

Marburg, 2022-09-27

Field safety notice (FSN): Calprotectin (REF: HYE-5767), LOT 443K101-1, 443K101-2, 443K012-1 and 443K022-1

Dear Customer,

This notice is to inform you about a quality issue with DRG product **Calprotectin (REF: HYE-5767), LOT 443K101-1, 443K101-2, 443K012-1 and 443K022-1.**

Description of the problem:

The user of this assay may observe increased frequency of failed recalibrations. This issue is caused by impaired stability of the listed lots. This was found out with an incoming complaint and could not be detected during our standardized production and QC process. In case an operator has used the kits of the affected lot recently, they may observe that

- one or both controls are out of range
- a recalibration failed
- results are found invalid.

Risk assessment:

Because the runs affected by the recalibration problem are always invalid runs, the nonconformity does not affect the quality of the results. There is a risk for delayed results due to invalid runs. To further minimize the risk this FSN is initiated.

Action to be taken by distributors and end-users:

Please check your inventory for the respective lot, stop using these kits immediately and promptly quarantine these products.

If you have forwarded any of the affected product(s) to another customer or laboratory, please provide them a copy of this letter.

If you faced above mentioned issue, please ask for replacement of the kits that were affected. All unused kits of the affected lot will be replaced as well.

Please complete and return the enclosed Response Form within 10 days so we are assured you have received this important communication.

Contact Persons:

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With kind regards,
DRG Instruments GmbH

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