

FIELD SAFETY NOTICE

December 23th, 2024

Dear valued customer,

Our records indicate that you have received CRP IP Reagent (reference ICRP-M230).

The purpose of this notification is to provide information regarding the CRP IP reagent, which may produce abnormal results when testing plasma samples.

Table 1

Product code	Product Name	Affected Lots
ICRP-M230	CRP IP	All lots

Internal investigations indicate that plasma samples may be incorrectly tested. Investigations are ongoing to identify the root cause of the issue.

Plasma samples from patients tested for CRP may be falsely reported as either decreased or elevated. When interpreted in conjunction with the patient's medical history, clinical evaluation, and other tests, such as falsely elevated or decreased results may lead to repeated testing, delaying patient results, creating diagnostic confusion, and necessitating additional diagnostic tests.

VitalScientific does not recommend reviewing previously reported results for patient outcomes. The results of any diagnostic test should be evaluated in conjunction with the patient's history, risk factors, clinical presentations, signs, symptoms, and results from other tests. Please discuss any concerns about previously reported results with your laboratory's Medical Director to determine the appropriate course of action.

VitalScientific has received no customer complaints and is not aware of any reports of patient health risks related to this event at this time.

Actions to be Taken by Distributor

1. CRP tests on plasma samples must be discontinued until further notice. Use only serum samples for CRP measurements.
2. Provide a copy of this FSN to all customers who have received VitalScientific CRP IP reagent concerned.
3. Ensure that this information is distributed to all relevant personal in your organization and keep a copy on file until further information.
4. 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,

Regulatory Affairs Manager

REPLY FORM ACKNOWLEDGING RECEIPT Safety Notice

COMPANY NAME :

ADDRESS :

PHONE NUMBER : Email :

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

By signing above, I acknowledge that I have read the Field Safety Notice regarding VitalScientific CRP IP (Ref. ICRP-M230) and will fully implement the recommended actions.

Document to return by email to: Valérie LAMBERT
Email : qara.ecs-sas@elitechgroup.com