Agilent Technologies

Agilent Technologies, Inc.
5301 Stevens Creek Blvd.
Santa Clara, CA, 95051, USA
www.agilent.com

Attention: Laboratory Manager
Reference number: FAS000000181

July 28, 2025

URGENT MEDICAL DEVICE CORRECTION

Subject: GA604 Weak Staining, GA60461-2, GA60461-2CN and GA60461-2J

Dear Valued Customer,

The purpose of this letter is to notify you that we have identified potential weak immunohistochemistry staining with FLEX Monoclonal Mouse Anti-Human Ready-to-use antibody CD20cy Clone L26 on Dako Omnis (product code GA604), specifically on Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma (CLL/SLL) tissue samples, which may result in false negative CD20 identification. Potential weak staining is not seen in other tissue types commonly tested with GA604.

Description of the issue

Weak staining has been observed in a few cases where GA604 was used to stain CLL/SLL tissue samples for CD20. This weak staining has not been observed in the majority of cases where GA604 was used to test CLL/SLL tissue. As a reminder, the diagnosis of CLL/SLL is made in the context of the histologic appearance by Hematoxylin and Eosin (H&E) staining, with the aid of a panel of immunohistochemical markers (routinely including other B cell markers such as PAX 5 or CD79), ancillary studies (e.g. flow cytometry on peripheral blood or bone marrow), and clinical information.

Our records indicate that you may have received one or more GA604 products listed in Table 1. If you are experiencing weak staining of CD20 in CLL/SLL tissue samples, please contact Agilent, as indicated in the Actions section.

TABLE 1. Affected Products and Lot Numbers

	Product Name	Part Number	Affected Lots
1	FLEX Mab a Hu CD20cy, cl L26, RTU(Omnis)	GA60461-2	41810164, 41700704
2	Mono MxH CD20cy, cl L26 RTU_Omnis_CN	GA60461-2CN	41781549, 41762487, 41651581
3	FLX Mab a HuCD20cy cl L26, RTU Omnis Jp	GA60461-2J	41810156, 41741883

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Evaluation of risk

The potential for a false negative CD20 IHC result using GA604 in low CD20 expressing CLL/SLL tissue has a remote risk of contributing to missed or misclassified lymphoma diagnosis or failure to utilize CD20-targeted lymphoma therapy. However, this remote risk is mitigated by standard of care and the Instructions for Use (IFU) which dictate clinicians rely on multiple sources of information – not just CD20 IHC – including clinical findings, tissue appearance under the microscope, other immunohistochemical markers, and additional testing platforms on samples that are routinely collected during diagnostic work up, like bone marrow and blood.

To ensure users are aware of this specific issue, an additional precaution statement is being added to the Precautions section of the IFU regarding CLL/SLL tissue.

Actions to be taken by the customer

1. Please check your inventory and identify if you have the affected product listed in Table 1. Be aware that these products show potential weak staining, which may lead to false negative CD20 identification when used on CLL/SLL tissue samples.
2. If you experience weak staining, please contact Agilent Technical Support for troubleshooting.
3. Please confirm that you have received, read, and understood this Field Safety Notification by completing and signing the enclosed Acknowledgement Form and returning it to fieldactions.notifications@agilent.com.

Transmission of this notice

We kindly ask you to share this notice with anyone who needs to be aware within your organization and forward to any organization where potentially affected devices may have been transferred. Please ensure that your organization maintains awareness of this notice.

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

Sincerely,

Brenda Tregellas
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Account number:

Acknowledgement Form for Customers
Agilent Reference Number: FAS000000181

Fill out this Acknowledgement Form to confirm receipt of the enclosed Field Safety Notification regarding **GA60461-2, GA60461-2CN and GA60461-2J**

Please complete the Acknowledgement Form within 7 days from receipt and email the form to fieldactions.notifications@agilent.com.

Acknowledgement:	
I have read and understood the Field Safety Notice and the instructions stated in this letter:	Yes ☐ No ☐
Date	
Company name	
Company address	
Company country	
Name and title of person completing this form	
e-mail address	
Phone number	+
Signature	