



Urgent Field Safety Notice

Product Correction

Immediate Action Required

Date Issued September 18, 2025

Product

Product Description	List Number	Serial Number	UDI
Alinity hq Analyzer	09P68-01	See Attachment B	

Explanation

An issue has been identified in Alinity hq Analyzer software versions 5.0 to 5.10.1. The Immature Granulocyte Saturation (IG Sat) flag is intended to indicate a high number of saturated events that impact the IG/%IG and Neutrophils (NEU/%NEU) parameters. However, the system does not visibly apply appropriate flagging to IG/%IG and NEU/%NEU results when saturation is present, which may prevent users from recognizing potentially impacted values.

When IG Sat is present, NEU is the most likely to be affected. Additionally, because White Blood Cell (WBC) differential results must total 100%, any distortion in IG values may also affect other parameters—such as Basophils (BASO), Monocytes (MONO), Lymphocytes (LYM), and Eosinophils (EOS)—potentially leading to inaccurate distribution across the full WBC differential.

A new software version for the Alinity hq Analyzer to resolve this issue is expected to be available in 2026. Your Abbott representative will contact you to schedule a mandatory upgrade.

Impact on Patient Results

There is a potential for incorrect results. As of issuance of this letter, there have been zero reported occurrences of impact to patient management or operator injury.

Necessary Actions to be Taken by Customer

If IG/%IG is above your laboratory established reference range (e.g. greater than 2%) review the results per your laboratory procedures. A manual smear review may need to be performed to confirm the results.

Complete and return the Customer Reply Form.

If you have forwarded the product listed above to other laboratories, please inform them of this Product Correction and provide to them a copy of this letter.

Please retain this letter for your laboratory records.

Contact Information

If you or any of the health care providers you serve have questions regarding this information please contact your local area Customer Service.

If you have experienced any patient or user injury associated with this Field Action, please immediately report the event to your local area Customer Service.