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

Date: August 4, 2025
Reference number: FAS0000000181
Attention: Agilent Distribution Partners in EEA countries

FSCA Cover Letter

Dear Agilent Distributor,

The purpose of this letter is to inform you that Agilent Technologies is initiating a Field Safety Corrective Action (FSCA) for **FLEX Monoclonal Mouse Anti-Human Ready-to-use antibody CD20cy Clone L26 on Dako Omnis (product code GA604)**.

Description of the problem:

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.

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

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.

Required actions:

Follow the instructions provided on the next page(s) in detail to assure timely and compliant implementation of this FSCA. An overview of timeframes for the different actions can be found after the instructions under "Timeframes".

Contact reference person:

For questions regarding this FSCA, please contact fieldactions@agilent.com.

We apologize for any inconvenience this may cause and appreciate your collaboration on this matter.

Sincerely,

Brenda Tregellas
VP, Global Quality, Life Sciences and Diagnostics Group (LDG)
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Actions to be taken by the Distributor:

1. Check that you have received the following documents together with this Cover Letter:
    a. Field Safety Notification and enclosed Acknowledgement Form
    b. Distributor Closure Form
2. Confirm receipt and understanding of this Cover Letter by completing and signing the Acknowledgement Form enclosed with this letter. The completed form must be returned to fieldactions@agilent.com by **August 6, 2025.**
3. Prepare documents for initial reporting and notification of affected customers:
    a. Assess for reportability in your country. If reportable, prepare documents needed for initial reporting.
    b. Identify and document all customers in receipt of the affected products covered by this FA.
    c. Translate the FSN and Acknowledgement Form to the local language, if applicable.
        - Please submit the initial FSCA report together with the translated FSN and a list of affected customers to your National Competent Authority (NCA). The FSCA report must be submitted by **August 6, 2025.**
    d. The Field Action team (fieldactions@agilent.com) must be cc'ed on the email to the NCA.
4. Start notifying affected customers **August 7, 2025.** Use the provided FSN and enclosed Acknowledgement Form to inform your customers. All customers must be notified by **August 14, 2025.**
5. Completed Acknowledgement Forms from customers must be archived, and the receipt date must be documented.
    a. If a customer does not respond to the FSN, Good Faith Effort (GFE) must be applied. GFE is defined as a minimum of three attempts to contact the customer, with a least one attempt being in writing. Make sure to document each GFE attempt. Once the customer has been contacted three times, the customer account can be closed by GFE.
        - The FSCA must be completed by **September 11, 2025.** The FA is completed when all customers have responded to the FSN by completing the Acknowledgement Form OR have been closed by Good Faith Effort.
6. Submit a final FSCA report to your NCA:
        - Submit the report to the NCA no later than **September 18, 2025.** The Field Action team must be cc'ed on the email to the NCA.

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Timeframes:

Action	Date
Sign and submit Acknowledgement Form	August 5, 2025
Initial reporting	August 5, 2025
Notify affected customers	August 7, 2025
FSCA completion	September 11, 2025
Final reporting	September 18, 2025

Reference number: FAS000000181

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Acknowledgement Form

Fill in this Acknowledgement Form to confirm receipt of the enclosed FSCA Cover letter and related documents, regarding **FLEX Monoclonal Mouse Anti-Human Ready-to-use antibody CD20cy Clone L26 on Dako Omnis (product code GA604)**

The Acknowledgement Form must be completed and emailed to fieldactions@agilent.com.

Acknowledgement:	
I have read and understood the FSCA Cover Letter and the instructions stated in this letter:	Yes ☑ No ☐
I confirm that I will act in accordance with the instructions stated in the FSCA Cover Letter and comply with the specified timeframes:	Yes ☑ No ☐
Date	13th August 2025
Company Name	BITA LIFESCIENCE SDN BHD
Country	MALAYSIA
Name and title of person completing this form	NURUL BAROKAH HASAN
e-mail address	regulatory@bitalifesc.com.my
Phone number	+603-7960 8286
Signature