Agilent Technologies Singapore
(International) Pte Ltd.
No.1 Yishun Avenue 7
Singapore, 768923

www.agilent.com

IMPORTANT FIELD NOTICE

Attn.: Laboratory Manager

May 23, 2023

Reference: PI000000096

Subject: GA61061-2 - FLEX Monoclonal Mouse Anti-Human CD31 (SRN# SG-MF-000014448) - Error in German Section of IFU

Dear Valued Customer,

The purpose of this letter is to notify you that we have identified an error in the German-translated section of the Instruction for Use for the product GA61061-2 - FLEX Monoclonal Mouse Anti-Human CD31, Endothelial Cell Clone JC70A Ready-to-Use (Dako Omnis). The entire German translated section contains the information for a different product (CD10). Our records indicate you have received affected lot numbers of this product.

INTENDED USE

GA61061-2

FLEX Monoclonal Mouse Anti-Human CD31, Endothelial Cell, Clone JC70A, Ready-to-Use (Dako Omnis), is intended for use in Immunohistochemistry (IHC) together with the Dako Omnis instrument. This antibody primarily labels endothelial cells. Results aid in the classification of benign and malignant vascular disorders, including angiosarcomas (1, 2). Differential classification is aided by the results from a panel of antibodies. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist. This antibody is intended to be used after the primary diagnosis of tumor has been made by conventional histopathology using nonimmunologic histochemical stains.

DESCRIPTION OF THE ISSUE

An error has been identified in the German translated section of the IFU for the GA61061-2 - FLEX Monoclonal Mouse Anti-Human CD31, Endothelial Cell Clone JC70A Ready-to-Use. The entire German translated section provides instructions for a different product (CD10).

TABLE 1. AFFECTED PRODUCTS AND LOT NUMBERS

	Product Code	Lot Numbers
1	GA61061-2	41370210, 41480598

PROBABILITY OF RISK TO PATIENTS/USERS

Based on our investigations, the mismatch between CD31 and CD10 instructions is deemed to be recognizable and apparent to users. Therefore, there is little risk to patients or users.

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ACTIONS TO BE TAKEN BY THE CUSTOMER

1. Verify your inventory and current product lot numbers and corresponding IFUs in use.
2. Please acknowledge that you have received, read, and understood the Field Notice by completing then signing the enclosed Acknowledgement Form and returning it to fieldactions@agilent.com
3. For the specific IFU distributed with the FLEX Monoclonal Mouse Anti-Human CD31, lot numbers included in Table 1, please find the correct IFU for GA61061-2.

Contact your local sales representative if you have any questions regarding this notification.

TRANSMISSION OF THIS NOTICE

We kindly ask you to inform those who need to be aware of this notification within your organization or any other organization to which the affected product(s) have been transferred. Please ensure that your organization maintains awareness of this notice.

PLEASE NOTE: No other Agilent devices are involved in this Field Notice.

Thank you for your attention to this matter. We apologize for any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure customer satisfaction.

Sincerely,

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