



Urgent Field Safety Notice

Sperm Concentration Rapid Test Kit; Bowel Health Rapid Test Kit

Date Issued: 2026-02-26

Reference Number: FSN26001

Dear Distributor(s)

The purpose of this letter is to notify you that Alltest has initiated a recall action for specific lots of **Sperm Concentration Rapid Test Kit and Bowel Health Rapid Test Kit.**

The following potentially affected product has been shipped to your facility:

Name of the device	Catalog Number	Lot	Qty
Sperm Concentration Rapid Test Kit	90-88-059	SAP25100006	5760 pcs
Bowel Health Rapid Test Kit	90-88-024	FOB25100040	10800 pcs

Description of the Issue

A critical quality discrepancy has been identified affecting above-mentioned products. It was observed that the printed product information on the Primary Packaging (foiled pouch) does not match the information on the product box for the aforementioned product lots.

Investigation revealed that the incident was attributed to a manufacturing packaging error.

Hazard giving rise to the FSCA

The overall risk to patient/user safety is low for the following reasons:

- The probability of a risk:

The discrepancy is visible on the packaging. Users can identify the printing error prior to test execution, allowing them to discontinue the product use.

- The severity of a risk:

Sperm Concentration Rapid Test Kit: In the rare event a user proceeds with testing despite the mismatch, the potential harm is limited to a very low level. When a normal sample identified as abnormal, it may lead to an unnecessary hospital visit for confirmation and minor mental stress. When an abnormal sample identified as normal, it may result in a delay in treatment, but user can seek medical assistance if symptoms persist. However, the test materials are non-hazardous and the device does not pose a direct safety threat.

Bowel Health Rapid Test Kit: Investigation confirms that while the pouch printing is incorrect, the correct product strip is included inside. Therefore, test performance and results are unaffected.

The defect is a labeling discrepancy that does not compromise the safety of the device. No adverse medical events are anticipated as a result of this issue.



Actions to be taken by the distributor(s)

1. Review current inventory of the above-mentioned product with affected lot number.
2. Segregate and return of any unused affected lots of products from your inventory.
3. Fill and forward the 'Respond form' as attached.
4. Forward this notification to all departments within your organization who may be in possession of this affected product; and any other organization to which this product may have been transferred.
5. Retain a copy of this communication for your records.
6. If you have any questions, need assistance, or wish to report something related to the impacted product, you may contact Alltest via email to info@alltests.com.cn

With kind regards,

General Manager

Hangzhou Alltest Biotech Co.,Ltd.

Response Form

1. Field Safety Notice (FSN) information			
FSN Reference number*	FSN26001	FSN Date*	2026-02-26
Product/ Device name*	Sperm Concentration Rapid Test Kit Bowel Health Rapid Test Kit		
Product Code(s)	90-88-059 90-88-024	Batch/Serial Number (s)	SAP25100006 FOB25100040

2. Distributor/Importer Details	
Distributor/ Importer name	
Address	
Contact Name/ Position	
Phone number	
Email	

3. Actions performed by the customer on behalf of the distributor		
<input type="checkbox"/>	From the affected lot, I have received _____ units in total. And _____ units has been sold. And _____ units has been disposed. _____ units remains on my site.	
<input type="checkbox"/>	I will return / dispose all remained units.	
<input type="checkbox"/>	I will forward this notification to all departments within my organization who may be in possession of this affected product; and any other organization to which this product may have been transferred.	

Name and Title of person completing questionnaire		Signature/Date*	
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*By signing this form, we acknowledge receipt and understanding of the accompanying Field Safety Notification, and that we have informed all potential users and have taken and will take appropriate actions in accordance with that Notification.