



March 26, 2021

## FIELD SAFETY NOTICE

Dear Oy Reagen Ltd customer,

This letter addresses potential problem in stability of the product within the shelf life. Reagen Ltd has submitted an initial incident report to the National Competent Authority. The incident leads to corrective actions (field safety corrective action, FSCA).

Oy Reagen Ltd notifies customers and distributors about FSCA via Field Safety Notice.

<b>Product</b>	<b>Reagen POC PUUMALA IgM</b>
<b>REF</b>	114001
 <b>LOT</b>	XC13/1 and XD15/1
	2021-05 and 2021-10
<b>ISSUE:</b>	Our internal quality control has observed variation in the quality of the test cassettes' foil pouch sealing. This may affect the stability of the product within the shelf life.
<b>IMPACT:</b>	<ul style="list-style-type: none"><li>• Low positive samples may give lower results than usually. Thus, those samples may give EQV or false negative results.</li><li>• Incident does not cause false positive results.</li><li>• Reagen Ltd has made corrective actions into the manufacturing process, so similar problem will not occur in other production lots of the product.</li><li>• Reagen Ltd has not received customer complaints/inquiries concerning the product lots in question.</li></ul>
<b>ACTION:</b>	<ul style="list-style-type: none"><li>• Dispose the product lots specified above.</li><li>• Please send a picture of the kits to be disposed to Reagen Ltd. The picture should show the kit labels and the amount of the kits.</li><li>• Reagen Ltd will replace the disposed kits.</li><li>• Please fill in and return this notice and the picture of the kits by 16.04.2021 to confirm that the corrective actions have taken place.</li></ul>



March 26, 2021

**Please confirm:**

I have read and understood the information within this Field Safety Notice.

**Check the appropriate box below:**

- We do not have these products in stock.  
 I confirm that the products listed above have been disposed.

Number of kits disposed: \_\_\_\_\_

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Name: \_\_\_\_\_ Title: \_\_\_\_\_

Tel: \_\_\_\_\_ Email: \_\_\_\_\_

Site Name: \_\_\_\_\_

Site Address: \_\_\_\_\_

**Transmission of this Field Safety Notice: (if appropriate)**

This notice needs to be passed on all those who need to be aware within your organisation or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please return to: [info@reagen.com](mailto:info@reagen.com)

If you have any questions regarding this notice or your need to order replacement products, please contact your local distributor / contact person at Reagen or [info@reagen.com](mailto:info@reagen.com).

We apologize for the possible inconvenience this incident may have caused you/your laboratory.

Reagen confirms that this incident has been notified to Your local National Competent Authority.

Sincerely,

Riikka-Liisa Miettinen  
Quality Manager

Oy Reagen Ltd

