

	Immediate Action Required
	Action Required
✓	Information Only



FIELD SAFETY NOTICE: ARKRAY ADAMS 8190V

INFORMATION ONLY

Field Safety Notice Reference Number: GBM0126FSN ADAMS 8190V SW1.14

Document Date: 28/07/2026

Type of Action: Customer Advisory Notice

Reason for this communication

ARKRAY is issuing this advisory notice following feedback from users and information shared with the Health Products Regulatory Authority (HPRA), regarding the usability of the ARKRAY ADAMS 8190V Software Version 1.14 when operating in the presence of certain haemoglobin variants. In case of genetically determined HbAE and HbAD samples, with the HA-8190V Software Version 1.14 an implemented correction factor for HbA1c applies and the HbA1c measurement result can be released as reliable. For not genetically determined other than HbAE and HbAD variant samples that may show a similar chromatogram pattern in the same D- or E-window(s), the HbA1c measurement result may be unreliable or inaccurate and being followed up on.

Software Version 1.14 continues to meet the design goals and performance specifications defined at release, and ARKRAY has not identified any defect or confirmed patient harm. However, some users reported variability in the usability and interpretation of results when haemoglobin variants were present, prompting ARKRAY to review the experience across sites.

To support consistency across all sites, ARKRAY has taken the precautionary step of standardising software versions in some regions

Action required by Users

No immediate action is required.

Customers should:

- Continue to follow standard laboratory procedures for reviewing chromatograms and variant flags.
- Ensure staff are familiar with the interpretation of results in the presence of haemoglobin variants.
- Contact ARKRAY if clarification or additional training is required.

No product return, software removal, or cessation of use is required. ARKRAY can confirm that all sites throughout Ireland were proactively downgraded to SW1.13 where applicable and based on feedback from users.

This action is being conducted with the knowledge of the Health Products Regulator Authority (HPRA).

If you require any further information, please contact our service hotline on; +44 (0) 1495 509145 or service.uk@arkray.com

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Customer Acknowledgement

I confirm that I have successfully received and reviewed the information provided regarding the
FIELD SAFETY NOTICE on ARKRAY ADAMS 8190V

Name: _____

Position: _____

Organisation: _____

Signature: _____

Date: _____

Please return the signed acknowledgement document to: service.uk@arkray.com

Return date requested: 11th August 2026

Comments/ Feedback