

FIELD SAFETY NOTICE

Dear Oy Reagen Ltd customer,

This letter addresses potential problem in stability of the product within the self-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.

Product	ReaScan TBE IgM
REF	114106
LOT	XA13/1
	2021-06
ISSUE:	Our internal quality control has observed fluctuation in test cassettes' foil pouch sealing which may affect the stability of the product within the shelf-life.
IMPACT:	• Low positive samples may give lower results than usually. Thus, those samples may give EQV or false negative results. • Incident does not cause false positive results. • We have made corrective actions into the manufacturing process, so similar problem will not occur in other production batches of the product. • Reagen Ltd has not received customer complaints/inquiries concerning the product batch in question.
ACTION:	• Dispose all the products listed above. • Please send us a picture of the kits including amount of the kits, which will be disposed and replaced. • Reagen Ltd will compensate all the disposed kits. • Complete and return the enclosed this notice by 16.04.2021 to confirm that corrective actions have taken place.



March 26, 2021

Check the appropriate box below:

- ☐ I have read and understood the information within the accompanying Oy Reagenä Ltd Notification. I confirm that all products listed above have been disposed.

Number of kits _____ disposed.

Or:

- ☐ We do not have this/these product/s in stock.

Signed: _____ 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: riikka-liisa.miettinen@reagenä.com

If you have any questions regarding this notice, please contact your contact person at Reagenä or Quality Manager. We apologize for the inconvenience this incidence has caused you/your laboratory.

The undersign confirms that this notice has been notified the appropriate Regulatory Agency.

Please, contact customer service, info@reagenä.com, to order replacement products.

Sincerely,

Riikka-Liisa Miettinen
Quality Manager
Oy Reagenä Ltd

