

**URGENT MEDICAL DEVICE RECALL**  
**Lab Vision Corporation**

January 14, 2016

Fisher Scientific PTE LTD  
8 PANDAN CRESCENT  
LL4 05-04/05 UE TECH PARK  
VN00000183/  
, 128464  
SG

Dear Lab Manager,

The purpose of this letter is to advise you that Lab Vision Corporation, part of Thermo Fisher Scientific, is voluntarily recalling the below listed lots of CEA / CD66e Ab2.

<b>Product Code</b>	<b>Product Name</b>	<b>Lot Number</b>	<b>EXP Date</b>
RB-368-R7	CEA / CD66e Ab-2	368R1407A	July 2016
		368R1407C	July 2016
		368R1407D	July 2016
		368R1407E	July 2016

All other lots of the above products manufactured by Lab Vision are unaffected.

**REASON FOR VOLUNTARY RECALL:**

The affected lots of Thermo Scientific CEA / CD66e Ab2 were produced with the incorrect dilution factor. They were produced with a dilution factor of 1:100 instead of the recommended 1:250.

- If the user is not following the IFU (datasheet) Method and not including appropriate controls as recommended, then the incorrect dilution factor could lead to non-specific staining (background or over staining).
- No complaints or adverse events have been reported to be associated with this mislabeled product.

**RISK TO HEALTH:**

If product is used per the IFU, no risk to patient diagnosis is anticipated.

Nonspecific interactions between the primary antibody and non-target epitopes on the tissue sample occur regularly during IHC testing. Use of a higher primary antibody concentration than recommended may increase such non-specific interactions, and thus increase background staining. This may occur with use of the Thermo Fisher CEA/CD66e Ab-2 product, as a result of the described labeling issue. High background staining – with resultant poor signal:noise ratio- would, however, be easily recognizable during Pathologist review, as it would be by the user with appropriate use of positive and negative controls. User troubleshooting guidance for ‘strong background staining’ due to a high primary antibody concentration, would be to reduce the concentration of the primary antibody or decrease the incubation time with the primary antibody

(per common IHC practices). These standard laboratory practices would be expected to correct any background staining issue related to use of the mislabeled product.

Formalin-fixed, paraffin-embedded tissue samples allow for retrieval of multiple sections. In the event of strong background staining, additional sections would be utilized with application of appropriate troubleshooting procedures to obtain a valid result. Limited delays in sample re-processing would not be expected to result in any immediate or long-range patient adverse health effects.

**PRODUCT AND DISTRIBUTION INFORMATION:**

Product Code	Product Name	Lot Numbers	Product Size	Manufacture Date	EXP Date
RB-368-R7	CEA / CD66e Ab-2	368R1407A 368R1407C 368R1407D 368R1407E	7 ml each	July 2014	July 2016

**ACTIONS TO BE TAKEN BY THE CUSTOMER/USER**

If you have any of the above lots in your possession, please contact Lab Vision with the information requested on the attached Acknowledgment Form.

- Upon identification of the affected lot, please notify Lab Vision of the quantity previously used and the quantity still in inventory.
- If any of the above listed lots were previously used, please review test results to ensure a valid result was obtained. If a valid result was obtained, no further action is required. If high background staining was seen, standard IHC troubleshooting guidance for high background staining can be used. (See "RISK TO HEALTH" section of this letter.)
- Affected product may be returned to Lab Vision. Please indicate on the Acknowledgement Form whether the product will be returned. Upon receipt of the form, RGA information will be sent for product requiring return.
- If it is preferred to destroy the product at the customer site, please indicate this on the Acknowledgement form.
- Please use the attached Recall Return Response Acknowledgement & Receipt Form.

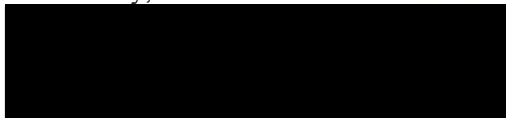
**TYPE OF ACTION BY THE MANUFACTURER:**

Process improvements are being investigated to ensure that this error does not reoccur.

We appreciate your immediate attention to this voluntary recall. 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 Sarah Rickert at 269-544-5628 or [sarah.rickert@thermofisher.com](mailto:sarah.rickert@thermofisher.com).

Sincerely,



Sarah Rickert

Quality Assurance & Regulatory Affairs Manager

**MEDICAL DEVICE RECALL RETURN RESPONSE**  
**Acknowledgment & Receipt Form**  
**Response Required**

**CUSTOMER INFORMATION:**  
Fisher Scientific PTE LTD  
8 PANDAN CRESCENT  
LL4 05-04/05 UE TECH PARK  
VN00000183/  
, 128464

Product Code	Product Name	Lot Number	Product Size	Manufacture Date	EXP Date
RB-368-R7	CEA / CD66e Ab-2	368R1407A 368R1407C 368R1407D 368R1407E	7 ml each	July 2014	July 2016

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

Any adverse events associated with the recalled product? \_\_\_\_\_ Yes \_\_\_\_\_ No

If yes, please explain:

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**AFFECTED PRODUCT INFORMATION**

Product/Brand Name	Manufacturer's Product No.	Lot No. (Please indicate)	Quantity in Inventory (# of vials)	Desired Action (Circle one)	Quantity Used (unavailable for return)
Thermo Scientific CEA / CD66e Ab-2	RB-368-R7			Destroy  Return	

**NOTE:** If you have no product in inventory, please indicate "0" in the "Quantity in Inventory" column. Use additional sheet(s) if necessary.

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

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**Page 1-Response Form**

**PLEASE RETURN COMPLETED RESPONSE FORMS TO THE FOLLOWING EMAIL [sarah.rickert@thermofisher.com](mailto:sarah.rickert@thermofisher.com) OR FAX NUMBER 269-372-2674, ATTN: Sarah Rickert**

**Signature of Receipt by Customer:** \_\_\_\_\_

Name/Title:	
Site Name	
Site Address	
City, State, Zip	
Telephone:	
Email Address:	