

FSN (Field Safety Notice)

ID	FSCA-FSN 2018TGS001
DATE	2018-10-18

Warning: Immediately stop using the indicated lots and eliminate any stock

Details of the affected device:

Device	In Vitro Diagnostic Medical Device		
Name	TGS TA EBV CS REF. YB500030		
Lots	00273	Expiration date	09-2019
	00291		12-2019

Description of the problem:

Post-market reports showed an unexpected loss of reactivity of the Positive Control of the Control Sets lot 00273 and 00291 for the EBV VCA IgM analyte. This is signaled by the instrument through visualization of the OMR message and causes the cancellation of the analytical session.

Impact:

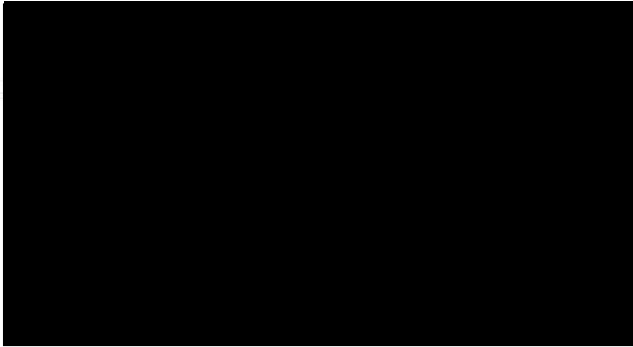
The tests performed internally, confirmed the problem. The loss of reactivity seems to be due not so much to stability problems of the controls but to an interaction between the matrix of the controls themselves and one of the reagents constituting the EBV VCA IgM test cartridge. However this has no impact on the evaluation of the tested samples. It should also be noted that all data must be interpreted together with the clinical and laboratory data available to the physician.

What actions to be taken by the user:

- Stop using the lots involved
- Identify and destroy the involved lots still available in stock
- Complete the attached confirmation form and return it to Technogenetics in accordance with the instructions contained therein.

Transmission:

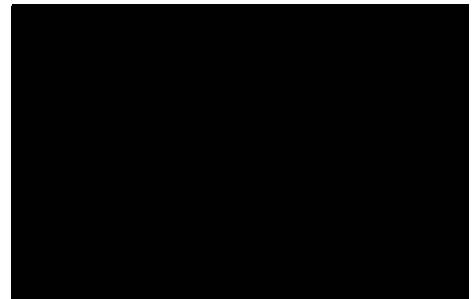
This notice must be distributed to all those people who need to be aware of it within the company or to any other organization and/or customer to whom the affected device has been provided.



This note has been sent to the Competent Authorities of the countries where the device has been distributed..

We apologize for any inconvenience caused.

Sincerely



Receipt confirmation form – Attach. Doc. N° FSCA-FSN 2018TGS001_EN

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(Please write in block letters)

Customer		Geographic area	
Contact		E-mail:	
Date of reception of FSN			

Lot of kit TGS TA Ref. YB500030 received:

<input type="checkbox"/> 00273	Received kit: _____	Used kits: _____	
		Remaining kits:	<input type="checkbox"/> destroyed kits n°: _____
<input type="checkbox"/> 00291	Received kit: _____	Used kits: _____	
		Remaining kits:	<input type="checkbox"/> destroyed kits n°: _____

Date: _____

Sign: _____

Timbro dell'Ente:

Send this form filled by e-mail or fax to:

qa@technogenetics.it

Fax. 0039 0371 610029