

Attn.: Laboratory Manager

August 07, 2023

FIELD NOTIFICATION
Subject: Artefacts/ High Background Staining

- GV800 EnVision FLEX, High pH (Dako Omnis)
- GV823 EnVision FLEX Mini Kit, High pH (Dako Omnis)

Dear Valued Customer,

The purpose of this letter is to notify you that we have identified an issue with increased level of artefacts/ high background staining on certain GV800 EnVision FLEX, High pH (Dako Omnis) Kits and kits of GV823 EnVision FLEX Mini Kit, High pH (Dako Omnis), that was evaluated to have low risk of incorrect results diagnosis . Our records indicate that you have received these products.

Intended Use

For in vitro diagnostic use. EnVision FLEX, High pH (Dako Omnis) visualization system is intended for automated laboratory use in qualitative or semiquantitative immunohistochemistry together with the Dako Omnis instrument. The system is intended detection of primary mouse and rabbit antibodies in formalin-fixed, paraffin-embedded (FFPE) tissue sections.

Description of the issue

It has come to our attention that we are currently facing challenges with the GV800/GV823 Kits where in certain cases an increase in debris formation on the stainer gap lids in the Dako Omnis is observed, which can lead to an increased level of artefacts and background staining on the stained slides. This issue is specifically related to the DM842 vials in the kits.

Despite the challenges described above, we want to assure you that the issue does not affect the analytical performance of the IHC staining when performed on Dako Omnis.

Table 1. Affected GV800/GV823 Lot Numbers

Product Name	Affected Lot Numbers
GV80011-2	41540598; 41526638A; 41507593A; 41526661; 41546221; 41507583; 41526637; 41507586; 41495896; 41495892; 41477488; 41468702; 41570251; 41526653; 41540597; 41507662; 41477504; 41468713; 41526660A; 41468721; 41507585
GV80011-2J	41540599; 41507650; 41495904; 41481156
GV82311-2	41507567

Table 2. Affected DM842 Lot Numbers

Product Name	Affected Lot Numbers
DM842	41533148, 41525904, 41525903, 41525902, 41511882, 41497698, 41511881, 41511880, 41481146, 41477605, 41477604, 41464636, 41506666, 41464634, 41464633, 41447283

Potential risk to Users

Due to the fact that high background staining and presence of artefacts is highly detectable and differs from expected primary antibody pattern, the likelihood of a false diagnosis is deemed as improbable.

Actions to be taken by the customer

1. In case increased background staining/ artefacts are observed on the slides, inspect the stainer gap lids on the Dako Omnis.
2. If debris (an opaque brown layer) is visible on the lids, perform the process for manual cleaning of the stainer gap lids as described in the Dako Omnis Basic User Guide section 24.

Please confirm the receipt of the Field Notification on the enclosed Acknowledgement Form and send to Agilent’s Field Action Team at fieldactions@agilent.com. In case of any question, please contact your local sales representative or field service engineer.

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. Please be assured that a permanent solution for this issue has our full attention. We apologize for any inconvenience that this action may cause, and we appreciate your understanding as we take action to ensure customer satisfaction.

Sincerely,



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