



URGENT FIELD ACTION

Attn.: Laboratory Manager

January 25, 2023

Subject: K5799 Histology FISH Accessory Kit - Error in Instructions For Use

Dear Valued Customer,

The purpose of this letter is to notify you that we have identified an issue with two variants of the K5799 Histology FISH Accessory Kit. Our records indicate you have received affected lot numbers of this product.

INTENDED USE

K579911-2

For in vitro diagnostic use. Histology FISH Accessory Kit is intended for laboratory use in the manual qualitative or quantitative fluorescence in situ hybridization (FISH) technique. The kit is used to visualize probe/target complexes on formalin-fixed, paraffin-embedded (FFPE) tissue section specimens.

K579911-5

For in vitro diagnostic use. Histology FISH Accessory Kit is intended for use in the fluorescence in situ hybridization (FISH) technique on formalin-fixed, paraffin-embedded tissue section specimens.

Reagents provided in this Histology FISH Accessory Kit can also be used together with HER2/CEN-17 IQISH Probe Mix (Code K5731, Vial 3). If reagents from Dako Histology FISH Accessory Kit, Code K5799, are used together with reagents from Code K5731, the procedure outlined in the package insert for Code K5731 must be followed.

DESCRIPTION OF THE ISSUE

An error has been identified in the IFU for the K5799 Histology FISH Accessory Kit., providing a wrong reference to the wash buffer used for dilution. The IFU states, "See procedure, section A.2" but it should read, "See procedure, section A.3."

TABLE 1. AFFECTED PRODUCTS AND LOT NUMBERS

	Product Code	Lot Numbers
1	K579911-2	41362749, 41394997, 41394997A, 41395596, 41456539
2	K579911-5	41345838, 41362739, 41398492, 41428156, 41473559

PROBABILITY OF RISK TO PATIENTS/USERS

Based on our investigations, there is a possibility that the user could use the wrong wash buffer resulting in signals being too weak. However, the probability of harm is deemed to be improbable.



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 Histology FISH Accessory Kit lot numbers included in Table 1, please find the correct IFU for [K579911-2](#) and [K579911-5](#).
4. 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,

A handwritten signature in blue ink that reads "Brenda Tregellas".

Brenda Tregellas

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