DIAGAST

Safety Information

I-Mag Screen Ref. : 59857 from batch 292000

Ref : FSN/2023/13 *07 Novembre 2025*

To Laboratory Managers, Directors of Healthcare Center and Pharmacovigilance Correspondents

Subject: Withdrawal of recommendations regarding the use of the I-Mag Screen reagent (ref. 59857)

Dear Customer,

As part of our safety communication of December 4, 2023 (FSN/2023/13), followed by a supplementary communication on February 27, 2024, we asked you to implement the following temporary measures for the use of the I-Mag Screen reagent (ref. 59857) in order to limit the risk of false negative results:

- Add the low-titer Internal Quality Control with each series of patients tested,
- If the low-titer Internal Quality Control result is negative for the corresponding antigen, you must:
  - ✓ Manually invalidate the patient result. If the IQCs are configured in the QDS software, invalidation occurs automatically,
  - ✓ Unload the panel currently in use,
  - ✓ Replace it with a new panel brought to room temperature,
  - ✓ Re-test the affected patients, including the low-titer IQC in the series.

After more than a year of follow-up, it is confirmed that:

- The frequency of false-negative results with the Sera CQI Fya has returned to a controlled level since batch 315000 (January 2024),
- The batches currently produced and distributed perform according to specifications.

A new version of the leaflet (DIA16202) has been published. It includes:

- System validation through Internal Quality Control at regular intervals, in accordance with local/national regulatory requirements,
- Visual inspection of images and interpretations for result validation.

Consequently, the previously applicable recommendations are withdrawn. You can now use the I-Mag Screen reagent in accordance with its new instructions for use (DIA16202).

We are continuously monitoring the product's performance and remain available to answer any questions you may have.

We sincerely thank you for your cooperation and for carefully implementing the temporary recommendations that were requested of you.

The ANSM (French National Agency for Medicines and Health Products Safety) has been informed of this communication.

For any further information, our Support team remains available:
- by email: hotline@diagast.com
- by phone: +33 (0)3 20 96 75 47

With our respectful regards,
Stéphane REFREGIER
Director of Quality & Regulatory Affairs

See below for the SCAF response form.

251 Avenue Eugène Avinée – Parc Eurasanté 59120 Loos – France

Safety Corrective Action Form (SCAF)
Receipt acknowledgement Form

Note: Please complete this form even if you do not have the devices in question and return it by email to hotline@diagast.com

Ref°: *FSN/2023/13*
Date: 07 November 2025

Affected Devices

Designation	Reference	Batch number
I-Mag Screen	59857	From batch 292000

Customer Information

Customer number	
Site name	
Name of signing manager	
Adress	
Phone	

We certify that we have read the safety corrective action sheet referenced above and have disseminated this information to the relevant personnel in our laboratory as well as to all users of this product, including customers to whom we may have transferred it.

Date :

Signature et company stamp :

251 Avenue Eugène Avinée – Parc Eurasanté 59120 Loos – France