TAKEN BY THE CUSTOMER/USER
If you have the above lot in your possession, please contact Richard Allan Scientific for directions on safe disposal or return.

- All other lots of the above products, or similar products manufactured by Richard Allan Scientific, are unaffected.
- Upon identification of the affected lot, please notify Richard Allan Scientific of the quantity and the preferred disposal/return method.
- If product is being disposed of, evidence of disposal is required to be sent to Richard Allan Scientific.
- If affected product has been used with no issues, please notify Richard Allan Scientific of the quantity that is unavailable for return or disposal.
- Please use the attached Recall Return Response Acknowledgement & Receipt Form.

TYPE OF ACTION BY THE MANUFACTURER:

Root Cause: The supplier mislabelled a Crystal Violet production run at their facility as Methylene Blue and shipped the product to Richard Allan Scientific, part of Thermo Fisher Scientific, as 500 ml Kwik Diff kit and the 4L Kwik Diff Solution #3. Methylene Blue is part of the Shandon Rapid Chrome Kwik-Diff Kit.

Corrective Actions: Richard Allan Scientific is working with the supplier to prevent reoccurrence of this issue. In addition, improvements to the product release process have been implemented since this event occurred. The product will be put on incoming inspection and further process improvements are being investigated to ensure that this incident doesn't occur again.

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We appreciate your immediate attention to this field correction. By returning the attached Acknowledgment Form you will facilitate our reporting of this matter to the FDA. We apologize for any inconvenience this may have caused and appreciate your understanding as we take action to ensure customer safety and satisfaction.

If you have any questions, please contact Michelle Bowerman at 269-544-5625 or michelle.bowerman@thermofisher.com

Sincerely,

Michelle L. Bowerman

Michelle Bowerman
Director of RA

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MEDICAL DEVICE RECALL RETURN RESPONSE

Acknowledgment & Receipt Form
Response Required

CUSTOMER INFORMATION:
[Customer name
Attn:
Address]

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I have read and understand the attached Customer Letter and recall instructions: _____
(initials)

Any adverse events associated with the recalled product? _____ Yes _____ No

Was this used on patient samples? _____ Yes _____ No

If yes, please explain:

_____

_____

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AFFECTED PRODUCT INFORMATION

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NOTE: If you have no product in inventory, please indicate "0" in the "Quantity in Inventory" column.

Use additional sheet(s) if necessary.

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RETURN RESPONSE (please provide additional information, if applicable):

PLEASE RETURN COMPLETED RESPONSE FORMS TO THE FOLLOWING EMAIL **mary.vowell@thermofisher.com** OR FAX NUMBER 269-372-2624, ATTN: Michelle Bowerman/ Mary Vowell

Signature of Receipt by Customer: _____

Name/Title:	
Site Name	
Site Address	
Telephone:	
Email Address:	