

## Product Notification

### HISCL FT-4 Reagent Package Insert Correction

#### Attention

Operators and Users of Sysmex HISCL FT-4 Reagent

#### Introduction

It was observed that there is a violation of law in a labeling non-conformance regarding the measurement range in the package insert for certain lots.

#### Affected Products

| Product code | Name of product               | Affected Lot No. |
|--------------|-------------------------------|------------------|
| AG273618     | HISCL FT-4 Reagent (50 test)  | ZS9204           |
| CB825811     | HISCL FT-4 Reagent (100 test) | ZS9304, ZS9305   |

#### Problem Description and Cause

It was observed that the products with the lots above were distributed to Japan market with the package insert describing new measurement range (0.25-8.00 ng / dL) before the regulatory authority approval at Japan during the regulatory submission change, despite of the current measurement range (0.25-6.00 ng / dL).

The assumed cause is a communication error between Japan regulatory authority and our regulatory affair staff.

#### Actions to be taken by the customer

1. Please distribute this customer letter to all appropriate persons in your organization.
2. The affected lot reagents will be replaced and the necessary instrument HISCL-5000/HISCL-800 configuration change will be also taken by our local representative.
3. Regardless of the affected lot reagents to be replaced, please confirm and sign the AOR (Customer's Acknowledgement of Receipt) on next page.

We deeply apologize for any inconvenience that this situation has caused and thank you for your patience and continued support.

Sincerely yours

Sysmex Corporation

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Yoshihiro Ookido  
Vice President at Sysmex Corporation  
Post-marketing Quality Assurance

# Product Notification

Oct. 2019

## Customer's Acknowledgment of Receipt (AoR)

We hereby confirm the receipt of Field Safety Notice (FSN) issued xx-xx, 20xx concerning the Field Safety Corrective Action on **xxxxx series** with regards to the **xxxxxxxxxxxx**.

*We confirm receipt of this FSN and completed the required actions contained therein. We confirm our inventory include products affected by this Field Action. The use and further distribution of the affected products is stopped. All products are put on hold and the amount below will be returned.*

|                                                                                                                                                                                                                                                                                                                    |                   |                            |
|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------|----------------------------|
| <b>Product Name</b>                                                                                                                                                                                                                                                                                                |                   |                            |
|                                                                                                                                                                                                                                                                                                                    |                   |                            |
| <b>Product Number</b>                                                                                                                                                                                                                                                                                              | <b>Lot Number</b> | <b>Quantity (returned)</b> |
|                                                                                                                                                                                                                                                                                                                    |                   |                            |
|                                                                                                                                                                                                                                                                                                                    |                   |                            |
|                                                                                                                                                                                                                                                                                                                    |                   |                            |
| <ul style="list-style-type: none"> <li>• Include a copy of the <b>completed Acknowledgement Form</b> in the returns package with the returned units</li> <li>• Ensure the <b>RAN number is clearly visible</b> on the returns package.</li> <li>• Please label returns as <b>"Field Action Returns"</b></li> </ul> |                   |                            |

OR

€ The affected products which are unavailable for return have been: € discarded € lost € other:

\_\_\_\_\_

Product Serial Number .....

Institution .....

Address .....

Responsible & authorized Person .....

Signature .....

Place / Date .....