

07.12.2016

Date: 07.12.2016

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To:

Attn:

From: Anne-Marie Ackermann

Subject: Field Safety Notification

Dear Partner,

The purpose of this letter is to advise you that Orion Diagnostica is conducting a Field Safety Corrective Action for:

Product name	Ref No
QuikRead FOB Sampling Set	138822
QuikRead FOB quantitative kit	138820
QuikRead go iFOBT kit	136189

Reason for Field Safety Correction Action and scope of error

Orion Diagnostica has during its regular stability tests noticed that QuikRead FOB Sampling Set (Cat.No. 138822) vials do not preserve the level of the faecal haemoglobin as specified in instructions for use.

Orion Diagnostica will replace sampling kits and reagent kits for clinical use from December 12th 2016 on. Further details at the end of this letter.

No complaints on the sample stability on QuikRead FOB Sampling Set have been received.

Orion Diagnostica Sampling vials are used with QuikRead FOB quantitative reagent kits or with QuikRead go iFOBT reagent kits. QuikRead FOB quantitative and QuikRead go iFOBT reagent kits fulfil their specifications. However, as the stability of the faecal sample in the sampler is also mentioned in the reagent kits' instructions for use, these kits are recalled as well.

Impact on patient results

Finding of occult blood in faeces mandates further investigations of the gastrointestinal tract. If the faecal haemoglobin concentration is decreased due to faecal sample storage, then initially low haemoglobin concentrations can show as negative in the test reading.

Based on our risk analysis such initially low values are seen mainly in non-malignant cases such as adenomas. Colonoscopy is considered the recommended method for patients with suspected excess of faecal blood. Thus decreased stability during sample storage increases risk of a negative test result and thereby delayed colonoscopy mainly in the non-malignant group. We therefore conclude that the patient risk is low.

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Actions by manufacturer

Orion Diagnostica has decided to discontinue deliveries and make a recall.

Next deliveries will start from December 12, 2016. These deliveries will contain kits with a new storage time for faeces in the sampling vial: 24 hours at +18...25°C and 5 days at +2...8 °C. Orion Diagnostica customer service will be in active contact with you to ensure smooth replacement and deliveries.

As further measure Orion Diagnostica has started a project to develop the sampling buffer further to ensure longer stability at room temperature and at 2...8°C. The updated buffer is estimated to be available during late spring 2017.

Measures required from Partners

The Field Safety Corrective Action concerns the following lots of QuikRead FOB Sampling Sets, QuikRead FOB quantitative and QuikRead go iFOBT.

Product name	Lot No
QuikRead FOB Sampling Set	1665413; 1701971; 1712234; 1725222; 1728480; 1733245
QuikRead FOB quantitative kit	JB10; JB89; JC64; JD20; JD79; JE52
QuikRead go iFOBT kit	JC02; JC91; JD75; JF47

We ask you kindly to take the following measures:

Phase I - Immediate Customer Information

Immediately discontinue shipping QuikRead FOB Sampling Set, QuikRead go iFOBT and QuikRead FOB quantitative kits of above mentioned lots to your customers.

Inform your customers and ask them to stop the use of these products. This information should be documented. A customer information letter for your use is attached.

Collect products from the listed lots back from your customers or ask the customers to return the products. After you have received the products we ask you to dispose of them.

Inform us that you have received this information and have informed your customers by signing the Immediate Customer Information Form attached.

Phase II - Inventories

Inform us about both the number of products you have in your stock and the number of products you have collected from your customers by filling in the attached Distributor Inventory Form.

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Replacement:

Your Orion Diagnostica Customer service contact person will contact you to organize the replacement kit delivery. Deliveries can start from December 12th, 2016 on. For urgent inquiries, kindly be in contact with your Customer service contact person or with OD.orders@oriondiagnostica.fi

We deeply regret any inconvenience to you and your customers caused by the recall.

Best regards,

Anne-Marie Ackermann
Product manager

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FIELD SAFETY NOTIFICATION

IMMEDIATE CUSTOMER INFORMATION FORM

Please complete and send to Orion Diagnostica by e-mail product.support@oriondiagnostica.fi or by fax +358-10-429 2794 immediately after receiving this letter on the removal from the market of

Product name: QuikRead FOB Sampling Set
Cat No: 138822
Lot: 1665413; 1701971; 1712234; 1725222; 1728480;
1733245

Product name: QuikRead FOB quantitative
Cat No: 138820
Lot: JB10; JB89; JC64; JD20; JD79; JE52

Product name: QuikRead go iFOBT
Cat No: 136189
Lot: JC02; JC91; JD75; JF47

We understand that we should immediately

1. discontinue distribution of the above mentioned products
2. inform the end-users and
3. collect products back from the customers or ask the customers to return the products.

We further understand that we are responsible for

4. treating both the returned products and the products in our stock as informed by Orion Diagnostica.

Name: _____ Title: _____

Distributor Name: _____

Country: _____

Signature: _____ Date: _____

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FIELD SAFETY NOTIFICATION

DISTRIBUTOR INVENTORY FORM

Please complete and send to Orion Diagnostica by e-mail product.support@oriondiagnostica.fi or by fax +358-10-429 2794 when all products have been returned by the customers. Separate form should be used for each different product lot.

Product name: QuikRead FOB Sampling Set
 Cat No: 138822
 Lot: 1665413; 1701971; 1712234; 1725222; 1728480; 1733245

Product name: QuikRead FOB quantitative
 Cat No: 138822
 Lot: JB10; JB89; JC64; JD20; JD79; JE52

Product name: QuikRead go iFOBT
 Cat No: 138822
 Lot: JC02; JC91; JD75; JF47

Please, fill in the following information:

Distributor Inventory:	Number of kits
QuikRead FOB Sampling Set	
QuikRead FOB quantitative	
QuikRead go iFOBT	
Returned from customers:	Number of kits
QuikRead FOB Sampling Set	
QuikRead FOB quantitative	
QuikRead go iFOBT	
Replacement needed:	Number of kits
QuikRead FOB Sampling Set	
QuikRead FOB quantitative	
QuikRead go iFOBT	

Name: _____ Title: _____

Distributor Name: _____

Country: _____

Signature: _____ Date: _____