

Important Field Notice

March 1, 2022

Attn.: Laboratory Manager

**Subject: AR176 Artisan Grocott's Methenamine Silver (GMS) Stain Kit Box 1 & 2
Lots 11302633, 11311107, 11316517 and 11326608**

Dear Valued Customer,

The purpose of this letter is to notify you that we have identified a potential performance issue with no potential patient risk for the **AR176 Artisan Grocott's Methenamine Silver (GMS) Stain Kit Box 1 & 2, Lots 11302633, 11311107, 11316517 and 11326608.**

Our records indicate you have received this affected product.

Intended use

*Grocott's Methenamine Silver (GMS) Stain Kit is intended for histological staining to aid identification of fungal organisms including *Pneumocystis jirovecii* (previously *P. carinii*) in formalin-fixed, paraffin-embedded tissue sections. 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. All reagents in the kit have been optimally prepared for use on Artisan Link and Artisan Link Pro Special Staining Systems and require no reconstitution or dilution.*

Description of the issue

Some customers reported strong fungal staining in both control tissue as well as patient tissue with the Lot numbers 11302633, 11311107, 11316517 and 11326608. In-house investigation of these lots demonstrates darker than expected staining, however most users find the staining is **functional and allows for identification** of fungal organisms. The affected products are identified below in **Table 1**, at this time, no other lots are impacted.

Table 1. Affected Product

	Finished Goods	Lot Number	Time of manufacture	Expiration date
1	AR1761A/B-2	11302633	2021JUL22	2022MAY31
2	AR1761A/B-2	11311107	2021AUG11	2022JUN30
3	AR1761A/B-2	11316517	2021SEP13	2022JUL31
4	AR1761A/B-2	11326608	2021SEP28	2022JUL31

Probability of potential risk to patients/users

Agilent's internal testing demonstrates that the staining in these four lots can demonstrate darker than expected fungal staining. However, this darker staining does not interfere with identification of fungal organisms. Therefore, test results with the darker staining pattern is deemed as **improbable** to lead to a false result or clinically significant delay in diagnosis. Repeated testing is not required.

Actions to be taken by the user

Please immediately take the following actions:

1. Verify your inventory and current kits in use.
2. If you have encountered a similar observation on the product, received from these 4 lots and if you wish to replace any unused kits, please follow the instructions on the enclosed Return Form, complete it and send it to fieldactions@agilent.com. It is important to fill all the red fields so we can process the replacement.
3. Once your request has been received, we will process it and proceed with replacement. You will receive further instructions on how to receive your replacement.
4. If you have further distributed this product, please identify your customers and notify them at once of this product Field Notice.

Contact your local sales representative if you have any questions regarding this notification, or if you would like assistance with completing the Return Form.

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,



Brenda Tregellas

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