

7 December 2016

Field Safety Notification QuikRead FOB Sampling Set, QuikRead FOB quantitative and QuikRead go iFOBT

Dear Customer,

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.

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.

Advise on action to be taken

- Customers are advised to stop using all QuikRead FOB Sampling Set, QuikRead FOB quantitative and QuikRead go iFOBT kits currently in use. Please follow further instructions given by your local distributor.
- Next 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.
- The deliveries of new kits will take place from Orion Diagnostica starting from December 12th, 2016 on. Further details will be informed by your local supplier.

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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.

We sincerely apologize for the inconvenience caused by this measure.

Best regards,

Anne-Marie Ackermann
Product Manager

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