

Date: March 20, 2026

Reference number: FAS000000202-2

Attention: Laboratory Manager

IMPORTANT FIELD ACTION NOTIFICATION

Subject: Artisan Periodic Acid-Schiff Stain Kit (AR165), Artisan Alcian Blue/PAS Stain Kit (AR169), Artisan PAS-Green Stain Kit (AR172), and Artisan Alcian Blue/PAS/Hematoxylin Stain Kit (AR178)

Dear Valued Customer,

The purpose of this letter is to notify you that we have initiated a Field Action for the following Artisan Periodic Acid-Schiff Stain Kits: Artisan Periodic Acid-Schiff Stain Kit (AR165), Artisan Alcian Blue/PAS Stain Kit (AR169), Artisan PAS-Green Stain Kit (AR172), and Artisan Alcian Blue/PAS/Hematoxylin Stain Kit (AR178).

Description of the issue

Agilent has identified weak or absent staining associated with specific lots of AR165, AR169, AR172 and AR178, as outlined in **Table 1**. In rare cases, this issue may impact staining performance. Weak or absent staining is readily detectable when the recommendations in the Instructions for Use (IFU) are followed. These products require the use of appropriate controls with every staining run.

It is important to continue running the required controls concurrently with patient specimens, following the same protocol, as specified in the IFU. These controls will detect any staining performance issues. If weak or absent staining is observed, contact your local contact for technical support and troubleshooting assistance.

Evaluation of risk

Weak or absent staining has a remote probability of inaccurate results or minor delay in diagnosis leading to disease progression and affecting timely therapy. Additionally, the likelihood of re-biopsy due to loss of sample is deemed improbable. The IFU contains a precautionary statement instructing the user to utilize appropriate controls with the patient tissues and other diagnostic tests. The staining issue is highly detectable when appropriate controls are used. In addition, the IFU indicates the following: "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."

If you have already used the affected lots per the intended use, no further action is required.

Table 1. Affected Products and Lot Numbers

	Product Name	Part Number	Affected Lot Numbers
1.	Artisan Periodic Acid-Schiff Stain Kit	AR165	11847851A, 11847852, 11849899, 11849899A, 11849900, 11849903, 11849904, 11867324, 11867324A, 11867325, 11872148, 11883418, 11883419, 11883422, 11883423, 11884247, 11891803, 11891803A, 11891804, 11902686, 11907615, 11907615A, 11907616, 11907620, 11908716, 11916012, 11916012A, 11916013, 11924455, 11924455A, 11924456, 11924459, 11924460, 11933842, 11933843, 11933846, 11934915, 11934915A, 11934917, 11944523, 11944525, 11950897
2.	Artisan Alcian Blue/PAS Stain Kit	AR169	11847858, 11849910, 11867331, 11867333, 11883429, 11891811, 11891813, 11891813A, 11902690, 11907624, 11907624A, 11907626, 11916018, 11924468A, 11924470A, 11929788, 11929788A, 11933852, 11933854, 11934922, 11934922A, 11944527, 11950903
3.	Artisan PAS-Green Stain Kit	AR172	11883434, 11884249, 11891817, 11891819, 11902693, 11907630, 11907631, 11916024A, 11924474, 11924476A, 11929790, 11933860, 11933862, 11950911
4.	Artisan Alcian Blue/PAS/Hematoxylin Stain Kit	AR178	11849928, 11849930, 11867353, 11883447, 11884257, 11891831, 11902699, 11907641, 11916038A, 11929792, 11933874, 11934926, 11934928

Actions to be taken by the customer

- Please review the Artisan Periodic Acid-Schiff Stain Kits' IFUs to ensure that all staining procedures are performed correctly. As stated in the product IFUs:
"... appropriate controls must be run simultaneously using the same protocol as the patient specimen. If unexpected staining is observed which cannot be explained by variations in laboratory procedures or improper storage, and a problem with the reagent is suspected contact Technical Support."
- If you have received an affected lot, as listed in **Table 1**, please continue to test the product per the IFU. If you experience weak or absent staining, contact your local contact for technical support and troubleshooting assistance.
- Please confirm that you have received, read, and understood this Field Action Notification by completing and signing the enclosed Acknowledgement Form and returning it to fieldactions@agilent.com.

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.

Thank you for your attention to this matter. Please be assured that this issue has our full attention. We regret any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure satisfaction.

PLEASE NOTE: No other Agilent devices are involved in this field action.

Sincerely,

**Brenda Tregellas**

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Account Number:
Agilent Reference Number: FAS000000202-2

ACKNOWLEDGMENT FORM

Fill in this Acknowledgment Form to confirm receipt and understanding of the enclosed Field Action Notification regarding Artisan Periodic Acid-Schiff Stain Kit (AR165), Artisan Alcian Blue/PAS Stain Kit (AR169), Artisan PAS-Green Stain Kit (AR172), and Artisan Alcian Blue/PAS/Hematoxylin Stain Kit (AR178). Please complete this Acknowledgment Form within 7 calendar days of receipt and email the form to fieldactions@agilent.com.

Acknowledgment:	
I confirm that I have received, read, and understood the Field Action Notification and the instructions stated in this letter:	Yes <input type="checkbox"/> No <input type="checkbox"/>
Date	
Company/Organization Name	
Address	
Country	
Name and title of person completing this form	
e-mail address	
Phone number	+
Signature	