

# FIELD SAFETY NOTICE (FSN)

April 8<sup>th</sup>, 2026

Dear valued customer,

Our records indicate that you have received GAMMA-GT Reagent (references listed in the table below).

The purpose of this notification is to inform you that falsely low Gamma GT results may be observed when hemolyzed samples are analyzed.

Product code	Product Name	Affected Lots
GISL-0420 GISL-0250	GAMMA-GT PLUS SL	All lots
GISL-M230	GAMMA-GT	

Two customer complaints have reported unexpected analytical results obtained with the Gamma-GT reagent.

Internal investigations have confirmed that hemolyzed serum samples may generate falsely low Gamma-GT results, sometimes reported as low as 0.0 U/L, which is inconsistent with the expected enzyme activity. No abnormal results have been observed with non-hemolyzed samples. Further experiments are ongoing to determine the root cause.

Consequently, an information will be added in the paragraph Samples of our instructions for use as follows "Samples must be free from hemolysis". The revised instructions for use will soon be available on our website.

### Potential Risk to Patient Health

The observed biases (in case of False normal results, Falsely Low result, or even no result generated) should not significantly impact the clinical management of patients.

Haemolysed samples are generally considered unsuitable for biochemical testing and are routinely identified and rejected with laboratory quality procedures. In addition, the result is interpreted in conjunction with the patient's medical history, clinical evaluation, and results from other tests such as ALT, AST, Alkaline phosphatase and Bilirubin markers. Such falsely low results may have lead to repeated testing.

Therefore, the overall risk to health is low to negligible and this is the reason why VitalScientific does not recommend a review of previously generated results.



Please discuss any concerns about previously reported results with your laboratory's Medical Director to determine the appropriate course of action.

VitalScientific is not aware of any reports of patient health risks related to this event at this time.

---

**Actions to be Taken by the Users/Laboratories**

1. Do not use hemolyzed samples.
2. Ensure that this information is distributed to all relevant personal in your organization and keep a copy on file .
3. Complete and return to VitalScientific the acknowledgement of receipt attached within 8 days.

Our instructions for use will be updated to include these new recommendations.

---

---

**Actions to be Taken by Distributor**

1. Provide a copy of this FSN to all customers who have received VitalScientific Gamma-GT reagent.
  2. Ensure that this information is distributed to all relevant personal in your organization and keep a copy on file .
  3. Complete and return to VitalScientific the acknowledgement of receipt attached within 8 days.
- 

The French Competent Authority (ANSM) has been notified of the distribution of this FSN.

Conscious of the disturbances that this situation may cause in your laboratories, we remain at your disposal should you require any further information or clarification.

Sincerely yours,

Personal data





## REPLY FORM ACKNOWLEDGING RECEIPT Field Safety Notice

COMPANY/LABORATORY NAME:.....

ADDRESS : .....

PHONE NUMBER : ..... Email : .....

### **To be completed by users/laboratories**

I acknowledge that I have read and understood the information in the safety notice concerning the GAMMA-GT reagent and have implemented the required actions.

Date :

Name /signature :

### **To be completed by distributors**

<input type="checkbox"/>	I confirm the receipt, the reading and understanding of the Field Safety Notice.	Date to complete Name and signature
<input type="checkbox"/>	I have identified customers that received or may have received this device	Date to complete Name and signature
<input type="checkbox"/>	I have informed the identified customers of this FSN	Date to complete Name and signature

By signing above, I acknowledge that I have read the Field Safety Notice regarding VitalScientific GAMMA-GT (Ref. GISL-0250/GISL-0420/ GISL-M230) and will fully implement the recommended actions.

Document to return by email to: **Personal data**